FACTORS ASSOCIATED WITH FUNCTIONAL OUTCOMES IN PERSONS WHO UNDERWENT POSTERIOR LUMBAR INTERBODY FUSION – A CROSS-SECTIONAL STUDY

REGISTRATION NO: 271710323

A DISSERTATION SUBMITTED TO

THE TAMILNADU

DR. M.G.R MEDICAL UNIVERSITY, CHENNAI,

AS PARTIAL FULFILLMENT OF THE

MASTER OF PHYSIOTHERAPY DEGREE

(ADVANCED PT IN ORTHOPAEDICS)

CHRISTIAN MEDICAL COLLEGE, VELLORE

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"FACTORS ASSOCIATED WITH FUNCTIONAL OUTCOMES IN PERSONS WHO UNDERWENT POSTERIOR LUMBAR INTERBODY FUSION – A CROSS-SECTIONAL STUDY"

Submitted to

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In partial fulfillment of the requirements for the award of

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From

THE TAMIL NADU Dr. M. G. R. MEDICAL UNIVERSITY, CHENNAI

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May 2019

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ABSTRACT

BACKGROUND: Lumbar fusion surgery is one of the most common spinal surgery. The goal of this surgery is to provide fusion of the vertebra and thereby improving functional outcomes. The purpose of this study is to investigate the association of low back and psychological variables with function in subjects who underwent posterior lumbar interbody fusion.

STUDY DESIGN: Cross-sectional study

METHODOLOGY: Twenty eight subjects who underwent Posterior Lumbar Interbody Fusion for spondylolisthesis with a post-operative duration between 3 and 12 months were assessed for demographic factors (age, sex, body mass index, duration of pain before surgery and Charlson Comorbidity Index), surgical factors (duration of surgery, number of levels fused, post-operative period), low back factors (pain intensity, lumbar range of motion and core strength) and psychological factor (kinesiophobia). Functional outcomes (Oswestry Disability Index and Short Form 12) were also assessed.

ANALYSIS: Spearman's correlation analysis was performed to evaluate the relationship of various factors with the functional outcome. The variables that correlated significantly with the functional outcomes were considered for further analysis in the regression model.

RESULTS: Low back pain both at rest and during movement demonstrated a significant positive correlation with ODI and a significant negative correlation with SF 12. Radiating pain during movement showed a significant positive correlation with ODI whereas, kinesiophobia showed a significant negative correlation with SF 12.

CONCLUSION: Low back pain (both at rest and during movement), radiating pain during movement and kinesiophobia were associated with functional outcomes.

KEYWORDS: Spinal fusion, Spondylolisthesis, Core strength, Kinesiophobia, Oswestry Disability Index and Quality of life.

1. INTRODUCTION

Spondylolisthesis – Definition and description:

The word spondylolisthesis is derived from the Greek words '*spondyl'* meaning spine and '*olisthesis'* meaning to slip or slide. Spondylolisthesis is the slippage or displacement (usually forward) of one or more vertebra over the other.[1] Wiltse et al classified spondylolisthesis into congenital (dysplastic), isthmic, degenerative, pathological, traumatic and iatrogenic, on the basis of etiology.[2,3] In adults, the most frequently occurring types are isthmic and degenerative.[4]

North American Spine Society (NASS) Evidence-Based Clinical Guidelines Committee has defined degenerative spondylolisthesis as, "An acquired anterior displacement of one vertebra over the adjacent vertebra, associated with degenerative changes, without an associated disruption or defect in the vertebral ring"[5]. NASS has also defined isthmic spondylolisthesis as "The anterior translation of one lumbar vertebra relative to the next caudal segment as a result of an abnormality in the pars interarticularis"[6]. Iatrogenic spondylolisthesis results from excessive removal of the posterior elements after laminectomy.[7] Traumatic spondylolisthesis is a rare condition, mostly seen in people with multiple injuries. It is caused by a fracture in a region other than the pars.[8] Pathological spondylolisthesis is caused either due to generalized systemic disorder that includes the bone and connective tissue or due to localized lesions such as tumor or infection that affects the posterior elements of the vertebra and causes instability[9]. Dysplastic spondylolisthesis is caused by a congenital defect in the facets or pars interarticularis.[10]

