CHAPTER 1

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“Just as the largest library, badly arranged, is not so useful as a very moderate one that is well arranged, so the greatest amount of knowledge, if not elaborated by our own thoughts, is worth much less than a far smaller volume that has been abundantly and repeatedly thought over.”

– Arthur Schopenhauer (1788-1860, German Philosopher)

1 INTRODUCTION

1.1 Definition

Spondylolysis is derived from the Greek *spondylo* meaning spine and *lysis* meaning to dissolve. It is defined as a defect in the pars interarticularis (PI) of the spine. It means slippage of the vertebrae when *–olisthesis* is added as the post fix i.e.spondylolisthesis. It was first described in the English literature in 1858 by Cambridge surgeon, George Murray Humphrey, in his book "Treatise on the Human Skeleton". However the importance of the pars interarticularis defect was first recognised in 1855 by Robert du Coblenz from the University of Marburg in Germany (Newell, 1995). Use of the word spondylolysis to describe the defect of the pars interarticularis appeared in 1884 and was credited to Franz Neugebauer of Warsaw (Newell, 1995). It represents a 'stress' or 'fatigue' fracture, seen most commonly in children and adolescents. Early subtle stress reactions within the bone of the posterior arch of the lumbar spine appear to be the first signs of a developing stress fracture (Wiltse et al, 1975).

1.2 Overview

The prevalence of symptomatic defects of the PI varies between 15% and 47% in the young athletic population, which is significantly higher than the general population (Micheli et al, 1995, Congeni et al, 1997). The cumulative incidence is higher since it includes the symptomatic and asymptomatic people in the general population. In the sporting population, however the cumulative incidence includes symptomatic lesions.

1.2.1 *In General population*

An incidence of 5.8% was in white Americans was observed by Baker (1956). McCarroll (1986) and Fredrikson (1984) reported similar estimates of 5-6% in general population with evidence of spondylolysis. The overall incidence was 3.5%, without significant variation between races and sexes. The incidence of lumbar spina bifida in the whole sample was 1.9%, but was 11.8% in those skeletons with spondylolysis (Eisenstein, 1978). The general incidence is 4-5% at the age of 6 years, and in 30-50% of cases these types do not progress to spondylolisthesis. Most cases are asymptomatic (80%) (Logroscino et al, 2001).

1.2.2 *In Sporting population*

Jackson (1976) demonstrated an incidence of spondylolysis of 11% in a survey of 100 competitive young female gymnasts, 4 times the 2.3% reported in the general white female population by Roche (1951). Hardcastle (1993) reported a 55% incidence of PI defects in a group of 20 elite young cricketing fast bowlers.

Rossi (1994) analysed that: a) the incidence of spondylolysis was higher in athletes (13.49%) than in the general population (4-7%); b) the incidence of spondylolysis was higher in the distal portion of the lumbar spine (in 81.40% of cases L5 was involved); c) in 52% of cases spondylolysis was associated with spondylolisthesis--the latter of grade 1 according to Meyerding's classification in 74.39% of cases; d) bilateral and single-segment forms prevailed; e) the incidence of spondylolysis differed in the various sports according to the specific mechanical stimulation involved (Rossi & Dragoni, 1994). The impact of sporting exposure has not been quantified.

1.3 Natural History

It is believed that excessive loading in repetitive hyperextension in the young sporting populations is a significant risk factor (Hardcastle et al, 1992). The natural history of spondylolysis i.e. fracture of the PI is unpredictable. The defect seems to lie on a continuum. The initial stress reaction is probably the earliest sign in the genesis of the stress fracture at the PI. In some cases stress fracture is propagated through the PI. Some heal with sclerosis but others do not and form a pseudoarthrosis. Some others may progress to spondylolisthesis. The degree of spondylolisthesis was as much as 28%, and progression of the olisthesis was unusual (Fredrickson et al, 1984). The data support the hypothesis that the spondylolytic defect is the result of a defect in the cartilaginous anlage of a vertebra. There is a hereditary pre-disposition to the defect and a strong association with spina bifida occulta. Progression of a slip was unlikely after adolescence and the slip was never symptomatic in the population that they studied (Fredrickson et al, 1984).

1.3.1 *Symptomatic Vs Asymptomatic defects*

5-9 year olds are unlikely to have a symptomatic PI defect. 10-16 years olds are likely to have a symptomatic PI defect. The mean age of the population complaining of back pain

with a spondylolysis is 15-16 years and symptoms are commonly associated with an adolescent growth spurt (Hensinger, 1989). Incidence increases upto 20 years then remains constant and by adulthood PI defects demonstrated by radiographs show prevalence between 5-10%.

Mechanical low back pain (LBP) is associated with participation in sport due to many other causes than spondylolysis (Micheli 1979). Waddell (1987) established the fact that the reliability of diagnosis of pars defect is non specific in 85% patients.
The significance of the pars defect is different in sporting population in all respects (Roche 1951, Jackson 1976, Hensinger 1989, Fredrickson 1984, Hardcastle 1992, Johnson 1993, Micheli 1995, Congeni 1997, Suh 1991). There is relatively increased loss of function in the sporting population than the general population. In the elite athletes the problem of LBP due to spondylolysis is a special entity. Early diagnosis and treatment is warranted in these individuals who earn a livelihood from their sport. Some of these defects heal with conservative treatment but many others do not tend to heal after a period of conservative treatment. Some patients remain painful even after union of the pars defect (Schneiderman et al 1995). The worst case may progress through to segmental instability, disc degeneration and progressive slip. To halt the vicious cycle one has to be aggressive in treating these cases. But there is a conflict in the literature over the management of symptomatic PI defects. This is particularly with respect to the dose response relationship to the degree and duration of immobilization by bracing (Steiner & Micheli 1985, Congeni et al 1997, Smith & Hu 1999).

Early subtle stress reactions in and around the PI presenting with symptoms are likely the first indication of a developing stress fracture and demonstrate the earliest stage in the natural history of the defect. It is at this early stage when the natural history of spondylolytic defect and the natural history of associated back pain and disability are most predictable. Many affected children and adolescents can participate in sports even if their defects in the pars have not healed, but they are at increased risk of developing endplate lesions and vertebral deformities (Farfan et al 1976). These complications could be avoided by obtaining bony union of the defect. A number of studies have indicated that the response to conservative treatment varies considerably (Steiner & MIcheli 1985, Blanda et al 1993, Merbs 1995, Morita et al 1995).

1.4 Treatment of symptomatic defects

Resolving symptoms following treatment at an early stage makes it possible for the athlete to return to previous performance levels. There are a few patients in this group who do not show signs of healing after conservative means and need surgery to fuse the defect in situ to resolve their symptoms, before it progresses to slippage or spondylolisthesis.

We do not have tools to predict the behaviour of a lytic defect in an athlete, whether it would require early direct repair or it requires conservative therapy.
The factors that are responsible for the healing of the defect are predicted on the basis of radiological research (Fuji et al 2004). No significantly associated factors have been identified which predicts the need for surgical intervention in certain patients.
Unresolving pain may be the only factor responsible for the decision making in treating patient with surgical means i.e. direct repair.

A significant correlation between the stage of the defect and successful bony union was reported (O'Neill & Micheli 1989). As determined by plain radiographs, union occurred in 73% of early stage defects, 39% of progressive defects and none in the terminal stage (sclerosis of the pars with non union). Plain radiographs cannot detect the defect accurately because of variability in the angle or site of the defect. Thus to quantify the union, reverse gantry CT scans have been performed in patients with unresolving symptoms.

Trunk muscles provide segmental stability and directly control the lumbar motion segments. Conservative treatment in the form of 'specific' trunk muscle stabilizing exercises may act to provide dynamic stability to the lumbar spine and may act to maintain the neutral zones of the motion segment within more normal limits during functional activity (O'Sullivan et al 1997). Thus conservative treatment remains the mainstay of treatment.

1.5 Surgical Management & Outcome

There are some individuals who experience disabling symptoms that are unresponsive to conservative treatment and preclude them from participating in their sport. Historically the symptomatic defects have been managed surgically with a postero-lateral fusion with or without a decompression.

Results of the surgery have been predictably good in terms of pain relief but not necessarily with regard to returning to competitive sports. In 1968, Kimura described the direct repair of a PI defect without instrumentation. Since then several techniques have been proposed for direct PI repair, including Buck's repair (screw fixation through Pars defect), direct wiring or the Morscher clamps.

Suh et al (1991) reported a series of 10 patients who had direct repair with AO screws, 9 out of whom had successful results, although only 6 returned to work. Despite the small numbers, their results did suggest that temporary pain relief with pars injection was of prognostic significance for predicting successful operative repair of spondylolysis. Pederson and Hagen (1988) had good to excellent results in 15 of 18 patients who had direct repair with AO screws. Roca et al (1989) reported successful outcome in 13/15 patients. Clinical success was noted in 13 patients within 6 months of surgery.

One of the key to successful outcome in PI repair is patient selection. Suh et al (1991) reported on the prognostic value of pars injection with local anaesthetic as a predictor of outcome after PI repair. The primary reason reported for failure of this technique is in performing it on a patient with degenerative disc disease (Roca et al 1989, Jeanneret 1996). Thus success reported in the literature declines as the age of the treated patient increases, all patients older than 25 years should have pars infiltration with local anaesthetics.

1.6 Factors affecting union of PI defect

Fuji et al (2004) reported the radiological outcome following conservative treatment in a large series of patients. They identified the factors which may influence the success of union of the defect using CT images. The stage of the defect was the most important predictor of the outcome (early, progressive and terminal stage).

The other significant factors are 1) the vertebral level of the defect, 2) the degree of lumbar lordosis, 3) slipping of the affected vertebra, 4) site of defect in the neural arch, 5) the condition of the contra-lateral PI. The PI is elongated if the defect is progressive or in the terminal stage of its pathogenesis.

1.7 Study Origin

We hypothesized that there may be many factors responsible for continued symptoms with non healing of the defect in certain group of patients. A data set of active sporting patients complaining of LBP limiting their sporting activity was initiated in QMC, Nottingham. A large proportion of these patients had been followed up at regular intervals. Most of these patients either attending the back pain clinic or the sports injuries clinic are required to fill in the pain and disability questionnaires (VAS, ODI and SF-36).

All patients had been investigated by SPECT and CT scans in the period between 1994 & 2001. Subsequently MRI scanning replaced the primary diagnostic modality after 2002. Many had follow up CT scans. A significant number of patients had surgical repair and returned to previous level of sporting activity.

There is little evidence in the literature regarding the outcome of surgery in a sporting population. From this unit, 22 patients undergoing direct repair of spondylolysis in the sporting population was reported with 93% successful outcome (Debnath et al 2003). Hardcastle (1992) reported on direct repair in 10 cricketers who did well to return to active career. Reitman et al (2002) reported 4 young athletes to have returned to competitive sports after surgery.

Thus, we were interested in studying the cohort of young sporting individuals who were treated conservatively and see their outcome. We are also interested to know why a sporting population required more surgery than the non sporting group. For our study, we have taken into consideration various clinical and non clinical factors leading to early direct repair of the PI defect with a successful outcome. We also thought that it would be appropriate to predict the factors in this select group who need early surgery and return to active sporting career.

1.8 Aims of the Research

The study aimed to answer the following questions:

1. To determine the factors responsible for non-operative method of managing symptomatic lumbar spondylolysis in young population
2. To establish the role of primary non-operative treatment for symptomatic lumbar spondylolysis in sporting individuals
3. To evaluate the outcome in different types of sports
4. To identify the most significant determinant of surgical intervention in lumbar pars defect
5. To identify the independent factors that predict a successful outcome in patients undergoing surgery for pars defect?
6. Can we establish an outcome predictive model based on these significant factors responsible for a successful outcome?

CHAPTER 2

Anatomy & Etiological Factors

2.1 Anatomy of Pars Interarticularis

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2.1.2 Facet joint

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2.2 Etiological Factors

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2.2.4 Developmental

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2.1 Anatomy of Pars Interarticularis

2.1.1 *Posterior elements*

The lumbar vertebrae is constituted of the vertebral body anteriorly and the neural arch posteriorly. The pedicles and the posterior arch together constitute the neural arch in a vertebra. The neural arch encloses the neural elements. The vertebral bodies are designed to form a column through which the weight is borne. The architecture of the vertebral body provides a strong but lightweight load bearing structure constructed with the minimal use of bone. It is virtually exclusively dedicated to the function of sustaining longitudinally applied loads. There are no features of the body that confer stability to the intervertebral joint in any direction. Lacking such features, the vertebral bodies are totally dependent on other structures for the stability in the horizontal plane, and foremost amongst these are the posterior elements of the vertebrae.

The posterior elements are designed in an irregular but symmetrical bone mass which is adapted to receive and dissipate the various forces that act upon the vertebra. All the muscles that act directly on the vertebral column are attached somewhere on the posterior elements with the exception of psoas major. This suggests that all the dynamic forces acting through the muscles on the vertebra are first delivered to the posterior elements. Panjabi et al (1989) described spinal stability of a motion segment is dependent on passive, active and neural control systems. The passive system constitutes the vertebrae, intervertebral discs, zygapophyseal joints and ligaments; the active system constituting the muscles and tendons surrounding and acting on the spinal column; the neural system comprising the nerves and central nervous system, which direct and control the active system providing stability. Panjabi thus defined spinal instability as a significant decrease in the capacity of the stabilizing systems of the spine to maintain intervertebral neutral zones within physiologic limits, so there is no major deformity, neurological deficit, or incapacitating pain.

2.1.2 *Facet joint*

The zygapophyseal joints (zapj) principal function is to provide a locking mechanism that resists forward slipping and twisting of the vertebral bodies. Consequently their shape, symmetry and orientation influence the distribution and concentration of force and load generation within the posterior elements. Articular tropism is being demonstrated in 25%

of the population, which relates to the degree of asymmetry between pairs of joints at the same vertebral level. An association between tropism and pattern of degeneration in the annulus was suggested (Bogduk 1995). Subsequently, MRI studies did not show any relationship between the degenerative changes and the orientation of lumbar facet joints (Boden et al, 1996). No studies were found which considered the role of articular tropism in the genesis of spondylolysis. Zapj may be an anatomical factor in the genesis of stress reaction and stress fractures. In the lumbar spine, the facet joints have been found to carry 3% to 35% of the static compressive load and dynamically upto 33% of the axial load, depending on the spinal posture. Miyake et al (1996) studied the influence of pars defect on the corresponding lamina and facet joints in patients with spondylolysis of L5 vertebrae and compared these with age-matched normal children and adolescents. Growth of the facet joint in the sagittal and transverse dimensions and of the lamina in its longitudinal dimension was remarkable upto the age of approximately 13 years and a little until 18 years of age. The transverse angle of the articular orientation also increased in children of the same age. The longitudinal dimensions of the lamina correlated with the sagittal dimension of the facet joint, and the transverse interlaminar angle also negatively correlated with the transverse facet angle. These results support the theory that growth of the facet joints is subsequent to that of the lamina (Mutch & Walmsley 1956). Van Schaik's (1985) had suggested that the transverse orientation of the caudal portions of the lamina corresponds to that of the facet joints. It is generally known that in newborn infants the surface of the facet joints is flat and in adults it is more or less curved. Such curving of the joint surface depends on a combination of intrinsic growth potential and extrinsic factors. When pars defects occur in young adults, they may affect the growth process, especially of the end portions of the facet joints and result in a rather infantile pattern of joint surfaces. In fact, the flat type was more frequently observed in children and adolescents with pars defects than in those with no pars defects.

Recent studies on human skeletons with spondylolytic defect suggests the normal anatomic configuration of the posterior neural arch results in a sequential increased separation between facet joints which allows adjacent segments to imbricate during hyperextension and thereby protects the intervening PI from excess pressure. An insufficient interfacet distance will increase contact pressure on the PI during extension

which may lead to the development of a pars defect (Ward & Latimar 2005). A feedback cycling model was developed recently which suggested that although three elements (anatomical features, microfracture and posture/activity) may cause lumbar spondylolysis independently, it is the nature and intensity of the interaction between the three during growth that most influences the development of spondylolysis (Masharawi et al 2007).

2.1.3 *Lamina*

The lamina protects the neural elements posteriorly. However, this protective function is complimented with another function which is frequently overlooked. The central location of the lamina within the posterior elements serves as a force transmission zone. This concept is important for appreciating how the stability of the lumbar spine can be compromised when a lamina is weakened by injury, disease and surgery. Without a lamina to transmit forces from the posterior elements, a vertebral body would be denied the benefit of these forces that either execute movement or provide stability.

The part of the lamina that forms the bridge of bone between the superior and inferior articular facets is the PI. It runs obliquely from the lateral border of the lamina to its upper border. The biomechanical significance of this is that it lies at the junction of the vertically oriented lamina and the horizontally projecting pedicle. It is therefore subject to considerable bending moments as the forces transmitted by the lamina undergo a change in direction into the pedicle. To withstand these forces the cortical bone in the PI is normally thicker than anywhere else in the lamina (Krenz & Troup 1973). Cyron (1979) showed that cortical bone is the main component of PI. In some individuals the cortical bone is insufficiently thick to withstand the forces applied to the PI (Cyron 1979). These individuals seem to be predisposed to fatigue fractures to the PI (Troup 1976, 1977, Cyron 1979).

Logically then measurement of the cortical bone thickness of the PI may be predictive of the development of PI defects particularly in at risk sporting populations. Ebraheim (1997) carried out a morphometric study, which provided detailed anatomic data about the lumbar isthmus and its relationship to adjacent structure. They reported that the measured anatomic parameters of the lumbar isthmus are related to the vertebral level

and have a significant correlation with the orientation of the zapj and the dimensions of the pedicles. This study demonstrated anatomic features unique to the L5 isthmus, which may result in increased shear forces from axial loading acting at this level. Most spondylolysis are reported to lie closer to the coronal plane than at 45° to it. Saifuddin (1998) used CT to study the angle relative to the coronal plane PI defects. The coronal plane was defined as a line parallel to the posterior cortex of the vertebral body at the level of the lysis. They found a wide variation in the angles between defects in the PI and the coronal plane. Only 32% of defects lie within 15° of either side of the 45° lateral oblique plane, and only 10% were actually perpendicular to the PI. This large variation in the angle of defect is an important factor in radiological demonstration of a spondylolysis and surgical fixation of the PI. A 3D-CT may be required to know the orientation of the defect (Fig 3).

2.1.4 *Pedicles*

The pedicles are the only connection between the posterior elements and the vertebral bodies and all forces sustained by any of the posterior elements are ultimately channelled towards the pedicles, which then transmit the resultant of these forces to the vertebral bodies. The pedicles transmit both tension and bending forces. The resistance of forward translation of one vertebra upon another is transmitted to the vertebral body as tension along the pedicles. Bending forces are exerted by the muscles attached to the posterior elements, the muscular action of which is transmitted to the vertebral bodies through the pedicles. The pedicles are superbly designed to sustain these forces being formed as a hollow beam with thick walls of cortical bone. Sherman (1977) described reactive sclerosis and hypertrophy of one pedicle and lamina with a contra-lateral spondylolysis in the same vertebra. He postulated that this was a physiological response to the stress of repetitive trauma in the presence of an unstable neural arch.

This resulted in hypertrophy and an increase in bone density (sclerosis) of the pedicle and lamina in the presence of a defective PI on the opposite side of the posterior element. Today pedicle stress reactions (reactive sclerosis) are a recognised indicator of possible contra-lateral PI defects.

2.2 Etiological Factors

2.2.1 Biomechanical

i) *Mechanical*

Several biomechanical analyses of lumbar spondylolysis of the PI have been performed using cadaveric specimens or models (Dietrich & Kurowski, 1985; Green et al, 1994; Ichikawa et al, 1982; Schulitz, 1980). Corresponding to the mechanical aetiology, the incidence of spondylolysis is higher in athletes, who repeatedly have to hyperextend and rotate their lumbar spine, for example gymnasts and javelin throwers. Dietrich and Kurowski (1985), using photoelastic experiments, reported stress concentrations in low lumbar vertebrae and found that the highest stresses appeared in PI, their results showing that factors of a purely mechanical nature are of fundamental importance in the aetiology of spondylolysis. Ichikawa et al (1982) performed biomechanical laboratory analysis on human cadaver material and, from axial compression and rotational bending, suggested that the incidence of spondylolysis depends upon the magnitude and direction of loads. Based on the analysis of the biomechanical movements in spondylolysis, Green et al (1994) reported on alternating flexion and extension movements causing large stresses in the PI using a human cadaveric lumbar spine. On the other hand they also reported that compressive loading had little effect. Schulitz and Niethard (1980) also reported that particular strains on the PI occur through hyperextension, axial stress and torsion of the lumbar spine. Soler and Calderon (2000) reported that torsion against resistance, as well as lumbar hyperextension and rotation, could cause spondylolysis. The conclusion drawn by Ward & Latimer (2005) after doing interfacetal measurements in thirty skeletons with lumbar spondylolysis was that individuals lacking sufficient increase in transverse interfacet dimensions are at greater risk of developing and maintaining the pars defects.

ii) *Effect of Cyclic loading*

PI defects appear to result from repeated forced cyclical movements of flexion-extension implying functional overloading of the PI (Ciullo, 1985; Hensinger 1989). Studies suggest that sheer stresses are greatest when the lumbar spine is extended (Letts et al 1986). In the young the PI is thin, the neural arch has not reached maximum strength and the intervertebral disc is less resistant to sheer (Hutton 1977, Cyron 1979). This is claimed to initiate a high concentration of sheer forces at the isthmus which are increased most

in movements combining extension and rotation/lateral flexion. Extension involves the downward movement of the inferior articular processes and the spinous process (SP), in contrast to flexion this movement is not limited by ligamentous tension but by bony impaction (Adams, 1988). This usually occurs between SP's. In individuals with wide interspinous spaces extension may be limited before the SP's come into contact and is limited by the impaction of the inferior articular process onto the lamina of the lower vertebra (Adams 1988). This type of impaction is accentuated when the joint is subjected to the action of the paravertebral muscles, as in addition to extending the lumbar spine they also generate a powerful compression load (El-Bohy 1989). These observations implicate active extension in the genesis of stress reactions in the region of the PI. During flexion of the lumbar spine the ZAP's offer resistance of upto 2000N against the forward translation that occurs with this movement (Adams 1995). This resistance passes from the inferior articular process through the lamina and pedicles, into the vertebral body. Adams (1988) demonstrated that, under specified conditions, many specimens can withstand several hundred thousand repetitions, but others failed after as a few as 1500 down to 139 repetitions. These in-vitro studies indicate that in certain individuals repeated flexion can induce fractures of the PI.

iii) *Dynamic stability of lumbar spine*

The concept of different trunk muscles playing differing roles in the provision of dynamic stability to the spine was proposed by Bergmark (1989). He hypothesised the presence of two muscle systems in the maintenance of spinal stability. The global muscle system consists of large, torque- producing muscles that act on the trunk and spine without being directly attached to it.

These muscles include the rectus abdominis, external oblique and the thoracic part of lumbar iliocostalis, and they provide general trunk stabilization, but they are not capable of having a direct segmental influence on the spine. The local muscle system consists of muscles that directly attach to the lumbar vertebrae and are responsible for providing segmental stability and directly controlling the lumbar segments. The transverse abdominis (TA), Internal Oblique (IO) and lumbar multifidus (LM) are the muscles known to tonically active during upright postures and during active spinal movements, with the TA capable of tonic activity irrespective of trunk position, direction of movement, or

loading of the spine. The TA and the posterior fibres of the IO also have a direct potential stabilizing role on the lumbar spine by way of their attachment to the lumbar spine through the thoracolumbar fascia. The LM is considered to have the greatest potential to provide dynamic control to the motion segment, particularly in the neutral zone. The co-contraction of the deep abdominal muscles with the LM has the potential to provide a dynamic corset for the lumbar spine, enhancing its segmental stability during functional tasks and the maintenance of neutral spinal postures, irrespective of position of the spine. This local muscle system may be dysfunctional in lumbar spondylolysis leading to chronic low back pain. The PI defect may render the motion segment doubly vulnerable during functional tasks.

iv) *Combination of forces leading to PI failure*

During repeated sheer and compression associated particularly with hyperextension, as characterised by actions in fast bowling (cricket) (Elliott et al 1993) and many gymnastic exercises, the inferior articular facet is subjected to repeated loading and stress. Cortical fatigue reproduced in vitro, results in PI stress fractures (Cyron 1976, Adams 1988). Forces observed in gymnasts and fast bowling are at least equal to the forces used in these experiments, and consequently would support the theory of repeated hyperextension as a primary mechanism in the development of isthmic stress fractures. The key point to remember is the only event that can occur prior to the development of such a fracture is a physiological stress reaction within local bony architecture. Chosa et al (2004) analysed a detailed 3-D L4/L5 motion segment model that took into consideration of the material nonlinearities of ligaments and annular fibres and the contact nonlinearities of the facet joints.

They evaluated the stress distribution in the PI and assessed the influence of loading direction by performing a biomechanical comparision under different lumbar loadings, including compression and combination of forces. The stress distribution in the PI was much higher than the other vertebral site and anatomically the PI is a weak structure. The stress was lower under compressive loading alone but higher under combination of compression and extension or rotation, supporting previous reports. The higher stress under extension, in particular could be due to the increased stress of the L5 – superior facet surface from contact. Under dynamic loading conditions in real life experience in

athletes the forces acting on the PI are much higher than the experimental conditions.

The literature further suggests the likely order of importance of hyperextension, sheer/tension, torque, compression and flexion. Combinations of these factors are more potent than in isolation but which combinations are most destructive is yet to be determined. The variation in biomechanical mechanisms would be consistent with variation in the sites of stress reactions and stress fractures within the posterior element reported in the literature.

2.2.2 Heredity & Familial tendencies

Bakke (1931) described a family of five children, four boys and one girl, in which two of the boys had spondylolysis. Friberg (1939) examined sixty-one members of one family and found that fifteen had defects in the pars inter-articularis. Wiltse in 1952 studied thirty-six families over a period of ten years who had one member of the family with a PI defect. The incidence of spondylolytic individuals was 26% excluding the patient who prompted the study. In 1956, Baker and McHolkick reported their radiographic findings in 400 unselected first-grade school children. They found 18 children had defects in the pars inter-articularis. All parents underwent further spinal radiographs. 27.6 % of parents had spondylolytic defects. Defects in the PI are rarely present at birth, and seldom appear clinically before the age at which a child can stand upright. Borkow and Kleiger (1971) reported the case of three and a half month-old child who had defects in the PI that were later documented at surgery.

Wiltse's series had a report of an eight month old as the youngest with a PI defect. Defects appear most frequently between the ages of five and a half and seven years (Baker 1956). Incidence increases to 20 years and then generally remains constant.

Genetic studies in the University of California concluded that there is a single recessive gene with incomplete penetrance. Genes involved sometimes show incomplete dominance, i.e. some affected individuals may actually be carriers (heterozygous) for the gene (Wiltse, 1962). Friberg (1939) reported an infant who had defects at several vertebral levels even though she had never walked. Several vertebrae in the same patient may show defects of the PI and different segments in identical twins may show

the defect. There is a five fold increase in the incidence of defects of the PI in the near relatives of people with spondylolisthesis (Wiltse, 1962). Heredity plays a major role in determining the occurrence of spondylolysis in an individual (Stinson, 1993).
Ciullo (1985) suggested that heredity plays a significant role in the clinical manifestation of this condition. When an inherited weakness exists, a resulting defect of the PI may develop. Support for this theory exists in animal studies where neural arch defects have not been demonstrated in other primates and animals.
Wynne-Davies and Scott (1979) reported a study of forty-seven families, 35 of which had isthmic spondylolysis. 15% of the relatives were similarly affected. They concluded that the pattern of inheritance was either autosomal dominant with reduced penetrance or was mulitfactorial. Fredrickson (1984) suggested that both the hypothesis regarding the inheritance pattern may be true. The two hypotheses are a) genetic heterogeneity with multiple Mendelian form, & b) multifactorial inheritance with some family members having a higher liability than others.

Dysplastic nature of the defect appears in otherwise normal appearing spines in young individuals. But as the adolescent spine grows into adulthood, the various forces acting as pivot at the PI causes this defect to propagate and may give rise to symptoms. There are considerable variations in the distribution of the defect in the different individuals of the families who were investigated for determining the incidence of spondylolysis (Wiltse, 1962). The trapezoid body of the fifth lumbar vertebra, so often seen in the adult with spondylolisthesis, is not present in the young child at the age when the defect appears.
All these studies used plain radiographs to demonstrate established defects and the issues of the specificity and sensitivity of the technique must be appreciated when drawing conclusions from the data.

2.2.3 Racial Variations

The earliest recorded findings and descriptions of lumbar spondylolysis reveal a large amount of information. This information has provided us with further knowledge of skeletons from 6000 to 10000 BC. Bridges (1989) described 20 % prevalence of PI defect in the skeletons of archaic Native Americans found in north-western Alabama. Amongst the skeletons found in the archaeological sites in Southern Britain, remains

show crude prevalence rates of PI defect range from 1.42% in the 18th and 19th centuries group to 5.08% in a medieval population, the Anglo-Saxon and Roman-British figures being 4.55% and 3.74% respectively (Waldron, 1991).

Eskimos have an unusually high incidence (20-50%) of the defect (Stewart, 1953, Lester & Shapiro 1968, Kettlekemp & Wright 1971). The effect of spondylolysis on Eskimos is difficult to determine but it is highly unlikely that it caused severe disability. Kettelkemp and Wright (1971) referred to the living descendents of these people as stoic and uncomplaining, and believed that the condition was compatible with rigorous physical activity required to survive for centuries under severe climatic conditions. It was noted that the frequency of PI defect increases during late adolescence and early adulthood. The relative frequency of spondylolysis in the Canadian Eskimos doubles from adolescence to early adulthood, being almost equally divided between complete and incomplete in the young adults (Merb 1995).

Eisenstein (1978) investigated 485 skeletons of adult South African “Whites” and “Blacks” of both sexes. The overall incidence was 3.5%, without significant variation between races and sexes. This evidence is probably true for any cosmopolitan society in the modern world where the incidence ranges between 4-7%. Subdivisions based on race and sex determined that white men had highest prevalence (6.4%), followed by black men (2.8%), white women (2.3%) and black women (1.1%) (Rowe & Roche, 1953).

Ward and Latimer (2005) 110 observed cases of unilateral or bilateral spondylolysis out of total of 3000 human skeletons in the Hamann-Todd collection, at the Cleveland Museum of Natural History, USA (Fig 1). They found only one specimen under the age of 20 years of age suggesting that subadult cases of true spondylolysis either heal spontaneously or they are rare.

More recently, the etiological basis of PI defect was explored on archeological skeletal remains on two American Indian tribes whose incidence of spondylolysi was high (Whitesides et al 2005). They observed that there was a genetically determined

difference in the upper sacral tilt which may be associated with high occurrence of pars defect.

2.2.4 Developmental and embryological factors

The theory of anomalous ossification is based on Schwegel's initial observation in 1859 of several foetuses having two centre of ossification for each side of the neural arch. According to Rowe & Roche (1953), Schwegel himself concluded that failure of fusion of these centres explained the origin of neural arch separations. Willis (1931), subscribed to the classical "single centre" theory, but indicated that a single centre occasionally could split and that the split centres could fail to fuse, this failure giving rise to the defect in the pars.

It was proposed that each lateral mass, which normally ossifies from one centre, ossifies from two centres in patients with spondylolisthesis. But further studies on at least 700 foetuses showed no evidence of a defect. The existence of only one ossification centre in each half of the neural arch has been confirmed by Sagi (1998) who attempted to delineate the exact location of the ossification centres and their respective paths of growth during foetal life. The pars begin to ossify at 12 to 13 weeks gestation by endochondral ossification. The ossification centre originates in the region of the pars in lower lumbar vertebrae, resulting in uneven distribution of trabeculation and cortication in this region. The ossification centre arises at the end of the pedicle in upper lumbar segments giving rise to uniform trabeculation through the pars.

In the upper lumbar spine, ossification centres appear earlier than in the lower lumbar spine. The origin of the upper lumbar ossific nucleus appears to localise in the base of the pedicle. However, in the lower lumbar segments (L4/5), the ossific nucleus originates more posteriorly and inferiorly in the region of the PI. Progression of the ossific nucleus is more advanced in the upper segments, and reaches into the PI, but the centre of the nucleus appears to be in the pedicle (Sagi1998).

By the 5th month the upper lumbar segments show a uniform distribution of trabeculation and cortication from the pedicle through the PI upto the inferior facet. In contrast, in the lower lumbar segments, due to the posterior position of the ossific nucleus, ossification has not progressed as much into the base of the pedicle, which is of much smaller

calibre in the lower segments. Additionally, there appears to exist a transition between dense trabecular bone in the PI and the inferior articulating facet and less dense trabecular bone at the base of the pedicle only in the lower segments. If this differential in tissue type and density were to persist into childhood, a potential area of weakness or a stress riser would be present. Such a discontinuity in substance will alter the distribution of the stresses and loads in the region of this discontinuity, such that they become concentrated in the adjacent zone. The strength of bone will be reduced because the stresses are no longer evenly distributed. When an infant becomes ambulatory, developing a lordotic lumbar spine and begins to bear weight through this weak region, a fatigue fracture could be propagated.

Stewart (1953) determined the angle of inclination of the superior surface of the sacrum with respect to the vertical plane in Alaskan male and female skeletons with and without defects in the neural arch and also in the skeletons of white males from the United States with arch defects. The average angle of inclination of the sacrum was slightly less in the skeletons with arch defects, but the difference was not significant. Thus, Wiltse (1962) ruled out the increased lumbar lordosis as an etiological factor.

The concept that dysplasia of the PI produces defects, was presented by Neugebauer as early as 1881. His material consisted mainly of female pelvis narrowed by gross lumbosacral spondylolisthesis. He suggested two types of etiology for the development of the PI defect. Type A as Congenital, by arrest of development (spondyloschizis lateralis congenital); Type B as traumatic (by fracture, fissure, incomplete injury, callus deformation, insufficient callus etc).

The developmental pattern would support Wiltse's hypothesis of isthmic spondylolysis being the result of a fatigue fracture in some congenitally weak PI. The conclusions of Sagi (1998) are consistent with the findings of Cyron and Hutton (1979) which demonstrated cortical bone density in the PI of the lower lumbar vertebrae. Differential ossification and density may result in a stress riser in the region of the PI, which is prone to stress fracture in early childhood. The fact that this occurs in the lower lumbar vertebrae where the incidence of isthmic spondylolysis predominates provides a developmentally based explanation for the frequency of PI defects at L5 than L4.

Plain radiographs of a two month old girl child was seen by one of the senior colleagues in our spinal unit in early 90s with normal pars interarticularis in her lumbar spine. Incidentally she developed a symptomatic spondyloptosis by the age of nineteen years (Fig 2a,b & c). This is a rare occurrence and supports the view that spondylolysis is probably an acquired defect. Although we cannot rule out the role of genetic predisposition in development of a pars defect later in childhood, the degree of genetic predisposition may be highly relevant to the development of such fatigue fractures in sporting adolescents and adults.

2.2.5 Acute Trauma or a fatigue fracture

Robert zu Coblenz, a former professor of medicine at University of Marburg, was the first to recognise the importance of the integrity of the neural arch in preventing forward slip of the fifth lumbar vertebra on the first sacral vertebrum (1855). Dr Robert described the effects of spinal stability by sawing through the arch and compared these with the results of severing the inter-vertebral discs and ligaments but leaving the arch intact. Thus, he can be regarded as the originator of experimental biomechanical studies of the lumbar spine. He apparently did not consider the question of fracture of PI as a clinical entity. Arbuthnot Lane from Guy's Hospital, London raised the possibility of acute fracture but rejected it later stating that 'these changes are the result of pressure alone, acting over a long period of time' (1885). Acute fracture of the PI may contribute to the etiology in a small percentage of patients (Cope R 1988, Klinghoffer 1982). Wiltse & Rothman (1989) referred to six athletes with fresh fractures which healed and did not account for the usual chronic defect.

Leon Wiltse (1975) was credited with first suggesting "the basic lesion (in spondylolysis) was a fatigue fracture of the PI which remains ununited." In 1968 Murray and Colwill titled their article "Stress fractures of the PI." The numerous recent reports on higher incidence of spondylolysis in athletes and gymnasts lend increasing support to fatigue fracture concept. The biomechanical evidence for this concept came from the work of Hutton et al (1977), who showed the pars defects can be reproduced by fatigue loading *in vitro.* The physical forces in the pathogenesis of isthmic spondylolysis is suggested by its high reported incidence in athletes participating in various sports

e.g. American football (Wiltse 1975), Cricket (Foster 1989), diving (Rossi 1990), gymnastics (Jackson 1976, Ciullo 1985, Micheli 1985, Smith 1999), weightlifting and wrestling (Granhed 1988), soccer (Debnath 2003). The probability that regional stresses within the vertebra can result in fracture in vivo is supported by a series of in vitro biomechanical studies (Dietrich 1985, Farfan 1975, Kip 1994). Dietrich (1985) studied the importance of mechanical factors in the aetiology of PI defects using biomechanical modelling methods with the aim of demonstrating that mechanical load and stress were predominant factors in the aetiology. He reported that during flexion and extension in standing the highest overall effective stresses occurred within the vertebral body, pedicle and the PI. Limitations in methodology also probably resulted in underestimation of the forces within the PI. Secondly he noted that the highest stresses occurred within the upper part of the PI of L4, and claimed this pattern could be reliably generalised to all the lumbar vertebrae. Damage testing showed different and varied modes of failure of the PI explained by small differences in load and geometry. In practice, as would occur with normal anatomical variation.

Size and shape of the vertebrae strongly influence stress within the vertebrae, even when other dimensions and loads acting on the body remain the same. He concluded that the PI are the elements of the human lumbar spine subject to the highest mechanical stress and that factors of a purely mechanical nature were found to be likely causes of spondylolysis in a normal human spine. Based on these results it was observed that due to natural variations in the structure of human spines, there are probably spines especially prone to failure and especially resistant to any pathologic changes.

2.2.6 Sporting association

Letts (1986) restricted the practice and competition of a group of young gymnasts to less than 24 hours per week and reported significantly less spondylolysis in this group. This supports the theory of overuse by repetitive movements as a factor in the development of PI defects.

Rossi (1978) retrospectively reviewed radiographs of elite athletes in Rome and found a 16% prevalence of spondylolysis in athletes in general, with significantly higher rates in divers (83%), weight lifters (45%), wrestlers (33%), gymnasts (38%), and track & field

athletes, particularly high jumpers (24%). The prevalence of spondylolisthesis was 32%. Thus he suggested that each sport does not carry the same risk. The main movements involved in the activity can group sports implicated in the development of symptomatic defects.

a) weight loading (wt lifting, power lifting)
b) rotation associated sports (squash, racquet ball, tennis, baseball and golf)
c) back arching sports (cricket –fast bowlers, gymnasts, volleyball, rowing, swimming and diving)

The common thread is the increased prevalence among adolescent athletes (Johnson, 1993). Soler and Calderon (2000) found overall percentage of spondylolysis in Spanish athletes to be 8%. Throwing sports had the highest prevalence (27%), followed by artistic gymnastics (17%), and weightlifting (13%). Jackson (1976) looked specifically at female gymnasts and found an 11% prevalence of spondylolysis in asymptomatic women, 54% of whom had spondylolisthesis. This was related to the repeated hyperextension movements of the lumbar spine.

Ferguson (1974) studied backpain in college football linemen, and found a 24% prevalence of spondylolysis and an 85% incidence of spondylolisthesis. They attributed this finding to the increased stresses placed on the PI during three or four point stance along with repetitive stress placed on this area during blocking and tackling.
Elliott (2000) reviewed several studies of fast bowlers in cricket that cite the prevalence of up to 55%. It is possible that these earlier studies may actually underestimate the prevalence of spondylolysis, especially in symptomatic athlete, given the data are based on radiographic diagnosis of spondylolysis.
The following factors may predispose to the PI defect in the athletes:

a) Lumbar hyperlordosis
b) High body weight
c) Strong paravertebral musculature opposed by relatively deficient abdominal musculature
d) Adolescent growth spurt
e) Abrupt changes in training intensity
f) Poor technique
g) Leg length inequality

Studies have indicated that athletes have an increased number of radiographic abnormalities of the lumbar spine (Sward et al, 1990). However it is not known whether these abnormalities are present before participation in college athletes. Jones et al (1999) studied the lumbar radiographs of incoming college football players and compared them with a age-matched control group to determine whether there is a higher prevalence of lumbar spine abnormalities in football players before competing at the Division 1 level. They found that football players entering college at the Division 1 level may have a similar prevalence of radiographic lumbar spine abnormalities, including spondylolysis and spondylolisthesis, as age-matched controls. Incidence of spondylolysis in their study population was 4.8%, less than the rate (6%) for the control group. The low incidence in their study suggests that there may be some bias in the study. The control group had greater mean age than the study group. They did not take into account the position played or the amount of previous weight training by the subjects. Inclusion of subjects who required less contact may have biased their study group.

Only 2.4% developed the defect during their college careers in a study by McCarroll et al (1986) and the rate of spondylolysis or spondylolisthesis was 15.2% in freshman footballers. Semon and Spengler (1981) found 21% (12/58) of symptomatic college football players had radiographically proven spondylolysis. Of all the players with low back pain in their study, there was no difference in time lost from practice or games between those athletes with spondylolysis and those with back pain and negative findings on radiographs. Muschik et al (1996) studied the effects of several years of competitive sports training on children and adolescents with spondylolisthesis. In 78 (91%) of the 86 athletes they found spondylolysis in L5 to be already present in the first radiograph. The spondylolysis was observed on both sides in 69 (80%) cases and on one side in nine (10%) cases. In four (5%) others, they found an elongated uninterrupted isthmus. In only four (5%), there was no change in the PI. In spite of regular intensive physical exertion, all remained asymptomatic.

2.2.7 Association of other vertebral anomalies

i) *Spina Bifida*

Spina bifida at L5 and S1 levels is associated with L5 PI defects (Hensinger 1989). This posterior element dysplasia further predisposes an individual to develop PI defects (Roche et al 1951). In the study by Muschik et al (1996), 41(63%) athletes had spina bifida occulta. In 34 of these the dorsal arch split was found in S1. Infrequently it was found in L5. This failure of ossification in the dorsal arch may be due to a mechanical osteochondrosis, which result from a particular instability of the spondylolisthetic segment. This instability has also been said to be the reason that spondylolisthesis with spina bifida leads to a greater displacement (Blackburne & Velikas, 1977), (Pfeil, 1987). Fredrickson (1984) suggested that spina bifida occulta has a strong association with spondylolysis and supports the argument that the defect has an inheritance factor.

ii) *Scheuermann's disease*

There is an increased incidence noticed in adolescents who have thoraco-lumbar Scheuermann's disease, the increased thoraco-lumbar kyphosis often being associated with an increased lumbar lordosis (Hensinger 1989).

iii) *Vertebral wedging*

The evaluation of the degree of vertebral wedging of a spondylolytic vertebra can be represented as the lumbar index, calculated as a quotient (in percent) between its posterior and anterior body heights (Saraste, 1987). The degree of wedging is regarded as an index of hypoplastic dysplasia, which is itself an aetiological factor in the development of the PI defects (Wiltse 1975). The lack of vertebral wedging at L4 spondylolysis in comparison with L5 spondylolysis may indicate different aetiologies for L4 and L5 spondylolysis (Saraste 1987).

iv) *Risk of vertebral slip*

Lumbar index is not associated with increased risk of slippage. Slippage is rare after the vertebral growth is complete (18-21 years), and periods of most likely and rapid slipping is between 9 and 15 years (Ciullo, 1985). Pfeil (1988) reported > 40% progressive spondylolisthesis (defined as an increase in displacement of 5%). Seitsalo et al (1991)

reported that 62/272 (23%) subjects with spondylolisthesis with clinical symptoms, a >10% displacement was observed. Blackburne and Velikas (1977) found such progression in 15% of their patients. Muschik et al (1996) found only 10 (13%) of athletes had increased displacement of >10%. Only one of the 86 subjects included in their study had progression. Competitive sports did not effect the progression of spondylolyitc spondylolisthesis. There was tendency towards a more frequent progression in the displacement during the growth spurt of early puberty. An increased risk of displacement progression is said to be the reduced effect of the multifidus muscle, which lacks a part of its attachment, the spinous process (in spina bifida cases). Muschik et al concluded in their study that participation in school and competitive sports is possible for children and adolescents with spondylolisthesis when the following conditions are met: a) limited spondylolyitc spondylolisthesis, b) lordosis in the displaced segment, c) absence of symptoms, d) regular medical monitoring.

CHAPTER 3

Review of Literature

3.1 Diagnosis & Management Strategies

3.1.1 Symptomatology

3.1.2 Diagnostic Measures

3.1.3 Management Strategies

3.2 Developing the Research

3 REVIEW OF LITERATURE

3.1 Diagnosis & Management strategies

3.1.1 Symptomatology

Low Back Pain (LBP)

LBP is the commonest complaint among competitive gymnasts, and participation in the sport has been associated with an increased prevalence of a number of structural injuries in the spine. Typically patients present with extension related LBP without radicular involvement. The second type of pain is due to segmental instability caused by the structural defect in the PI (Ciullo et al 1985).

Of particular concern among these athletes is symptomatic spondylolysis. Micheli and Wood (1995) reported that spondylolysis accounted for approximately 50% of the cases of low back pain seen at an adolescent sports medicine clinic. In gymnasts, the frequent occurrence of pars lesions is likely related to the stress associated with the extreme repetitive extension, flexion and rotational motions of the lumbar spine necessary to compete in the sport (Jackson et al 1976, Soler & Calderon, 2000). Sward et al (1990) noted abnormalities on plain radiographs in 42% of elite gymnasts (aged 14-25 years). In Rossi's (1995) series, 33% of athletes had spondylolysis and most of them had LBP.

Athletes have an increased number of skeletal abnormalities which may contribute to the symptoms. Apart from spondylolysis and spondylolisthesis, the other causes include Schmorl's node, disc space narrowing, scoliosis and apophyseal abnormalities (Hellstrom et al 1990). The athletes with abnormal radiographic results have a higher frequency of LBP compared with those with no abnormal radiographs. Iwamoto et al (2004) studied prospectively, the relationship between prevalent abnormal radiographs of the lumbar spine in the high school and college football players and the incidence of LBP during one year period after the start of participation in football. With regard to high school players, the incidence of LBP was 54.1% in players with at least 1 of the above 6 abnormalities and 37.1% in those with no such abnormalities. Players with spondylolysis had a significantly higher incidence of LBP (80%) than those without the six main abnormalities.

The lumbar spine in football players is subjected to compressive, shear and lateral bending loads of large magnitude during playing. This dynamic loading pattern places the lumbar spine motion segments at risk of stress on the laminae (Gatt et al 1997). This repetitive stress on the laminae when playing may be the main reason for the high incidence of LBP in players with spondylolysis. The players who didn't have radiographic detection of spondylolysis may also have back pain due to a pars stress reaction. A stress reaction is not visible on plain radiographs.

Four back pain syndromes have been defined in the realms of spinal medicine. The symptomatic disc lesion, root entrapment syndrome, back or referred pain and neurogenic claudication. The incidence of LBP syndromes in patients with spondylolysis and without has been studied (Porter and Hibbert, 1984). They noted that there is a significantly higher incidence of back and/or referred pain in patients with spondylolysis than without (32.8% vs 18.2%). Only two patients in their series had sufficiently disabling root symptoms, tension signs and abnormal neurological signs fulfiling the criteria of a symptomatic disc lesion. The pain source in the pars defect in younger patients is rarely due to disc degeneration. As one reaches the age of 25years, the probability of disc degeneration increases (Szypryt et al 1989). Many individuals may remain asymptomatic even with an abnormal PI. In children, the symptoms of LBP have been generally attributed to the fatigue fracture of the PI. In adults, the source of pain remains uncertain.

The nature of the LBP in spondylolysis has been studied by few authors. Histologically, the pathogenesis of the spondylolysis or elongation of the PI has been suggested to be similar to the stress fracture of growing bone. There is a tendency to stress-related deformation and elongation of the bone tissue and to the pathologic consolidation leading to fibrous-cartilaginous pseudoarthrosis. The function of nerve endings in musculoskeletal tissues can be inferred from their histologic appearance. Freeman and Wyke (1967) classified articular sensory receptors into four types. The first three types have an encapsulated appearance, called mechanceptors and are associated primarily with proprioception and probably nociception. The fourth type consists of smaller free nerve endings that appear to function as nociceptors (Ashton et al 1992). Wiltse et al (1975) described a well developed ligamentous structure in the PI defect. The presence of neural elements in and around this tissue constitutes some evidence that this structure could be an additional source of pain in patients with LBP in presence of spondylolysis.

In 1994, Eisenstein et al reported the presence of neuropeptides and immunoreactive nerve fibres in the spondylolysis defect. They named it the 'spondylolysis ligament' they did not characterize the nerve endings histologically.

Sometimes pain may develop long after (in early or mid adulthood) the initial lesion has occurred e.g. during childhood or adolescence. Why symptoms develop late, in relation to the initial occurrence of the defect is a matter of debate. It is thought that the PI defect constitutes a non-united fracture at a level of the spine (usually the LS region) which is subjected to significant and repeated mechanical stresses. Schneiderman et al (1995) identified high density of neural tissue capable of nociceptive function from the connective tissue and scar harvested from PI defect. Injection of the pars defect with local anaesthetic has been recommended to determine if the pain generator is the pars defect (Suh et al, 1991). The finding of nociceptive nerve endings within the pars defect lends credibility to pars injection as a diagnostic test in the evaluation of LBP in spondylolysis.

It has been suggested that the interposed tissue within the pars defect may be a source of back pain in some patients with symptomatic spondylolysis. The existence of slow conducting pain fibres of C type could be detected in spondylolyitc tissue using staining for Substance P and CGRP. Substance P is also known to stimulate the release of prostaglandin E2 and collagenase (Lotz et al 1987). This peptide may have a role in the pathogenesis of painful non-union of bone. A recent study by Boszczyk et al (2006) suggest that the 'spondylolysis ligament' has the hallmarks of a normal ligament i.e. fibrocartilaginous enthesis at either end of an ordered collagenous fibrous strcuture. The fibrocartilage is believed to dissipate concentration at the hard/soft tissue boundary.

These findings are suggestive of multifactorial nature of the pain arising from the pars defect. But why some asymptomatic individuals continue to remain asymtomatic throughout adult life with large PI defect? These questions remain to be solved.

Does the pars defect lead to chronic instability and disc degeneration? Lumbar instability is considered to be a significant factor in chronic low back pain. Ciullo (1985) suggested two possible sources of painful PI defect. Firstly, the pain is often associated with the development of an acute stress fracture, and once the acute processes subside so does the pain. Secondly, segmental instability as a result of or associated with the PI defect

may be a cause of pain. However, segmental instability as a source of pain remains a contentious issue (Bogduk, 1997).

Other likely sources of pain are at the intervertebral disc at the level of spondylolysis and the level above, the facet joints (including their capsules), and all the musculo-ligamentous structures that serve the stressed segmental level. These structures have the anatomic basis for nociception (Ashton et al 1992). Most cases of disc space narrowing were combined with spinal instability, whereas spinal instability was much less frequently combined with disc space narrowing, suggesting that cases of disc space narrowing can result from progression of spinal instability (Ashton et al 1992). When this happens it may be an irreversible phenomenon. Subsequent development of facet arthropathy with stretched capsule of the joint may be attributing to the pain syndrome in spondylolysis. This may eventually lead to spinal canal narrowing and stenotic symptoms. Thus, disc space narrowing with facet arthropathy may result in a higher incidence of low back pain in slightly older group of patients.

Farfan et al (1976) suggested that torsion and shear forces may be increased in spondylolisthesis, resulting in accelerated disc degeneration. Repetitive mechanical overloading may initiate enzymatic degradation of the disc, which will compromise its mechanical competence and cause pain by the production of neurogenic inflammatory mediators. Weinstein (2000) has named this process the degenerative spiral. Increased instability resulting in disc degeneration may be the reason that a previously asymptomatic pars defect in a younger person becomes symptomatic in adult life.

Saraste et al (1987) suggested that a low lumbar index in L5 defects is a risk factor for the development of low back symptoms. L4 spondylolysis in itself a positive risk factor for the development of low back pain symptoms. Early disc degeneration and loss of disc space height is strongly correlated with low back symptoms on spondylolysis patients (Saraste, 1987). More than 25% slip at the lower lumbar level increased the risk of developing low back symptoms by many fold. Athletes seem to present a different picture of greater incidence and prevalence of symptomatic lesions (Stinson 1993) which develop at a different age than those of the more asymptomatic normal population. It may be that minor skeletal abnormalities that are asymptomatic in less active individuals develop into symptomatic dysfunction in athletes who are placing greater physical

demands on their spines. However, it is observed that in many young sportsmen, a new acute symptomatic defect develops from repeated microtrauma.
Bogduk (1997) reviewed the issues of painful PI defect on the normal population. He postulated that:

1) The condition is as prevalent amongst patients with back pain as it is within the normal population.
2) No studies have established just how often a PI defect is the cause of the pain in patients at large, or in patients in whom a deficit is evident radiographically.
3) Anatomically the defect is filled with fibrous scar and riddled with free nerve endings therefore it could be a source of pain (Eisenstein 1994).
4) PI defects are not necessarily painful; in a survey of 32,600 asymptomatic individuals a PI defect was present in 7.2% (Moreton 1966).
5) It is difficult to incriminate PI defects as a source of pain on the basis of radiographic findings (Libson 1982, Frerickson, 1984).
6) Diagnostic blocks with local anaesthetic agents have some value in incriminating the PI defect as the source of pain.

The theories suggested are based on singular studies in literature. The evidence is weak regarding the source of pain from the PI defect. Studies are required to compare the normal against the sporting population who are symptomatic from a PI defect. Also it is important to esatblish the occurrence of the defect and the actual onset of the symtoms. Surgeons and physicians can speculate the source of pain to be the PI defect after clinical and imaging studies only when some individuals present with LBP. As observed many remain asymptomatic and whether these popluation is at risk of developing the pain at some point in future.

3.1.2 Diagnostic strategies

i) *Clinical*

The typical athlete e.g. a fast bowler (cricket) or a gymnast with a subradiographic stress reaction in the posterior elements of the lumbar spine has aching low back pain, usually unilateral, that is exacerbated by motions such as twisting and hyperextension. The pain upon hyperextension is most pronounced unilaterally in the paraspinous area and can be well localized over an area of 2 to 3 cm in diameter by the patient. Patients often volunteer that the pain is on one side “along the belt line.”

The aching in the lower back is present with daily activities but becomes more pronounced when the patient competes and performs manoeuvres involving the extremes of lumbar motion. The common aggravating activities elicited in the history for a fast bowler are related to running and delivering the bowl with a twisting lumbar spine. In a long term follow-up study by Saraste (1987), only 13% reported periods of disabling pain.

Physical examination reveals accentuation of pain by the standing one-leg lumbar extension manoeuvre. Some of the more symptomatic patients may have lumbar paraspinous muscle spasms and pain throughout the range of motion in the lumbar spine. Most patients are able to place their fingertips to the floor, and none of our patients with this entity have had signs of nerve root irritation when straight leg raise was tested.

ii) *Imaging techniques*

Stress reactions and fractures in and around the PI can be imaged with plain radiography, bone scintigraphy, Single Photon Emission Computerised Tomography (SPECT) imaging, Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI).

a. *Plain X-rays*

On standard lateral, antero-posterior and oblique views of the spine spondylolytic defects can be overlooked. Ravichandran (1980) showed that the isolated lateral deviation and rotation of a spinous process as seen in the AP radiograph seems to be associated with pathology in the PI. Early subtle stress reactions and to a lesser extent variation in the orientation of spondylolytic defects around the three orthogonal planes are the most likely reasons that account for the poor sensitivity of plain radiographs, resulting in a significant negative rate. Libson and Bloom (1982) used an angulated AP view to detect the defects in the PI more clearly. A 20% false negative rate has been reported if oblique images are not used (Libson, 1982). Consequently, a normal x-ray series, including lateral oblique views, does not exclude the possibility of a spondylolysis (Saifuddin 1998, Harvey 1998).

The lateral view should be taken with the patient standing. A 25° to 45° oblique view is usually needed to demonstrate spondylolysis. But there is increased radiation in this position and thus nowadays the oblique view has been abandoned.
PI defects are not necessarily painful (Moreton, 1996) and on the basis of radiographic evidence it is not possible to demonstrate any causal relationship (Libson 1982, Collier 1984, Fredrickson 1984, Bogduk 1997).
Thus, x-rays provide no information as to the symptomatic or asymptomatic nature of the lesion and are particularly insensitive to the initial stress reactions characteristic of early stages of spondylolysis.

b. *Bone scans & SPECT imaging*
Bone scintigraphy has been shown to be useful in the evaluation of stress changes in the PI. Both planar bone scintigraphy (PBS) and single photon emission computed tomography (SPECT) are more sensitive than plain radiographs in detecting pars lesions (Fig 4a). They may also be able to distinguish between radiographic lesions that are active and those that are inactive and presumable asymptomatic (Bellah et 1991; Bodner et al, 1988; Collier et al, 1985; Jackson et al, 1981; Lowe et al, 1984; Papanicolaou et al, 1985; Van der Oever et al 1987).

SPECT offers a more sensitive indicator of low intensity metabolic bone activity and bony remodelling, especially in early subtle stress reactions, than PBS (Harvey 1998). Also, by virtue of multiplanar tomography, anatomic localization of metabolic bone activity is greatly enhanced, increasing its specificity over PBS. As asymptomatic lesions are common (Moreton 1996, Bogduk 1997) the diagnostic requirement is to distinguish between painful and non-painful defects. Some studies suggest that when spondylolysis is the likely cause of pain, defects in the PI are associated with increased scintigraphic activity, best shown by SPECT (Lowe, 1983; Collier, 1985). However, the association between increased scintigraphic activity and symptomatic spondylolysis has not been established, (Collier, 1985), and association does not prove any causal relationship.

Bellah (1991) claims that a normal SPECT scan virtually exclude injury to the PI as a cause of symptoms, yet Collier (1985) found that not all negative SPECT scans are asymptomatic. Van der Oever (1987) described the role of negative bone scans.

It may mean a non-union of the defect. Bone scans have low specificity. Lowe (1984) showed patients with chronic low back pain with suspected spondylolysis to have normal PBS. On the other hand Lusins et al (1992) emphasised that as spondylolysis becomes chronic, SPECT reverts to normal even though spondylolysis has not healed completely.

As spondylolytic defect progresses to a slip, scintigraphy becomes positive again. It is also emphasised that the limited utility of PBS due to superimposition of vertebral structures. Anderson (2000) in a follow-up study of 34 patients with painful stress injuries, 31 became completely asymptomatic over time. This resolution was reflected in the SPECT ratios, which decreased by an average of 13%. Additionally, the subset of patients who remained symptomatic at their follow-up, SPECT study had a significantly smaller decrease in the SPECT ratios compared with the group that became asymptomatic. Thus, the reduction in SPECT ratio corresponds to the resolution of symptoms. What has not been shown is a direct correlation between the absolute ratio and the severity of symptoms. This would require quantification of pain, such as that measured with a visual analogue scale. From their study it was concluded that a follow-up SPECT scintigraphy is not required for most patients with stress injuries to the PI. Clinically, there may be a role for a follow-up SPECT study when there has been an atypical clinical course and if an objective, quantifiable indicator of progress would be helpful in guiding treatment options. Reduction in the SPECT intensity relates directly to the symptom improvement. But if there is a non healing defect or a stress reaction which has progressed to a fracture it may be difficult to predict the outcome with SPECT imaging. In the study by Debnath et al (2003) it has been demonstrated that as the time lag from the onset of low back pain increases the value of SPECT diminishes. Beyond a period of six months, SPECT looses its sensitivity as well as specificity.

c. *CT scans*

Computerised tomography is most often applied using the reverse gantry angle technique so that the scan plane is perpendicular to the defect, and in thin sections, CT is the most specific investigation for demonstrating a spondylolysis. It is the investigation of choice for identifying radiographically occult lesions (Harvey 1998).

CT has been mainstay in the identification of the location of the lesion, and for estimating the potential for the defect to heal. The 'incomplete ring' sign has been proposed as a method of detecting pars fracture (Langston & Gavant, 1985). The ring of the bony spinal canal is composed of the posterior aspect of the vertebral body, the medial walls of the pedicles, the antero-medial PI and lamina, and the anterior portion of the spinous process. If this ring is intact, a fracture through the pars can be excluded.
Callus formation around the side of the fracture indicates potential for bony healing of the lesion, whereas wide, well corticated margins indicate an established non-union (Harvey 1998).

There is considerable variation in the angle of the defect as seen on reverse gantry CT scans. The sagittal and axial orientation varies from individual to individual. Debnath & Jones (2004) studied volumetric 3-D reconstruction CT scans of the patients with lumbar spondylolysis at L5 vertebrae. The mean sagittal pars angle was 44.5° (15-73°) and the mean axial pars angle was noted to be 17° (-7 to 80°). This wide variation in the angle of the defect may be due to the fact that repetitive stress leads to failure of the trabecular bone in the lines of stress. Thus the lines of stress may depend upon each individual's weight bearing characteristics at the L5 vertebral level.
The morphology of the defect in terms of its width, site, orientation and gapping is essential in planning for operative fixation. Preoperative evaluation of the defect is feasible with 3D-CT scans (Fig 3). 3D-CT scans provide us with the spacial orientation of the defect but it needs expertise to interpret.

d. *MRI scans*
MRI scans are nowadays routinely used for the early diagnosis and treatment of patients with suspected stress injuries to the lumbar PI. With the use of high magnetic field strength, fat saturation techniques, and dedicated coil technology, high resolution MR images can be obtained that demonstrate the subtle bone marrow edema of early stress injuries, thus providing greater sensitivity than any other imaging modalities. (Arendt et al, 1997, Grenier et al, 1989, Saifuddin 1997). Thin slices (3 mm on T1 W images and 4 mm on T2W images), with a smaller (0.3mm) intermediate gap, were used to assess pars integrity by Udeshi & Reeves (1999).

They concluded that they were able to assess 98.2% of pars defect on T1W images and 93% on T2 W images. The stress injuries in the PI initially manifest as bone marrow oedema visible as abnormal high T2 signal on sagittal fat presaturated MRI images of the PI. Signal abnormalities are also seen in the adjacent pedicle and articular process. As the stress injury progresses, thinning, fragmentation, or irregularity of the PI are visible on MRI. Hollenberg et al (2002) classified the PI defect into five grades on the basis of MRI scans. Thin slices (3-3.5mm) with small (0.5 to 1.0mm) interim age gaps were used, and both T1 and T2 W images were assessed. The following grading scheme was applied: grade 0 – normal; grade 1 – T2 signal abnormalities consistent with oedema but no true spondylolysis; grade 2 – T2 signal abnormalities visible on T1 or T2 W images; grade 3 - visible complete unilateral or bilateral spondylolysis with associated abnormal T2 signal; grade 4 – complete spondylolysis without abnormal T2 signal (old united fracture). This classification was subjected to reliability and reproducibility tests and found to have Kappa coefficients for inter-observer reliability ranging from 0.706 to 0.906. They also reported that 42% of their patients to have either a stress reaction or a true spondylolysis, based on the above classification system. Thus, today MRI scan has become a useful diagnostic tool for assessment and management of patients with stress reaction of the PI.

3.1.3 Management Strategies

i) Conservative

a. *Physiotherapy & Bracing*

Clinicians understanding of the natural history of spondylolysis and spondylolisthesis remain incomplete. The prognosis for a 6 year old child with a PI defect in terms of disability and pain appears to follow that of general population. Pain with these lesions is rare in childhood and adolescence. Pain does increase as the age of the study population increases (Beutler et al 2003).

The anterior translation of spondylolisthesis is usually painless. The aim of managing painful lesions in young active individuals is to achieve bony union or at least a fibrous union of the PI defect in order to eliminate movement across the defect.

The treatment and management of symptomatic spondylolysis in sporting populations is mainly based on observation rather than experimental study. No randomised –controlled trials have been done investigating the effectiveness of conservative or surgical treatment. Sample selection in studies was generally small and poorly controlled. Consequently, the evidence base for interventions must be described as weak and inconclusive.

Conservative treatment in the form of bracing and avoidance of sports for at least three to six months has been recommended. Steiner and Micheli (1985) treated symptomatic patients with spondylolysis or low grade spondylolisthesis. The brace used in their study was a modified version of the Boston brace used for scoliosis, and was worn for 23 hours per day for six months, followed by a weaning period of the same time. Participation in sports was permitted, provided the brace was worn and the activity did not produce symptoms. Physical therapy included hamstring and lumbosacral stretching, and abdominal strengthening was instituted at the onset of treatment. Excellent or good results were achieved in 78% of patients with only 9% subsequently requiring surgery.

Bell et al (1988) treated patients with physical therapy and bracing with low grade spondylolisthesis for an average of 25 months. All patients were asymptomatic at the end of the treatment and had no patient had progression of slip. D'Hemecourt et al (2002) treated a total of 73 athletes with spondylolysis. All were treated with bracing for 23 hours a day along with physical therapy. Athletes who were pain free 4 to 6 weeks after the commencement of bracing were allowed to participate in sport wearing the brace, provided they remain pain free and avoided lumbar hyperextension. This intervention led to a good or excellent outcome in 80% of patients. Male athletes and low risk sports had better outcomes.

Anderson et al (2000) studied retrospectively, 34 patients with symptomatic pars defect who were treated with bracing. All patients had an initial and a follow up SPECT imaging. At final follow up, 91% of patients were asymptomatic, and the remaining 9% had occasional symptoms only with activity. The average SPECT ratio before brace treatment was 1.45. After treatment, this ratio significantly decreased to 1.27 ($p=.03$).

Patients diagnosed and braced early, more active stage of the condition (with greater intensity on SPECT) had more predictable symptom relief. An initial SPECT ratio of >1.5 was associated with complete symptom resolution after brace treatment.

Maharam and Sharkey (1992) reported successful treatment of symptomatic pars defect with pulsed electromagnetic fields. After 8 weeks of treatment for 8 hours a day, bony union was demonstrated on CT in three patients and the patients remained pain free. Fellander-Tsai and Micheli (1998) used a bone growth stimulator to successfully treat two patients who had previously failed conventional conservative treatment in the brace.

Fuzii et al (2004) evaluated retrospectively the effects of prognostic variable on bony union of pars defect in 134 patients less than 18 years of age with 239 defects of the pars who had been treated conservatively. The results showed that the spinal level and the stage of the defect were predominant factors. The site of the pars defect, the presence or development of slip, the condition of the contralateral pars, the degree of lumbar lordosis and the degree of lumbar inclination significantly affected union.

A commonly cited concern with spinal orthoses is their deconditioning effect on the paraspinal muscles and trunk stabilizers. Some studies have shown a significant reduction in muscle activity during bracing (Cholewicki J et al 2007), while others found either unchanged or increased activity of erector spinae muscles in the braced state (Nachemson AL, 1987). The main benefit of bracing in patients with painful spondylolysis or pars stress injuries may be as a means of restricting activities (kinesthetic reminder) rather than biomechanically stabilizing the pars defect.

b. *Trunk Stabilization exercises*

Physical therapy included hamstring and lumbosacral stretching, and abdominal strengthening was instituted at the onset of treatment.

The basic components of conservative treatment can be split into 4 areas of common ground characterised by the wide variations in practice:

1) Reduction of activity level that causes the pain and relative immobilization
2) Stretching hamstrings and glutei
3) Abdominal strengthening exercises and back extensors, including core stability and functional dynamic stabilization programs

4) Graded return to provocative exercise when symptoms subside to allow comfortable exercise

Criteria for return to sport are dominated by symptom based decisions and rarely based on the natural history of the lesion in terms of healing. An exercise regimen to the limits of the patient's tolerance should be maintained and early discontinuation of the orthosis (if used) is advised as soon as the clinical condition permits.

Jackson (1981) stated that bone scans must return to normal before return to provoking sport. Hamstring and gluteal stretching has been suggested based on the observations that the commonest reported findings is tight hamstrings and that a decrease in hamstring tightness is a common clinical guide to success or failure of treatment (Hensinger 1989). There is no experimental evidence to support or refute this opinion.

c. *Management Plan*

Herring & Kibler (1998) had modelled a plan of management for young athletes especially gymnasts with a suspected pars lesion. It proved to be of good successs in many of the patients. There is a similar plan of management which is followed in our institute by the physical therapists is shown in the Fig 15. In the diagnostic stage, initial history & examination is followed by plain Xrays of the lumbar spine. Before 2001, SPECT imaging was performed in all suspected cases but since 2002, MRI is the mainstay of imaging. A pre treatment questionnaire was filled by each patient, which included VAS, ODI and SF-36. The radiologist confirmed pars lesion and the stage at which the lesion was i.e. acute or progressive or terminal phase. Depending on the phase of the lesion a regime of physical therapy was instituted for 5-8 months. Initial phase of 12 weeks was spent in absolute rest and restriction from any activities. We considered bracing only if the patient continued to have pain. The rehabilitation phase was divided into acute stage which lsted at least 4 weeks followed by recovery and later functional stage. Range of motion and low impact aerobic conditioning was instituted when patient was painfree. Core strength and spinal stabilization exercises were advised as the patient could tolerate. The athlete was advised return to sports when he/she had full range of pain free lumbar spinal motion and normal core and trunk strength with appropriate aerobic fitness. The athlete was trained for gradual return to the skillful application of the movements required for each sporting event

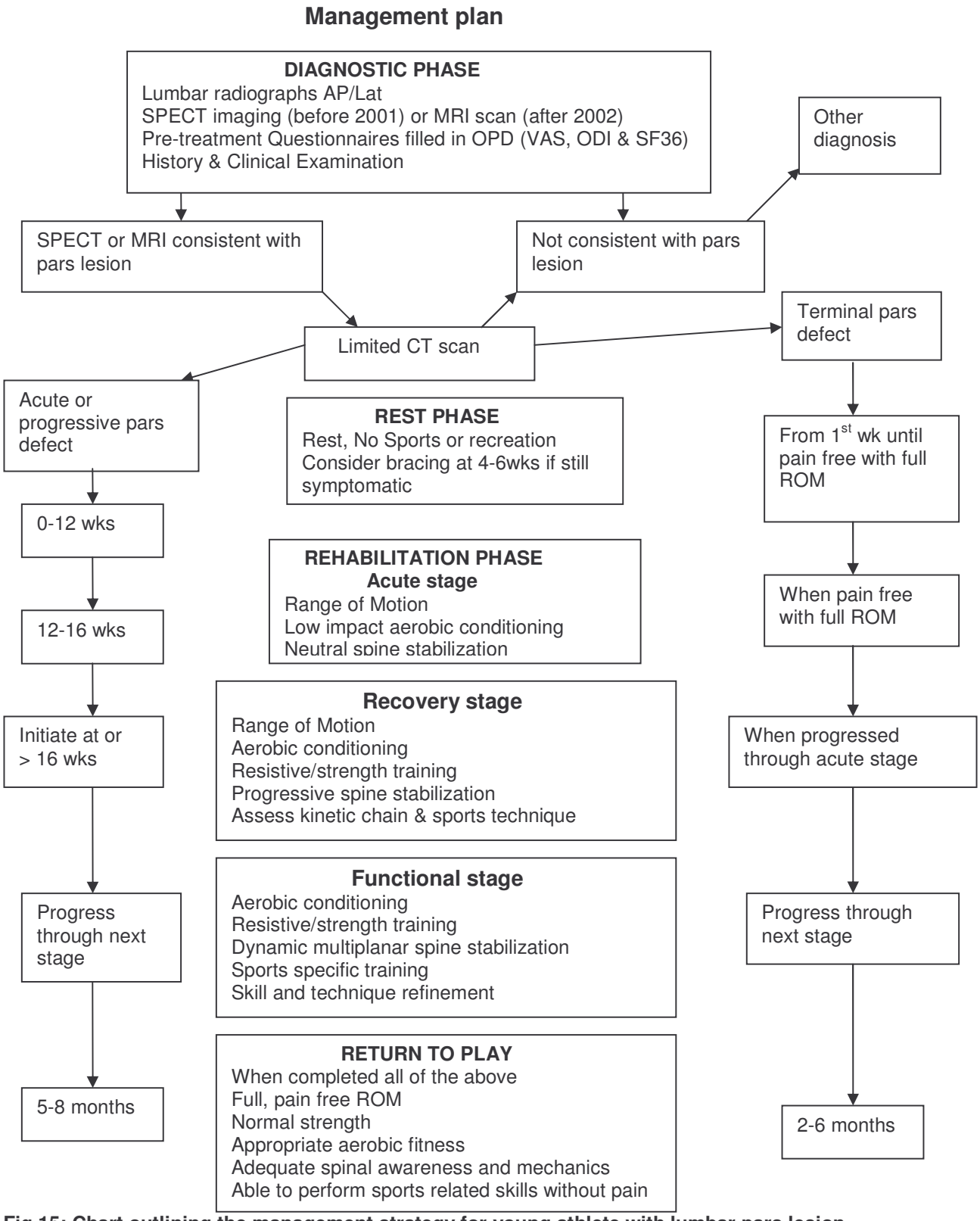


Fig 15: Chart outlining the management strategy for young athlete with lumbar pars lesion at QMC, Nottingham (Modified from Herring & Kibler, 1998)

ii) Surgical treatment

A small percentage of patients need an operation. Incidence of unmanageable low back pain because of a pars defect in the young, competitive athlete is low. However, there are some individuals who experience disabling symptoms that are unresponsive to conservative treatment and preclude them from participating in their sport. Historically, postero-lateral arthrodesis with or without excision of the posterior elements has been the usual procedure. However, the disadvantage of that operation is the resulting loss of a motion segment at the level that fuses, which increase the load on the adjoining, segment thus leading to disc degeneration. The results of surgery have been predictably good in terms of pain relief but not necessarily with regard to returning to competitive sports. The rationale for direct repair of the defect of PI is that the defect is the main locus of pain.

i) *Direct repair (different techniques)*

Several techniques have been described for direct repair of the pars defect. Repair of the pars defect is an appealing option for symptomatic patients who had failed to respond to conservative measures since it preserves movement. MRI is required to exclude more proximal disc degeneration in this group since the degenerate disc may be the pain generator. The direct repair of the PI was first described by Kimura in 1968. Buck (1970) first described the direct repair using a screw across the defect on both sides. This technique is technically difficult and the screw interferes with the potential area of bone incorporation. The surface area of the defect is small. Although good results have been reported, there is a significant learning curve for correct placement of the screw. Sometimes the configuration of the defect disallows placement of the screw at L5 level. Several small series of patients have reported with satisfactory outcomes using different techniques. The success rate varied between 63% and 100%. Kip et al (1994) concluded from a biomechanical analysis that repair with a screw had the greatest strength. They suggested that the technique which should resist the extension forces across the pars should be able to stabilize the posterior segment and result in healing of the defect. Buck's fusion has been used for treatment of ten fast bowlers in Western Australia by Hardcastle et al (1993). All but one returned to active cricket following Buck's fusion. Buck did not mention specific exclusion criteria. In his first 16 patients he reported one failure, although details of activity and outcome measurements

were not included. He did conclude based on his one failure, that a gap of more than 4 mm at the defect was probably a contraindication to this procedure. Suh et al (1991) reported a series of ten patients, nine of whom had successful results, although only six returned to work. They evaluated the prognostic value of pars infiltration with lidocaine in six of their patients. They suggested that the temporary pain relief with pars injection was of prognostic significance for predicting successful operative repair of spondylolysis. Wu et al (1999) followed this protocol in 93 patients with a mean age of 23 years who underwent surgery and reported success in 91.3%. It has been reported that a successful outcome is more likely to occur in younger patients. Pederson and Hagen (1988), in a study of 18 patients with direct repair of the defect with screw fixation, reported that three of these had pseudoarthrosis of the site of the defect bilaterally or unilaterally with a poor clinical result.