Epidemiology:

The incidence of lumbar spondylolisthesis varies depending upon ethnicity, sex, family history, associated diseases and sports activities.[11] The published data for large population-based studies has shown that elderly Caucasian Americans have a higher prevalence rate of degenerative spondylolisthesis than in the black people.[12,13] Activities that causes hyperextension of spine, such as gymnastics, diving, weightlifting, volleyball and football increases the incidence of pars fracture and leads to spondylolisthesis.[14]

Clinically relevant anatomy:

Spondylolisthesis, regardless of the type, is most commonly preceded by spondylolysis. This pathology involves a fractured pars interarticularis of the lumbar vertebrae, which leads to slippage of the corpus of the vertebrae. Oblique lumbar views highlight the classic "Scottie dog," the ear of which is the superior articular process, the eye is the pedicle, the head is the transverse process, the neck is the pars interarticularis, the front limb is the inferior articular process and the hind limb is the opposite inferior articular process.

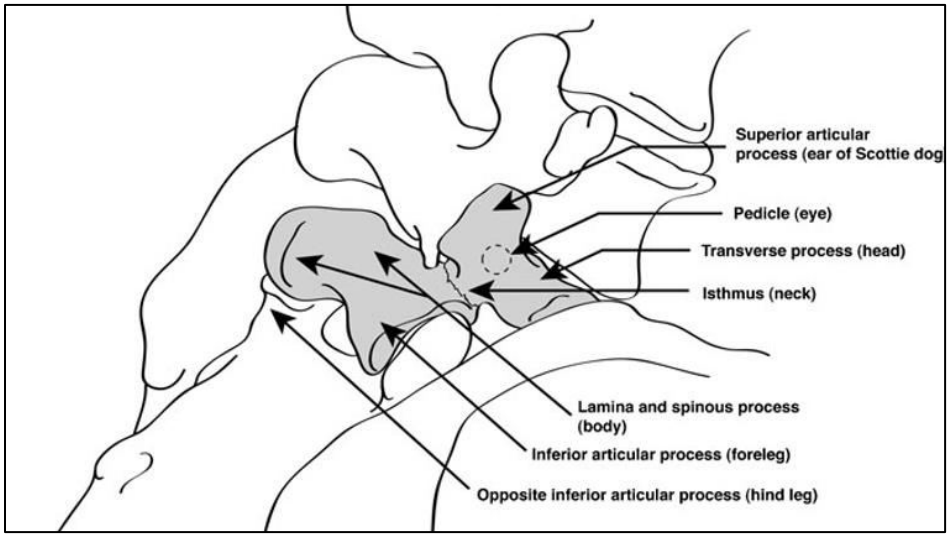


Fig 1: Scottie dog in oblique view.[15]

Alteration in biomechanics:

Biomechanical studies have demonstrated an increase in stress in the *pars interarticularis* with the column in extension and increase of shear forces through the same area, with persistence of lordosis.[16] Spondylolisthesis most commonly occurs at the L5-S1 level with anterior translation of the L5 vertebral body on the S1 vertebral body. The L4-5 level is the second most common location for spondylolisthesis.[17]

Classification:

Meyerding's classification of spondylolisthesis is based on the percentage of anterior translation relative to the adjacent level. Grade I - upto 25% , grade II - between 25% and 50%, grade III - between 50% and 75%, grade IV - greater than 75% and grade V - more than 100 % (Spondyloptosis).[18]

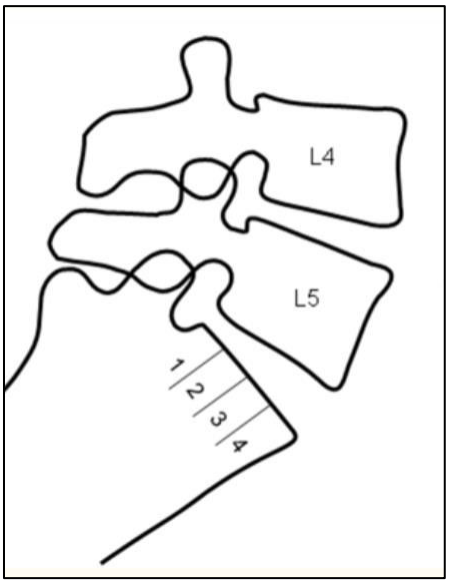


Fig 2: Meyerding's classification based on the percentage of anterior translation.[12]