They accepted slips as high as 10 mm as surgical candidates. Roca et al (1989) had 1-10 year follow up on 15 patients, 13 of whom had a satisfactory outcome. Clinical success was noted by six months in 13 patients. All 13 returned to their preoperative sports. No defect was greater than 3 mm at the time of surgery. Tonino and van der Werf (1994) had 10 year follow-up. There were satisfactory results in 85%. All surgical candidates had to have a normal preoperative discogram. More than 4 mm slips were excluded. Dai et al (2001) examined the efficacy of direct repair in 46 patients with spondylolysis. They attained an excellent or good functional outcome in 93.4% of all patients. They however noted that the success of such a procedure was highly dependent on the presence of normal adjacent discs as assessed by MRI studies. Failure of direct PI repair has been attributed to the presence of significant disk degeneration or segmental instability. Szypryt et al (1989) recommended segmental fusion instead of direct pars repair in patients more than 25 years of age due to the increased incidence of disc degeneration. Debnath & Freeman (2003) reported the clinical outcome of 19 athletes who underwent direct repair of the defect with screw fixation. ODI (Oswestry Disability Index) and SF 36 (Short form) scores were used to evaluate the final outcome. The mean scores improved significantly in all domains of SF 36 health questionnaire ($p<0.001$). All but one patient who was 33 years of age had returned to active sporting life within seven months of surgery.

Nicoll and Scott (1986) reported the technique of wiring the two adjacent transverse processes on seven patients. One wire breakage followed by non-union was reported. Bradford & Iza (1985) reported results on 21 patients using Scott wiring technique. They had reported 90% good or excellent results. There are inherent problems with this technique. Exposure is extensive and requires stripping of the muscle from the transverse process completely. There is significant risk to the nerve root, and substantial bleeding is common. The wire is prone to fatigue failure and cannot be place under good tension without breaking. The fixation is dependent on the weak bony elements – the transverse and spinous processes.

In 1984, Morscher et al presented a technique using hook-screw to repair the pars defect. A modified Harrington hook is placed over the inferior edge of the lamina, and a screw is inserted into the superior articular process. Heifti et al (1992) reported that only nineteen (58%) of the thirty three patients who had fixation with a hook-screw had a clear union bilaterally and six (18%) had pseudoarthrosis bilaterally. The major problem with this technique is the screw placement. An analysis of screw placement showed that there was a 15% technical error with penetration of the inferior articular process of the vertebra above and transpedicular placement. Other errors include using short screws that were only unicortical and did not penetrate both cortices of the superior articular process. The technique has several other disadvantages: it requires special instrumentation, the screw is technically difficult to implant, and the hardware is bulky.

A biomechanical comparision of these techniques was conducted on calf spines (Deguchi et al, 1999). All were found to increase stiffness approaching that of the intact spine. Buck screws and the hook systems allowed the least motion. A clinical comparision was also reported comparing outcomes of patients undergoing Buck repair versus Morscher clamps (Dreyzin & Esses, 1994). This was a small study in an older population with a mean age of 35 years. Restriction criteria for patient selection were not discussed. Outcomes were similar in both groups with good or excellent results in about 50% patients. Another small study included 11 patients who underwent direct repair with either Buck screws and Morscher clamps (Jeanneret, 1993). They did not specify the exclusion criteria but implied that all patients had normal appearing discs on MRI scans.

This was a younger population, with 7 of 11 under 20 years of age. They did not detail activity levels in their results, nor did they compare techniques. They reported good or excellent results in 63% of patients overall.

Kakiuchi (1997) described a technique of repair using a pedicle screw, rod and laminar hook fixation. The configuration of the head of the screw, which is designed to allow it to connect with the rod at the necessary angle, simplified the placement of the rod. He reported sixteen patients who underwent this technique of direct repair. Five of these patients were more than forty years old and the oldest was sixty years old.

A solid osseous union of the defect was achieved in all patients without any failure of the patients without any failure or loosening of the implant. The good results achieved in the older age patient are the main difference in outcome from other studies. Use of direct repair of the PI in cases of multilevel pars defect (segmental wiring) has been reported (Ogawa et al, 2007). Although this technique is very effective in the general adolescent and young adult population, there is no literature describing its effectiveness in returning elite level athletes to competition.

Songer & Rovin (1998) described another technique of direct repair using a cable-screw construct. A special pedicle cable-screw was placed into the pedicle of the involved vertebra. A double cable was passed underneath the lamina, threaded through the hole of the pedicle screw, and wrapped around the spinous process. The cables were simultaneously tensioned and crimped. A tricortical bone graft was compressed between the pedicle and lamina. Seven patients had direct repair using this technique. All had good to excellent clinical outcome.

All the techniques used for direct repair have produced good to excellent results. The failure modes of these techniques are dependent on patient selection and the mechanical failure of the instrumentation leading to non-union of the defect. Because success reported in the literature declines as the age of the treated patient increases, all patients older than 25 years should undergo diagnostic infiltration of the pars defect. The mechanical failure of instrumentation may result from high stress on the pars with

extension and torsional forces. The surface area of the defect is small for incorporation of a bone graft across the defect.

ii) *Description of techniques*

a) *Buck's repair*

Buck's fusion is performed using a 4.5-mm stainless steel AO cortical lag screw for adults. For young individual less than 14 years of age one needs to make decision intra-operatively regarding the thinness of the screw (3.5mm screw is an option since the lamina is slender in many young ones). An on table radiograph guidance is required for correct placement of the pedicle screw.

The involved pars interarticularis is exposed through a posterior paraspinal incision. The natural cleavage plane between the multifidus and longissimus muscles is exposed to reach the defect. The pars defect and adjoining lamina are cleaned of soft tissue. Good, bleeding bone is exposed both on pedicle side and the laminar side. During preparation of the pars defect, a small burr or a small curette may be used to square off the defect. Once the screw is inserted across the pars defect to 75% of its length, the position is verified by radiographs. The screw compresses the spondylolytic defect and enters the lateral aspect of the respective pedicle. Cancellous grafts from iliac crest are taken with a 4mm diameter trephine. This is packed into the defect and the screw is inserted completely. A final radiograph is taken for confirmation of the placement of the screw (Fig 10 f).

After surgery, patients are mobilized without support. A static isometric exercise program incorporating spinal stabilization exercise is started at 6 weeks and cardiovascular program for strength and endurance at 12 weeks. The functional restoration program is continued until the patient felt able to return to sport. A plain radiograph is taken between 6 & 12 months. If the patient remained asymptomatic, he or she was allowed to return to sport.

b) *Scott's repair*

This modfied technique of repair was performed in our series of patients before 1998. Through a posterior longitudinal midline incision, the paravertebral muscles are stripped to expose the spinous processes, lamina, and both transverse processes, leaving the facet joints and the capsule undisturbed. The presence of the pars interarticularis defect is confirmed. The defects are cleared of any fibrous and cartilaginous tissues. The sclerotic bone margins are curetted. The soft tissues are mobilised from the anterior surface of the base of the transverse process with a Cobb's elevator. A tunnel is created for the wires to pass. An 18-gauge wire then is passed around the base of the transverse process on either side from the superior to the inferior direction and pulled through. The end of the wire then is passed superiorly to the base of the spinous process of the affected segment and back through the interspinous ligament. The wires then are pulled tight by twisting in the usual way, and the ends are inverted.

Cancellous bone chips, obtained from the ala of sacrum, are packed onto the surface of each defect in such a way as to be trapped by the tightened wires. Radiographs are taken to confirm the adequacy of the repair. In couple of cases two screws are inserted into both pedicles and the wire is passed around the screw heads and then around the spinous process (Fig12 a & b). Bracing was done for a period of three months following the surgery. A physical therapy protocol was followed and patients were allowed to return to sport if asymptomatic.

iii) *Management algorithm*

An algorithm was developed in our spinal unit over the years (Fig 16). Following initial history and examination, imaging i.e. plain X-rays, SPECT imaging (before 2001) or MRI scan (after 2002) were performed. Pre treatment questionnaires were filled by the patients. Once the stage of the pars lesion was identified conservative treatment was instituted primarily. The patients were re-evaluated after failure of conservative treatment for at least six months with the patients complaining of continued pain. Surgeons offered surgical repair following an rG-CTscan (reverse gantry) and a pars injection with local anaesthetic in the theatre. All the patients were advised direct repair with Buck's fusion if pars block improved the pain.

On MRI scan if there was evidence of disc degeneration (Hig Intensity Zone –HIZ) at that level then a discogram was performed to rule out if there was concordant pain produced due to the disc degeneration. The patients were offered direct repair of the spondylolysis or pars defect if discography was negative. All patients were evaluated with VAS, ODI, SF-36 forms and BPSQ forms.

3.2 Developing the research

The transition zone between the end of conservative treatment and surgical repair is grey. Some patients continue to be symptomatic and decision to operate on these patients is easier than the group of patients who become asymptomatic for a certain period. This group has recurrence of LBP on resuming activity. These patients show minimal signs of progression or union of the defect on CT scans.

There are patient factors which may directly or indirectly influence the decision regarding the surgical repair of the defect. There are patients with disabling symptoms in spite of adequate conservative treatment. Most athletes or young active professional sportsmen or women would like to return to their previous level of sports since they may be earning their livelihood through the sport. The onset of symptoms and the length of treatment in these patients may lead to a good clinical outcome but it is difficult to predict which group or which individuals will require surgical repair of the defect. Who are these individuals who will do well following operation? Surgical decision in the individuals with persistent symptoms is based on the fact that they remain painful and radiology may show evidence of non-reactive fracture ends in the PI. But not all individuals will be offered surgery. A select group of active sporting individuals may be offered the surgery and in many cases it is surgeon dependent decision.

Thus, if considering all the factors responsible for a good outcome following surgery were analysed then predicting a successful outcome may become possible in that select group of individuals. In this thesis, the various indicator variables of a good outcome were recorded and analysed categorically. Each factor was correlated against the successful clinical outcome to determine the significant predictors which when present in a patient one can predict a successful outcome.

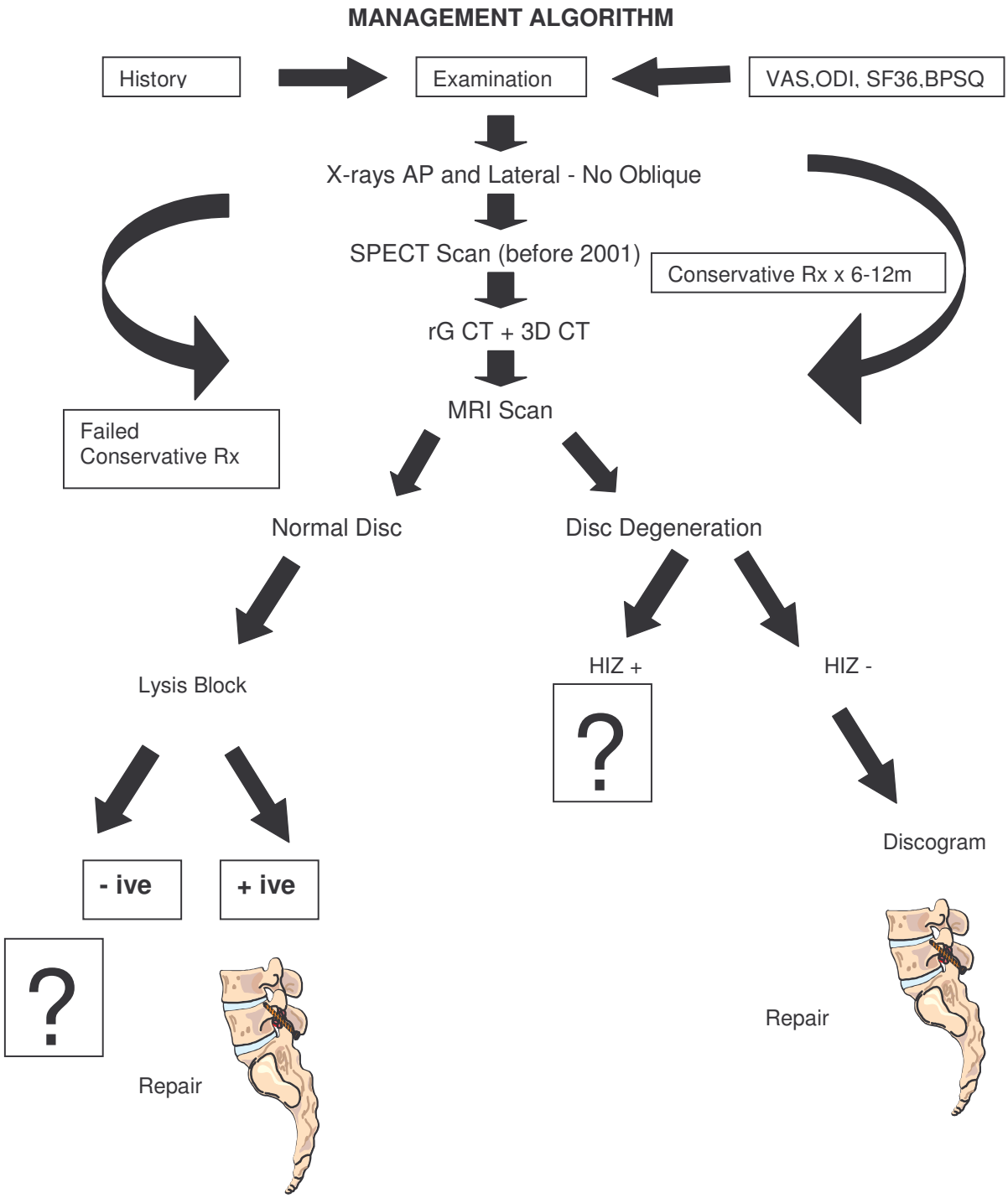


Fig 16: Algorithm followed at QMC, Nottingham, proceeding to surgical repair of Lumbar spondylolysis

CHAPTER 4

Methods

4.1 Research Question

4.2 Hypothesis

4.3 Study Design

4.4 Ethical Approval

4.5 Medical record review & Database

4.6 Imaging studies

4.7 Questionnaires

4.8 Sample size and power study

4.9 Statistical analysis

4.10 Limitations of methods

4 METHODS

4.1 Research Question

a. Do all patients need a primary conservative treatment for symptomatic pars defect or spondylolysis?
b. What are the predictive factors for a successful outcome following surgical treatment for symptomatic pars defect or spondylolysis?

4.2 Hypotheses

The following null hypotheses were assumed for each study:

Study 1

A. H_0: There is no difference in the mean change in the outcome in conservatively treated patients

A_1. H_0: There is no difference in the outcome in conservatively treated patients below the age of 14years

A_2. H_0: There is no difference in the outcome in conservatively treated patients between 15-19years of age

A_3. H_0: There is no difference in the outcome in conservatively treated patients between 20-24years of age

A_4. H_0: There is no difference in the outcome in conservatively treated patients between 25-29years of age

A_5. H_0: There is no difference in the outcome in conservatively treated patients above the age of 30years

A_6. H_0: There is no difference in outcome in conservatively treated two groups i.e. unilateral versus bilateral pars defect

A_7. H_0: There is no difference in the age between the sporting and non-sporting group of patients treated conservatively

A_8. H_0: There is no difference in the outcome between the sporting and non-sporting group of patients treated conservatively

Study 2

B. H_0: There is no difference in the mean change in the outcome in surgically treated patients

B_1. H_0: There is no difference in the outcome in surgically treated patients below the age of 14years

B_2. H_0: There is no difference in the outcome in surgically treated patients between 15-19years of age

B_3. H_0: There is no difference in the outcome in surgically treated patients between 20-24years of age

B_4. H_0: There is no difference in the outcome in surgically treated patients between 25-29years of age

B_5. H_0: There is no difference in the outcome in surgically treated patients above the age of 30years

B_6. H_0: There is no difference in outcome in surgically treated two groups i.e. unilateral versus bilateral pars defect

C_1. H_0: The regression coefficient is zero for the predictor variables in surgically treated patients

C_2. H_0: There is no predictive factor which can determine the outcome following surgical repair for the symptomatic pars defect or spondylolysis

4.3 Study design

This research was carried out as a qualitative, descriptive and analytic study with a non-randomized cohort of patients investigated for pars defect or spondylolysis in Queens Medical Centre, Nottingham. The clinical data in the research was collected from the medical records and from a set of questionnaires in a retrospective cross-sectional and observational manner.

There were three procedures involved:

1) Selection of subjects for the study
2) Medical record review and data collection (clinical history and investigation results) and questionnaire survey
3) Descriptive analysis and multiple hypotheses testing of the data

Medical records of 600 patients who consulted in the Spinal clinic (OPD & Back pain) or Sports inury clinic at QMC between 1994 and 2007 were reviewed. Of these, 286 patients were identified from the records between the age group of 8 and 35 years to have positive clinical and radiological evidence of symptomatic pars defect or spondylolysis. 37 patients had been lost to follow-up and therefore excluded from the study. Patient demographics were collected for 249 patients. Of these 194 patients had been treated conservatively and 55 patients were treated surgically. We sent questionnaires to all these patients on repeated occasions. At the end we had 123/194 patients from the conservative group who responded and 50/55 patients in the operated group who responded. This has been outlined in the Fig 17. We collected the data and made a database including the following variables for each patient.

Database for study 1: This data each subject with level, number, laterality and distribution of lumbar spondylolysis, investigations, outcome with VAS, ODI, SF-36 and Back pain and sports questionnaire (BPSQ) and return to sports. The background data also contains gender, age, date of onset of symptoms with current limitation in sport, pain in flexion or extension, type of sport, level of sport and length of treatment.

Database for study 2: These contain the same as above along with the time and type of surgery that was performed.

Sample selection

4.3.1 *Study 1*

A total number of 123 patients treated conservatively following confirmation by imaging studies (SPECT,CT or MRI scans) as having stress fractures of the lumbar pars interarticularis (PI) at QMC from 1994 to 2007, ranging in age from 8 to 35 years have been selected for the study.

This study is designed to answer the following questions:

1. Does initial conservative treatment have good outcome in majority of patient?
2. Do unilateral pars defect have good outcome following conservative treatement?
3. Is there a difference in outcome between the sporting and non sporting group?
4. Do different types of sport play a role on the outcome?

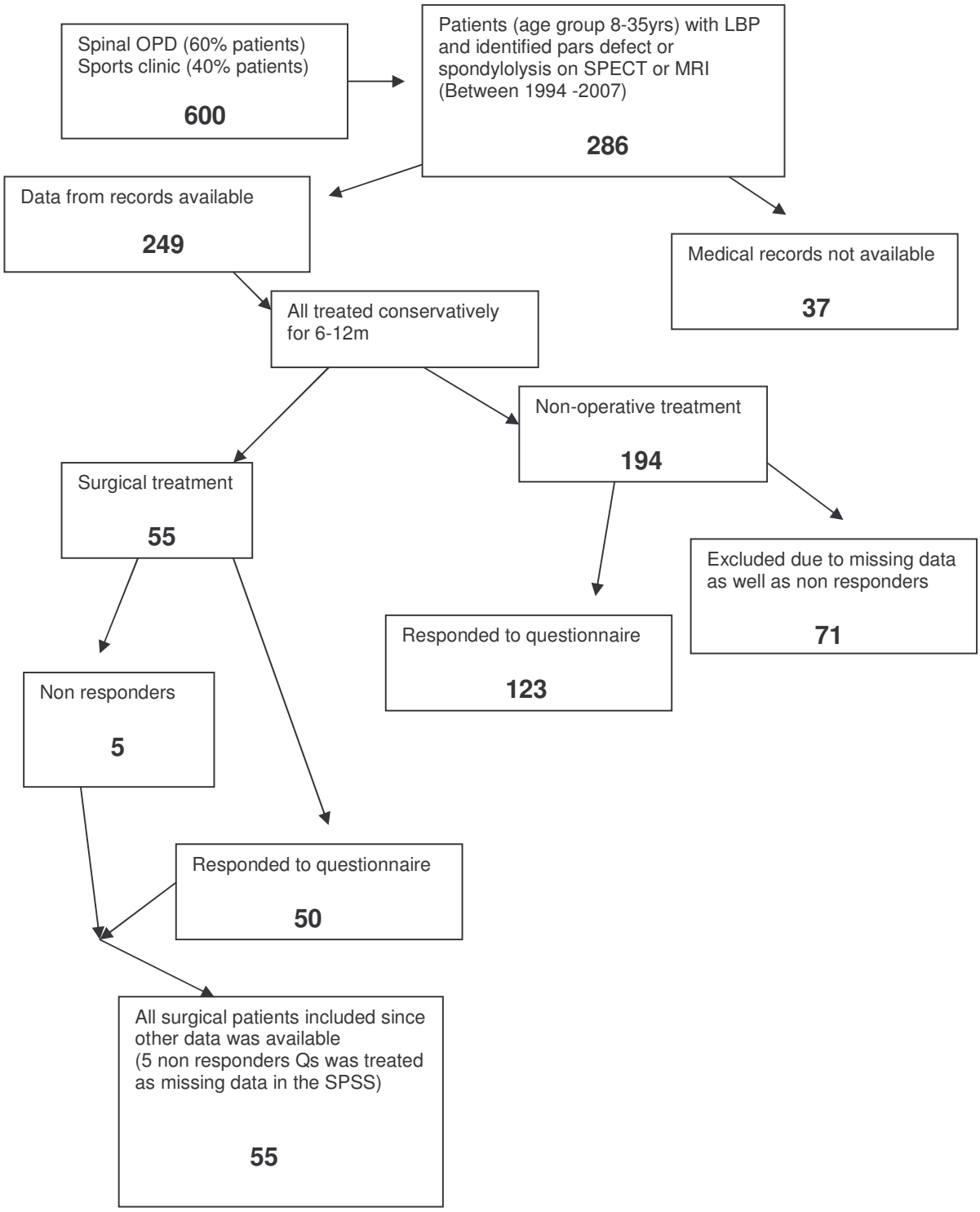


Fig 17: Flowchart showing the final cohort after exclusion in the two study groups

Inclusion Criteria:

1. All patients should have complained of low back pain as a definite clinical symptom when they consulted their physicians. Back pain was defined as self reported pain situated between the inferior angle of the scapula and the inferior gluteal folds which extended laterally no further than the axillary midline. Limitation of sporting activity was confirmed by the subject self-report recorded in the case notes.
2. All patients should have shown lumbar spondylolysis proved by imaging techniques by either CT scan ± SPECT scan ± MRI scan . A positive SPECT is defined as a scan carried out and reported on as a result of the current episode of back pain, which demonstrated abnormally increased scintigraphic uptake within the posterior elements of the lumbar spine. A positive CT is defined as either sclerosis or frank defect and gap at the involved PI. A positive MRI scan is defined as high signal on T1W image at the affected PI. All were reported by the consultant radiologist.
3. All patients should have been treated conservatively.
4. The patients between the age of 8 & 16 years of age were also included with the consent of the parents or guardians.

Exclusion Criteria:

1. The patients known to have deceased (information from GPs) were excluded.
2. The patients who were operated were not included in the study 1.
3. The patients investigated before 1994 and after 2007 were excluded.

4.3.2 *Study 2*

This study is designed to answer the following?

1. What is the most significant determinant of surgical intervention in lumbar pars defect
2. What are the independent predictors of a successful outcome following surgery
3. Can we establish an outcome predictive model based on these significant factors responsible for a successful outcome?

A total number of 55 patients treated operatively following confirmation by imaging as having lumbar pars defect or spondylolysis at QMC from 1994 to 2007, ranging in age from 8 to 35 years have been selected for the study.

All inclusion criteria are the same but patients who had failed conservative treatment and were treated surgically were included. All exclusion criteria except number 2 remains same.

4.4 Ethical Approval

Ethical approval was sought and granted from the Nottingham Research Ethics Committee 2 vide no 06/Q2404/31.

4.5 Medical Record review and Database design

We identified all together 194 patients who were included as the suitable subjects for the study 1 (conservative group). We identified 55 patients who were included as the suitable subjects for the study 2 (surgical group). All patients attending the Spinal or Sports injury clinic follow a protocol of filling up the VAS, ODI and SF-36 questionnaires as a part of their assessment on a routine basis as well as all patients undergo non-operative treatment for a period of 6-12months. During this period of study all outcome questionnaires along with the BPSQ were sent to all. 123 patients responded in the conservative group and 50 patients responded in the surgical group. But we had access to pre and post operative VAS & ODI scores in 3 patients in the surgical group. These 3 patients were treated as missing data for questionnaire scores in the SPSS database.The rest of the 2 patients who had only background data available were also treated as missing data in the scores for questionnaire in the SPSS database.

The questionnaires were sent in two different time zones. The first period was between 2000 & 2001 when we sent questionnaire packs to 114 patients in the conservative group and 22 patients in the surgical group. By the middle of year 2001 and after three attempts at sending the pack of questionnaires, we had successful responses from 73 patients (conservative group) and 20 patients (surgical group). All these patients had SPECT as primary imaging. The response rate was 64% in the conservative group and 90% in the surgical group.

The second period was in the year 2007, when we included the rest of the 80 patients in the conservative group and 33 patients in the surgical group. MRI scans were performed in this batch of patients instead of SPECT imaging. Of the 80 patients 50 patients responded in the conservative group and 30 patients responded in the surgical group. The response rate was 62.5% in the conservative group and 90% in the surgical group.

The medical records of the 123 patients (conservative treatment) and 55 patients (operative treatment) were analyzed to obtain the following information:

4.5.1 *Background factors*

Age, gender, Body Mass Index, age at onset of low back pain, first consultation, diagnosis, imaging findings, sporting or non sporting activity, type of sports and a contact address or telephone number for questionnaire survey. The identities of the patient's GP were recorded.

4.5.2 *Treatment*

The kind of treatment, either conservative or operative was recorded.

4.5.3 *Objective variables*

The level of lumbar spondylolysis or stress injury along with unilateral or bilateral involvement of the PI was recorded. The level of sporting activity and return to sports following the treatment was recorded.

4.5.4 *Subjective variables*

Pre and post treatment VAS (Visual Analogue scores), ODI (Oswestry Disability Index) and SF-36 scores were recorded for each patient. The pre treatment questionnaires were filled during the first or second visit at the clinic. Both study groups had their post treatment questionnaires answered at minimum 2 years after treatment. A new set of questionnaires developed specifically for the sporting individuals (Back pain and Sports Questionnaire) were scored and recorded at the same time they answered other questionnaires i.e. at least 2 years after the treatment.

All data was stored as a database in Excel and SPSS format using a proforma designed by the researcher. This enabled reliable data capture and allowed for further descriptive and statistical analysis (Kinnear 1999). All data was classified as nominal, ordinal or scale and identified in the SPSS programme for preparing the analysis. The Excel sheet later was destroyed for data protection after cross referencing with the SPSS database. Only encrypted SPSS database was used to analyze the data.

4.6 Imaging analysis

The radiological report of each image will be reviewed in order to confirm the level and type of spondylolysis. Each case was classified according to the radiological findings esp. on CT ± SPECT ± MRI scanning.

1. Negative Scans
2. Incomplete/ complete fractures
3. unilateral/bilateral fractures
4. acute/chronic pars defect
5. Level of spondylolysis

The classification used was developed earlier by Micheli (1989) and later Saiffuddin (1998) which stages the spondylolysis into early defects, progressive defects and terminal.

GPs were contacted by letters informing them that their patients were invited to participate in this study. The GPs were asked to confirm the accurate address of patients and to send the questionnaire on to the patients, avoiding attempting to contact deceased patients.

4.7 Questionnaires

4.7.1 *VAS and ODI*

The questionnaires are standard forms used for knowing the intensity of Low Back Pain (VAS- Visual Analogue Scores) and the disability (ODI – Oswestry disability Index) caused by it. This forms a reliable way to understand the nature of the back pain and compare the pre and post treatment scores. The VAS ranged from 0 (no pain) to 10 (worst pain imaginable). ODI scoring is based on ten item response (Appendix7.1 & 7.2.)

4.7.2 *SF-36*

SF-36 scores are standard scoring system used for understanding the physical and mental state of patients with bodily pain. There are standard norms for each set of age groups in United Kingdom. This scoring in the pre and post treatment groups of patients with symptomatic lumbar spondylolysis gives an adequate understanding of the health in general. (Appendix 7.3)

4.7.3 *Back Pain & Sports Questionnaire (BPSQ)*

A new questionnaire was developed which is designed to gather reliable answers to the questions with regard to the onset and nature of pain, the sports they are engaged in and the level of sporting activity with return to sports as and when. (Appendix 7.4)

For knowing the current state of pain we have the VAS scores and Pain drawing. This will give us valuable information regarding the grades (excellent, good, fair and poor) which are a well recognized grading system for knowing the clinical outcome. Steiner and Micheli (1985) had proposed the criteria for evaluating patients with spondylolysis.

The questionnaires were sent out together with a letter and a formal information sheet informing the patients of the nature and purpose of the research. Parents and minors of patients under the age of 16 years of age were asked to complete the questionnaire for their child. The right to refuse to reply the questions was also addressed. Patients were reminded by telephones if the questionnaires were not returned by eight weeks.

4.8 Sample size and Power study

4.8.1 *Defining successful outcome*

After identifying the associations of variables in the two groups of patients in question i.e. sporting vs the non-sporting group it was required to identify the variables which are most important in deciding the need for early surgery in each group.

Selection of a meaningful dependent variable i.e. definition of success was always difficult. Athletes may return to play after a sufficient time for healing and recovery, when symptoms are minimal or absent. An athlete has to get through the endurance test for the sports they are playing before resuming full activities.

Therefore, for a sporting individual to return to his/her previous level of sporting activity, one needs to define the success of treatment. Since we have used the outcome scores as the predictors of successful outcome we define in this work three assessment tools. The first was a subjective assessment from patient's perspective defined as decrease in VAS score > 80% from pre treatment to post treatment stage. A moderate correlation was found between VAS and functional capacity of athletes (change of VAS by 80%, $r=0.52$, $p<0.005$) (Yildiz Y et al, 2003). This moderate correlation may be due to the fact that the percentage improvement may not be equated for all since some may have a higher grade of pain initially. Therefore, the change is much higher if someone improves from VAS=7 to VAS=1 than some who improves from VAS=4 to VAS=0.

A second assessment was objective and clinical based. Objective assessment was done by using ODI and SF-36 scores. The ODI was focused on physical activities and not the psychological consequences of acute or chronic pain. Self-reported disability scores e.g. ODI have become, in their own right, a dimension of disability (Fairbank JC, 2000). It is believed that the absolute values of these scores are not necessarily comparable between patients, because different people interpret their conditions differently. However, it is assumed that they will do so to a similar degree on each occasion they complete the questionnaires, and thus the percentage change may be a more comparable guide between patients. This was borne out by the higher correlations found when the percentage change was examined (Little & MacDonald, 1994). The U. S. Food and Drug Administration (FDA) has chosen a minimum 15-point change in patients who undergo spinal fusion before surgery and at follow-up (Lipscombe, personal communication, May, 1999) as a successful outcome. Since return to sport requires for the individual to have no or minimal diability. Therefore, to reach a realistic target one needs to score below 10 in ODI at the final follow-up to be able to return to sports.

A third definition of success was return to sport for the sporting group at the previous level of sports.

4.8.2 *Sample size calculations*

Effect size is a measure of the effectiveness of the treatment. Based on a normal distribution of values in a study population, an effect size of 0 indicates that the mean of the experimental group is at the 50th percentile of the control group. In reverse, this means that if the statistical means of both groups are equal, the effect size is 0. An effect size of 0.5 indicates that the difference between two compared groups is 0.5 standard deviations. If the standard deviations are not the same in the compared groups, a pooled standard deviation across both groups is used. Cohen (1988) defined effect sizes as small (0.2), medium (0.5), and large (0.8). As a rule of thumb, for any given clinical score, one-half of its standard deviation represents a medium effect and 0.8 of its standard deviation represents a large effect. In general, one-half of a standard deviation of a continuous outcome constitutes a clinically meaningful difference (Norman GR et al, 2003). Since a medium effect size is often considered a clinically significant magnitude of difference i.e. a sample size large enough to detect a 25% difference in primary outcome e.g ODI. This study doesnot involve comparison between the two groups. Here, each group is studied separately to see the change in outcome scores following treatment. Therefore, taking the conventional values of 0.05 for Type I error and 0.20 for type II error (a power of 0.80) the power in these two groups was measured separately i.e. conservatively and surgically treated patients with lumbar spondylolysis. 30 patients are required in each group to appreciate a difference between the pre and post treatment stage with a $p< 0.05$. This will be able to measure at least 25% difference in the primary outcome in each group. To increase the power of the study to 90% then one needs to include 45 patients in each group. Investigators should typically add 5% to 10% to their sample size to account for losses to followup, depending on the characteristics of their sample and the study design (Zlowdozki & Bhandari, 2009). Therefore, finally the estimated sample size was 50 in each group.

For multiple linear regression models to predict a successful outcome where success was defined as a dichotomous outcome, one requires at least 5 cases per independent variable which is generally considered acceptable for a small database. Entry and exit criteria into the model were set using Type I error rate of 0.05 and power of 0.8. Therefore, a surgical study group consisting of 55 patients could allow for a maximum of 11 independent variables to be inserted into the stepwise regression model.

4.9 Statistical analysis

Data collected was stored finally in SPSS (version16). Specific patient identifiers were removed before transfer the Excel spreadsheet to the SPSS datasheet for independent analysis. Descriptive analysis was carried out following normality curves for each study sample. Frequency distribution for each variable was recorded and tabulated.
Multiple hypotheses testing was performed using the statistical software SPSS (version 16). Six lines of statistical analysis were explored using $p<0.05$ as the level of significance.

1) The first was to know if the dataset showing the outcome measures follow a normal distribution.
2) The second was to validate the BPSQ against the standard questionnaires VAS, ODI and SF-36. This involves analyzing the general characteristics, reliability, external validity, responsiveness to change and floor & ceiling effect of the new questionnaire (BPSQ).
3) The third was testing the null hypothesis that there was no difference between the preoperative and postoperative outcome measures.
4) The fourth utilized correlation testing between the outcome measures and predictive factors in each study group.
5) The fifth was a stepwise regression modeling which was performed to determine the predictors of outcome and develop a regression equation.
6) The sixth was to analyze ROC (Receiver Operating Characteristics) for each outcome measures in both study groups i.e. Conservative and Operative group.

4.10 Limitations of the study

4.10.1 Study 1

It was a retrospective study of a relatively uncommon diagnosis in the general population. Although the prevalence is higher in sporting population it is asymptomatic in the majority. Therefore, clinical diagnosis is only possible when someone is symptomatic and consults a surgeon. Some patients ignore the problem and may present late in their life with back pain. All these factors reduce the number of patients considerably.
Information collected retrospectively may be affected by patient characteristics, reporting tendency, expectations, and the current status of pain and functioning (Boyer et al 1995).

Study sample consisted of majority who were involved in some form of sports at various levels. Non sporting individuals were mostly sedentary workers in offices or local business. Only 5/30 were manual labourers and 2/30 worked as postmen. None in this series belong to group of people with high activity (e.g. army or police personnel). Therefore, a potential selection bias towards the sporting group may reflect upon the outcome. But the opposite is true as well i.e. analysis in the general population who has rarely low back pain symptoms due to spondylolysis as compared to the sporting population may not be true reflection of incident cases. Athletes are often model patients, following doctors' orders faithfully and working hard in physical therapy. They are highly motivated to make a rapid recovery and to return to full participation in sports. The opposite may be true for some sporting individuals who may lack further motivation to excel due to bodily pain and take up different career instead of sports and do recreational sports. The results obtained following conservative treatment may be biased if there were individuals who returned to previous level of sports but couldn't continue after a specific period of time. Some of these may have returned for surgical treatment. Potential financial benefits for the patients from insurance companies may influence the treatment and its outcome.

The choice of pathway for patients in different clinics i.e. spinal versus sports injury clinic, may have had influence on the outcome. Since sports injury physicians may influence trial of conservative or non-operative physical therapy for a prolonged period of time which may be required to improve the symptoms in an individual. Spinal surgical clinics may be biased towards surgery if someone fails to improve after a specific period of time. This problem was relatively negated by including the patients who had conservative treatment for a period of 6-12 months.

The study was done at two separate point in time i.e. when SPECT scanning was the primary diagnostic imaging tool and the other when MRI scanning replaced SPECT imaging as the primary diagnostic tool. The data thus was collected at two points in time but most patients had similar characteristics i.e. common denominator was sporting individuals.

The accuracy of patient recall might be low and its impact on outcome assessment in retrospective studies is significant. The patient's memory of his or her health status is required in retrospective studies, and this memory can be flawed by experiences that have occurred in the interval.

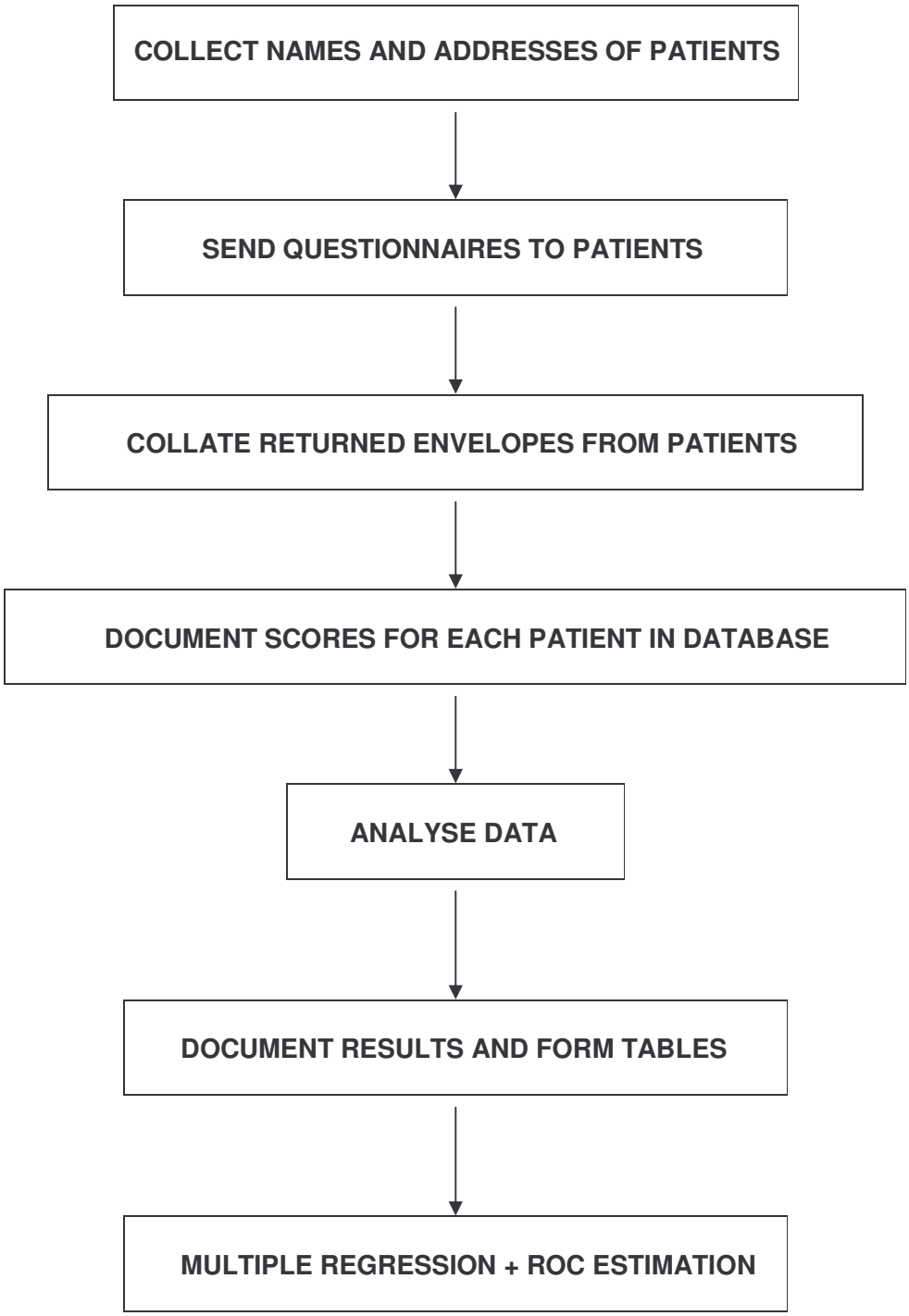
4.10.2 Study 2

The number of patients who undergo surgery for the pars defect or spondylolysis in the younger age group is relatively low in comparision to other causes of spine surgery e.g. fusion for low back pain. The interactions between the risk factors and the taking several effect modifiers into account all at once are extremely difficult because of necessity of large sample size. The information was available for many variables but it was allowed to adjust for only the most important confounders since the surgical group had only 55 cases. The natural history could contribute to the improvement following surgery. Surgeon preference in timing of surgery or the professional athletes who may be surgically treated early may have influence on the final outcome of the cohort. Recall bias may be high for the patients who answered the questionnaires at different times after the operation. This may overestimate the effectiveness of treatment.

4.11 Surgeons who contributed

Between 1994 and 1999 most surgeries were performed by Mr J K Webb and Prof R C Mulholand. The method of direct repair by Buck's method was preffered by Mr J K Webb. Prof Mulholand preferred to use Modified Scott's technique and was involved in four cases. In the ensuing years between 2000 and 2007 along with Mr J K Webb other surgeons who contributed were Mr S M H Mehdian, Mr M P Grevitt, Prof B J C Freeman and Mr C Adams. Mr J K Webb was involved in majority (34) of the Buck's repair followed by Mr S M H Mehdian (6), Mr M P Grevitt (4), Prof B J C Freeman (6) and Mr C Adamas (1).

Fig 18: FLOWCHART FOR THE STUDY



CHAPTER 5

Outcome Instruments in Lumbar Spondylolysis

5.1 Introduction

5.2 Outcome measures in spinal disorders

5.3 What is required to measure?

5.4 Role Oswestry Disability Index

5.5 Measuring pain

5.6 Role of SF-36

5.7 Need for a new questionnaire

5.8 Conclusion

5 OUTCOME INSTRUMENTS IN LUMBAR SPONDYLOLYSIS

5.1 Introduction

Various questionnaires have been used when evaluating patients with low back pain. The ideal outcome of treatment is a return to the normal or usual quality of life for a given age and medical condition (Silver et al 1990). There are reliable and valid measuring instruments for surveying low back pain in the population since the first survey of sickness and disability (Katz et al 1973). Clinicians and researchers increasingly recognise the importance of the patient's perspective in the evaluation of the effectiveness of treatment. More confusion results from the large number of subjective patient based measurements available to us in present day's state of the art in medicine. Patient based outcome measures are classified as generic or disease specific (Patrick & Deyo, 1989). Both types of instruments have been evolving in back pain research during the past twenty five years. Generic measures include global ratings of health status, as well as multi dimensional measures of health related quality of life e.g. Sickness Impact Profile (SIP), SF-36 Health Survey, Nottingham Health Profile (NHP), EuroQol (EQ-D5), and others (Bergner et al, 1981; Ware & Sherbourne, 1992; Hunt et al, 1985; Kind, 1996). Generic measures are applicable to patients across different types of conditions. Items in a disease specific measure assess only those aspects of health that tend to be affected by the disease. The disease specific questionnaires are Oswestry Disability Index (ODI), Roland –Morris Questionnaire, Scoliosis Research Society Questionnaire (SRS), Low back outcome score , Million Visual Analogue Scale (MVAS), Quebec Back Pain Disability scale (QBPDS) , Low Back Pain Rating Scale (LBPRS) and few more (Fairbank et al, 1980; Roland & Morris, 1983; Helenius et al, 2005; Holt et al, 2002; Million et al, 1982; Kopec et al, 1995;Manniche et al, 1994). There are 82 condition-specific outcome scales of which nine measures are commonly used.

5.2 Outcome measures in spinal disorders

Although, generic health measures provide a comprehensive picture of patients' physical and mental health, they are influenced by patients' co-morbidities. The disabilities from co-morbidities influence the patients' response to treatment.

Thus, a generic measure should be used along with a condition specific measure as cited above (Patrick & Deyo, 1989; Deyo et al, 1994). However, combination of the above subjective measures may not quantify the amount of disability in a patient with low back pain. The variation in patient population makes it more difficult to use a specific measure which remains constant in its reliability, validity and responsiveness throughout the period of treatment. Thus, the researchers find it extremely difficult to compare one study with the other since we cannot quantify the dysfunction and pain in patients with low back pain. Without direct comparisons across similar populations, differences in measurement properties may be difficult to interpret (Bombardier, 2000).

In choosing an outcome measure, the investigator should take into account the type of patients studied and the specific objectives of the investigation (Patrick & Deyo, 1989; Deyo et al, 1998). Unfortunately, the type of information needed to select the optimal instrument is often unavailable. Moreover, choosing a measure optimally adapted to the study population may conflict with efforts to standardize instruments.
Several questionnaires are available for assessing functional outcome related to low back pain. The ODI was developed to assess the level of pain and interference with several physical activities, sleeping, self care, sex life, social life and traveling (Fairbank et al, 1980; Fairbank & Pynsent, 2000). Roland and Morris created a 24 items response questionnaire measuring activity limitations due to back pain (Roland & Morris, 1983). Million et al developed a set of 15 questionnaires with visual analogue scale for each (Million et al, 1982). Waddell and Main proposed a brief nine-item scale to assess physical disability associated with low back pain (Waddell & Main, 1984). The LBOS is a 13 item questionnaire intended as a comprehensive rating system for patients with back pain. It includes weighted questions that pertain to current pain, employment, domestic and sport activities, use of drugs and medical services, rest, sex life and daily activities. The Aberdeen Low back Pain Scale (ALBDS) questions assess the effect of various activities on the level of pain, location and duration of pain, use of painkillers, weakness, bed days and pain interference with sleep, physical activities, work, sex life and leisure (Ruta et al, 1994). The LBPRS consists of three scales of measure i.e. pain, disability and physical impairment. Impairment is measured by testing endurance and flexibility. This is omitted if the scale is self administered.

The 15 item scale pertains to various specific activities, contact with people, ability of work, and expectations of future pain (Manniche et al, 1994). The QBPDS contains 20 items of physical disability associated with low back pain. The items refer to specific simple activities, and covers sleeping and resting, sitting, standing, ambulation, movement, bending and stooping and handling large or heavy objects. Pain intensity and social role activities are not included (Kopec et al, 1995). The NASS (North American Spine Society) Lumbar Spine Outcome Assessment Instrument incorporates a modified version of ODI (Daltroy et al, 1996). In addition to pain, it contains a neurogenic symptom scale, questions about satisfaction with one's current condition and a scale of expectations met. The SRS has developed a patient oriented outcome questionnaire to assess impact of surgical treatment for adolescent idiopathic scoliosis (Merola et al, 2002). This provides information on back pain, cosmetic aspects, patient satisfaction and level of activity.

5.3 What is required to be measured in symptomatic spondylolysis?

Lower back pain is the major symptom in patients with lumbar spondylolysis or acute stress injuries of the posterior elements. The symptoms vary according to the level of activity. The incidence of low back pain in the athletic younger population is much higher than the general population. The athlete with spondylolysis typically presents with insidious onset of low back pain, although presentation after an acute event is occasionally seen (McTimoney & Micheli, 2003). The history may reveal an increase in volume or intensity of training in one of the high risk sports (e.g. gymnasts, weight lifting,). The pain is aggravated by hyperextension of the lumbar spine. Most often there are no neurological symptoms. The disability arising in the young athlete due to pain is related to the sports they are involved in. Persistent pain resistant to conservative treatment and daily interference in the sporting activities are the main indication for surgical repair of the spondylolysis. Thus, there is a need for a quantitative measure of dysfunction in these patients which is required to establish the need for surgery and the final functional outcome.

5.4 Role of Oswestry Disability Index

Primary Outcome measure has been chosen as ODI (Oswestry Disability Index) and VAS (Visual Analogue Scale) in this study. The ODI was developed as a measure for both assessment and outcome (Fairbank et al, 1980). The ten items can be completed in approximately 5 minutes and scored in less than 1 minute. The administration is easy. Version 2.0 is now recommended and no permission is required for its use. The questionnaire focuses on abilities (personal care, lifting, walking, sitting, standing, sleeping, sex life, social life and traveling in combination with pain) and on pain level. However, no sports related endurance questions are not included in this measurement.

ODI remains a valid and vigorous measure of condition-specific disability. The ODI has found favour in studies of patients with more severe symptoms, although it also appears to provide a robust indication of those with minor symptoms (Fairbank et al, 1980; Fairbank & Pynsent, 2000). ODI and VAS scoring has high test-retest correlation, which makes it an appropriate primary outcome measure. Taylor et al compared the responsiveness of the LBOS with that of ODI and SF-36 in patients with low back pain or sciatica. The results depended on the method of calculating effect size and the direction of self-reported change. Overall, the LBOS seemed more responsive than SF-36, but less responsive than ODI (Taylor et al, 1999).

5.5 Measuring pain in lumbar spondylolysis

The International Association for the study of Pain (IASP) defines pain as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (Merskey & Bogduk, 1994).

Pain is an individual subjective experience. It is, however, important to quantify it for several reasons; one of the most compelling reasons is that assigning a measurement of pain gives patients some sense of control over their condition and has positive effects on their coping abilities. Pain measurements also provide a means of assessing the efficacy of response to treatment and prognosis. The VAS is a well-studied method for measuring both acute and chronic pain, and its usefulness has been validated by several investigators (Katz & Melzack, 1999; Carlsson, 1983).

It is a 10 cm horizontal or vertical line with word anchors at each end, such as “no pain” and “pain as bad as it could be”. The person is asked to make a mark on the line to represent pain intensity. This mark is converted to distance in either centimetres or millimetres from the “no pain” anchor to give a pain score that can range from 0–10 cm or 0–100 mm.

The VAS is called a Graphic Rating Scale (GRS) if descriptive words are placed along the line. Clarke and Spear found the VAS reliable and sensitive to changes in the self assessment of well being (Clarke & Spear, 1964). Swedish lumbar Spine study group concluded that the VAS of back pain is responsive enough to detect the minimal clinically important difference after treatment (Hagg et al, 2003).

5.6 Role of SF36 in lumbar spondylolysis

It yields an eight scale profile of scores as well as physical and mental health summary measures (Ware & Sherbourne, 1992). It has been useful in comparing general and specific populations, comparing the relative burden of the diseases, differentiating the health benefits produced by a wide range of different treatments and screening individual patients (Ware, 2000).

The eight scales are hypothesised to form two distinct higher ordered clusters according to the physical and mental health variance that they have in common. Analytical studies have confirmed physical and mental health factors that account for 80-85% of the reliable variance in the eight scales in the US and UK general population. Three scales (Physical functioning, Role Physical, Bodily pain) correlate most highly with the physical component and contribute most to the scoring of the Physical Component Summary (PCS) measure (Ware et al, 1994).These are shown to be the most valid SF-36 scales for measuring physical health. The mental component correlates highly with the Mental Health, Role –Emotional, and Social Functioning Scales, which also contribute most to the scoring of the Mental Component Summary (MCS) measure. Three of the scales (Vitality, General Health and Social Functioning) have noteworthy correlations with both components. The Mental Health scales have been shown to be useful in screening for psychiatric disorders (Ware et al, 1994).

The scales that load highest on the physical component are most responsive to treatments that change physical morbidity, whereas scales loading highest on the mental component respond most to drugs and therapies that target mental health (Ware, 2000). Using a cut-off score of 42, the MCS has a sensitivity of 74% and specificity of 81% in detecting patients diagnosed with depression (Ware et al, 1994). Results from clinical studies comparing scores for patients before and after treatment have largely supported hypotheses about the validity of SF-36 scales based on results of psychometric studies (Ware et al, 1994).

The SF-36 scoring system was constructed to satisfy minimum psychometric standards necessary for group comparison. Reliability estimates for physical and mental scores usually exceed 0.90 (Ware, 2000). According to psychometric theory, measures that discriminate well among different groups of patients at one particular time tend to do well in capturing changes over time (Berwick et al, 1991). Changes in SF-36 scores in one group over time can usually be measured with greater precision than differences between two groups (Ware et al, 1994). The Mental Health component in the SF-36 is the most valid measure of mental health in studies to date (McHorney et al, 1993). Because of the widespread use of the SF-36 across a variety of applications, evidence from many types of validity research is relevant to these interpretations. All eight scales show high reliability when used to monitor health in groups of patients and at least four scales possess adequate reliability for use in managing individual patients (Ruta et al, 1994). For assessing disability in people with low back pain, measurements obtained with the modified ODI, SF-36 (PCS) and the QBPDS were the most reliable and had sufficient width scale to reliably detect improvement or worsening in most subjects (Davidson & Keating, 2002).

5.7 Need for a new questionnaire

Thus, combining the three outcome measures does give us an overall response following treatment in patients with symptomatic lumbar spondylolysis. We do generate information about the physical and mental well being but we are lacking measure of the quality and quantity of sporting activity of the individual involved in the treatment. In the young sporting group of people it is imperative that we know what the limitations in the sporting activity are.

How and when are they able to return to sports at the level that is required of them? Are they able to perform with the same vigour following treatment of lumbar spondylolysis? Unfortunately, the type of information needed to select the optimal instrument for sporting population with lower back pain is unavailable in the literature. Although there are valid, reliable and responsive questionnaires for return to sports after Knee surgery e.g. Cincinnati Sports Activity Scale (CSAS) and Cincinnati Sports Function scale (CSFS) (Smith et al, 2004), there are no such instruments for sporting population with Low Back Pain.

To answer the above questions in their research, a questionnaire was created by Dr Gregory (2005) and Dr Geum-Dong Bae (2003) at Nottingham, which was based on the well recognised grading system of Steiner and Micheli (1985) who proposed reasonable criteria for clinical evaluation of patients with spondylolysis (Steiner & Micheli, 1985). But this was not enough to differentiate between different levels of function. The generic questionnaire (Back Pain & Sports Questionnaire –BPSQ) for sporting in this study is based on the combination of the above set of questionnaires (Nottingham questionnaire, CSAS and CSFS questionnaires) along with inclusion of treatment received and return to sporting career. The questionnaire contains 9 items which are relevant to the individuals involved in the sports who have low back pain. This gives us an estimation of the level of sporting activity one is involved with and the time lapsed in having the required treatment for a successful outcome. The successful return to the previous level will for most athletes require the near absence of functional limitations. However, some continue to participate in functionally challenging activities, and even compete at a high level despite major functional complaints. The questionnaire will be able to improve our understanding of the overall quality of sports these athletes are engaged in following surgical or conservative treatment.

The use of ODI, VAS and SF-36 was established in a previous study showing the outcome of symptomatic lumbar spondylolysis treated with direct repair (Surgical) in a group of sporting individuals (Debnath et al, 2003). There were significant improvement in ODI and all domains of SF-36 and the individual athletes who had returned to active sports after a mean of seven months following surgery.

A simple version of the generic questionnaire was included during the data collection for the study. Later on this was improved upon by combining the CSAS and CSFS and it is called Back Pain & Sports Questionnaire (BPSQ).

5.7 Conclusion

Thus, it is believed that combining the ODI, VAS, SF-36 and generic sporting questionnaire (BPSQ) will provide one with the necessary information to predict the outcome following treatment for symptomatic lumbar spondylolysis in young active athlete.

CHAPTER 6

Back Pain & Sports Questionnaire (BPSQ)

6.1 Introduction

6.2 What is BPSQ?

6.3 General Characteristics

6.4 Validity of BPSQ

6.5 Summary

6 BACK PAIN & SPORTS QUESTIONNAIRE

6.1 Introduction

As discussed earlier in the chapter for outcome measures that there was need for generic sporting questionnaire which will allow one to estimate the sporting activity of an individual and advice regarding the return to the active level of sports following treatment for low back pain due to lumbar pars injuries. This generic questionnaire was developed and was named Back Pain and Sports Questionnaire (BPSQ) to know the actual disability in sports an individual is involved in, since neither the ODI nor the SF-36 provided the answer directly pertaining to the symptoms due to lumbar pars injuries. The VAS, ODI and SF-36 questionnaires are frequently used for pain measure, disability and general health respectively for evaluation of back pain. Using these questionnaires alone or in combination it is often difficult to predict the actual disability following treatment for lumbar pars injuries or spondylolysis. Validated measures of symptoms and function are necessary in clinical practice and trials in order to evaluate treatment efforts (Bjorklund et al, 2007)

6.2 What is BPSQ?

A condition-specific measurement tool is required to asses the aspects of relevance for the specific target group which would be more responsive to treatment effects than a generic health questionnaire (Garratt et al, 2001). To asses the functional status in patients with LBP the back specific questionnaires have mixed contents that reflect constructs of both pain and physical functioning (Grotle et al, 2005). Since the effect of LBP is variable in individuals which may be manifested in decreased activity levels, it is conceivable that the questionnaire specific to the sporting individuals should be able to assess the combined effect of pain and activity limitations (Rainville et al, 1992). Sometimes a well constructed questionnaire with composite measures may provide an overall sum score that may give some idea in a target group showing the effect of treatment. By combining the Cincinnati Sports Activity Scale (CSAS) and Cincinnati Sports Function scale (CSFS) (Smith et al, 2004) and previously used questionnaire by Dr Geum-Dong Bae (2003) at Nottingham, the BPSQ scoring was developed.

6.3 General Characteristics

A ten item questionnaire was developed for assessment of sporting activities including the composite measure of pain and functional disability as well as the treatment that was instituted. Following further review, the final question was removed which was a dichotomous variable. The question was related to whether someone had surgical treatment or not. It was perceived that the scoring couldn't be evenly perfomed if someone had surgery. Someone who had no surgery would be rated higher due to the scoring. Therefore, final BPSQ questionnaire didn't include the final question and a 9 item questionnaires were weighted with respective scores.

BPSQ score enables the status of an individual back with a single number in the range of 0-90. Most questionnaires in Spinal problems use normalized scores from 0-100. Therfore, BPSQ was developed keeping in line with the established questionnaires but due to the exclusion of one question the maximum score was reduced to 90. The factors assessed were pain (total score -45), function or sporting activity (total score -30) and non-operative treatment received (total score -15). Since the main complaint of the individual is LBP, the four items of the questionnaire measure the pain. The pain is qualified to know how it restricts the individual from functional activity which is in fact their sporting activity. The expression of functional limitations refers to the sporting restriction and the inability to perform at the previous level which constitutes other four items of the questionnaire. One of these items includes the history of any previous injuries which may confound the current problem. The last item is related to the initial non-operative treatment that was instituted in each individual case. The principle of *the higher the score – the better the health/function* was used for scoring. If a question was omitted by a respondent, then the total score of the scale was adjusted by removing the maximum score for that question. All items when scored produce a single score from 0-90.

6.4 Weighting

6.4.1 *Items measuring pain*

This scale was designed to know the timing & exact nature of the current LBP, the intensity and its relation to the sporting activity.

For the 1st item i.e. the timing of the episode of LBP, three response alternatives were given. The three responses i.e. < 1month, 1-6month and >6month were scored as 10,5,

0 respectively. The fourth response was ongoing pain which is not scored since the responder is not able to perform the sporting activity which he/she is interested.

An onset of pain with less than one month duration would be more acute onset pain and therefore, the individual is disabled more than chronic pain of more than one month duration. Therefore, it has been given maximum score of 10. An individual with pain onset of more than six months duration has chronic pain which may be related to other pathologies than pars defect or lumbar spondylolysis. They score 0 on the rating since it may be less useful in clinical assessment for further management.
The 3rd and 4th items measured the association of pain with the sporting activity. These two items has only two responses, i.e. *yes* scores 0 and *no* scores10. In the item 3 the individual scores 0, if the occurrence of pain is due to playing the sport. This signifies the relationship of the sport to the lumbar pain. The item 4 is related to item 3 in confirming the fact that the movements during the sport does cause the LBP therefore a 'yes' would score 0. These two questions are justified by the fact that if the outcome is better following treatment in future the item 4 would score 10 if the individual has no pain while playing the sport even though he/she had onset of pain while playing the sport.
The 8th item in the measurement includes five responses which are in line with the general recommendation of 5-7 response alternatives for scales where intensity or frequency is judged. This is again patient's perception of pain and dysfunction. The five responses were weighted from best to worse from 15 to 0 respectively. The scoring follows this *No pain with sporting activities* – 15, *occasional pain with sporting activity* – 10, *always have pain with sporting activity taking analgesia* – 5, *always have pain preventing sporting activity* – 3 and *always have pain in daily activities of living* – 0.

6.4.2 *Items measuring the sporting activity*
The scale was designed to know about the type of sports and activity level which may have specific implications on the functional capacity to perform the sports.
Item 2 has two subsets but only one subset was scored. The first subset response is to know what type of sport one is actively participating which will enable us to record the data regarding the type of sports. This may have some insight into the diagnosis because some trunk twisting sports are more prone to causing symptoms in lumbar pars defect. The 2nd subset has four responses which measures the activity level of the individual which is weighted maximum for highly active sporting individuals. This also

gives us an idea of the amount of endurance required for competitiveness in their respective sports.

The successful return to competition at the previous level will for most athletes require near absence of functional limitations. Therefore, it is important to know the individual's competitiveness in the respective sports which also implies more motivation in the individual. The weighting follows the following pattern: i.e. *professional* scored highest as 10, *semi-professional/university* both scored as 5 and *amateur/non professional* scores as 0.

Item 5 determines the knowledge of any other injuries in the body that has occurred at sports. This is important to know since a previous injury to other joints may increase the morbidity. This may increase the treatment time and therefore may have an unsatisfactory outcome. If the responder answers this question with a *yes* it is rated 0 and *no* rated 10.

Items 6 and 7 measured the time of returning to the sports and the rate of current sporting ability respectively. The time of return to respective sport would give us an idea of the severity of the dysfunction and the rehabilitation that followed. The timing of return to sports has four responses i.e. *< 1month* scored as10, *1-6months* scored as 5, *6-12 months* scored as 3 and *never* scored as 0.

Current sporting ability gives us an insight into the individual's performance. Patients may reduce their activity levels for many reasons other than functional impairment, reducing the relation between actual sports activity and the subjective rating of functional limitation. One may hypothesize that the typical behavior involves accepting some degree of discomfort and pain during the initial return to competitive activity; later the condition will either improve, allowing the level of competitive participation to be maintained, or deteriorate, forcing the patient to adjust his/her competitive participation, or to choose to retire from competitive participation (in that particular sport) altogether. It has been observed that patients with major knee problems at follow up had a lower CSAS score mode, reflecting the reduced intensity of sports activity compared with that of those without such problems (Smith et al 2004). This logic was applied in BPSQ scoring for spinal problems and return to competitive sports. The current sporting ability has four responses and they are weighted as follows: *fully competitive* scored as 10, *some limitations* scored as 5, *>50% limitations* scored as 3 and *not able to perform* scored as 0.

6.4.3 *Items measuring treatment*

We considered the number of non-operative treatment modalities one goes through in treating LBP and included ten responses in this question. Many of these patients who presented to us had multiple treatments before attending our clinic. Thus, we had scored 1 for each response in the item 9 and the scale was done on the basis: *< 2 therapeutic modes* scored as 15, *2-5 therapies* scored as 10 and *>5 therapies* scored as 0.

The choice of scores of maximum 15 and minimum 0 is the fact that the scoring would be out of a maximum of 90.

6.5 Validity of the BPSQ

A specific outcome questionnaire to be valid should answer five questions which are (Muller et al, 2004):

1) Whether it is a reliable questionnaire?
2) Is it responsive to changes?
3) Can the results be compared to the literature?
4) Is the questionnaire available in target language?
5) Is it easy to complete and score?

6.5.1 *Criterion questionnaires*

The reliability and validity of the BPSQ was assessed by comparing with one pain specific questionnaire, one back pain specific questionnaire and one generic health questionnaire. The other questionnaires which were consulted were CSAS and CSFS. BPSQ were sent at the same time as the other questionnaire. The responders answered the questionnaires at the same time. These criterion questionnaires are widely used and have been validated self-administered questionnaires (Carlsson, 1983; Fairbank et al, 1980; Fairbank & Pynsent, 2000; Ware , 2000; Ware et al, 1994). The criterion questionnaires are discussed in the previous chapter.

6.5.2 *Reliability*

At first, we have used Pearson's correlation coefficient which is a measure of correlation between the BPSQ scores and the scores of the criterion questionnaires.

This estimates the concurrent criterion validity and it was considered to be good if r≥0.60, moderate if r≥0.30 and 0.59 and weak if r<0.30 (Grotle et al, 2005; Andersen, 2000). The results suggest that the pre treatment scores were poorly correlated with the BPSQ scores (r <0.30) in most of the scores except for pre treatment ODI (r=0.32). This indicated that there was poor concurrent criterion validity with the pre treatment criterion questionnaire scores. (Table 1a)

But on the other hand the correlation coefficient between the total scores of the BPSQ and the post treatment specific criterion questionnaires indicated that there was high moderate correlation between each other (all exceeded 0.4). (Table 1b). The highest correlation observed was between the post treatment SF-36 physical component scores (r =0.55). The physical components which were moderately correlated were Physical functioning (r=0.58) followed by Role Physical (r=0.56) and Bodily Pain (r=0.48) [Table 1c]. Thus, there was agreement with post treatment outcome measures.

6.5.3 *Floor and Ceiling effect*

The percentage of subjects which have maximal and minimal points in the score is described by the *floor and ceiling* effects (Bombardier, 2000). We explored the presence of floor and ceiling effects by examining the frequency of highest and lowest possible scores at baseline BPSQ domain scores. Floor effects were considered present if more than 15% of participants had a minimal score at baseline, ceiling effect were considered present if more than 15% of participants had a maximum baseline score (McHorney & Taylor 1995). If ceiling or floor effects are present, a scale is unable to detect an improvement or decline in sense of competence in a considerable part of the target population.

The distribution of scores and the magnitude of the floor and ceiling effects give an indication of the adequacy of the questionnaire for the tested sample. The scores of BPSQ were normally distributed with a mean for the BPSQ scores of 45.75 ± 22.15 (0-90) for the combined data of study 1 and 2 (Table 2a & b). The results show that the floor effect was 14.1% and the ceiling effect was 1.2%. This means that it is possible to detect an improvement on this subscale in a considerable part of the target population.

TABLES for BPSQ SCORING

Table 1a: Bivariate correlation (Pearson's correlation coefficient) between the BPSQ scores and pre treatment scores of criterion questionnaires

		prevas	preodi	presf36pcs	presf36mcs
BPSQ	Pearsons	-.232(**)	-.329(**)	.294(**)	.193(*)
	2-tailed	.003	.000	.000	.014
	N	163	163	163	163

Table 1b: Bivariate correlation (Pearson's correlation coefficient) between the BPSQ scores and post treatment scores of criterion questionnaires

		postvas	postodi	postsf36pcs	postsf36mcs
BPSQ	Pearsons	-.430(**)	-.477(**)	.552(**)	.443(**)
	2-tailed	.000	.000	.000	.000
	N	163	163	163	163

** Correlation is significant at the 0.01 level (2-tailed).
* Correlation is significant at the 0.05 level (2-tailed).

Table 1c : Bivariate correlation (Pearson's correlation coefficient) between the BPSQ scores and post treatment scores individual SF-36 components

		postrxPF	postrxRP	postrxBP	postrxGH	postrxVt	postrxSF	postrxRE	postrxMH
BPSQ	Pearsons	.582(**)	.559(**)	.487(**)	.433(**)	.399(**)	.520(**)	.525(**)	.373(*
	2 tailed	.000	.000	.000	.000	.000	.000	.000	.00
	N	163	163	163	163	163	163	163	16

Table 2a: Showing Floor & Ceiling Effect Pre-treatment scores

Questionnaire	Number	Floor Value	Ceiling Value	% Floor	% Ceiling
vas	178	10	3	0.6	5.6
odi	176	72	20	0.6	0.6
sf36pcs	170	14	49	1.2	0.6
sf36mcs	170	23.8	68.7	0.6	0.6
sf36PF	170	15.2	55	1.8	0.6
BPSQ	163	0	90	14.1	1.2

Table 2b: Showing Floor & Ceiling effect Post-treatment scores

Questionnaire	Number	Floor Value	Ceiling Value	% Floor	% Ceiling
vas	178	6	0	0.6	50
odi	176	64	0	0.6	13.6
sf36pcs	170	21.4	60.5	0.6	0.6
sf36mcs	170	24.1	64.7	0.6	0.6
sf36PF	170	19.4	57.1	0.6	20

6.5.4 *Responsiveness to changes*

Responsiveness could be evaluated using the receiver operating characteristics (ROC) curve which is constructed by calculating the sensitivity (true positive rate) and specificity (true negative rate) of the cut off point for each of the possible score values. These are useful in assessing the accuracy of the predictors. One can plot the sensitivity versus specificity, keeping in mind that each point on the plot corresponds to a specific threshold. An index of "goodness" of the questionnaire is the area under the curve (AUC). The performance of BPSQ scores are evaluated for return to sports for the sporting individuals in the study group.

Fig 18: Graph showing the ROC for BPSQ scores

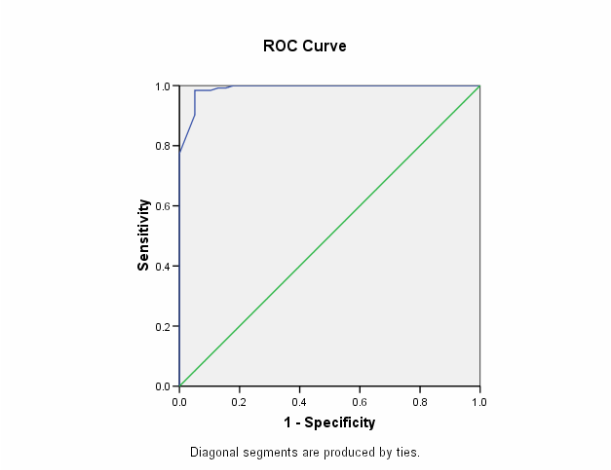


Table 3a: Showing the area under the curve for BPSQ scores

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.990	.006	.000	.978	1.003

a Under the nonparametric assumption
b Null hypothesis: true area = 0.5

A poorly discriminating questionnaire has an area of 0.5 and a perfect test has an area of 1.0. (Zou et al, 1997; Beck et al, 1986; Armitage & Berry, 1994) The ROC technique can also be used to optimize cut off values with regard to a given prevalence in the target population and cost ratio of false-positive and false-negative results. (Greiner et al 2000).