Clinical presentation:

Symptoms of spondylolisthesis include low back pain that radiates down one or both legs, numbness, tingling sensation, walking difficulty and intermittent neurogenic claudication[5,6].

Conservative management:

Nonsurgical management is tried out first, which includes non-steroidal anti-inflammatory drugs (NSAIDs), opioid analgesics, epidural steroid injections and physical therapy.[19]

Physical therapy includes a well-structured physical therapy regimen along with pain relief modalities, activity modification and patient education on the benefits of a healthy lifestyle (eg. control of diabetes, weight loss programs, cessation of nicotine consumption, etc.)[20].

Surgical management:

Lumbar fusion surgery is done when there is an increased functional disability or when conservative management fails. Lumbar fusion surgery is the most common spinal surgery, the rate of which has increased significantly in the last decades[21]. There are several lumbar fusion approaches like Anterior lumbar interbody fusion(ALIF), Posterior lumbar interbody fusion(PLIF), Transforaminal lumbar interbody fusion(TLIF), Lateral lumbar interbody fusion(LLIF), Oblique lumbar interbody fusion(OLIF) and minimally invasive procedures.[22]

Posterior Lumbar Interbody Fusion:

Posterior lumbar interbody fusion (PLIF) is performed to decompress the neural tissues and fuse the affected segments[23]. The goal of this surgery is to achieve successful fusion thereby improving the functional outcomes and reducing the patient's morbidity.[24]

Surgical complications:

Even though advances in surgical techniques and rehabilitation are considered to likely restore low back function, recent studies report an incidence of 22% reoperation rate at the 8-year follow-up for patients treated surgically in the SPORT (Spine Patient Outcomes Research Trial) trial.[25] Some of the major complications after lumbar fusion surgery are dural tear and malpositioning of screws intraoperatively, neurological complications like foot drop or sensory involvement in the early post-operative period, and late post-operative complications like nonunion, instrumentation failure and adjacent segmental degeneration.[26,27]

Factors affecting the functional outcomes:

Multiple factors have been identified to affect functional outcomes after lumbar fusion for degenerative disc disease. These include age, body mass index, salary insurance status, number of comorbidities, number of levels fused, time since surgery, and preoperative ODI score but were not significantly associated with the outcome, whereas intra-operative blood loss and the duration of surgery were significantly associated with the outcome.[24] After lumbar fusion for spondylolisthesis, workers' compensation was identified as one of the risk factor for worst outcomes. [28] Smoking was found to have a

negative effect on spinal fusion done for isthmic spondylolisthesis and degenerative disc disease.[29]

After spinal fusion, most athletes returned to full unrestricted play after sufficient reduction in pain and restoration of range of motion. Nevertheless, they are generally restrained from full-contact sports.[30]

The spinal fusion rate has been claimed as 88 percent and its believed to be a prerequisite for clinical success in patients after spinal fusion surgery.[31] But, it does not explain the limited functional ability of the patients who had undergone spinal fusion. Moreover, the functional outcome after any surgery is multi-factor oriented. Therefore, exploring the factors associated with the functional outcomes may provide a foundational knowledge and an insight for designing appropriate rehabilitation guidelines.

1.1 NEED FOR THE STUDY:

Most of the studies have evaluated the functional outcomes after posterior lumbar interbody fusion but the contribution of low back factors like pain, lumbar range of motion and core strength to the functional outcomes is not very clear. Similarly, even though kinesiophobia has been positively correlated with functional disabilities and physical deconditioning in persons with chronic low back pain and after lumbar disc herniation surgery, its association with functional ability in patients after posterior lumbar interbody fusion is not yet found. The low back impairment variables or factors, chosen for this study were based on the findings from previous research and published clinical guidelines. A better understanding of the factors and its association with the functional outcomes are necessary for a successful rehabilitation.