The traditional ROC curve plots sensitivity on the vertical axis and the specificity on the horizontal axis. Fig 18 above represents the ROC curve corresponding to this data set combining both groups.

Each point on the ROC curve corresponds to a specific threshold. The most commonly used quantitative summary measures of the ROC curve is the area under the curve (AUC) (Beurskens et al, 1996; Stratford et al, 1994; Davidson & Keating, 2002). AUC is connected to a couple of well-known statistical measures that facilitates comparison and improves interpretation. The first of these measures is the probability of concordance.

Table 3b: Showing the coordinate under the curve in Fig 18 for BPSQ scores

Positive if Greater Than or Equal To(a)	Sensitivity	1 – Specificity
-1.00	1.000	1.000
4.00	1.000	.410
11.50	1.000	.385
19.00	1.000	.282
24.00	1.000	.256
26.50	1.000	.205
29.00	1.000	.179
31.50	,992	.154
34.00	**.992**	**.128**
35.50	**.984**	**.103**
37.00	**.984**	**.051**
46.00	.903	.051
51.50	.718	.000
59.00	.460	.000
76.50	.016	.000
81.00	.000	.000

a The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

If, in a randomly selected pair of patients, the one with the higher BPSQ score returns to sports and the one with the lower BPSQ score does not return to sports than this pair is said to be a concordant pair.

The AUC of the BPSQ scores were 0.990 which was significant (p<0.001) [Table 3a]. The cut off point when the sensitivity is <1 was between the scores of 34 & 37 (shown in bold in Table 3b). Thus, a sporting individual having a score below 37 may find it difficult to return to sports after treatment for lumbar pars injuries.

There is a gray area between 37 & 46 when the outcome i.e. return to sport may swing either way. This may depend on other physical or treatment factors. One of the factors may be the professional aspects of the sporting individual i.w. motivation to improve and do well in sports. BPSQ scores above 37 will in all probabilities have returned to sports following treatment for lumbar spondylolysis.

Table 4: Showing the threshold value and its relationship with return to sport

			BPSQ threshold		Total
			37 or Below	Over 37	
Return to sport	no	Count	37	2	39
		% within return to sport	94.9%	5.1%	100.0%
	yes	Count	10	122	132
		% within return to sport	7.6%	92.4%	100.0%
Total		Count	47	124**	171
		% within return to sport	27.5%	72.5%	100.0%

** Chi Square test (2 tailed) p<0.001

6.5.5 *External validity*

Similar AUC was also drawn for the post treatment VAS and ODI scores which was shown to be 0.78 (p<0.01) and 0.80 (p<0.01) respectively [Table 5, 6a]. In other studies ROC estimation was found to be 0.76 in a population of patients (Beurskens et al 1996) who were not severely affected (mean ODI 26.2 ± 13.5) as in this study group of sporting individuals (mean ODI 35.5 ± 7.8). In such a population with less severe LBP may return to sports with post treatment ODI scores of 9-11. These scores could be considered minimal disability due to pain. The sensitivity is 90% at the score of 11 (Table 6b). But ODI is not a sports specific questionnaire and therefore the responsive to change may not reflect the nature of functional ability in a sporting individual.

Fig 19: Graph showing the ROC for post VAS scores

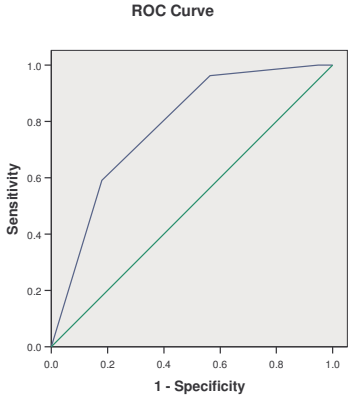


Table 5: Showing the area under the curve in Fig 19 for post VAS scores

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.780	.046	.000	.691	.870

a Under the nonparametric assumption
b Null hypothesis: true area = 0.5

Fig 20: Graph showing the ROC for post ODI scores

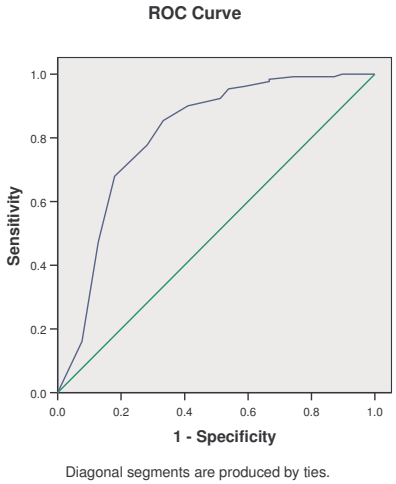


Table 6a: Showing the area under the curve in Fig 20 for post Rx ODI scores

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.809	.046	.000	.719	.899

Thus, BPSQ scores are comparable and may be better than the nearest dependable questionnaires i.e. the post treatment ODI and VAS scores in this study population consisting of patients who are sporting individuals between 8 & 35 years of age and are keen on returning to sporting activity.

Table 6b: Showing the coordinate under the curve in Fig 20 for post Rx ODI scores

Positive if Less Than or Equal To(a)	Sensitivity	1 - Specificity
-1.00	.000	.000
1.00	.160	.077
3.00	.473	.128
5.00	.679	.179
7.00	.779	.282
9.00	**.855**	**.333**
11.00	**.901**	**.410**
13.00	.924	.513
23.00	.992	.744
26.00	.992	.769
30.00	.992	.795

a The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values

How change in ODI and SF-36 scores correlate with BPSQ scores?

Since the BPSQ scores were a one off questionnaire it is difficult to know the change in the scoring following successful return to sports. But most patients had responded who had returned to sports along with the other questionnaire i.e. ODI and SF-36. First independent t-test was run to see which change in scores from pre and post treatment stage was responsible for final outcome i.e. return to sports. The significant ones were was correlated with the BPSQ scores.

Table 7a: Showing significance of change in scores from pre and post treatment stage and the return to sports

Change in Scores	Return to sports	Mean	SD	Sig (2 tailed) t-test
VAS	No	3.76	0.67	0.33
VAS	Yes	3.9	0.65	
ODI	No	25.6	7.2	0.008
ODI	Yes	29.5	6.8	
SF-36pcs	No	10.5	5.2	0.000
SF-36pcs	Yes	15.6	5.2	
SF-36mcs	No	8.2	6.2	0.000
SF-36mcs	Yes	13.0	5.5	

Table 7b: Showing the correlation between the change in scores and BPSQ

Score	(Spearman's ρ)	BPSQ	Change in VAS	Change in ODI	Change in SF36pcs	Change in SF36mcs
BPSQ	Corr Coeff	1.000	0.121	0.20	0.34	0.136
	Sig (2 tailed) p	--	0.123	0.01	0.000	0.08

Test statistics shows that there is significant correlation between change in ODI and SF-36pcs with BPSQ scores ($p<0.05$). (Table 7a & b).

6.5.6 *Availability & Ease of administration*

At this point in time the BPSQ scoring system is just developed for our study and there is no available translation in any of the languages. This questionnaire is a easy set of nine items and gives fewer opportunities of error (Muller et al, 2004).

6.6 Conclusion

The BPSQ scoring system appears to be effective and accurate for measuring the outcome following treatment for symptomatic lumbar spondylolysis.

CHAPTER 7

Results

7.1 Study 1

7.1.1 Patient Demographics

7.1.2 Return to Sports

7.1.3 Correlational Statistics

7.2 Study 2

7.2.1 Patient Demographics

7.2.2 Correlational Statistics

7.2.3 Multiple Regression Analysis

7.3 Combined Study 1 & 2

7.3.1 Receiver Operating Characteristics

7 RESULTS

7.1 Study 1

7.1.1 Patient demographics

i) *Target subject group*

Review of the medical records of the patients who attended the Spinal clinic or the Sports Medicine clinic at QMC between 1994 and 2007, 196 patients were identified with lumbar pars injuries who met the inclusion criteria. 123 patients were finally included in the study group 1 who had a record of the demographics and who completed the questionnaires.

The initial response rate was 30% in Study 1 (Conservative group) after 4 weeks of posting the questionnaires. A second set of postal questionnaires were sent out to the remainder. Subsequently the response rate increased to 50% in Study 1 (Conservative group). Subsequently, brief telephonic questionnaire with the remainder of the subjects was organized. This form of follow up was required in some patients who failed to respond. Its role was to collect reliable qualitative data about the natural history of the associated back pain, interims of change in self reported pain and self reported disability. This method was chosen based on the principals outlined by Thomas and Nelson (1996), all categories were mutually exclusive.

A brief explanation of the project was provided and the verbal consent was sought. We recorded the scores for current VAS, ODI, SF-36 and BPSQ along with return to sporting activity. Recovery of function is a gold standard for measuring the natural history of back pain in the general population (Rowland & Morris, 1983).

Finally, we had 63% responders in Study 1(conservative treatment).

The general features of the target subjects are summarized as follow:

ii) *Age & sex*

The mean age of onset of back pain was 21.7 years, ranging from 8 to 35 years. The mean age of onset of back pain in the unilateral spondylolysis group was 22.6 years and in the bilateral spondylolysis group was 21.3 years (Fig 21). In order to analyze further to assess the significance of age in the treatment of spondylolysis we divided the patients into five groups of age.

The groups were: 1) 8-14 years, 2) 15-19 years, 3) 20-24 years, 4) 25-29 years and 5) >30 years.

There were 9 patients in Group 1, 43 patients in group 2, 32 patients in group 3, 19 patients in group 4 and 17 patients in group 5. The Male: Female ratio was 74:49. In the unilateral group the Male: Female ratio was 29:14 (i.e.67% male). In the bilateral group the Male: Female ratio was 42:35 (54% male)(Table 8).

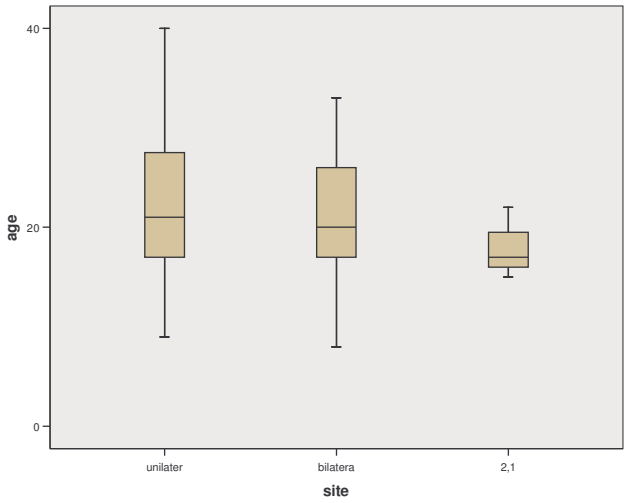


Fig 21: Box plots showing the mean age in unilateral, bilateral and multilevel pars defect in the patients treated conservatively

Table 8: Patient demographics of Study 1

Factors	Unilateral	Bilateral	Multilevel	Combined
No of patients	43	77	3	123
M:F	29:14	42:35	3:0	74:49
Mean age of onset (range)	22.6 (9-40)	21.3 (8-33)	18 (15-22)	21.7 (8-40)
Sporting vs Nonsporting	36:7	59:18	3:0	98:25
Level of sporting activity Total (M:F)				
Professional	14 (11:3)	19 (12:7)	2 (2:0)	35(25:10)
Semi- Professional	11 (10:1)	17 (11:6)	1(1:0)	29(22:7)
Non-Professional	10 (4:6)	23 (11:12)	0	33 (15:18)
None	8 (4:4)	18 (8:10)	0	25 (14:11)
Mean length of Rx (range)	4.2 (3-7)	6.5 (3-12)	6.7 (3-12)	5.8 (3-12)

iii) *Sports*

98 of the 123 (79.6%) subjects were involved in sports at the time of consultation for low back pain at the QMC, Nottingham. 25/123 (20.4%) were not taking part in any sports. Cricket (22) and football (22) were the most commonly played sport followed by tennis (7), swimming (7), rugby (6) and gymnastics (6). 7/98 played multiple sports. The details regarding the individual sports can be seen in table 9a.

The activity level of sports was determined by the BPSQ questionnaire through which it was known whether the patient was professional or semi professional or non professional. 35/98 (35%) were professional players, 29/98 (29.5%) were semi professional and 33/98 (33.6%) were amateur sportsmen and women (Table 8).

We have also tried to classify the type of sports according to the movements that can generally occur in the body during the sporting activity. This classification was based upon a small survey of sporting individuals, post graduate research students in sports as well as teachers in sports and human movement which was carried out in University of Wales Institute, Cardiff. The predominant movement was recorded into four major groups. i.e. *trunk twisting, kicking, throwing and lifting*. Although all sports require multiple movements, for this study only the predominant movement was taken into account. This was done to explain the site of lumbar lesion in spondylolysis. It may also be beneficial to physiotherapist and rehabilitation experts in sports medicine to identify the problem and modify the pattern of movement to prevent pain and reduce dysfunction.

Table 9a: Showing the types of sports with examples

Type of sports	**Name of sports**
Trunk Twisting	Swimming, Gymnastics, Athletics, Canoeing, Rowing, Tennis, Squash, Badminton, Hockey, Aerobics, Equestrian, Cycling, Dancing, Skiing, Cricket
Kicking	Football
Throwing	Netball, Javeline
Lifting	Weight lifting, Rugby

Table 9b: Showing the number of patients in each type of sports

Gender	Laterality	Throwing	Trunk Twisting	Kicking	Lifting	Total
Male	Unilateral	8	9	8	0	25
	Bilateral	5	17	11	1	34
	Multiple	0	2	0	0	2
	Total	13	28	19	1	61
Female	Unilateral	3	7	1	1	12
	Bilateral	3	22	0	0	25
	Total	6	29	1	1	37

Many of the sports were difficult to classify but once the predominant movement was explained to the subjects who completed the survey the answers were similar. One of the classic examples is cricket which couldn't be classified as trunk twisting alone but also has throwing for bowlers and fielders. Another example is Rugby which most thought that lifting was a major movement other than throwing and trunk twisting and kicking. It is evident from the tables that the majority of the pars injuries occurred in patients who had element of trunk twisting along with other body movements. The number of patients in the *throwing* sports was 19/98 (19.4%), *Trunk Twisting* sports were 57/98 (58%), *Kicking* sports were 20/98 (20.4%) and *lifting* sports were 2/98 (2.2%) [Table 9a& b].

iv) *Laterality & Sports*

It was observed that the cricketers (13) who had unilateral spondylolysis had more commonly left sided pars defect than the right (10 left *vs.* 3 right). Nine of these cricketers were right-handed bowlers. Of the 3 unilateral pars defect on the right side (L5), one fracture occurred in one of the only two cricketers known to bowl left handed; one occurred in a professional cricketer. This fast bowler had complete fractures at L2 to L4 with an incomplete fracture at L3 all in the left pars. Amongst these cricketers, incomplete lesion occurred in 9/22 and complete lesions in13/22. Most incomplete lesions were observed in L4 (4/22) followed by L5 and L3. One young fast bowler in cricket had healed L5 pars lesion followed up for more than two years. He developed another pars defect at L3 which was also treated conservatively (Fig 7a-d). 14/22 (63%) had lesions at L5 lumbar level. There were 10 cricketers with bilateral pars lesions most common location being L5 (6).

Bilateral complete L5 fractures were present in 7/22 soccer players. One professional soccer player had an incomplete lesion at L3 and bilateral completer lesion at L4. One keen amateur soccer player who also played cricket and bowled left handed had two incomplete fractures (one on the left L4 and one on the right L5). Right-sided defect was more commonly noted in soccer players (7:1), tennis players (3:0), swimmers (3:0) and gymnasts (2) [Appendix Table 1]. Although most soccer players were right foot dominant, they frequently used their left foot for kicking.

v) *Low Back Pain*

The mean period of low back pain before consultation widely varied from 1month to 124months. But most sporting individuals (80%) consulted early within the first six months of onset of pain. The non sporting group (95%) had consulted with a delay of more than six months. Back pain in extension (92%) was more common than the pain in flexion.

vi) *Investigations*

The investigative algorithm before 2001 included X rays, SPECT imaging along with CT scans to identify the pars lesion. MRI scan was performed only in patients when there was need to exclude disc degeneration as the cause of the low back pain. Between 2001 & 2002 there was a transition period when the radiological investigation at QMC was excluding SPECT imaging and introduced MRI scan as the primary form of imaging modality. Since 2002 most patients had MRI scans and CT scans for the diagnosis of pars lesion.

Fig 22: Bar diagram showing grades of increased uptake in SPECT

87/123 patients had positive uptake on SPECT imaging of which 32/87 unilaterally and 52/87 bilaterally positive. 3/87 had multi level involvement (Appendix Table 2).

On SPECT imaging, incomplete lesions were observed in 22/87 (25%) and complete lesions were seen in 63/87 (75%) patients (Appendix Table 4). SPECT images were also graded according to the amount of uptake in them. Mild uptake was observed in 35/87 (40%), moderate uptake was observed in 39/87 (45%) and 13/87(15%) had marked uptake on the SPECT scans (Fig 22). The lumbar levels were 43/87 (49.5%) at L5, 20/87 (22.9%) at L4, 18/87 (20.6%) at L3 and 6/87 (7%) at L2 (Fig 22). CT scans were available in 61/123 (49.5%) of which 22/61 showed unilateral pars defect or increased sclerosis and 39/61 showed bilateral pars defect (Appendix Table 3). 36/46 patients who had MRI scan were included from the last five years. 10/46 patients who had MRI scan during the period when SPECT imaging was the investigation of choice (Appendix Table 5). 13/36 had grade 1 and 23/36 had grade 2-4 lesion in MRI scan (Hollander grades) [Appendix Table 4]. Marrow oedema and signal abnormalities were observed in 15 cases unilaterally and 31 cases bilaterally in the lumbar pars (Appendix Table 6) (Fig 6a & b).

vii) *Site & Type of pars defects*

In most subjects, 74/123 (60%), the pars lesions were observed at the level of L5 vertebra, where as the remaining 49/123 (40%) showed presence of lesion at various levels (Table 10). The most common level being L4:14 (11.3%) followed by L3:12 (9.7%) and L2:3 (2.4%). Multiple level involvements were observed in 20/123 (16.2%).

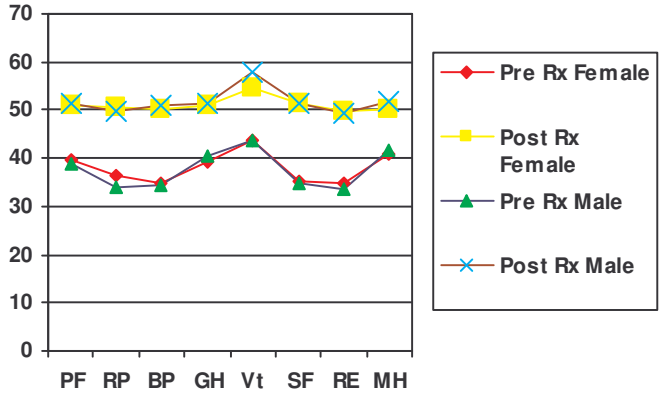
Table 10: Levels of pars defects in the lumbar spine

Site	**Lumbar levels**				
	L5	**L4**	**L3**	**L2**	**Multilevel**
Unilateral	14	10	5	2	12
Bilateral	60	4	7	1	5
Unilateral+ Bilateral	0	0	0	0	3
Total	74	14	12	3	20

3/20 multiple level pars injuries had combined unilateral pars lesion at a higher lumbar level i.e. L4 or L3 or L2 and bilateral pars lesion at L5. 77/123 (62.6% had bilateral pars lesion and 43/123 (37.4%) had unilateral involvement. But when the multiple levels of lesions were excluded we were left with bilateral pars lesion in 72/123 (58.5%) and unilateral pars lesion in 31/123 (25.2%). At the L5 lumbar level 60/74 (81%) were bilateral lesions and 14/74 (19%) were unilateral lesions (Table 9). In the males 43/74 (58%) of the lesion was located at L5 while in the females 31/49 (63%) were located at L5 level. Spina bifida was noted in 8/43 (18.6%) patients with unilateral pars defects and 12/77(15.5%) patients with bilateral pars defects.

viii) *Outcome of conservative treatment*

All patients underwent a strict protocol of activity restriction, bracing, and physical therapy for a period of 6 months. The treatment regimen consisted of a resting phase (4–12weeks) and a rehabilitation phase (10–20 weeks). If the individual remained symptomatic after the first 4 weeks, we considered antilordotic bracing. After 3 months of rest and provided the athlete was asymptomatic with a full range of pain-free motion in the lumbar spine, a graded rehabilitation programme was commenced, starting with low impact aerobic exercise and early neutral spinal stabilization training. Subsequently, the training involved sports specific and dynamic multiplanar spinal stabilization exercises. The mean pre treatment and post treatment VAS score was 4.5 and 0.65 respectively (SD – 0.8)[p<0.01]. The mean pretreatment ODI was 35.5 (SD -7.8). The post-treatment ODI was 6.9 (SD – 7.6) [p<0.01].



PF- Physical Functioning, RP – Role Physical , BP- Bodily Pain, GH – General Health, Vt – Vitality , SF – Social functioning RE- Role emotional, MH – Mental Health

Fig 23: Global SF-36 scores of all male and female patients showing Pre-treatment and 24 months post-treatment

In the SF-36 scores, the mean score for the physical component of health improved from 34.9 (SD - 5.3) to 49.3 (SD -6.6) ($p< 0.001$). The mean score for the mental component of health improved from 40.2 (SD -5.2) to 52.0 (SD-6.0) ($p<0.001$). The mean BPSQ score was 44.3 ± 24.2 (range 0-80) [Table 11a]. The mean pre-treatment and post-treatment VAS and ODI scores were slightly better in males as compared to females (Table 11b). There was significant improvement in all components of the SF-36 scores (Fig 23).

Table 11a: Showing outcome scores of all patients treated conservatively

Outcome scores	Mean	SD	Min	Max
PreRx VAS	4.53	0.88	3	8
PostRx VAS	0.65	0.8	0	4
PreRx ODI	35.6	7.8	22	70
PostRx ODI	6.9	7.6	0	38
PreRx SF36pcs	34.9	5.6	14	49
PostRx SF36pcs	49.3	6.6	21.4	59.3
PreRx SF36mcs	40.2	5.2	28.2	59.1
PostRx SF36mcs	52.1	6.0	34.6	64.7
BPSQ	44.3	24.2	30	63

Table 11b: Showing the outcome of the patients treated conservatively with reference to their gender

Scores	Gender	Mean (CI)	SD	Range
Pre Rx VAS	Male	4.25 (4.0-4.5)	0.76	3-6
	Female	4.7 (4.5-4.9)	0.93	3-8
Post Rx VAS	Male	0.35 (0.2-0.5)	0.53	0-2
	Female	0.83 (0.62-1.0)	0.90	0-4
Pre Rx ODI	Male	34.7 (33-36.5)	7.8	22-70
	Female	36.8 (34.5-39.1)	7.9	24-68
Post Rx ODI	Male	6.6 (4.8-8.3)	7.5	0-36
	Female	7.5 (5.2-9.8)	7.5	0-38
Pre Rx SF36pcs	Male	34.5 (33.2-37.3)	5.7	14-49
	Female	35.7 (34-37.3)	5.7	14-48
Post Rx SF36pcs	Male	49.4 (47.8-51.0)	6.7	21.4-59.3
	Female	49.3 (47.5-51.1)	6.3	34.9-59.3
Pre Rx SF36mcs	Male	40.4 (39.2-41.5)	4.9	30.9-59.1
	Female	40.1 (38.5-41.7)	5.6	28.2-53.4
Post Rx SF36mcs	Male	52.7 (51.4-53.9)	5.4	37.8-64.7
	Female	51.1 (49.1-53.1)	6.8	31.6-62.0
BPSQ scores	Male	46.8 (30-63)	23.2	0-80
	Female	40.7 (28-80)	25.4	0-80

ix) *Unilateral versus Bilateral*

In the unilateral group, 28/36 (77%) patients had complete relief of pain by a mean time of 4.2months (range 3-7months) of conservative treatment. 4/36 improved partially and had undergone further few months of treatment and did not require surgery. Some of these patients also had CT scans, which revealed healing pars defect in 2 patients and incomplete unilateral lesions in the other 2 patients. They were asymptomatic at 1 year and, at the 2-year follow-up, had returned to active sports. 4/36 patients did improve but couldn't return back to previous level of activity. Three cricketers (bowlers) had multilevel involvement on the left side of lumbar spine, which was contralateral to their bowling arm *i.e.*, right side. Two of the above 3 cricket bowlers had stress reactions at L2 and L3, with a unilateral spondylolysis at L4. One of the 3 cricket bowlers had unilateral spondylolysis at L3 and L5 pars interarticularis on the left side (Fig 7a-d).

In the bilateral group, 47/59 (79%) patients had complete pain relief at a mean time of 6.5 months (3-12months) of conservative treatment. 8/59 (13.5%) required extended treatment but did not require any further surgical intervention (Table 6). These patients were treated with anti-lordotic bracing but half of these were non compliant.

In the unilateral group, the mean pre treatment and post treatment VAS score was 4.25 (SD- 0.7) and 0.35 respectively (SD - 0.5) [p<0.001]. The mean pretreatment ODI was 33.4 (SD -4.9). The post-treatment ODI was 5.5 (SD – 6.4). In the SF-36 scores, the mean score for the physical component of health improved from 34.7 (SD - 5.7) to 49.7 (SD -7.0) (p< 0.001). The mean score for the mental component of health improved from 40 (SD -4.1) to 52.9 (SD-4.9) (p<0.001). The mean BPSQ score was 46.6 (range 0-65) [Table 11c].

In the bilateral group, the mean pre treatment and post treatment VAS score was 4.7 (SD- 0.9) and 0.83 respectively (SD – 0.9) [p<0.001]. The mean pretreatment ODI was 37.0 (SD -8.9). The post-treatment ODI was 7.9 (SD – 8.3). In the SF-36 scores, the mean score for the physical component of health improved from 35.0 (SD – 5.7) to 49.1 (SD -6.5) (p< 0.001). The mean score for the mental component of health improved from 40.4 (SD -5.8) to 51.5 (SD-6.6) (p<0.001). The mean BPSQ score was 42.5 (range 0-80) [Table 11c].

Table 11c: Showing the outcome of the patients treated conservatively with reference to their laterality

Scores	Laterality	Mean (CI)	SD	Range
Pre Rx VAS	Unilateral	4.25 (4.0-4.5)	0.76	3-6
	Bilateral	4.7 (4.5-4.9)	0.93	3-8
Post Rx VAS	Unilateral	0.35 (0.2-0.5)	0.53	0-2
	Bilateral	0.83 (0.62-1.0)	0.90	0-4
Pre Rx ODI	Unilateral	33.48 (32-35)	4.96	24-44
	Bilateral	37.0 (34.9-39.0)	8.90	22-70
Post Rx ODI	Unilateral	5.5 (3.5-7.4)	6.4	0-28
	Bilateral	7.9 (6.0-9.8)	8.3	0-38
Pre Rx SF36pcs	Unilateral	34.7 (33 – 36.5)	5.7	14-48
	Bilateral	35 (33.8-36.4)	5.7	14-49
Post Rx SF36pcs	Unilateral	49.7 (47.5-51.9)	7.0	21.4-59.3
	Bilateral	49.1 (47.6-50.6)	6.5	33.2-59.3
Pre Rx SF36mcs	Unilateral	40 (38.7-41.2)	4.1	34.1-53.4
	Bilateral	40.4 (39 -41.7)	5.8	28.2-59.1
Post Rx SF36mcs	Unilateral	52.9 (51.3-54.4)	4.9	39.3-64.7
	Bilateral	51.5 (40.9-53.0)	6.6	31.6-62.2
BPSQ scores	Unilateral	46.6 (37-65)	22.8	0-65
	Bilateral	42.5 (33-47)	25.2	0-80

7.1.2 Return to sports

i) *Male versus female*

56/62 males (90%) returned to sporting activity whereas only 28/36 female (77%) athletes returned to sporting activity. (Table 12a)

Table 12a: Showing return to sports with reference to gender

Return to Sports			Sex		Total
No			**Male**	**Female**	
	Site	Unilateral	3	1	4
		Bilateral	2	7	9
		Total	5	8	13
Yes	**Site**	Unilateral	22	10	32
		Bilateral	31	18	49
		Unilateral + Bilateral	3	0	3
		Total	56	28	84
No sports	**Site**	Unilateral	4	2	6
		Bilateral	8	10	18
		Total	12	12	24
			73	**48**	**121**

ii) *Unilateral versus Bilateral*

In the unilateral pars defect group, 32/36 sporting individuals returned to active sports. All 14 professionals returned to their previous active levels. There were 5 cricket bowlers, 4 footballers, 2 tennis players, 1 each in hockey, swimming and rugby.

The four patients who did not return to sports were semi-professional players of cricket (1) & rugby (1) and amateur in aerobics (1) & football (1). Two examples are sited (Fig 4 and 5) one with a unilateral left L5 defect healed and the other with bilateral L5 defect did not heal but both had successful return to sport (football) (Table 12b).

In the bilateral pars defect group, 49/59 sporting individuals returned to active sports. 14/19 professionals returned to their previous level of sports. 16/17 semi-professionals returned to their previous active level of sports. 19/23 amateur sporting individuals returned to previous level of active sports. The 9 patients who did not get back to their previous level of sports were involved in multisports (2), tennis (2), gymnastics (1), badminton (1), judo (1) dancing (1) and javeline throw (1) (Table 11b) (Fig 8 a & b).

Table 12b: Showing the numbers who return to active sports with the levels of activity

	Level of sports	**Return to previous level**	**Did not return**	**Total**
Unilateral	Professional	14	0	14
	Semi Professional	9	2	11
	Non professional	9	2	11
	Total	32	4	36
Bilateral	Professional	14 + 2	4	18 +2
	Semi Professional	16 + 1	1	17 +1
	Non professional	19	4	23
	Total	49 +3	9	58 +3

iii) *Outcome scores*

The sporting individuals who returned to active sports had post-treatment ODI scores <10 and minimum BPSQ scores of 48. The physical components of SF-36 scores were also analyzed. The physical functioning (PF) and bodily pain (BP) scores were above 40 and 37.5 respectively in the individuals who had returned to active sports (Table 12c).

Table 12c: Showing the scores at which patients returned to active sports following treatment

Scores	**Unilateral** (32)	**Bilateral** (48)	**Multiple** (3)
Post Rx ODI	0-12	0-10	0-6
BPSQ	48-75	48-90	65-75
Post Rx PF	40.4-57.1	42.5-57.1	52.9
Post Rx BP	37.9-62.7	41.8-62.7	46.5-55.9

7.1.3 Correlational Statistics

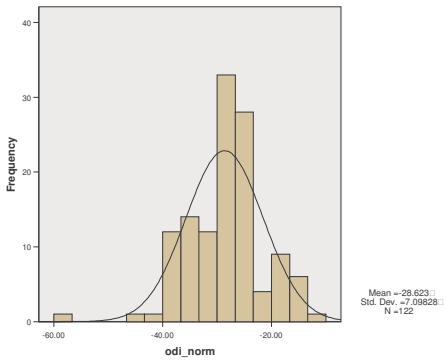
i) *Paired t-test for the outcome variables in the study group 1*

Paired t-test is used here since we have one outcome measurement variable and two nominal variables in each individual. One of the nominal variables has only two values.

The most common design is that one nominal variable represents different individuals, while the other is “before” and “after” some treatment. Using a paired t-test has much more statistical power when the difference between groups is small relative to the variation within groups.

The paired t-test is only appropriate when there is just one observation for each combination of the nominal values. The difference between the observations is calculated for each pair, and the mean and standard error of these differences are calculated. Dividing the mean by the standard error of the mean yields a test statistic, that is t-distributed with degrees of freedom equal to one less than the number of pairs.At first we determined that the data available was normally distributed (Fig 24)

Fig 24: Histogram showing normal distribution of the mean difference in ODI scores in Study 1



Null Hypothesis A: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis group treated conservatively. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables with their mean, standard deviation and the standard error of the mean are displayed in appendix table 9. When paired sampling consisting of 123 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$). (Table 13)

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the conservative group*".

Table 13: Showing paired sample t-Test for Study 1

Paired Outcome scores		Paired Differences					Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
					Lower	Upper	
Pair 1	preodi - postodi	28.6	7.09	.64	27.35	29.89	.000
Pair 2	prevas - postvas	3.8	.66	.05	3.76	3.99	.000
Pair 3	presf36pcs - pstsf36pcs	-14.34	5.64	.51	-15.36	-13.32	.000
Pair 4	presf36mcs - postsf36mcs	-11.88	6.07	.55	-12.97	-10.78	.000
Pair 5	prerxPF - pstrxPF	-12.02	5.37	.49	-12.99	-11.05	.000
Pair 6	prerxRP - pstrxRP	-15.12	7.66	.70	-16.50	-13.73	.000
Pair 7	prerxBP - pstrxBP	-16.17	7.37	.67	-17.50	-14.84	.000
Pair 8	prerxGH - pstrxGH	-11.26	7.48	.68	-12.61	-9.91	.000
Pair 9	prerxVt - pstrxVt	-13.08	7.18	.65	-14.38	-11.78	.000
Pair 10	prerxSF - pstrxSF	-16.14	7.15	.65	-17.43	-14.84	.000
Pair 11	prerxRE - pstrxRE	-15.60	10.99	1.00	-17.59	-13.61	.000
Pair 12	prerxMH - pstrxMH	-9.48	6.89	.62	-10.73	-8.23	.000

We subsequently divided our study group into different age groups to see if there is any deviation from of our first hypothesis. The age groups were <14 years, 15-19 years, 20-24 years, 25-29 years and >30 years.

Null Hypothesis A_1: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis below the age of 14 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table10. When paired sampling consisting of 9 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$) (Appendix Table 11).

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis below 14 years of age*".

Null Hypothesis A_2: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 15 & 19 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table12. When paired sampling consisting of 43 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$). (Appendix Table 13)

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 15 & 19 years*".

Null Hypothesis A_3: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 20 & 24 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table14. When paired sampling consisting of 32 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$) (Appendix Table 15).

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 20 & 24 years*".

Null Hypothesis A_4: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 25 & 29 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table 16. When paired sampling consisting of 20 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$). (Appendix Table 17)

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 25 & 29 years*".

Null Hypothesis A_5: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis above the age of 30 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table 18. When paired sampling consisting of 17 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$) (Appendix Table 19).

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis above the age of 30 years*". All the outcome measures achieved statistical significance validating their sensitivity.

ii) *Unilateral versus Bilateral Lumbar spondylolysis*

We assumed the Null hypothesis and tested the two groups i.e. unilateral versus bilateral spondylolysis.

Null Hypothesis A_6: *"There is no difference in the outcome scores between the two groups"*

On analyzing the dataset and running an independent samples t-test it was detected that in the pre-treatment phase, only two outcome variables between the two groups showed significant difference. They were pre treatment VAS (p=0.009) and pre-treatment ODI (p=0.019) [Appendix Table 20a & b]. There was no other variable in the dataset which showed significant difference between the two groups in the pre-treatment phase. In the post-treatment phase only one outcome variable between the two groups showed a significant difference i.e. post treatment VAS (p=0.002) [Appendix Table 21a & b]. Thus, the null hypothesis is true for all outcome scores except pre treatment VAS and ODI and post treatment VAS scores.

iii) *Sporting versus Non sporting group*

We assumed the Null hypothesis and tested the two groups.

Null Hypothesis A_7:

There is no difference in the age between the sporting and the non sporting group

Null Hypothesis A_8:

There is no difference in the outcome scores between the sporting and non sporting group

An independent samples t-test detected that there was significant difference between the two groups in their age (mean 20.7 vs 25.4 years, p <0.001) [Appendix Table 22a]. There was significant difference between the two groups in all pre and post treatment outcome scores (Appendix Table 22b). There was significant difference between the two groups in all pre treatment SF 36 scores except Role physical (p=0.058), Social Function (p=0.55) and Mental health (p=0.38). There was significant difference between the two groups in all post treatment SF 36 scores [Appendix Table 22c].

iv) *Correlation testing*

Correlation testing was performed using the Spearman method to detect relationships. This does not prove cause or effect, but only association. The correlation coefficient expresses the strength of the association between only two variables, and ranges from +1 to -1. The closer it is to zero, the weaker the association between the variables. Statistical “significance” is represented by the p value, whereas relevance is suggested by the size of the correlation coefficient. The sign indicates whether the relationship is direct or inverse.

Statistically significant correlations of the outcome variable pre treatment VAS score with the other outcome and background variables are shown (Appendix Table 23a & b). From the table it is evident that the most important correlation is with post treatment ODI ($\rho = 0.634$, $p < 0.01$) and post treatment VAS scores ($\rho = 0.626$, $p < 0.01$). The other variables that are significantly correlated in descending order are severity of back pain, post treatment SF36pcs, pre treatment ODI, pre treatment SF36pcs, return to sports, BPSQ scores, age and type of sports.

In the SF36 most components were correlated significantly with the pre treatment VAS scores except pre treatment Bodily Pain (BP), Social Functioning (SF), Role emotional (RE), Mental Health (MH), and post treatment General Health (GH) [Appendix Table 23b].

RESULTS

7.2 Study 2

7.2.1 Patient demographics

i) *Target subject group*

Review of the 55 medical records of the patients who had surgery for lumbar spondylolysis at QMC and Park hospital between 1994 and 2007. We also did questionnaire survey of these patients to know their outcome. The initial response was 50% in this group after 4 weeks of posting the questionnaires. We sent a second set of postal questionnaires to the remainder. Subsequently the response rate increased to 75% in Study 2 after a period of three months. Subsequently brief telephonic questionnaire with the remainder of the subjects was carried out. Finally, 90% responders in the surgical group had been recorded.

The general features of the target subjects are summarized as follow:

ii) *Age & sex*

The mean age of onset of back pain was 18.3 years, ranging from 8 to 35 years. The mean age of onset of back pain in the unilateral spondylolysis group was 19.2 years and in the bilateral spondylolysis group was 18.5 years (Fig 25).

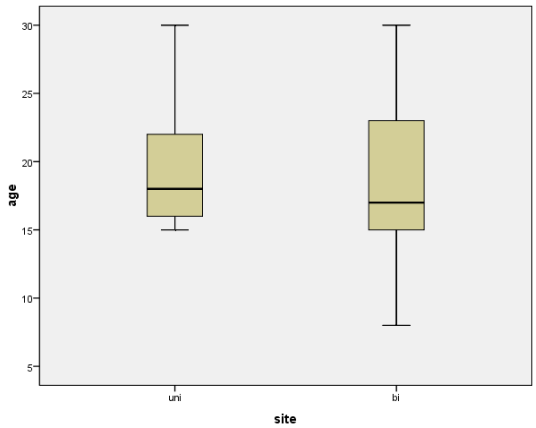


Fig 25: Box Plot showing the mean age in unilateral and bilateral pars defect in Study 2

For analyzing further to assess the significance of age in the treatment of spondylolysis we divided the patients into five groups of age. The groups were: 1) 8-14 years, 2) 15-19years, 3) 20-24 years, 4) 25-29 years and 5) >30 years. We had 10 patients in Group 1, 24 patients in group 2, 11 patients in group 3, 7 patients in group 4 and 3 patients in group 5.

The Male: Female ratio was 40:15 (72% male). In the unilateral group the Male: Female ratio was 7:1 (i.e.87% male). In the bilateral group the Male: Female ratio was 33:14 (71% male) [Table 14].

Table 14: Showing the patient demographics of Study 2

Factors	**Unilateral**	**Bilateral**	**Combined**
No of patients	8	47	55
M:F	7:1	33:14	40:15
Mean age of onset (range)	19.2 (15-30)	18.5 (8-30)	18.3 (8-30)
Sporting vs Nonsporting	8:0	44:3	52:3
Level of sporting activity Total (M:F)			
Professional	4 (4:0)	23 (18:5)	27 (22:5)
Semi- Professional	4 (3:1)	10 (8:2)	14 (11:3)
Non-Professional	0	7 (5:2)	7 (5:2)
None	0	7 (2:5)	7 (2:5)
Mean length of Rx (range)	6.5 (6-9)	7.5 (6-12)	7.3 (6-14)

iii) *Sports*

There was 52/55 (94%) subjects were involved in sports at the time of consultation for low back pain at the QMC, Nottingham. 3/52 (6%) were not taking part in any sports. Football (22) followed by cricket (8) were the most commonly played sport followed by gymnastics (3), swimming (3), athletics (3) tennis (3) and others (Table 21).

The activity level of sports was determined by clinical consultation and also recorded from the BPSQ questionnaire. 27/52 (52%) were professional players, 14/52 (27%) were semi professional and 7/52 (13.5%) were amateur sportsmen and women (Table 14).

Table 15: Showing the number of patients in each type of sports

Gender	Laterality	Throwing	Trunk Twisting	Kicking	Total
Male	Unilateral	1	3	4	8
	Bilateral	1	10	19	30
	Total	2	13	23	38
Female	Unilateral	0	1	0	1
	Bilateral	0	10	3	13
	Total	0	11	3	14

As explained earlier in the previous chapter, the type of sports according to the movements was also recorded in this group. Similar preponderance of pars injuries was observed to occur in combination of *trunk twisting* and other body movements as in the non-operated group. The number of patients in the *kicking* sports was 26/52 (50%), *throwing and trunk twisting* sports were 2/52 (3.8%) and 24/52 (46.2%) respectively [Table 15].

iv) *Low Back Pain*

The mean duration of symptoms before surgery was 5.7 months (3 to 36). Low back pain of sudden onset occurring during sporting activity was the presenting complaint in 23 patients. Most unilateral pars lesions (7/8) had acute onset of symptoms and presented to us within a mean of 6 weeks (range 4-16 weeks) of onset of low back pain. The remainder had insidious onset of low back pain with some patients having radiation of pain to the legs. All patients had been initially treated conservatively for a minimum of six months.

v) *Site & Type of pars defects*

The investigative algorithm before 2001 included X rays, SPECT imaging along with CT scans to identify the pars lesion. MRI scan was performed only in patients when there was need to exclude disc degeneration as the cause of the low back pain.

Between 2001 & 2002 there was a transition period when the radiological investigation at QMC was excluding SPECT imaging and introduced MRI scan as the primary form of imaging modality. Since 2002 most patients had MRI scans and CT scans for the diagnosis of pars lesion (Fig 16).

Before 2001, 22/55 patients had undergone SPECT imaging with positive uptake (Appendix Table 24). At L5, 11 patients had bilateral and four unilateral increased uptake on SPECT imaging. Two patients with negative SPECT scans, but a high degree of clinical suspicion, had reverse-gantry CT which revealed a lytic defect. The mean width of the gap was 3.5 mm (1 to 8); in 8/22 patients (36%) it was 2 mm or less.

The lumbar levels were 43/55 (78%) at L5, 3/55 (5.5%) at L4, 4/55 (7.2%) at L3 (Table 15). CT scans were available in 52 cases of which 9 showed unilateral pars defect or increased sclerosis and 43 showed bilateral pars defect (Appendix Table 24). 36 patients had MRI scans as the primary form of imaging. Most (80%) of these MRI scans showed grade 3-4 lesions.

Multiple level involvements were observed in 5/55 (9%). 3/5 multiple level pars injuries had combined unilateral pars lesion at a higher lumbar level i.e. L4 or L3 and bilateral pars lesion at L5 (Table 15).

Table 16: Showing the levels of lumbar pars defect

Site	L5	L4	L3	Multilevel
Unilateral	5	1	2	0
Bilateral	38	2	2	3
Uni+ Bilateral	0	0	0	2
Total	43	3	4	5

vi) *Surgical treatment*

Modified Buck's screw repair of the pars defect was carried out in 44 patients (33M: 11 F). Unilateral repair was performed in 8 patients (7M: 1F) and bilateral repair was performed in 36 patients (26M: 10F) using Buck's method.

Between 1994 & 98, Scotts's repair with screws & wires were performed in 4 patients (2M: 2F). Alar transverse repair was performed at 3 patients (1M: 2F). Two patients underwent further surgeries i.e. one patient had postero-lateral fusion at L4/5 for continued back pain. One female gymnast had been scheduled for Buck's repair and on exposure of her spine it revealed fused pars defect at L4/5 (Table 17).

Table 17: Showing the number of surgical repairs performed in uni or bilateral pars defects

Surgical treatment	Male		Female		Total
	Unilateral	Bilateral	Unilateral	Bilateral	
Bucks direct repair	7	26	1	10	44
Scotts repair	0	2	0	2	4
Alar transverse repair	0	1	0	2	3
Postero-lateral fusion	0	2	0	0	2
Multiple surgeries	0	0	0	1	1
Exposed but healed pars	0	0	0	1	1
Total	7	31	1	16	55

In the unilateral group, the levels of lumbar pars repair with Buck's technique were 5 at L5, 1 at L4 and 2 at L3. One female patient had alar transverse fusion at left L3 pars. Only female patient required further surgery (fusion) for non union of the pars who had a bifid spine at L5 (Fig 13 a-d). She was involved in amateur sports (Table 18).

In the bilateral group, Buck's repair was performed for pars defects in 28 patients at L5, 2 patients at L4 and 1 patient for both L4 and L5 bilateral defects. One patient had bilateral Buck's repair at L3 and L5 levels. Two patients in the series had multiple levels Buck's repair i.e. bilateral at L5 and unilateral at L4 (Table 18).

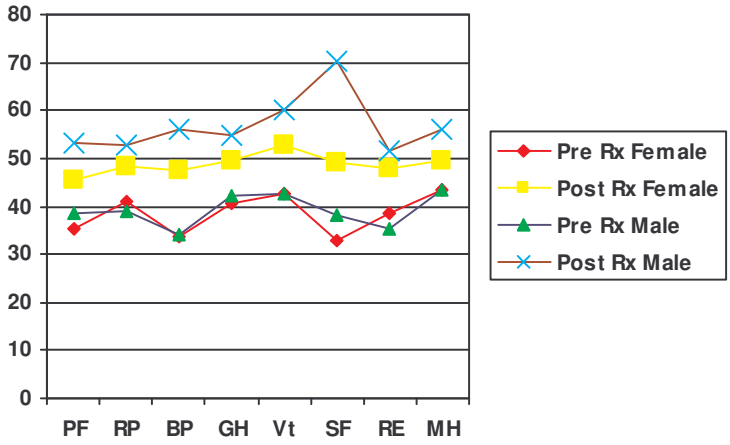
Table 18: Showing the number of operations according to levels of lumbar pars defect

Laterality	Surgery	Lumbar level						Total
		L5	L4	L3	L4/5	L3/5	Multilevel	
Unilateral	**Bucks repair**	5	1	2	-	-	-	8
	Alar Transverse fusion	-	-	1	-	-	-	1
Bilateral	**Bucks repair**	30	2	-	1	1	2	36
	Scotts repair	3	-	1	-	-	-	4
	Alar Transverse fusion	2	-	-	-	-	-	2
	Post-lateral fusion	2	-	-	-	-	-	2
	Exposed but healed pars	-	-	-	1	-	-	1
	Multiple surgeries	1	-	-	-	-	-	1

2/4 patients in the Scotts repair group had alleviation of their symptoms of low back pain but rest of the two patients had undergone postero-lateral fusion and the other continued to live with analgesic medication.

vii) *Outcome of surgical treatment*

The mean pre treatment and post treatment VAS score was 6.6 (SD-0.97) and 0.8 (SD-1.12) respectively [$p<0.01$]. The mean pretreatment ODI was 37.6 (SD -10.5) and the mean post-treatment ODI was 9.2 (SD – 13.4) [$p<0.01$]. In the SF-36 scores, the mean score for the physical component of health improved from 32.7 (SD – 7.1) to 50.1 (SD -8.8) ($p< 0.001$). The mean score for the mental component of health improved from 42.8 (SD -8.4) to 54.4 (SD-8.2) ($p<0.001$). The mean BPSQ score was 49.6 (range 15-73) [Appendix Table 25]. There was significant improvement in all components of the SF-36 scores (Fig 26). The most notable were the physical components esp. Physical functioning, Role physical and Bodily pain (Appendix Table 26).



PF- Physical Functioning, RP – Role Physical , BP- Bodily Pain, GH – General Health, Vt – Vitality , SF – Social functioning RE- Role emotional, MH – Mental Health

Fig 26: Global SF-36 scores of all male and female patients showing preoperative and 24 months postoperative in the Study 2

a) *Male versus Female*

The mean pre and post operative VAS scores were similar in both the genders. The mean pre and post operative ODI scores were better in males (35.8 & 6.6 respectively) as compared to females (42.9 & 15.0 respectively) [Table 19]. There was no difference in both components of SF-36 scores in either group.

Table 19: Showing the outcome of the patients with reference to their gender

Scores	Gender	Mean (CI)	SD	Range
Pre Rx VAS	Male	6.6 (6.2-7.0)	1.1	5-10
	Female	6.4 (5.8-6.9)	0.86	5-8
Post Rx VAS	Male	0.76 (0.3-1.2)	1.25	0-6
	Female	0.92 (0.24-1.5)	1.1	0-3
Pre Rx ODI	Male	35.8 (32.5-39.1)	8.8	20-56
	Female	42.9 (33.8-52.0)	15.1	24-72
Post Rx ODI	Male	6.6 (2.8-10.4)	10.2	0-38
	Female	15.0 (3.0-27.1)	19.9	0-64
Pre Rx SF36pcs	Male	32.4 (29.7-35.1)	7.3	15.7-43.5
	Female	31.5 (30.5-39.7)	7.6	21-44
Post Rx SF36pcs	Male	51.8 (48.6-55.0)	8.6	22.6-60.5
	Female	47.2 (41.2-53.1)	9.8	28.4-57.9
Pre Rx SF36mcs	Male	40.4 (39.2-41.5)	4.9	30.9-59.1
	Female	41.5 (36.0-47.0)	9.0	23.8-52.3
Post Rx SF36mcs	Male	55.6 (53.1-58.2)	6.7	34.8-62.0
	Female	51.6 (44.9-58.3)	11.1	24.1-62.6
BPSQ scores	Male	51.4 (46.9-55.9)	12.0	15-73
	Female	45.5 (33.9-57.1)	19.2	15-73

b) *Unilateral versus Bilateral*

The mean pre- and post-treatment ODI scores were better in unilateral patients as compared to bilateral ones (Table 20).

In the unilateral group with Buck's repair, 7/8 (87%) patients had complete relief of pain at a mean time of 6.5months (range 6-9months) following surgery. One female patient had further physiotherapy without improvement. She required further CT scan which revealed a non-union of the repaired unilateral L5 defect. She had an associated spina bifida at L5 vertebra. She underwent further fusion after removal of the screw (Fig 13a-d). More recently, one female gymnast with unilateral pars defect and a spina bifida at L5 underwent Buck's screw repair and stabilization of the bifid spine with malleable wire (Fig 9a-h).

In the bilateral group, with Buck's repair in single level i.e. 30/32 (93%) patients had complete pain relief at a mean time of 7.5 months (range 6-12months) following surgical repair of the pars defect. 2/32 (7%) required extended treatment but didn't require any further surgical intervention. The rest four patients who had multiple level of Buck's repair had extended period of physical therapy. One of them returned to active sports after one year following bilateral L4/5 pars repair.

Table 20: Showing the outcome of the patients with reference to their laterality

Scores	Laterality	Mean (CI)	SD	Range
Pre Rx VAS	Unilateral	6.8 (6.1-7.5)	0.83	4-6
	Bilateral	6.5 (6.1-6.8)	1.09	5-10
Post Rx VAS	Unilateral	0.87 (0.06-1.81)	1.1	0-3
	Bilateral	0.80 (0.37-1.2)	1.23	0-6
Pre Rx ODI	Unilateral	33.25 (26-40)	8.6	20-46
	Bilateral	39.0 (34-43)	11.8	22-72
Post Rx ODI	Unilateral	3.5 (0.16-7.16)	4.3	0-12
	Bilateral	10.5 (5.2-15.7)	15.3	0-64
Pre Rx SF36pcs	Unilateral	35.2 (31.4-38.9)	4.5	28-42
	Bilateral	32.8 (30-35.5)	7.9	15.7-44.5
Post Rx SF36pcs	Unilateral	54 (47.6-60.3)	7.5	38-60
	Bilateral	49.6 (46.4-52.8)	9.4	22.6-60.5
Pre Rx SF36mcs	Unilateral	45.1 (36-54.2)	10.9	29-57.4
	Bilateral	43 (40.2 -45.9)	8.2	23.8-68.7
Post Rx SF36mcs	Unilateral	54 (46.2-61.7)	9.3	32.4-61.5
	Bilateral	54.5 (51.7-57.4)	8.3	24.1-62.6
BPSQ scores	Unilateral	51.3 (37-65.6)	17	15-68
	Bilateral	49.2 (44.3-54.1)	14.2	15-73

In the unilateral group, the mean pre and post-treatment VAS score was 6.8 (SD- 0.8) and 0.87 (SD – 1.1) respectively [$p<0.001$]. The mean pre and post-treatment ODI was 33.2 (SD -8.6) and 3.5 (SD – 4.3) respectively [$p<0.01$]. In the SF-36 scores, the mean score for the physical component of health improved from 35.2 (SD – 4.5) to 54 (SD - 7.5) [$p< 0.001$]. The mean score for the mental component of health improved from 45.1 (SD -10.9) to 54 (SD-9.3) [$p<0.001$]. The mean BPSQ score was 51.3 (range 15-68) [Table 20].

In the bilateral group, the mean pre and post operative VAS score was 6.5 (SD- 1.0) and 0.80 respectively (SD – 1.2) [$p<0.001$]. The mean pre and post-operative ODI was 39.0 (SD -11.8) and 10.5 (SD – 15.3) respectively [$p<0.01$]. In the SF-36 scores, the mean score for the physical component of health improved from 32.8 (SD – 7.9) pre operatively to 49.6 (SD -9.4) post-operatively [$p< 0.001$]. The mean score for the mental component of health improved from 43.0 (SD -8.2) to 54.5 (SD-8.3) [$p<0.001$]. The mean BPSQ score was 49.2 (range 15-73) [Table 20].

There was significant improvement in all components of the SF-36 scores (Fig 26). The most notable were the physical components esp. Physical functioning, Role physical and Bodily pain (Appendix Table 26).

c) *Return to sports*

44/52 (84%) individuals had returned to the sports they were involved in after undergoing the strict protocol for physical rehabilitation (Table 21). In the unilateral pars defect group, 3 cricketers, 3 footballers, 1 gymnast & I netballer did well to return to their respective sports between 6-9 months of operation. One of the cricketers who had multilevel involvement, *i.e.*, stress reaction at L2 and L3 had undergone direct repair for the L4 defect. He returned back to playing cricket after a period of 10 months.

Table 21: Showing the number of athletes who returned to sport after surgery

Name of Sports (no)	Number returning to Pre-injury status	Number who fail to return to sports (*)
Football (22)	20	2 (1P:1NP)
Cricket (8)	8	0
Gymnastics (3)	1	2 (1P:1NP)
Swimming (3)	2	1(NP)
Athletics (3)	3	0
Tennis/Squash (2+1)	3	0
Hockey (2)	2	0
Rugby (1)	1	0
Netball (2)	1	1 (SP)
Karate (2)	1	1 (SP)
Horse riding (1)	1	0
Multisport (Dance) (1)	0	1 (NP)
Golf (1)	1	0

(*)P= Professional, SP= Semi-professional, NP= Non professional

One cricketer who had a defect repaired at right L4 pars continued to have low back pain (when bowling) and required a further 6months of training and a CT scan was performed (showing healed defect) before resuming sporting activity.

In the bilateral pars defect group, there were 19 footballers at various levels. Of these 14 returned to the same level at which they had been competing before the onset of their symptoms. Three of them returned after an extended period of physical therapy and reconditioning. Four cricketers returned to fast bowling after six months of rehabilitation and reconditioning (Fig 10a-h). Two fast bowlers with mixed bowling actions were required to change their action before returning to cricket. Two other cricketers who had a Buck's fusion returned to sport, but had further symptoms after two years with a new lysis at a different level (L3). Both these lesions resolved after conservative treatment.

2/3 gymnast gave up their sports after surgery although they remained symptom free. One gymnast returned to the state level. All three sprinters and hurdler had returned to their previous activity levels. Three players in the racquet sports had returned to same level of sports as they were previous to their surgery (Fig11a &b). A female hockey player and sprinter who had repair of bilateral defects at L5 returned to hockey nine months after surgery. One professional golfer who was treated by a Buck's fusion which was soundly healed after one year, returned to golf. One netball player and one martial arts semi-professional did not return to sports. Two footballers (one professional and one nonprofessional) did not return to their active sporting levels. The non professional footballer had a painful non union of L5 pars and underwent subsequent postero-lateral fusion (Fig 14a-d).

Table 22: Showing the scores at which patients returned to active sports after surgery

Scores	**Unilateral** (7)	**Bilateral** (30)
Post Rx ODI	0-12	0-14
BPSQ	48-68	48-73
Post Rx PF	36.2-57.1	46.7-57.1
Post Rx BP	38.9-62.7	39-62.7

All the sporting individuals who returned to sports had their post-treatment ODI score of <10 and minimum BPSQ scores of 48. The physical functioning (PF) scores in the unilateral and bilateral group were above 36.2 and 46.7 respectively. The mean bodily pain (BP) scores in the unilateral and bilateral group were above & 38.9 and 39 respectively (Table 22).

7.2.2 Correlational Statistics

i) *Paired t-test for the outcome variables in the study group 2*

Paired t-test is used again to compare the means of two variables and their difference with a null hypothesis. The data was normally distributed as indicated by the Q-Q plots for each outcome scores. For example, a Q-Q plotting of pre-operative ODI scores showing normally distributed data. The circles in the graph showing individual values plotted along the straight line which represents the perfect normal distribution of the data (Fig 27).

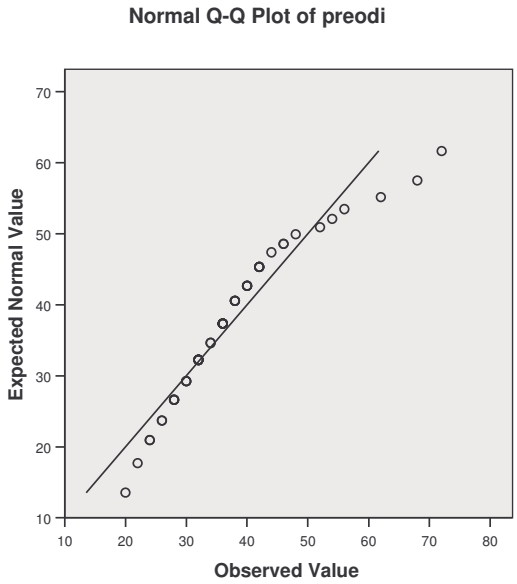


Fig 27: Q-Q plot showing the normal distribution of Pre operative ODI scores

Null Hypothesis B: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis group treated surgically. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequency distribution for the test variables with their mean, standard deviation and the standard error of the mean are displayed in appendix table 27a & b.

When paired sampling consisting of 50 patients' outcome was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$) [Table 23]

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post surgical stage in this surgical cohort of lumbar spondylolysis*".

Table 23: Showing the mean difference between the pre and post treatment scores

Paired Outcome scores		Paired Differences					Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		
					Lower	Upper	
Pair 1	preodi - postodi	28.37	8.67	1.18	26.00	30.73	.000
Pair 2	prevas - postvas	5.81	1.03	.13	5.53	6.09	.000
Pair 3	presf36pcs - pstsf36pcs	-17.29	7.59	1.07	-19.45	-15.14	.000
Pair 4	presf36mcs - postsf36mcs	-11.60	8.39	1.18	-13.99	-9.21	.000
Pair 5	prerxPF - pstrxPF	-12.96	6.54	.92	-14.82	-11.10	.000
Pair 6	prerxRP - pstrxRP	-14.78	10.70	1.51	-17.83	-11.74	.000
Pair 7	prerxBP - pstrxBP	-19.62	7.69	1.08	-21.80	-17.43	.000
Pair 8	prerxGH - pstrxGH	-11.56	7.46	1.05	-13.68	-9.44	.000
Pair 9	prerxVt - pstrxVt	-15.24	9.34	1.32	-17.89	-12.58	.000
Pair 10	prerxSF - pstrxSF	-16.79	5.59	.79	-18.38	-15.20	.000
Pair 11	prerxRE - pstrxRE	-14.00	11.88	1.68	-17.38	-10.62	.000
Pair 12	prerxMH - pstrxMH	-10.78	8.07	1.14	-13.08	-8.49	.000

Similar to the conservative group, we subsequently divided our study group into different age groups to see if there is any deviation from of our first hypothesis. The age groups were <14 years, 15-19 years, 20-24 years, 25-29 years and >30 years.

Null Hypothesis B_1: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis below the age of 14 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequency distribution for the test variables are displayed in appendix table 28a. When paired sampling consisting of outcome scores of 10 patients' was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 ($p<0.01$) [Appendix Table 28b].

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis below 14 years of age*".

Null Hypothesis B_2: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 15 & 19 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequency distribution for the test variables are displayed in appendix table 29a. When paired sampling consisting outcome scores of 24 patients' was performed, it was observed that there were significant differences in the VAS, ODI, SF36pcs, SF36mcs and all the components of SF36 [p<0.01] (Appendix Table 29b)

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 15 & 19 years*".

Null Hypothesis B_3: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 20 & 24 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table 30a. When paired sampling consisting of outcome scores in 11 patients' was performed, it was observed that there were significant differences in the VAS, ODI in 11 patients and SF36pcs, SF36mcs in 9 patients and other components of SF36 (p<0.01) [Appendix Table 30b].

We are allowed to reject the null hypothesis. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 20 & 24 years*".

Null Hypothesis B_4: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis between the ages of 25 & 29 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table 31a. When paired sampling consisting of outcome scores in 7 patients' was performed, it was observed that there were significant differences in all 7 patients in VAS, ODI and 5 patients in the SF36pcs (p<0.01) but there was no difference in the SF36mcs scores (p=0.111).[Appendix Table 31b]. We are allowed to reject the null hypothesis if we exclude the SF36mcs scores. Therefore, the alternative hypothesis is "*there is significant difference in the mean change in the outcome scores in the post treatment stage in the patients with lumbar spondylolysis between the ages of 25 & 29 years*".

Null Hypothesis B_5: *The mean difference between paired observations is zero in the patients with lumbar spondylolysis above the age of 30 years. The paired observations are the outcome variables VAS, ODI, SF36pcs, SF36mcs, and individual components of SF36.*

The frequencies for the test variables are displayed in appendix table 32a. When paired sampling consisting of outcome scores in 2 patients' was performed, it was observed that there were significant differences in the VAS ($p<0.05$), but not others [Appendix Table 32b]. We are not allowed to reject the null hypothesis.

All the outcome measures in this surgical group achieve statistical significance and the paired sample tests validate their sensitivity of the outcome scores in the age group below 30 years.

ii) *Unilateral versus Bilateral Lumbar spondylolysis*
We assumed the Null hypothesis and tested the two groups i.e. unilateral versus bilateral spondylolysis by independent sample t-test.

Null Hypothesis B_6:*"There is no difference in the outcome scores between the two groups"*

On analysing the dataset and running an independent samples t-test it was detected that only significant difference in the two outcome variables between the two groups was ODI ($p=0.014$) [Table 24, Appendix Table 34a & b]. There was no other variable in the dataset which showed significant difference between the two groups.

Table 24: Showing independent Samples t-Test showing significant difference in only one outcome score i.e. Post op ODI

	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
				Lower	Upper
Post ODI	.014	-6.717	2.612	-12.009	-1.425

iii) *Correlation testing*

Correlation testing was performed using the Spearman method to detect an association. We followed the same principle as in the conservative group.

Statistically significant correlations of the outcome variable Pre treatment VAS score with the other outcome and background variables are shown in appendix table 34a and b. The most consistent association with the preoperative VAS score are the post-operative VAS i.e. $\rho = 0.53$ ($p<0.01$). Both the pre and post operative ODI scores were also significantly correlated i.e. $\rho = 0.51$ ($p<0.01$) and $\rho = 0.33$ ($p<0.05$) respectively [Appendix Table 34a]. The other variables that are significantly correlated in descending order are pre operative SF36pcs ($\rho = 0.357$), pre operative SF36mcs ($\rho = 0.348$) , age of the patient ($\rho = 0.337$), BMI ($\rho = 0.343$) , return to sports ($\rho = 0.29$). In the SF36 most components were correlated significantly with the pre operative VAS scores except post-operative Bodily Pain (BP) [Appendix Table 34b].

7.2.3 Multiple Regression Analysis

i) *Distribution of data*

The normality test accepted that the data presented to the SPSS (ver 15) had a normal distribution of the outcome variable as shown (Fig 28).

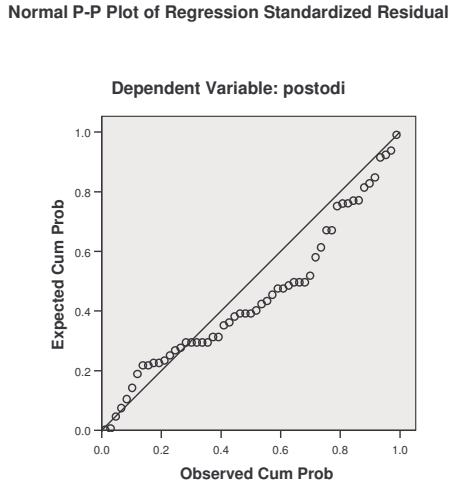


Fig 28: Normal P-P plot showing the linearity of the post operative ODI scores

ii) *Co-linearity*

Correlations between the background/preoperative factors and the post-operative VAS and ODI, were determined by Spearman rank correlation coefficient analysis (Table 43a & b). Independent variables such as the demographics (age, gender, onset of back pain, sporting vs non sporting, type of sports, imaging), objective variables (side and site of pars defect, level of sporting activity, return to sports) and subjective variables (pre and post operative Vas, ODI, SF-36 scores) and surgical options that correlated ($p<0.01$) with the post-operative outcome (ODI) were used in a standard linear multiple regression analysis, and this was followed by a stepwise regression procedure to reveal the most important predicting factors for a good outcome.

We have taken postoperative ODI as the dependent variable for the regression analysis because of two reasons:

1) In the independent sample t-test between unilateral and bilateral group, postoperative ODI was the only score which was most significant variable determining the difference between the two groups (Table 42a,b &c).
2) Although the correlation analysis suggested a higher Spearman rank of post operative VAS score than post-operative ODI, clinically VAS score is fairly subjective and can change on a daily basis. ODI scores have more consistency and test-retest reliability is very high.

iii) *Linear regression modeling*

a) *Variables*

1) The *regression equation* takes the form of $Y= b_1*x_1 + b_2*x_2 + c + e$, where Y is the true dependent (in this study postoperative ODI), the b's are the regression coefficients for the corresponding (independent) terms, where 'c' is the constant or intercept, and e is the error term reflected in the residuals. This could be simplified to $y= c + b_1*x_1 + b_2*x_2$, where y is the estimated dependent and 'c' is the constant (which includes the error term) and the equation with no interaction effects are called *main effect models*.
2) The *dependent variable* is the predicted variable in the regression equation. Post operative ODI is a continuous variable which is quite appropriate to use in the regression model.
3) The *independent variables* are the predictor variables in the regression equation. Some of the chosen predictors are continuous, some are interval and some are ordinal variables.
4) The *predicted values* are the values of each case based on using the regression equation for all cases in the analysis.
5) The use of *dummy variables* in this study was required to add values of a nominal or ordinal variable to the regression equation. We have thus converted the lumbar levels and name of surgeries into dummy variables i.e. coded as 0 for others and 1 for the variable.

iv) *Regression model*

a) *Multiple correlations*

R^2 called the multiple correlations is the percent of the variance in the dependent explained uniquely or jointly by the independents. R-squared can also be interpreted as the proportionate reduction in error in estimating the dependent when knowing the independents. Thus, R^2 reflects the number of errors made when using the regression model to guess the value of the dependent, in ration to the total errors made when using only the dependent's mean as the basis of estimating all cases. For small samples, adjusted R^2 is used as a conservative reduction to R^2 to penalize for adding variables and is required when the number of independent variables is high relative to the number of cases or when comparing models with different number of independents. R^2 change refers to the amount of R^2 increases or decreases when a variable is added to or deleted from the equation as is done in this model.

In the analysis for the current study, R^2 and the adjusted R^2 had gradually increased at each step of regression model. In the model 1 it is observed that the R^2 is 0.783 and the adjusted R^2 is 0.603 with preoperative ODI as the independent variable which can predict the post-operative ODI in 60.3%. When the regression modeling is completed overall inclusion of the independent variables (preoperative ODI, preoperative SF36pcs, BPSQ scores, Buck's repair, multiple operations, professional sporting individual and pars defect at L3), the adjusted R^2 was 0.868. This indicates that the regression model is a good predictor of the outcome variable i.e. post-operative ODI (Table 25).

Table 25: Showing the multivariate variable selection by stepwise regression modeling

Model	R^2	Adjusted R^2	Variable names
1	.783	.603	pre ODI
2	.862	.730	Pre ODI, BPSQ
3	.890	.775	Pre ODI, BPSQ, Mutiple opn
7	.943	.868	Pre ODI, BPSQ, preop SF36, Buck's, Professional, Mutiple opn, L3 pars defect

b) *Regression coefficients*

Ordinary least squares are used to draw the best fit regression line. This mathematical principle helps in producing a line such that the sum of squared deviations of the distances of all the points to the line is minimized.

Null Hypothesis C_1: *The regression coefficient is zero for the predictor variables in surgically treated patients.*

The regression coefficient (b) is the average amount the dependent increases when the independent increases one unit and other independents are held constant.

Table 26: Showing the summary of the regression model with BPSQ scores inclusive

Model	R	R^2	Adjusted R^2	Standard Error of the Estimate
1	0.943[a]	0.860	0.868	5.222

[a] Predictors: preop odi, preop SF36pcs, BPSQ , professional, Buck's repair, multiple ops, L3 pars defect
[b]Dependent variable: postop ODI

Table 27: Showing the regression coefficients when BPSQ scores were included

Independent variable	Regression coefficient (B)	Standardized coefficient	p value
Intercept	36.415	-	0.000
Preop ODI	0.218	0.174	0.057
Preop SF36pcs	-0.495	-0.258	0.001
Buck's repair	-7.235	-0.190	0.012
Multiple Opn	28.634	0.308	0.000
Professional	-6.274	-0.205	0.003
L3 pars defect	22.443	0.241	0.002
BPSQ	-.197	-.202	0.016

When this regression model is used as in Table 26 & 27 which includes BPSQ scores, the preopODI becomes less significant ($p > 0.05$) than what is required in this study group. Therefore, this model cannot predict the outcome near accurately and therefore, the BPSQ scoring has to be excluded from the final regression equation.

The final regression model used showed godd fit and predicted values were more accurate with $p<0.001$. All the values reach a statistical significance.

Table 28: Showing the summary of the final regression model

Model	R	R^2	Adjusted R^2	Standard Error of the Estimate
1	0.913[a]	0.833	0.809	6.151

[a] Predictors: preop odi, preop SF36pcs, professional, Buck's repair, multiple ops, L3 pars defect
[b]Dependent variable: postop ODI

Thus, (b) is the slope of the regression line: the larger the (b), the steeper the slope, the more dependent changes for each unit changes in the independent. It simply explains which independent variables are most important in predicting the dependent variable. The intercept or constant expressed in the equation as 'c' is the estimated Y value when all the independents have a value of 0. The intercept or value of 'c' in the modeling was -30.121 (CI: 11.197 to 49.045) [Table 29]. Therefore, the null hypothesis is rejected. This equation has a slope with a constant value.

Table 29: Showing the final regression equation

Independent variable	Regression coefficient (B)	Standardized coefficient	95% Confidence Interval regression coefficient Lower Bound	Upper Bound	p value
Intercept	30.121	-	11.197	49.045	0.003
Preop ODI	0.327	0.256	0.087	0.567	0.009
Preop SF36pcs	-0.581	-0.298	-.866	-0.295	0.000
Buck's repair	-11.872	-0.315	-17.727	-6.018	0.000
Multiple Opn	26.503	0.269	11.622	41.385	0.001
Professional	-6.792	-0.220	-10.960	-2.624	0.002
L3 pars defect	21.034	0.213	6.408	35.660	0.006

In this study, the regression coefficients between all the parameters confirmed the fundamental influence on the post operative outcome in lumbar spondylolysis. The close relationship between the outcome variable and the independent predictor variables was obvious with values of the regression coefficients in table 29.

The regression equation may be derived with the above coefficients. The negative values of preop SF 36, Buck's repair and professional means these variables are protective for the patient. If physical conditioning is good and the individual is professional who has a Buck's repair will have agood outcome i.e. post op ODI score.

c) *Significance testing*

One assumes that the regression equation explains a dynamic change process. Thus, to assess that it is a significant change i.e. unit changes in x to 'b' changes in y, it is important to test the null hypothesis. Significance of individual 'b' coefficients are assessed by '*t-test'*. We used two tailed *t-test* since our model constitutes a 'b' coefficient which is significantly higher or lower than zero. This means we have negative coefficients. The two tailed significance in the probability level is reported at $P<0.05$ (instead of $P< 0.1$ which is relevant for single tailed t-test).