The intention of our study is to identify potentially modifiable variables like pain, lumbar range of motion, core strength and kinesiophobia that may be the target for future evidence-based rehabilitation guidelines.

Therefore, the purpose of this study is to evaluate the association of low back and psychological variables with functional outcomes in persons who underwent posterior lumbar interbody fusion.

2. AIMS AND OBJECTIVES

AIM:

To find the association of low back, psychological, demographic and surgical factors with functional outcomes in persons who underwent posterior lumbar interbody fusion.

PRIMARY OBJECTIVE:

1. To evaluate the association of low back pain, lumbar range of motion and core strength with functional outcomes in persons who underwent posterior lumbar interbody fusion.

SECONDARY OBJECTIVES:

1. To evaluate the association of kinesiophobia with functional outcomes in persons who underwent posterior lumbar interbody fusion.

2. To evaluate the association of demographic and surgical variables with functional outcomes in persons who underwent posterior lumbar interbody fusion.

HYPOTHESES:

Null hypothesis: There is no association of low back pain, lumbar range of motion and core strength with functional outcomes after posterior lumbar interbody fusion.

Alternate hypothesis: There is a significant association of low back pain, lumbar range of motion and core strength with functional outcomes after posterior lumbar interbody fusion.

3. LITERATURE REVIEW

Factors identified to affect the functional outcomes:

Andersen et al., 2001 prospectively followed 426 spinal fusion subjects with smoking habit for a period of 2 years. They found that smoking more than 10 cigarettes daily before the operation and attempted fusion at two or more levels increased the risk of nonunion: odds ratio, 2.01 ($P < 0.016$) and odds ratio, 3.03 ($P < 0.001$), respectively. They also found that smoking cessation increased fusion rates to near those of nonsmokers. But smoking had no measurable influence on functional outcome, as assessed by the Dallas Pain Questionnaire.[29]

Anderson et al., 2016 wanted to identify the prognostic factors for return to work among patients with workers' compensation claims after fusion for spondylolisthesis. In this study, 70.1% (n=481) of subjects who did not return to work had markedly worse outcomes, shown by higher medical costs, chronic opioid dependence and higher rates of failed back syndrome, total disability, and additional surgery. Psychiatric comorbidity also increased after fusion but was much higher in those who did not return to work.[28]

Abduljabbar et al., 2017 had done a retrospective cohort study to assess the association of demographic and perioperative factors with clinical outcomes of lumbar interbody fusion with a porous nitinol implant for degenerative disc disease. Estimated blood loss and duration of surgery were significantly associated with higher postoperative ODI scores. Smoking status, salary insurance status, age, body mass index, number of comorbidities, number of levels fused, time since surgery, and preoperative ODI score were not significantly associated with outcome.[24]

Pain after Posterior lumbar interbody fusion:

World Health organization low back initiative (1999) expert advisory panel has declared Visual Analogue Scale as the recommended measure for low back and radicular pain.[32]

Olaogun et al., 2004 suggested that Visual Analogue Scale (VAS) is a reliable and valid measure for clinical rating of low back pain.[33]

Kong et al., 2010 conducted a retrospective cross-sectional study to evaluate the degree of postoperative pain and patients' satisfaction after lumbar fusion from a nationwide survey in Korea. This study included 629 patients who underwent spinal fusion for Lumbar Degenerative Disease (LDD). This survey was done in 123 hospitals with 171 spine surgeons. The mean visual analog scale score of back pain and radicular pain was 5.0 ± 2.6 and 4.4 ± 3.0, respectively. The mean ODI was 44.3 ± 19.4. ODI was significantly increased with older age, workers' compensation, and increased fusion extent. Correlated factors of dissatisfaction were severe back pain, higher ODI, multiple operation, and insufficient explanation about postoperative pain. Patients' satisfaction was not as high as expected after fusion. It has concluded that the decision for performing a lumbar fusion in those patients must be done more carefully, and it should be explained more precisely that chronic pain may persist after spinal surgery.[34]

Lumbar range of motion:

Saur et al., 1996 proved that the noninvasive inclinometer technique is a highly reliable and valid tool to measure lumbar flexion range of motion, but the measurement technique for extension needs further refinement.[35]

Ruiz et al., 2014 conducted a study in subjects who underwent different lumbar interventions like injection, decompression, and/or fusion. Oswestry disability index correlated inversely with lumbar range of motion in all planes and appeared to be a better predictor of lumbar motion parameters than the Visual analogue scale[36].