Standard errors of estimate (SEE), confidence intervals and prediction intervals around the mean are also important in showing the prediction potential of the model. For large samples, SEE approximates the standard error of a predicted value or it Is the standard deviation of the residuals. In a good model, the mean of dependent variable will be greater than 1.96 times SEE. If the confidence interval of the regression coefficient includes 0, then there is no significant linear relationship between x and y. Thus, we are unable to reject the null hypothesis in that situation. In other words the variable x is independent of y. The confidence interval of y (dependent variable) is also called the standard error of mean prediction. The prediction interval of y is plus/minus the estimated value plus or minus 1.96 times (SEE + S^2_y) where S^2_y is the standard error of the mean prediction.

All the variables selected by the models has significant *t-test* values at each modeling sequence ($p<0.05$). This indicates that the independent variables which are selected by the regression model have significant effect on the post-operative ODI. The SEE and confidence interval does not include any 0 (zero) regression coefficient for each predictor observed suggesting to reject the null hypothesis. A lower confidence interval for each predictor variable also suggests that these independent variables when put in the regression equation will allow a significant change in the outcome of each patient (recorded as ODI).

d) *Multivariate analysis*

In stage one, the independent variable best correlated with the dependent is included in the equation. In the second stage, the remaining independent variable with the highest partial correlation with the dependent, controlling for the first independent, is entered. This process is repeated, at each stage partialling for previously-entered independents, until the addition of a remaining independent does not increase R squared by a significant amount.

The standard linear multiple regression model showed the best predictors for low disability on the ODI as pre operative ODI followed by others as observed (Table 25).

The standardized coefficients were quantified and the effect was compared for all predictor variables on the post-operative outcome (ODI) predictive equation: firstly, the preoperative ODI followed by the preoperative SF36pcs scores, Bucks direct repair , professionalism, multiple operations and L3 lumbar pars defect. The model has an adjusted R^2 of 0.809 with an SEE of 6.151. This means that these pre-operative variables explained 80.9% of the post-operative ODI scores (Table 28). The types of sports according to the predominant movement were taken into account in one of the regression models but no significant values were achieved (Appendix table 35a & b).

e) *Regression equation*
The multiple linear equation for predicting post operative ODI scores is:

Post operative ODI score = 30.121 + (0.327 x pre operative ODI score) + (-0.581 x preoperative SF36pcs score) + (-11.872 x Bucks repair) + (26.503 x Multiple operation) + (-6.792 x professional) + (21.034 x L3 pars defect).

Buck's repair, professional sports person, multiple operation and L3 pars defect are scored as 1 if the individual had any of these particular characteristics otherwise if none of these are positive then scored as 0.

Thus, for example having a professional with a pre-operative ODI score of 26 and pre operative SF36pcs score of 34 and having an Buck's repair (patient coded 8 in the surgical SPSS database) and a L4 lumbar level is predicted to have a post operative ODI score of

$Y_{(Buck's)}$ = 30.121 © + (0.327 x 26) + (-0.581 x 34) + (-11.872 x 1) + (26.503 x0) + (-6.792 x1) + (21.034x 0)

$Y_{(Buck's)}$ = 30.121 + 8.502 – 19.754 – 11.872 - 6.792

$Y_{(Buck's)}$ = 38.623 – 38.418
= 0.215

Thus, the post operative ODI score can be predicted in this individual as <1 when the individual has a Buck's repair. But if the same individual had any other surgery instead of Buck's repair of the defect then the equation would be:

$Y_{(Other)} = 30.121 + 8.502 – 19.754 – 6.792$

$Y_{(Other)} = 12.077$

This indicates an estimated prediction of the post-operative ODI of such a patient who had a Buck's direct repair of the pars defect at L4 lumbar level. This estimation takes into account the value of the age since 87% of the patients in this series were under the age of 25 years.

Although we thought age could be a predictor variable, it has been rejected by the regression modeling since there were only seven patients above the age of 25 years.

f) *Residuals*

Residuals are the difference between the observed values and those predicted by the regression equation. Outliers are data points which lie outside the general linear pattern of which the midline is the regression line. The removal of outliers from the data set under analysis can at times dramatically affect the performance of the regression model. The standardized residuals (the difference between the measured and the predicted post-operative ODI score) was very minor and does not affect the regression model and the prediction (Fig 29).

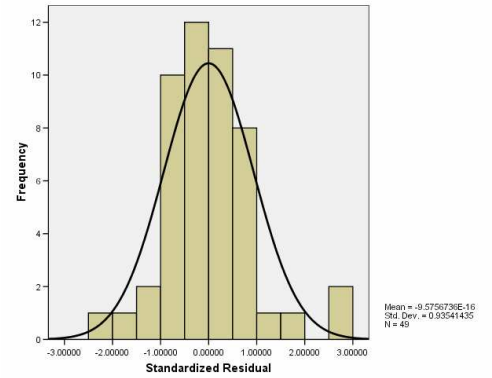


Fig 29: Histogram with normal curve showing standardized residuals for the variables put in the regression model

7.3 Combined Analysis of Study 1 & 2

Predicting Surgical Treatment For Lumbar Spondylolysis Using Receiver Operating Characteristic (ROC) Estimation

ROC was first developed in the 1950s as a by product of research into making sense of radio frequency signals contaminated by noise. It has become a remarkable tool for medical decision making and predicting the sensitivity and specificity of a diagnostic test or a scoring system (Metz, 1978). The basic principles on the receiver operating characteristic (ROC) has been already discussed in short in previous chapter for determining the responsiveness to change for the BPSQ scoring in predicting return to sport. In fact ROC has been also used in medical decision making for mass screening to show the discriminative ability of a test. This is made possible by the position of the full curve in a graph plotting the relation between the true positive rate (TPR) and the false positive rate (FPR) over a wide range of cut off points. The increase in the area under the ROC curve, or the shift of the curve upward and to the left in the diagram means that the test has better discriminative ability (Vinatier & Monnier, 1988; Akobeng, 2007; Kovacs, 2007; Mannion et al, 2006).

The current data was normally distributed. The ROC curve was constructed by using the outcome variable as the test variable and the state variable as surgery versus conservative management in the SPSS program. All the outcome variables were fed serially and each were tested for the area under the curve (AUC) estimation. Coordinates of the curves were observed for the values of specificity and sensitivity.

i) *Interpretation of the ROC*

At first we have to appreciate that the ROC curve has a large area under the curve. The AUC for pre treatment VAS score in this study of 55 surgical cases versus 123 non operated cases was 0.94 (CI: 0.904 – 0.974, $p<0.001$) [Fig 31, table 30a & b].

Fig 30: Graph showing the ROC for pre VAS scores in the combined Study 1 & 2

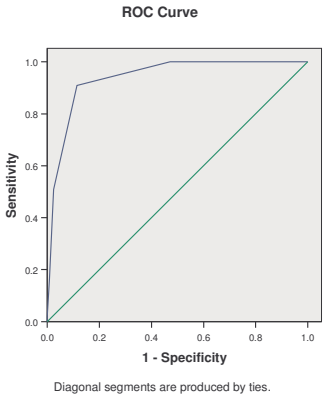


Table 30a: Showing the area under the curve

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.940	.017	.000	.905	.974

a Under the nonparametric assumption, b Null hypothesis: true area = 0.5

Table 30b: Showing the coordinates of the curve in Fig 30

Positive if Greater Than or Equal To(a)	Sensitivity	1 - Specificity
2.0000	1.000	1.000
3.5000	1.000	.919
4.5000	1.000	.472
5.5000	**.909**	**.114**
6.5000	.509	.024
7.5000	.164	.008
9.0000	.018	.000
11.0000	.000	.000

a The smallest cutoff value is the minimum observed test value minus 1, and the largest cutoff value is the maximum observed test value plus 1. All the other cutoff values are the averages of two consecutive ordered observed test values.

This is quite a significant area since no other outcome variables had any significant curve i.e. AUC for pre treatment ODI was 0.55 (p =0.294) and for pre treatment SF36pcs was 0.58 (p=0.07) [Fig31 & 32, tables 31 & 32]. This suggests that the pre treatment VAS scores are the best indicator of a patient requiring surgery over the period of 6-12 months.

Fig 31: Graph showing the ROC for pre ODI scores in the combined Study 1 & 2

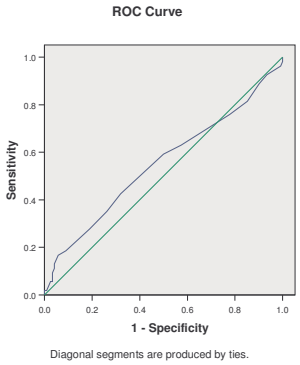


Table 31: Showing the area under the curve in Fig 31

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.550	.050	.294	.452	.647

a Under the nonparametric assumption
b Null hypothesis: true area = 0.5

Fig 32: Showing the ROC for SF36pcs scores in the combined study groups 1 & 2

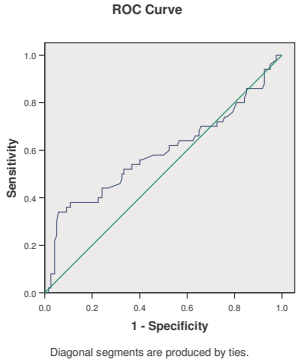


Table 32: Showing the area under the curve for Fig 32

Area	Std. Error(a)	Asymptotic Sig.(b)	Asymptotic 95% Confidence Interval	
			Lower Bound	Upper Bound
.588	.053	.070	.484	.693

a Under the nonparametric assumption
b Null hypothesis: true area = 0.5

In this study, higher score on the pre treatment VAS score equates the patient being more at risk of having surgery following low back pain due to lumbar spondylolysis. We wish to split our patients into two groups: One group at risk of having surgery and the other not at risk of undergoing surgery.

The pre treatment VAS score was rejected by the model summary in regression analysis since only surgical group was taken into account for the regression modelling. This can be explained by the fact that post treatment ODI was taken as the dependent variable in the surgical group which included pain status as well as disability; therefore VAS was excluded as a predictor variable. Although combining the two groups and comparing them for difference in outcome is not appropriate because the groups are mutually exclusive. One group has had conservative treatment and many improved and the other group who had conservative treatment and had failed and instead had operation. It is important to do some assumptions for knowing the difference between the two groups. The first assumption is that both groups were presented at the same point in time. Both groups had equal variances with relative matching in age, sex and sporting abilities. One group is suggested to have conservative treatment and the other is suggested an operative treatment. Now the predictor variables are taken into effect and a ROC was evaluated for each of them taking the two similar groups.
For this combined group the **null hypothesis C_2**: There is no predictive factor which can determine the outcome following surgical repair of a symptomatic pars defect or spondylolysis or in statistical parlance the area under the ROC curve for the outcome variable is less than 0.5.

To interpret and the ROC of the outcome variables we followed few steps as follows: The question is at what values on our scoring system do we set the cut-off limit whereby those patients at this cut-off score or above are classified as at risk, and those below the cut-off value are not at risk.

The cut-off value is a balancing act. If we set the value too high then our:

Specificity will be *high* which is the same as suggesting that our *1-specificity* will be *low,* i.e. test will not get many false positive results. This would mean that we are not eligible

to classify someone at risk who really is not at risk, but our *sensitivity* will be *low* i.e. many people who are at risk will not be identified as their scores fall below the cut-off value.

As we lower the cut-off value our *sensitivity* will *increase* but unfortunately our *specificity* will *fall* i.e. our *1-specificity* will be *high* which means that we will get more false positives. Thus, we will be left with classifying people at risk who are really not at risk.

So where is the best place to have this cut-off value?

ROC plots the *sensitivity* of the test (ie the proportion of true positives correctly identified) against the *1-specificity* of the test (ie the proportion of false positives identified) for all possible cut-off values.

Which coordinates we use from the ROC curve to decide our cut-off value is a matter of judgment affected by factors such as how important sensitivity (and specificity) is. In this cohort of patients, the scoring should be sensitive enough to estimate the need for surgery. Since VAS scoring is a subjective variable, the specificity is not of much consequence. The area under the curve is > 0.5 i.e. it is 0.94 ($p<0.001$). Therefore, the null hypothesis is rejected.

From a purely mathematical point of view the best cut-off value to use is the points on the curve that are closest to the top left hand corner of the square as this top left hand corner represents the best possible situation 100% sensitivity and 100% specificity (ie 0% 1-specificity) (Fig 30). The coordinates 0.909 as sensitivity and 0.114 as 1-specificity were chosen which gives us from the coordinates of the curve table a cut-off value of 5.5 (sited bold in table 30b). Thus, we would use scores of pre operative VAS as greater or equal to 5.5 to classify patients at risk of having surgery. As our scoring system only has integer values from 1 to 10 this effectively states scores of 6 or above are at risk.

ii) *Summary*

ROC estimated the AUC of 0.94 ($p <0.001$) for the pre treatment VAS score which indicates that the most significant predictor of a patient with lumbar spondylolysis to undergo surgery.

CHAPTER 8

Discussion

8.1 Study 1

8.2 Study 2

8 DISCUSSION

8.1 Study 1

The aim of treatment in symptomatic lumbar pars lesion is to reduce the low back pain and also prevent any recurrence of pain. It is not quite clear whether the diagnosis when made prior to the development of overt fracture increases the chances of healing of the lesion, thus rendering the patient asymptomatic. It is generally assumed that a stress reaction, a micro-fracture and an overt fracture may be the consecutive stages in the evolution of spondylolysis (Blanda et al 1993; Congeni et al 1997; Itoh et al 1996). It is also assumed that early diagnosis and treatment may induce healing of such lesions. Researchers have reported that following non-operative treatment of those athletes with symptoms greater than six months, 80% were classified as chronic fractures on CT scan (Congeni et al 1997). He also suggested that athletes with shorter duration of symptoms had chronic as well as acute and incomplete fractures.

8.1.1 *Age & gender*

Most patients were males in this study who were below the age of 20 years (30%). This suggests that there is a significant association with the diagnosis of lumbar pars defect or active spondylolysis. The M:F ratio is approximately 3:2 in the whole cohort. The high proportion of males with active spondylolysis is similar to that found in previous studies and it would appear that males are more susceptible to developing pars stress fracture than females (Congeni & Swanson, 2004, Beutler et al 2003). The high proportion of active spondylolysis in adolescent males is probably multifactorial. It has been suggested that during adolescent period lumbar spine has a reduced bone mineral density (BMD) in the lumbar spine as compared to adulthood (Zanchetta et al 1995). This difference was most prominent in cortical bone, the main component of the pars interarticularis, and the pars would appear to be particularly at risk of mechanical stress throughout puberty. The male adolescent spine may be more vulnerable on account of having a generally lower BMD when compared to female counterpart (Zanchetta et al 1995). The male spine is not as flexible as female spine and the increased rigidity may adversely effect the distribution of torsional loads throughout the spinal column (Kondratek et al, 2005). This factor may contribute to an increase in stress at the pars and eventual fatigue failure.

The higher incidence of males may also be due to the involvement of sporting activities in male members of the society. In this study, there was significant difference in their age between the sporting and non-sporting group i.e. mean 20.7years vs 25.4years, ($p<0.001$). High velocity torsional loading sports may have influence in the adolescent male members to develop pars defect earlier than the general population.

8.1.2 *Imaging (SPECT vs MRI)*

Bone scintigraphy is of little value for primary diagnosis, it helps to distinguish between those patients with established non-union of the defect, and those in whom healing is still progressing. Although we didn't record the SPECT ratios, we recorded the intensity of uptake on the imaging. In our series, 74/87 (85%) patients had positive uptake (mild to moderate intensity). These patients presented early i.e. within six months of onset of low back pain. Of these, 28 (38%) were unilateral and 46 (62%) were bilateral spondylolysis. 35 patients had confirmation of pars defect without sclerosis on CT scan. We had 12 patients between the ages of 8 & 14 years who returned to active sports following conservative treatment. The alleviation of symptoms in the current study cohort of patients who had SPECT imaging as a part of their routine investigation confirmed the assumption of other authors that early active pars lesion has potential to heal and the patient could be asymptomatic enough to return their previous level of sporting activity.

In our institute, there was a trend in early part of the millennium of combining SPECT imaging with CT scan to improve early diagnosis (Gregory et al 2004). It was quite logical since SPECT provides information about the metabolic activity of the bone in response to repeated stress and CT scan provided morphological evidence of the state of the pars. Combining both the imaging modalities, Gregory et al had identified the complete lesions with chronic appearances of smooth sclerotic margins which may not heal (Gregory et al 2004). These lesions could be detected by MRI scans.

With the advent of MRI scan as a tool for early diagnosis, the cost effectiveness of combination of SPECT and CT scan was questionable for diagnosis and follow-up of patients with pars defect. Thus, the SPECT imaging was discontinued for diagnosis of spondylolysis in acute low back pain. MRI scan was used instead as primary mode of imaging for symptomatic low back pain.

As the stress injury progresses, thinning, fragmentation or irregularity of the pars are visible on MRI. When this stage is reached, probably the fibrous healing takes place instead of osseous healing. This doesn't prevent successful short term clinical results following conservative treatment. A re-MRI scan following treatment will be ideal for detecting morphological evidence of healing of the pars defect but this is not possible due to many factors. In our series, of the 46 who had positive lesion on MRI scans 13/46 (35.3%) were in grade 1 and the rest were in higher grades. All the sporting individuals in the grade 1 group had improved symptoms and had returned back to sporting activity. This may be due to the early stage of the disease characterized by edema and stress reaction. This group of patients was young and was involved in high level of sporting activity. Most of them were professionals or semi professionals. Therefore, early thin slice MRI scanning in young athletes or sporting individuals who present acutely with LBP of few days onset is recommended to determine the stage of the disease. It certainly influences resumption of early physical activity if the regime of physical rehabilitation protocol is followed.

8.1.3 *Bracing vs Non bracing*

Earlier studies have documented the evidence of anti-lordotic bracing improves the outcome in these young patients. Wiltse had used brace or corsets in his patients with success. One patient healed even without a brace who continued gymnastics (Wiltse et al 1975). Another early report in the literature suggested six months of bracing followed by 6 months of weaning with an additional physiotherapy. This resulted in 67% successful outcome (Turner et al 1971). Steiner & Micheli treated their patients with a modified Boston brace worn for 23 hours a day for six months followed by a weaning period of six months. Sporting activities were allowed in the brace. They reported 78% excellent or good results in their group of 67 patients with symptomatic grade 1 spondylolisthesis. d'Hemecourt et al (2002) addressed the return to sport after diagnosis of spondylolysis in 73 patients who were treated conservatively. All were treated with Boston brace for 23 hours a day in addition to physical therapy. The sporting individuals who were pain free after 4 to 6 weeks after commencement of bracing were allowed to participate in sport in the brace provided they avoided lumbar hyper extension. They had an 80% success rate with most male athletes returning to sports.

High risk sports were five times more likely to have an unfavourable outcome than low risk sports (Odds Ratio -5, 95%CI= 2.4-7.5, p=0.003). Blanda et al reported a specific protocol of restricted activity, bracing and physical therapy in 82 patients (66 Males:16 Females). 85% had L5 lumbar pars defect followed by 15% in L4 lumbar level. 37 had unilateral and 25 had unilateral pars defect. They had successful outcome in 90% patients who returned to active level of sports (Blanda et al 1993). Iwamoto et al also treated their patient cohort with activity restriction and bracing for a mean period of 5.4 months (range 1.0-11.5months) and had successful outcome in 87.5% patients returning to their original sporting activities despite non bony union (Iwamoto et al 2004). In our series, the mean length of treatment and return to sports was 5.8 months (range 3-12 months). Our management algorithm is standardized for the patients treated conservatively (Fig 15). In our series males did better than female gender in returning to sports (90% vs 77%).

Biomechanical studies questions the role of lumbar immobilization in low back pain due to pars lesion. None of the orthosis whether rigid or soft had any stabilizing effect on intervertebral motion (Axelsson et al 1992). All the studies on lumbosacral bracing were reviewed and the conclusion drawn from these biomechanical literatures is that lumbosacral bracing may be able to restrict the gross body motion, but it has no real effect on restriction of intervertebral mobility (Calmels et al 1996).

In our series of patients bracing was done only if there is persistence of pain after a period of rest i.e. 4-6 weeks. One may require anti-lordotic bracing for 6-12 weeks to be considered in the treatment regime. In this series very few patients (less than 10% required anti lordotic bracing. Compliance of bracing in young sporting individuals was the main issue in this small group of patients who had persistent pain after 6 weeks. Some patient had extra 3-4 weeks of rest without any brace. It is a matter of debate and beyond the scope the present study to compare the effectiveness of brace and effectiveness of extra weeks of rest. Our observation is in favour of no brace since biomechanically it does not control the movement at the pars defect. But it does restrict the highly active sporting individuals to continue their activity which may have a beneficial role providing rest.

8.1.4 *Physical Therapy & Rehabilitation*

Dynamic spinal stabilization and sports specific training are recommended for athletes' rehabilitation. A strong emphasis has been laid on core stabilization involving training and strengthening of specific abdominal and lumbar musculature (O'Sullivan et al 1997; Richardson et al 1999).

The importance of the lumbar multifidus (LM) muscle in the dynamic stabilization and segmental control of spine has been acknowledged (Goel et al 1993; Panjabi et al 1989). It has been suggested that specific submaximal training of these "stability" muscles of the lumbar spine and the integration of the training into functional tasks decrease both pain and functional disability in those suffering from mechanical low back pain (Richardson et al 1999). The rehabilitation of an athlete with symptomatic pars injury involves several stages progressing from resting phase to active phases that emphasize conditioning, neuromuscular control, strength and normalization of mechanics of lumbar spine (Herring et al 1998).

In this series the specific training and dynamic stabilization of the LM muscle probably provides a pain free lower back in majority of young athletes after a generous period of rest. Pain from the pars lesion can lead to loss of neuromuscular control of LM muscle and there may be atrophy in chronic cases. It has been observed that most patients presenting within 3 months of the onset of back pain had significant relief from rest. This muscle is like the vastus medialis muscle in the knee which looses its function due to an injury to the knee. Rehabilitation of this muscle improves the endurance and function of the knee. Similarly, knowledge from the physical rehabilitation programme where core training is directed towards the LM muscle and Transverse abdominis muscle and results obtained in the recovery phase in this series of patients, it is recommended to follow a strict trunk stabilization protocol.

8.1.5 *Individual sports*

Managing individuals involved in specific sporting activities which involve the stress on the lumbar pars due to the hyperextension and rotation of the lumbar spine is a challenge.

The high incidence of this lesion may also be due to an increased exposure to a structured regime of sports activities. School and club sports involve weekly training sessions and weekend competitions. The increase in training load may be an important risk factor in the development of spondylolysis. The torsion of trunk in trunk twisting sports may have significance in the development of lesion in certain sports e.g. cricket.

Each sport has been classified into a specific group according to the predominant bodily movement involved in the respective sport. The four groups indicating the basic movements are i.e. *throwing, trunk twisting, lifting and kicking*. Since many of the major sports involve combination of the movements, it has been assumed that other movements will confound the issue. Therefore, to identify the sporting type according to the bodily motion can guide us to the effect of the sports on the lumbar spine esp. the pars interarticularis [Table 10]. This helps us to identify the side of the lesion in unilateral cases due to the preponderance of hand dominance e.g. cricket. But it is difficult to explain bilateral lesions in other sports e.g. football or gymnastics, where hand or foot predominance does not guide us to any form of rehabilitation or training of the individual in the specific sports.

Most of the sports are included in the *trunk twisting* sports e.g. tennis, cricket, swimming and gymnastics etc. although there are simultaneous movement of the appendicular skeleton. From our database we believe that *trunk twisting* sports results in more pars lesion then any other movements.

i) *Cricket*

This sport is very popular in UK which has mainly three activities: bowling, batting and fielding. Bowling requires *throwing and trunk twisting* movements i.e. propelling the ball from a hand held above the head with the elbow maintained nearly straight.
Batting involves swinging action of the shoulder and variable amount of trunk twisting on both sides to hit the ball with a bat. Fielding involves throwing the ball or stopping the ball. Cricketers generally use the dominant hand for each activity in the field.

Most stress in the lumbar pars occurs in the fast bowlers. Our analysis suggest that right handed bowlers may have increased stress in the left lumbar pars region and left sided bowlers may have increased right lumbar pars region. But the stresses in the lumbar pars region also depends on the type of bowling action as described by Elliot et al. i.e side-on, front-on or mixed action (Elliott et al 2000). Mixed action is probably a predisposing factor in the development of pars defect (Foster et al 1989; Hardcastle et al 1992; Ranawat et al 2003). Our series of 21/22 bowlers had successful outcome following change in their bowling style after a successful rehabilitation phase.

It has been observed that certain morphological configuration of the inter facet region, enhanced moment created during the spinal torsional motions may increase the risk of spondylolysis. The transverse orientation of the pars fractures may indicate a moment applied contra-laterally (Masharawi et al 2007). This view is supported by the fact that right hand cricket bowlers have left sided pars lesion. Does this observation help us to prevent the occurrence of pars injuries in young adults who may be predisposed to the condition due to the orientation of the facet joints?

Cricket bowlers who are training to be professional cricketers from an early age may need to alter their bowling action if they develop low back pain. The England and Wales cricket Board have introduced directives for fast bowlers to prevent these lumbar stress injuries. They limit the number of overs bowled by 13-19 years old per spell and per match according the age (E&WCB 2000).

ii) *Soccer*

Involvement of pars injuries in soccer was reported previously (Debnath et al 2003). Subsequent studies on soccer players at our institute revealed a number of facts (Gregory et al 2004; Debnath et al 2007). Soccer involves kicking a ball with either foot but the players who are right dominant may use the right foot more than the left. It also involves variable amount of *trunk twisting* since the kicking with either foot involves a swinging motion through the hips and the force of the kick is generated by a firm stance on one leg and twisting motion of the lumbar spine. In this series, it is observed that the pars lesion was symmetrical i.e. left vs right (12:10).

Gregory et al (2004) speculated that foot dominance of soccer players have little role to play in producing the spondylolysis in a similar way as seen in the cricket bowlers. This may be due to the reason that the cricket bowlers exclusively use one arm throughout their life and similar motion of the lumbar spine at each delivery results in a regular pattern of stress at the pars interarticularis (Elliott et al 2000). The soccer players' tendency is to kick the ball using either foot with a variety of movements of the lumbar spine resulting in stress at the pars interarticularis dissimilar to the cricketers.

iii) *Gymnastics*

Many gymnasts become symptomatic early in the childhood and find it is extremely difficult to pursue their career as gymnasts due the low back pain during their regular training activities. Management strategies in gymnasts were followed with considerable success in many studies (Ciullo et al 1985; Jackson et al 1976; Dixon et al 1993). Incorporating the concepts of dynamic lumbar stabilization and sport specific training into their rehabilitation programs would certainly improve the chances of alleviating their symptoms and return to their sporting activities (Standaert et al 2002).

Our series of gymnast had difficulty retraining within the given time frame. Some of them returned with back pain after a period of pain free active level of gymnastics for second time. These patients are difficult to treat conservatively. One may apply our algorithm and offer them surgical repair if the spondylolysis is confirmed to be the pain source. This has given good pain relief as well active participation even at national level of competition.

8.1.6 *Laterality of pars lesion*

In the unilateral group 77% had complete relief of symptoms by a mean time of 4.2 months. In the bilateral group 79% had pain relief at a mean time of 6.5 months. This may be due to the fact that the unilateral lesions are destined to heal earlier than the bilateral lesion. This may be multi-factorial. The diagnosis of unilateral pars lesion has been difficult in earlier days. The prevalence has increased due to the advanced imaging modalities. The patients may be presenting early and are critically evaluated for the specific diagnosis.

One sided lesion may be a stress reaction in many cases which when rested results in healing of the stress reaction. Sometimes there may be incomplete defect or fractures which again need a specific period of rest for its potential healing. Some of these lesions were associated with spina bifida. If some one with spina bifida has a unilateral complete lesion then in all probabilities there is high risk of non-union. Clinical relief from symptoms may not suggest a bony union in many cases. It may be in all probabilities a fibrous union leading to the stability of the unilateral lesion. Younger age groups have more chances of healing and from our series it has been observed that the younger the patient with unilateral lesion, return to sporting activity is quicker. In the unilateral group 90% returned to sports whereas only 80% returned to active sports in bilateral group. Therefore, it is recommended that the patients with bilateral lesions should be treated for a longer period and rehabilitation is carried out following strict physical therapist's guideline.

8.1.7 *Lumbar level*

In our series, most patients with L4 pars lesion 11/14 (78%) did much better much earlier than the patients with L5 pars lesions. 60% lesions were in the L5 level followed by L4 (11.3%). Most bilateral lesions were at L5 level (81%). More female patients had L5 lumbar level affected. This may bed due to the increased lumbar lordosis in women. This finding is in concordant with Sonne-Holm et al (2007) who found highly significant correlation. Therefore, woman may be high risk in developing spondylolysis at L5 level. In our series, healing of L4 lesions was better than L5 lesions. This suggests the different pathogenesis in the evolution of the lesion at these two levels.

8.1.8 *Return to sports*

It has been observed that osseous healing does not occur in many patients but they return to active sports (Sys et al 2001). Osseous healing was noted more frequently in lesions that were diagnosed one month or less after the first appearance of symptoms. Sys et al couldn't confirm this direct relationship in their study of 34 elite athletes with symptomatic spondylolysis. Many studies have suggested the occurrence of fibrous healing with good outcome in young sporting individuals (Letts et al 196; Debnath et al 2007; Ciullo et al 1985).

Once chronic spondylolysis is noted, sports can be resumed, but repetitive activities with high demands in the lumbar spine should be avoided (Creillard et al 1995). The challenge of management of active young athletes lies in the identification of those patients who go on to progressive spondylolisthesis and controlling the pain in all patients who are symptomatic (Creillard et al 1995). Long term study on natural history suggests that bilateral pars defect will develop symptomatic progression in only a small percentage of subjects (Beutler et al 2003). Therefore, one should advise for continuing the activities once the acute pain subsides.

It has been reported that the union of the defects were higher at L4 as compared to L5 (Fuji et al 2004). This may be due to the fact that load on the facet joints were significantly higher at L5/S1 as compared to L4/5 facets under axial compression (Shirazi et al 1996). The successful return to their respective sporting activity in 85% of young athletes in this study suggest that if a strict guideline of dynamic spinal stabilization is followed directed at the specific technique of movements of the predominant body movement i.e. trunk twisting activities at the recovery stage of the rehabilitation phase for each individual, most pars lesion may be treated conservatively.

The patients who tend to have longer onset of symptoms i.e. more than six months of low back pain, and who are non professionals with less motivation may be ones who cannot return to their previous activity level.

8.1.9 *Summary*

If the young sporting individual reports within the six months of onset of symptoms and the sporting activity worsen the symptoms of low back pain, one must suspect pars lesion. This needs to be followed up with plain radiography and MRI scanning. SPECT imaging has a role in determining the stage of the pars lesion but cost implications of multiple imaging studies does preclude its use in favour of MRI scans. The MRI scans should be graded and a treatment protocol of rest for 4-6 weeks followed by the functional restorative program is instituted. CT scans should be performed if there is no change in the symptoms after the period of rest.

Patients with unilateral pars lesions have a better outcome than bilateral pars lesions. Patients with bilateral pars lesions may require more time in the treatment phase for a good functional outcome. Male member of the sporting population have better outcome than female members, probably due to increased motivation and physical conditioning. Bracing is not required in most patients if the pain subsides on restriction of activity. Full functional recovery to previous level of activity is possible with the help of dynamic spinal stabilization exercises and physical therapy. This process can be quite laborious for the physical therapist. Patient compliance is a must for progressing to the return to play stage when fully functional pain free range of motion in the lumbar spine is mandatory to function at the previous level of activity. Individual sporting techniques should be considered for alteration to improve the biomechanics of the lumbar spine without compromising the performance. The individuals involved in trunk twisting sports should be evaluated carefully for the muscle imbalance in the lumbar spine which should be addressed by the physical therapist.

8 DISCUSSION

8.2 STUDY 2

The treatment of spondylolysis depends upon the severity of the symptoms and the sporting activity of the patient (Blanda et al 1993). Surgical intervention is reserved for patients who do not respond to conservative measures. (Standaert et al 2000). Several surgical techniques have been described to stabilise a spondylolytic defect in the lumbar spine (Buck et al 1970 & 1979; Morscher et al 1984; Scott 1987; Nicol & Scott 1986; Johnson et al 1992; Kakiuchi et al 1997; Songer et al 1998; Tokuhashi et al 1996; Salib et al 1993; Ivanic et al 2003 Debnath et al 2003; Nozawa et al 2003; Roca et al 2005; Gillet et al 1999; Hardcastle et al 1993; Hefti et al 1997; Debusscher et al 2007; Ulibarri et al 2006; Chung et al 2007 and Ogawa et al 2007). The goal of the pars defect reconstruction is to obtain the consolidation of the isthmus, to restore the anatomy and the stability of the spine, and to preserve the mobility of the stage concerned.

It has been already written in the first half of this study that most patients get better with conservative treatment without evidence of healing of the spondylolysis. Thus, we are looking at a very small number who present as acute or chronic back pain preventing them from continuing the sporting activity. The natural history of bilateral spondylolysis follows a clinical course similar to general population. But the indication of surgery is only speculation based on facts generated by different published articles and experience of the surgeons treating these small groups of patients.

8.2.1 *Age*

There is a great divide in the literature regarding the age at which the direct repair is indicated. Approximately 50% cases with spondylolysis are associated with low back pain in the young athletic population (Micheli & Wood, 1995). In contrast, the low back pain is associated with only 5% of the patients who are older than 25 years.
All patients who did well in our series were mostly below the age of 25 years. This may be due to a selection bias for performing Buck's repair in this demanding group of active sporting individuals.

We included age as one of the predictor variable in the linear regression model by making it ordinal variable (making five groups). Although age at surgery showed a low co-linearity ($\rho = 0.32$, $p<0.05$) it was not significant enough to be included in the regression model. The stepwise regression excluded age as one of the predicting factors for a successful outcome.

This result may be due to the fact that we have most patients in that age group below 25 years and have little to predict from above the age of 25 years. It was observed in the paired sample tests for the three patients entered in the test in the age group above 30 years that suggested a high mean post operative ODI score. None of the outcome measures had any significant difference between the pre and post-operative state. Although our regression modeling does not allow the age group as one of the predictors of good outcome we remain biased on the fact that most patients who had significant difference between the pre and post-operative scores were below the age of 30 years. Thus, we suggest that direct repair is allowed definitely in the age group below 25 years with a sporting background and to make a decision in the age group above 25 years especially above 30 years, one may not be able to predict the outcome for direct repair in this group due to the involvement of disc as a concomitant source of pain or may be also due to facet joint arthropathy.

In the younger age group if the unstable segment is stabilized with a screw fixation as doing a fracture fixation, there is immediate relief from pain. Once the pain is reduced, the physical functioning could gradually improve over a period of 12 weeks. This was evident in most of the patients who underwent a rehabilitation program following the surgery. Gradually they could return to active sports to their previous level especially if the patient's age was below 20 years.

Dai et al (2001) included 46 patients with 98 pars defect repair between ages of 15 & 56 years with a mean age of 38.2 years. Interestingly they had fused the facet joint in 26 patients who showed disc degeneration on MRI scan. They reported 93.4% of excellent or good results and 95.9% of bony healing without internal fixation which are comparable to those achieved with internal fixation reported in the literature.

There is no mention of the age of the patients who required facet fusion i.e. had degenerate disc. These results are controversial in the face of spondylotic changes in the spine at that age group.

Many authors have suggested direct repair for symptomatic patients under the age of 25–35 years (Bradford et al 1985, Johnson et al 1992). Roca et al (2005) prospectively analyzed 19 consecutive cases of spondylolysis repair using a new hook screw and reported 12/13 patients below 20 years had 92% union of the defect while 6 patients above the age of 20 years had non-union. Although there was non-union 4/6 had excellent clinical outcome. If we compare our study with their group of patients we could comment on clinical grounds since we don't have any post-operative follow-up CT scans to see if there was bony healing present in our series. There were at least two non-unions in our group. They required subsequent fusion. But certainly below the age of 20 years most patients had an asymptomatic course of life and returned to previous level of activity. Some may have fibrous healing of the defect. Kakiuchi et al (1997) reported 5/16 patients who had direct repair with their method of repair (variable angle pedicle screw, rod and laminar hook). All the patients were above the age of 40 years and in fact one patient was 60 years of age. All these patients had varying grades of degenerate disc disease confirmed by MRI scan. 13 patients had remained free of symptoms following the repair and returned to previous activity level. This report contradicts the views of the previous authors as well the findings in our series. Since our study population was specifically based on younger people, we cannot comment on people older than 35 years of age.

Debusscher & Troussel (2007) performed direct repair of the isthmus with a new kind of pedicle screw hook system in 23 patients whose mean age was 34 years (range16-52years). They reported 87% good outcome (100 % radiological union) in patients below 30 years of age against the 73% good outcome (82% radiological union) in patients above 30 years of age. All patients below 30 years had no degenerate disc disease. They went on to suggest that direct repair can be carried out on patients with moderate degenerative disk disease. If we analyze the paper further we observe that the patients were in labour class working people. All patients with fair results showed MRI signal modification before surgery.

None of these patients were from the sporting population and thus the demands of movement of their lumbar spine were questionable.

8.2.2 *Gender*

The ratio of male to female in this surgical group was 2.4:1. There was no difference between the two genders in the outcome scores except for pre and post operative ODI. This may be due to physical differences between the two genders. The disability is perceived more by women than men with the same level of pars defect. Some of these women were not in the highly professional group as the men were and may be lacking the motivation required to return to the previous sporting activity. Some of them were active tennis player or gymnast in contrast to being a footballer or cricket fast bowler. The physical and mental component of SF36 scores was similar in both genders. And when put in the stepwise linear regression it was excluded from the model suggesting that there is little difference in outcome between the genders.

8.2.3 *Sporting versus Non sporting*

A direct relationship has been observed between the symptomatic pars defect and strenuous, intense sports activities between the ages of 5 and 15 years. (Mazel C 1991) The association of movement related low back pain in lumbar spondylolysis prevents the athletes to perform at a maximum level.

Observation from this study suggests that most sports persons who are involved either professionally or semi-professionally reported early with lower back pain. The mean age (28 years) is higher for the non sporting group although one could criticize that there were only three patients from the non sporting population in this surgical cohort. The intensity of low back pain was also moderate to severe in all the patients who had surgery. The mean preoperative VAS grading was severe (>6).

If we take two studies done in the recent times which included ODI scores as one of the outcome measures, we could make some inferences regarding the pain and disability status of these patients. In Debusscher' s series of 23 patients (mean age of 34 years) who were from the general population, the mean preoperative and post-operative ODI scores recorded were 72.5 (percentage of disability >60%) and 15.9 respectively.

In contrast, in our first reported series of 22 sporting individuals the mean preoperative and post-operative ODI score of 39.5 and 10.7 respectively, was recorded (Debnath et al 2003). Observation from the current study on 52 sporting individuals (which include the previous 22) with a pars defect repair, the mean preoperative and post-operative ODI are 37.5 and 9.2 respectively. If we consider our non operative group where we have 98 sporting individuals versus 24 patients who were from the general population, we observe that the pre treatment ODI was significantly higher in the later group (34 vs 41) .

Thus, comparing the two different series of patients it is observed that there is a significant difference in the status of pain and disability according to the population characteristics. A lower ODI score between 30 & 40 may be quite disabling for the sporting population than a score of 50-70 in the general population. The perception of disability or functional limitation is individual based. On an average if someone has a higher ODI and a higher change of score may show a significantly high success. But if someone has a lower ODI score in the range of 20-30, then any change in the score may be perceived as success since the disability was low to start with.

8.2.4 *Type of Sports*

Sports are part of the socio-cultural fabric of all countries. Five major sport profiles are recognized as having international appeal i.e. soccer, cricket, tennis, martial arts and field hockey. Our surgical patient cohort had football, cricket, gymnastics, swimming, tennis, hockey and martial arts and all of these have the common denominator of predominant body movement i.e. *trunk twisting*. The classification of the individual sports was based on (in our previous chapter) the predominant movement occurring in the trunk and other joints during the sporting activity. This was necessary to understand the relevance of *trunk twisting* (which is required in most sports) towards developing a stress fracture in the pars interarticularis. But it didn't have any effect on the final outcome. The regression model disallowed the bodily movements and had produced no significance. Logic would suggest that *trunk twisting* will have no effect on the final outcome since it has no variation in certain sports. Unless there is ground reaction force acting in conjunction with *trunk twisting* the forces dissipating through the pars may not be sufficient to to produce the lesion.

But the true effect on the outcome may be evaluated if we know the pattern of *trunk twisting* e.g. fast bowling in cricket. Some preliminary studies of 3-D lower trunk motion analysis in cricket fast bowlers suggested that the motion of the lower trunk, especially side flexion, during front foot contact in addition to variables known to be related to lower back injuries (e.g. shoulder counter rotation) should be examined for a comprehensive guide to the actions that cause such injuries (Ranson et al 2008). These preliminary studies puts my theory of necessary ground reaction force which is generated at the time of contact during the bowling action in cricket may have increased loading of the pars leading its failure. In this series most patients were footballers (22) followed by cricketers (8) and others which included gymnasts, swimmers, athletics and tennis. It is well established fact that gymnasts have a high incidence of pars injuries. Gymnasts also use surfaces to land thus producing ground reaction force acting through their spine which plays a major role in the evolution of their pars lesion. But why would swimmers get pars lesion? Their lumbar spine has a regular pattern of twisting motion which is rhythmic and associated simultaneously with a kicking action of the lower limbs against the resistance to the water. This may produce enough force to produce the lesion. Therefore, stabilizing the dissociated segment i.e. the pars with internal fixation would provide immediate stability and improve the function of the lumbar muscles when trained.

8.2.5 *Professional versus non professional*

At this modern day and age, any sporting event has tremendous financial returns to the sporting individuals who are good at their respective sport. Therefore, the sporting people are trained in particular sports from a very young age. In young children or adolescents who are involved in school or junior club sports and suffer from such lumbar pars stress injuries, significant disruption to school and club may result in significant worries for the peers. This also has worried parents who are concerned of the child's future (Abernethy et al 2003). Currently, it has been observed that more and more parents are aware that the direct repair of the symptomatic pars defect gives a good outcome in young individuals in the short term and they could possibly return to their previous active level of sports.

It is appreciated from the study that professionalism factor plays an important role for lumbar pars defect surgery. Successful outcome i.e. return to sports in 94% patients in the early cohort of athletes who were rated to be professional or semi-professional footballers or cricketers [Debnath et al, 2003].It is beyond the scope of this study to analyse the financial implications in professional sportsman who have lumbar spine stress injuries, but we have included this predictor variable to evaluate the outcome of surgery in professional and non professional sporting individuals.

43 individuals in the study group were professional or semi-professional sportsperson. The regression model selected this predictor variable for a significant successful outcome. The mathematical number derived for the slope is negative which mean that this number is subtracted from the total ODI to predict the outcome (i.e. a lower ODI if professional). Thus, in reality professional sporting individuals have more chance of having a successful outcome than a non-professional individual. This mathematical result does signify that professionalism is a major factor which influences the individual to choose surgical repair instead of waiting and loosing valuable time and finances. One can appreciate the increased motivation for doing well and perform better in the sports to earn their livelihood. The other factor that may be relevant is the physical conditioning of highly active sports persons. Their conditioning is probably set at a much higher level than the less active sporting individuals of their age.

In the young professional sporting individuals the story of money plays a big role in decision making when such problems of low back pain arise. These young people as well as the sponsoring organizations loose substantial amounts of money if one has a physical disability or pain occurring due to the stress incurred by the respective sport on the lumbar spine. Gabbett et al (2001) studied the severity and cost of injuries in 72 amateur rugby league players with a mean age of 28 years. Injuries were classified according the number of games missed in the season. Major injuries related missing of more than five games. A proportion of injuries sustained in this sample resulted in a loss of training, playing and employment or study time and all had significant direct and indirect economic costs. Therefore, economic issues should be taken into account when dealing with highly active professional young ones who would do well with surgical repair early in the course of the treatment.

8.2.6 *Imaging*

MRI as a primary diagnostic tool allows one to make a decision for proceeding to surgery based on the clinical knowledge of symptoms. It is difficult to signify the role of identifying complete healing of the stress fracture by a follow-up MRI or CT scan unless the patient is symptomatic. Plain radiographs were sufficient to indicate the signs of union in the defect. In this series, there were no signs of spondylolisthesis or loosening of the screws, nor were there any broken screws.

One can only presume that healing has taken place but only a CT scan at final follow-up could determine the nature of the healing i.e. fibrous or osseous. Fuji et al (2004) suggested that the stage of the defect was the most predominant predictor of successful union but whether successful union has any implications on the outcome is a matter of speculation. In this series, it was not justified for further radiological exposure of the surgical patients who returned to active sports without recurrence symptoms. Finally, imaging modalities i.e. MRI or CT scans cannot be a predictor variable of a successful outcome following Buck's repair. This is due to the fact that the variable is a binary one (presence or absence of defect) and one has to make objective measurements e.g. the fracture gap in millimeters or the inclination of the defect in degrees, for making it a nominal or categorical variable to be put in the linear regression model. Thus, imaging modalities were excluded by the regression model.

8.2.7 *Unilateral versus bilateral*

The unilateral lumbar spondylolysis as an entity does exist and the healing potential is significantly higher than bilateral pars defects in their terminal stage (Debnath et al 2007). Unilateral spondylolysis predisposes the contralateral side to stress fracture, especially in athletes actively engaged in sporting activities involving torsion of the trunk (Sairyo et al 2005). In a biomechanical study of finite element models on lumbar motion segment it was estimated that the lumbar spine with a unilateral pars defect was able to maintain spinal stability as the intact lumbar spine, but the contralateral pars experienced greater stress (Wang JP et al 2006).

Surgical treatment for unilateral pars defect is rare and we had 8 patients who had direct repair of the unilateral pars defect with screw. Only one did not unite or remained symptomatic who had a bifid spine at the same level (Fig.13d).

All these patients had a better outcome than the bilateral pars defect group. Our paired sample testing suggested us to consider alternative hypothesis i.e. there was significant difference in the post-operative outcome between these two groups.

In the regression modeling, laterality as a predicting factor for a successful outcome was rejected. This may be due to the reason that the numbers in the unilateral group were less as compared to the bilateral group. The other reason may be that similar proportion of patients was better in each group at the end of the complete rehabilitation.

8.2.8 *Lumbar Levels of spondylolysis*

Since the common site of defect was L5 level whether unilateral or bilateral we had assumed that L5 pars defect would be associated with more complications following surgical repair of the defect i.e. non union or remain symptomatic. The proportion of union of defects at L4 was significantly higher than at L5 (Fig11 a & b). Fuji et al (2004) concluded that the likelihood of union of the progressive defects at L5 was less than 5%. We had eight patients who underwent re-operation for recurrence of symptoms between 1 & 4 years. Six were at L5 and two at L3 vertebral level. One female patient had multiple operations for a bilateral pars defect at L5 and did not return to the sports i.e. netball. One professional female gymnast who had a Scott's repair for bilateral defects at L3 was not able to perform gymnastics at the previous level and underwent further fusion operations for symptomatic non-union. Another semi-professional footballer who had Scotts repair for bilateral pars defect at L5 had returned for a fusion for recurrence of back pain. One professional footballer with Bucks repair at L5 bilaterally returned back with non union and recurrence of symptoms after a painfree period of high level football for two years (Fig 14a-d). Another semi-professional hockey player who had an alar-transverse fusion at left L3 pars defect returned back after one year with painful. Both these patients underwent uninstrumented postero-lateral fusion with a successful outcome. One twenty five year old male footballer had continued to be symptomatic after Buck's repair for pars defect at L5 and subsequently underwent postero-lateral fusion at L5/S1 but continues to have low back pain with a high ODI. One patient as mentioned earlier had a bifid spine and an unilateral pars defect repair had a recurrence of pain and underwent fusion at two years.

Thus, failure of surgical intervention in eight patients suggested that we should find a correlation between the failures of surgical management with the vertebral levels of lumbar defect. Linear regression model in its final step included L3 vertebral level as one of the poor prognostic indicators of surgical treatment of pars defect repair. This is an interesting outcome of the regression analysis which may be explained. In this cohort, only three patients had L3 vertebral levels involved. Of these three one had Buck's repair who did well to return to sports.

But in the other two, one who had Scott's repair and the other who had alar-transverse fusion failed to have a successful outcome. Two out of three failures at the same segment is recognized mathematically as a poor prognostic factor. It would be prudent to give advice on the basis of two patients. One needs a robust number of patients in the L3 level to predict the outcome.

Alternatively, there may be a biomechanical basis for unsuccessful attempt at repair of the pars defect at L3. The answer may lie in the amount of motion involved in each lumbar segment in flexion or extension or in rotation. McGregor et al (2001) analysed global motion in lumbar spine in presence of spondylolysis. They observed that the ROM in flexion and extension was also found to be significantly greater than normal if the subject presented with a spondylolysis i.e. they are hypermobile. In extension, isthmic spondylolisthesis subjects tended to present with a restriction in ROM but only if the defect was located at the lumbosacral junction. If we look back in Kanayama's (1996) phase lag study on lumbar motion it is noted that lower lumbar and lumbosacral motion (L3-S1) was initiated at the L3-L4 motion segment. The L4-L5 segmental motion delayed from the L3-L4 motion by an average of 6° and preceded the L5-S1 motion by an average of 8°. In extension, motions in the L3-L4 and L4-L5 segments were small, and the L5-S1 segmental motion only contributed to the total lower lumbar motion. Wong et al (2006) used a new spinal motion tracking system which was computerized to reveal the data in flexion and extension continuously. A linear-liked pattern of the Intervertebral Flexion/Extension curves in different levels was found and this decreased in descending order from L1–L2 to L5–S1 at different points of range of motion in flexion. Every segment of the lumbar spine flexes in forward bending, but the motion is unevenly contributed at different levels.

Combining the knowledge of these three biomechanical analyses of lumbar motion in flexion and extension it may be reasonably stated that there is initiation of motion at L3 vertebral segment prior to the L5/S1 segment in flexion. If there is a lag in motion in caudal direction, the load on the pars defect at the mid-lumbar level in flexion may be more and also an increase in micromotion at this segment may not be conducive to healing of the defect.

Finite element modelling on L4/5 motion segment has confirmed the increased stresses due to hyperextension and rotation (Chosa et al 2004). Further finite element modelling suggested that in the lumbar spine with a bilateral pars defect, the rotation angle, the vertebral body displacement, the disc stress, and the endplate stress, was increased more when compared to the intact lumbar spine under extension or torsion (Wang et al 2006).

8.2.9 *Outcome scores*

Pain and disability have been established outcome measures in both low-back pain and non-specific neck pain patients (Deyo et al 1998 & Kjellman et al 1992). Kjellman et al (1992) showed that different outcome variables were influenced by different predictive factors. Disability was influenced by high pain intensity, low general health, low expectations of treatment and lengthy symptom duration.

The combination of the two distinct study groups was based on few assumptions i.e. non operative and the surgical group. Receiver Operating Characteristics (ROC) curve to predict the most relevant outcome variable determining the need for surgery was estimated [Fig 30]. ROC estimated the AUC of 0.94 ($p < 0.001$) for the pre treatment VAS score. This indicates the sensitivity of VAS score or in other words severity of low back pain as the single most determinant in predicting the need for surgical intervention in a patient who had a course of conservative therapy which failed to relief symptoms. From the curve it is estimated that preoperative VAS is 90% sensitive predictor for patients having a direct repair of the pars defect.

In the current study the predictive factors for outcome of pain intensity i.e. VAS scores had better scores in the Spearman correlation coefficient analysis than the ODI scores. Since ODI scoring is the “gold standard” for evaluating the effect of low back pain on activities of daily living and VAS scoring is a subjective feeling which is highly variable at different points of time, ODI was considered the standard to determine the post-operative outcome. In the linear regression model it was used as the dependent variable.

In a study, the Scoliosis Research Society (SRS) outcome instruments was used in measuring the outcome of young patients with isthmic spondylolysis. The mean follow-up was 20.8 years and all had ODI scoring as well VAS scoring. There was a significant inverse correlation between SRS total score and ODI. The patients who underwent scoring had posterior or postero-lateral in-situ fusion and most patients had spondylolisthesis.

Most recent published clinical outcome for repair of multilevel lumbar pars defect used the Japanese Orthopaedic Association (JOA) Scoring and Macnab criteria for assessing the clinical results in seven patients (Ogawa et al 2007). The JOA scoring uses subjective symptoms, clinical signs, restrictions in activities of daily living and urinary function. This scoring is probably not suitable in evaluation direct repair for spondylolysis in sporting population.

Macnab criteria (Macnab et al 1973) were also used in another study where outcome was assed in a cohort of patients with Scotts wiring technique in lumbar spine for spondylolysis (Zahid et al 2003). This criterion was developed for patients with low back pain who had degenerative disease and return to work was one of them. Thus this outcome scoring is also not a valid scoring system for symptomatic lumbar spondylolysis.

As described in chapter 6, for this study specifically a condition specific scoring system (BPSQ) was developed for young sporting people who have lumbar pars stress injuries. This has been shown to be a reliable scoring system with a good external validity and responsive to changes.

The floor effect and ceiling effect were 14.1% and 1.2% respectively which means that the scoring system can detect an improvement and may suggest the return to sports after treatment for lumbar pars stress injuries or spondylolysis.

SF-36 scoring was used along with ODI in this study for assessing disability in this cohort of patients with spondylolysis. It has been recorded in earlier studies that along with ODI and QBPDS, SF-36 physical component scores were most reliable for assessing disability in people with low back pain. In the regression model 2, preoperative SF-36pcs score was recorded as a significant predictor of outcome following surgical repair of pars defect. Therefore, combining all the outcome measures in a clinic based situation would allow us to understand the pain status, functional disability, motivation and physical abilities as well as the sporting abilities. Preoperative scores similar to the study group would give us an indication for surgical intervention. This outcome scores also may be used to predict the final outcome when used in the regression equation.

8.2.10 *Predicting post-operative outcome*

The outcome predictive equation was finally based on six main discriminants: preoperative ODI, preoperative SF-36 pcs, Buck's fusion and professional sporting individual, multiple operations and vertebral level of L3. The last two can be included in the equation if there are patients with such characteristic. The precision of the predicted postoperative ODI scoring with the 4-item model may be more reliable than the 6-item model. The global quality of the model was reliable with an adjusted R^2 =0.809. This means that the equation can predict the final outcome in 80.9% patients with a symptomatic lumbar spondylolysis who undergoes Buck's fusion.

The surgical repair should be offered to the select group of individual who are active and young with a high motivation for sports and whose pain has not been controlled after 6 months of non-operative treatment.

8.2.11 *Outcome of Buck's direct repair*

The short term outcome following surgery has been excellent in both unilateral and bilateral spondylolysis patients in this cohort. 34/38 (87%) patients who had Buck's repair had an excellent or good outcome as recorded by ODI and SF-36 scores. In the unilateral group, 7/8 patients returned to sport after a mean of 6 months following

surgical repair of their unilateral defect. In the bilateral group, 20/25 sporting individuals had returned to active sports after a mean of 7.5 months. In the Buck's repair group 17 professional footballers and 7 cricketers returned to the same level at which they had been competing before the onset of their symptoms within 8 months of the surgery. One of the county cricket bowlers in our series had his repair for a L5 pars defect when he was 18 years of age. He had a significant contribution in his county club team as a bowler for six years until he had suffered another stress injury at a different level. He had to give up bowling at that level of sports following the second injury. This healed after few months of rest and rehabilitation as followed in our conservative group.

The biomechanics of increased disc stresses in spondylolysis was studied on lumbar spondylolysis simulation models by Sairyo et al (2006). Buck's direct repair model was simulated with 4.0 mm cannulated Titanium screws, placed bilaterally across the defect. The stresses at the annulus and nucleus pulposus decreased to 125% and 120% respectively in the Buck's repair model. The results from this study suggest that the Buck's technique may be able to restore the disc stresses back to normal at both cranial and caudal disc levels.

The above biomechanical basis can be translated to a clinical outcome model of a sporting young person and predict that there is less chance of developing disc degeneration if one has a Buck's repair for a pars defect. Buck's fusion stabilizes the spondylolytic segment and restores the biomechanics around the motion segment which enables a professional sporting individual to return to previous active level of sporting without endangering the progression of disc degeneration and recurrence of low back pain. The clinician should suspect another stress injury at a more cranial level if there is recurrence of low back pain within a short period of time following surgery (i.e. two years).

8.2.12 *Role of early surgery in lumbar spondylolysis*

From this study it is established that there is alleviation of pain following the stabilization of the spondylolyitc segment in active professional sportsmen or women who are well motivated for a successful return to their livelihood. For most surgical interventions there are cost implications.

The economic aspects of a disease can sometime give insight into the cost-effectiveness of a procedure. One can either approach 'lumbar spondylolysis' treatment by understanding the cost-effectiveness of the surgery i.e. measuring consequences with a physical unit (ODI or SF-36) or via a cost-benefit approach where one measures the consequences in monetary units. In the present study, the comparison of the two treatment approaches of spondylolysis could be looked through the window of physical consequences without the costs involved.

When a patient is a professional sporting individual who takes part in the long duration of restricted rehabilitation phase (conservative treatment) for a symptomatic pars defect, could be using up more resources than if one had surgery. This individual is using up the allocated resources during this phase of conservative treatment. If he or she fails to return to professional sports, we offer surgery to cure him/her of the ongoing pain. The lost time and monetary unit may have implications both to the provider of the health care as well as the receiver. The cost effectiveness of surgical repair may outweigh that of conservative approach for the extra amount of time lost by the professional and the amount of resources used up for that period of time when an unsuccessful attempt was made at alleviating pain.

Future research should provide a comprehensive cost-effective analysis of conservative versus surgical treatment in lumbar spondylolysis. Whether the fracture of the pars heals or not probably does not relate to successful outcome but the financial benefits may affect the process of cure in lumbar spondylolysis.

8.2.13 *Summary*

The outcome following direct repair of pars defect beyond 30 years of age is unpredictable. There is no significant difference in the functional outcome between the two genders but the pain and disability scores were better in males. Low back pain is the single most important predictor for one having a surgical intervention. Preoperative VAS score of >6 is 90% sensitive indicator for direct repair of pars defect. Professionalism in sports has a high impact on the outcome of an individual following surgical repair of the defect. Unilateral spondylolysis do slightly better than bilateral spondylolysis following Buck's repair.

Higher lumbar levels of spondylolysis i.e. L3 may be associated with a poor outcome following surgery. Preoperative ODI and SF-36 pcs scores are significant predictor of a good functional outcome. BPSQ scores may show good functional outcome in individuals who could return to respective sports following treatment for lumbar spondylolysis. Buck's repair at L5 and L4 level has excellent to good short term and mid term outcome. Medical resources are finite and future economic evaluations for the purpose of decision making between conservative and surgical treatment for lumbar spondylolysis should become an integral part of outcome research. Thus, future research should be directed towards the cost effectiveness of the two methods of treatment.

CHAPTER 9

CONCLUSION

9.1 Study 1

9.2 Study 2

9.3 Model case & Outcome

9.4 Strength & Weakness of the study

9 CONCLUSION

9.1 Study 1

1) Male sporting individuals younger than 20 years of age are more commonly symptomatic due to lumbar pars reaction or defect or spondylolysis.
2) Non-operative treatment results in successful outcome in any age group between 14-30years.
3) Non-operative treatment of rest and physical rehabilitation results in a good functional outcome in most (85%) individuals.
4) Grade 1 or 2 changes on MRI grading for lumbar spondylolysis or stress injuries of lumbar pars may be treated conservatively with a successful outcome.
5) Unilateral lumbar pars lesions do heal earlier and return to sports earlier than bilateral pars lesion.
6) Sporting individuals do better than non-sporting population after non-operative treatment.
7) Back Pain and Sports Questionnaire (BPSQ) scoring can reliably measure the outcome and reliably suggest the return to sports is scores were higher than 46.

9.2 Study 2

1) Younger age has not been a significant predictor for surgical intervention but it was observed that outcome following direct repair of pars defect beyond 30 years may run an unpredictable course.
2) Sporting individuals do better than non-sporting ones.
3) There is no effect of trunk twisting sports on the final outcome.
4) Professional sporting individuals have a better outcome following surgical repair of the pars defect.
5) There is little difference in the final outcome between the unilateral and bilateral spondylolysis groups but unilateral group takes up less time for rehabilitation.
6) L5 and L4 lumbar spondylolysis may have better outcome following surgery as compared to multiple levels or L3 lumbar level.

7) Preoperative ODI and SF-36 physical component scores were significant predictor of a successful outcome in young professional sporting individuals who have Buck's repair for lumbar spondylolysis.
8) Post operative ODI is a dependable outcome measure in lumbar spondylolysis which had significant correlation with other outcome measures.
9) There are six independent predictive factors for a successful outcome in a sporting individual following Buck's repair for lumbar spondylolysis. The outcome predictive equation following multiple regression was derived as:

Post operative ODI score = 30.121 + (0.327 x preop ODI score)
+ (-0.581 x preop SF36pcs score)
+ (-11.872 x Bucks)
+ (26.503 x multiple operations)
+ (-6.123 x professional)
+ (21.034 x L3 pars defect)

9.3 Model case & Outcome

A CLINICAL MODEL OF PREDICTIING OUTCOME FROM THE REGRESSION EQUATION

One 17 year old college triathalonist had his Buck's repair for a bilateral L5 pars defect when he was 18 years of age (case 10). He had a preoperative ODI score of 34 and SF-36pcs score of 42.5. His ODI and SF-36pcs scores at two years post-operatively were 4 and 50.2 respectively. The BPSQ score was 40. He had returned to his college level of sports.

Predictive modelling:

$$\begin{aligned}\text{Postoperative ODI} = {} & 30.121 + (0.327 \times 34) \\ & + (-0.581 \times 42.5) \\ & + (-11.872 \times 1) \\ & + (26.503 \times 0) \\ & + (-6.123 \times 0) \\ & + (21.034 \times 0)\end{aligned}$$

$$\begin{aligned}&= 30.121 + 11.118 + (-24.692) + (-11.872) \\ &= 41.239 - 36.564 \\ &= 4.675\end{aligned}$$

This score of 4.675 suggests that he has a successful outcome. In fact his post-operative ODI score was 4. This example validates the regression equation and we can predict the outcome by calculating an approximate score of ODI at preoperative stage.

9.4 Strength & Weakness

In an ideal world, the methodology applied to a research question must be ethical and practical. We have tried to acknowledge our imperfections in the form of limitations in the methods and also the interpretation of the results as formulated.

9.4.1 Strength

The following are the strength of methodology of the research:

- It caused no inconvenience, distress or danger to the patients as they were either seen in the clinic situation as a part of a regular out-patient clinic attendance and review of their case notes
- Answering the health questionnaires and sports based questionnaire posed no harm to the patients
- The case series of symptomatic lumbar spondylolysis both treated non-operatively and operatively with record of their outcome was by far the largest presented series in the literature to date
- A reasonable consistency amongst the small number of clinicians (Sports physician and surgeons) who were involved in the approach to diagnosis and management for the patients with lumbar spondylolysis
- One musculoskeletal radiologist with a spinal interest had been involved in the reporting of the SPECT, CT and MRI scans which suggested consistency in radiological reports
- The interest in the management of a sporting population in Spinal unit and the Sports Medicine unit at QMC provides a large number of sporting individuals which gives one a chance to study the pattern of treatment and outcome in lumbar spondylolysis
- Identification of predictive factors in lumbar spondylolysis especially young sporting individuals is valuable since many patients returned to active level of sports
- Special emphasis was given to collecting information on as many variables as possible that could affect the return to sporting activity

- Demonstration of routine assessment tools in low back pain i.e. VAS, ODI and SF-36 could actually detect success as well as develop a model predictive of outcome in cases where surgery is performed
- A new questionnaire (BPSQ) for young sporting individual was developed for measuring outcome

At conclusion of the study the following strengths were apparent:

- This study includes a mix of qualitative and quantitative techniques of analysis
- The inclusion criteria was strictly followed after a diagnosis of lumbar spondylolysis which was confirmed on each patient by either SPECT or MRI scan as preliminary imaging modality
- A high response rate in both non operative and surgical group
- Number of cases in both the study groups were adequate to apply the statistical test i.e. paired correlation statistics and linear regression analysis
- Management guidelines for lumbar spondylolysis was well defined
- Collection of the data was well supervised
- Data analysis have been independently performed by a statistician and results were interpreted and validated by the researcher
- Stratification of analysis by gender and laterality of spondylolysis provides valuable information for the treating physician/surgeon
- This study has a large representative sample of sporting population which provides a significant knowledge regarding the behavior of symptomatic lumbar spondylolysis in highly active sporting individuals
- The outcome score (Post treatment ODI) i.e. the dependent variable was chosen after correlation statistics which is a valid score for determining pain and disability
- This study also describes the development and validation of a simple questionnaire which could measure the outcome following treatment in sporting population with lumbar spondylolysis

- The results of multiple regression provides a practical guide to the prediction of post treatment ODI score which provides a valuable guide to the treating surgeon
- Use of Receiver Operating Characteristics (ROC) curve assessed the outcome measuring ability of BPSQ scoring system

9.4.2 Weakness

- It was a retrospective study i.e. level 3 evidence, of a relatively uncommon diagnosis in the general population. Information collected retrospectively may be affected by patient characteristics such as reporting tendency, expectations, and the current status of pain and functioning
- A potential selection bias towards the sporting group may reflect upon the outcome
- The data thus collected was at two points in time with separate patient population although with similar characteristics
- The accuracy of patient recall might be low and its impact on outcome assessment in retrospective studies are significant
- Recall bias may be high for the patients who answered the questionnaires at different times after the operation. This may overestimate the effectiveness of treatment esp. surgery of the lumbar spine
- The interactions between the risk factors and the taking several effect modifiers into account all at once are extremely difficult because of necessity of large sample size
- More than ten predictor variables were not allowed by the regression model, therefore less control on confounders

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APPENDICES

Appendix 1

Glossary

apophyseal joint	facet joint made between the inferior and superior articular processes of adjacent vertebrae
bilateral spondylolyses	spondylolyses occurring in the left and right pars interarticularies at the same lumbar level
bone stress reaction	area of bone with increased scintigraphic activity on SPECT or sclerosis on CT
complete fractures	disruption of the pars interarticularis traversing both cortices
fatigue fractures	stress fractures resulting from repetitive stresses, none of which can individually produce a fracture, but over a period produce a mechanical failure.
incomplete fractures	disruption of the pars interarticularis traversing only one cortex
insufficiency fractures	stress fractures resulting from normal stress on abnormal bone (eg osteomalacia, osteoporosis, Paget's disease, hyperparathyroidism, rheumatoid arthritis, osteogenesis imperfecta, rickets, irradiation)
isthmus	pars interarticularis
lamellar bone	is bone that replaces woven bone in growth and repair. It has parallel fibres giving rise to greater Strength than woven bone.

lumbar motion segment	two adjacent vertebrae, the interposing intervertebral disc and the structures which restrain the relative movement of the two vertebrae, such as ligaments
Non union	unable to unite after fracture
Pars interarticularis	bridge of bone between inferior and superior articular process of vertebra (also called isthmus)
periosteum	a dense fibrous membrane covering the surface of bones
SPECT negative	no areas of increased scintigraphic activity on SPECT
SPECT positive	one or more area of increased scintigraphic activity On SPECT
spondylolisthesis	[Greek *spondylo,* of spine +/- *listhesis*, slip] slip of one vertebral body relative to the adjacent vertebral body, classified by Wiltse 1976
spondylolschisis	an osseous defect in the neural arch (term used mainly from 1854 to 1955)
spondylolysis	[Greek *spondylo,* of spine +/- *lysis,* dissolution or separation] separation or crack in neural arch of vertebrae
stress fractures	occur in normal bone subject to repeated cyclical loading, that load being less than that which causes acute fracture. Can be insufficiency fractures or fatigue fractures.
stress riser	discontinuity in a substance that will alter the distribution of stresses and loads in the region of the discontinuity such that they become concentrated in the adjacent material

Appendix 2

Ethical Approval

Nottingham Research Ethics Committee 2
1 Standard Court
Park Row
Nottingham
NG1 6GN

Telephone: 01159123344
Fax: 01159123300

19 May 2006

Mr B Freeman
Consultant Spine Surgeon
Spinal Unit
Queen's Medical Centre
Nottingham, NG7 2UH

Dear Mr Freeman,

Full title of study: **FACTORS PREDICTING THE OUTCOME FOLLOWING TREATMENT FOR LUMBAR SPONDYLOLYSIS**
REC reference number: **06/Q2404/31**

Thank you for your letter of 03 May 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	1	06 March 2006
Investigator CV		
Investigator CV		01 February 2006
Investigator CV		
Protocol	1	28 February 2006
Peer Review		31 January 2006
Peer Review		13 February 2006
Statistician Comments		16 February 2006
Questionnaire	1	28 February 2006
Questionnaire: Pain Score	1	28 February 2006
Questionnaire: General and Sport Related Questionnaire	1	14 March 2006
Letter of invitation to participant	2	03 May 2006
Participant Consent Form	1	14 March 2006
Response to Request for Further Information		03 May 2006
Flowchart	1	28 February 2006

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care □inda□zation.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q2404/31	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Dr M Hewitt/Ms L Ellis
Chair/Co-ordinator

Email: □inda.ellis@rushcliffe-pct.nhs.uk

Appendix 3

Patient Consent

The University of Nottingham

CONSENT FORM

Title of Project: FACTORS PREDICTING OUTCOME FOLLOWING SURGERY IN LUMBAR SPONDYLOLYSIS

Name of Researcher: U K DEBNATH, B J C FREEMAN

Please initial box

1. I confirm that I have read and understand the information sheet dated 14.03.2006 version 1 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the above study. ☐

_____	_____	
Name of Patient	Signature	Date
_____	_____	Date
Name of Person taking consent (if different from researcher)	Signature	
_____	_____	
Researcher	Signature	Date

1 for patient; 1 for researcher; 1 to be kept with hospital notes

Version 1 dated 26.04.2006

Appendix 4

Patient Information sheet

FACTORS PREDICTING OUTCOME FOLLOWING TREATMENT IN LUMBAR SPONDYLOLYSIS

Mr/Mrs/Miss

Dear _____

I am conducting a study on patients who have suffered or may still be suffering from low back pain. This pain may be due to a stress fracture in the lower back in young sporting people. I understand that the Doctors in the Spinal Unit or the Sports Injury clinic at the QMC, Nottingham, thought that you might be suffering from a stress fracture of the lumbar spine and arranged further investigations to confirm this. I am requesting that all patients investigated for stress fracture of the lumbar spine (otherwise medically known as Spondylolysis) kindly complete and return the enclosed questionnaire. This information gathered will enable Doctors to have a better idea of the factors involved in the occurrence of such fractures and enable us to provide better advice to future patients investigated for stress fracture of the lumbar spine. The understanding of the clinical outcome following the treatment received will provide more information for advice regarding the impact a stress fracture will have on sports and when they may be able to return to sporting activity.

The questionnaires should take just 10 minutes to complete. Each questionnaire has a number at the top so that we can record when someone returns them completed and this will enable us to avoid sending out a reminder to those who return the questionnaire. The results will be reported in a way that will not reveal your identity and confidentiality of the information you provide will be strictly maintained in this study. Please read the enclosed Information sheet to find out more about this research. If you have any questions about this research please contact me by telephone or post at the address indicated at the foot of this letter. If you are not prepared to provide the information requested, please indicate this on the questionnaire and return it to us in the prepaid envelope. We shall not write to you further in the future regarding this.

This study has Ethical approval from the Nottingham Local Research Ethics Committee and will be carried out by Mr U. K Debnath, FRCS, Specialist Registrar in Orthopaedics, who is a DM (Orth) Student in the Division of Orthopaedics and Accident Surgery. I, Mr B J C Freeman,
FRCS (Orth), consultant Spine Surgery at The Centre for Spinal Studies & Surgery in the University of Nottingham, is supervising the research. If you would like a summary of the results, please request one from the address given below.

Thank You,

Yours sincerely,

Mr B.J.C. FREEMAN, FRCS (Orth)
The Centre for Spinal Studies and Surgery,
Queens Medical Centre,
University of Nottingham, West Block, D Floor
NOTTINGHAM, NG7 2UH
Phone: 0115 970 9273, 0115 924 9924 (ext 42413)
e-mail: brian.freeman@qmc.nhs.uk

version 1, 14.03.2006

Appendix 5

Questionnaires

1. VAS

2. ODI

3. SF-36

4. BPSQ

Appendix 6

CD-ROM CONTENTS

1. Tables

2. SPSS database

LEVEL OF EVIDENCE

PUBLICATIONS