Core strength:

Hodges and Richardson., 1996 concluded that delayed onset of transverse abdominis muscle contraction indicates deficit in motor control and therefore, inefficient muscular stabilization of the spine.[37]

Von Garnier et al., 2009 evaluated inter observer and test-retest reliability in prone test using a pressure biofeedback unit which indicates the activity of transverse abdominis muscle. Participants were 40 nurses who had atleast one episode of low back pain. Prone test was found to have a high test-retest reliability but relatively low inter observer reliability.[38]

Lee et al., 2017 did a study on 59 women who underwent one or two spinal level Posterior lumbar interbody fusion to assess the effect of supervised lumbar stabilization exercise. After lumbar fusion surgery, there was a decrease in back extensor muscle strength by 7.5% from pre-operative status to three months post-operative period. There was a significant improvement in the back extensor muscle strength and lesser functional disability in the lumbar stabilization exercise group.[39]

Psychological factor - Kinesiophobia:

Svensson et al., 2011 conducted a cross sectional study to investigate kinesiophobia in subjects who underwent surgery for lumbar disc herniation and found that nearly half of the patients had kinesiophobia. They also found that these patients had more

disability, pain, depression, catastrophizing thoughts, lower self-efficacy and poorer health related quality of life than the subjects without kinesiophobia.[40]

Larssen et al., 2014 showed a positive correlation of kinesiophobia with functional abilities and physical deconditioning in persons with chronic low back pain[41].

Functional outcome after lumbar fusion surgery:

Truszczynka et al., 2014 evaluated lumbar spine-related functional disability after lumbar decompression with posterior lumbar interbody fusion (PLIF) for degenerative stenosis and concluded that there was a significant reduction in Oswestry Disability Index score and that was maintained for a duration of ten years.[42]

Hegde et al., 2017 - Functional outcome after posterior lumbar fusion surgery was found to produce good to satisfactory functional results in cases of isthmic spondylolisthesis of lower lumbar vertebra.[43]

Quality of Life after lumbar fusion surgery:

Juricek et al., 2010 evaluated quality of life in subjects who underwent elective lumbar stabilization and fusion. They found that there was clinically significant improvement in all the domains of Short Form (SF) - 36 except mental health, social function and mental composite score. Nevertheless, post-operatively all the values of SF-36 were lower than the standards for that population.[44]

Pekkanen et al., 2013 has reported that patients who underwent spinal fusion had a significant decrease in disability in the early recovery phase and the decrease in disability was paralleled to corresponding improvement in perceived quality of life.[45]

4. METHODOLOGY

4.1 STUDY DESIGN: Cross-sectional study.

4.2 STUDY POPULATION: Patients who underwent Posterior Lumbar Interbody Fusion with a postoperative duration between 3 and 12 months.

4.3 SAMPLE SIZE: Total of 28 subjects.

4.4 SAMPLING METHOD: Convenience Sampling.

4.5 STUDY SETTING: Physiotherapy Outpatient Unit, PMR department, Christian Medical College and Hospital, Vellore.

4.6 STUDY DURATION: Eight months.

4.7 CRITERIA FOR SELECTION:

Inclusion criteria:

- Patients who underwent posterior lumbar interbody fusion for degenerative or isthmic spondylolisthesis.
- Post-operative duration between 3 to 12 months.
- Both gender.
- Age >18 years.

Exclusion criteria:

- Infective spondylitis
- Subjects who decline from participation.

4.8 VARIABLES:

Independent variables:

Demographic factors:

- Age
- Gender
- Body mass index: Weight (kg)/height^2(m^2)
- Duration of pain before surgery
- Comorbidities

Surgical factors:

- Duration of surgery
- Number of levels fused- Single level/Double level/Multiple level
- Time since surgery

Low back factors:

- Low back and radiating (leg) pain intensity- At rest and during movement
- Lumbar active range of motion - Flexion
- Core muscle strength

Psychological factor:

- Kinesiophobia

Dependent variables:

- Oswestry Disability Index
- Quality of life (Short Form-12 questionnaire)

4.9 MATERIALS AND TOOLS:

- Visual Analogue Scale

- Digital inclinometer

- Sphygmomanometer

4.10 PROCEDURE OF THE STUDY:

Recruitment:

Patients who had undergone posterior lumbar interbody fusion for degenerative or isthmic spondylolisthesis with a post-operative duration between 3 and 12 months were selected according to the eligibility criteria. The study period was from June 2018 to December 2018. Informed consent was obtained from all the subjects.

Assessment:

Demographic factors:

The demographic factors such as age, sex, body mass index, duration of pain before surgery and comorbidities were documented. Participants' weight(kg) and height(m) were measured using weighing scale and wall mounted height scale respectively and BMI was calculated using the formula, BMI = weight/height^2. Age, duration of pain before surgery were taken from hospital records. Charlson Comorbidity Index was used to assess comorbidities. Higher scores indicated higher comorbidity.

Surgical factors:

The following surgical factors were collected from the hospital records that included the duration of surgery, number of levels fused and duration since surgery.

Low back factors:

Low back factors that included pain intensity in low back and leg, lumbar range of motion and core strength were assessed.

Pain intensity was assessed using Visual Analogue Scale, a 10 cm horizontal scale between the extremes of "no pain at all" and "worst pain imaginable." Subjects were asked

to position the slider on the scale, according to their pain intensity. Then, the reading was directly taken from the other side of the slider.

Lumbar range of motion was assessed using a digital inclinometer. Before testing lumbar range, forward and sideward bending of the trunk was demonstrated in standing without knee flexion. Participants were made to stand in a comfortable position with feet in line with shoulder and asked to practice 2-3 times. T12-L1 and L5-S1 levels were identified on palpation and marked. The middle of the platform of the inclinometer was placed at T12 – L1 level. At this point, the inclinometer was zeroed and then the patient was instructed to bend forward maximally. The value obtained was recorded. The inclinometer was then placed at L5-S1 level, zeroed and the patient was again instructed to bend forward maximally, and the value was recorded. To obtain lumbar range of motion, those two readings were subtracted (Fig.1).

Core strength was assessed using a sphygmomanometer. Participants were positioned in prone lying, with the feet off the plinth and with the arms beside the trunk. Thereafter, the inflatable bag was placed between the anterior superior iliac spines. Before starting the contraction, the bag was inflated to a pressure of 70 mmHg with the valve closed. Participants were instructed to breathe normally using mainly the abdominal wall and then the inflatable bag was adjusted to 70 mmHg again. Patients were requested to perform transverse abdominis muscle contractions with the following verbal commands, “Draw in your abdomen without moving the spine or pelvis” and were asked to maintain these contractions for 10 seconds. The reduction of pressure was recorded. This procedure was repeated twice and the average value was noted. A pressure reduction of at least 4 mmHg was defined as a successful result (Fig.2).

Fig.1 Lumbar spine flexion measurement using digital inclinometer

Fig.2 Core strength measurement using sphygmomanometer

Psychological factor:

Psychological factor (kinesiophobia) was assessed using Shortened version of Tampa scale for kinesiophobia (TSK-11). Total of 11 items was scored from 1 (strongly disagree) to 4 (strongly agree). Total score ranges from 11 to 44. Higher scores indicated higher kinesiophobia.

Functional outcomes:

Oswestry Disability Index was used as a low back functional tool which consists of 10 sections, each section with a score of 0 to 5.

ODI score (%) = (Total scored / Total possible score) x 100

Interpretation of scores:

0% to 20%: minimal disability

21% to 40%: moderate disability

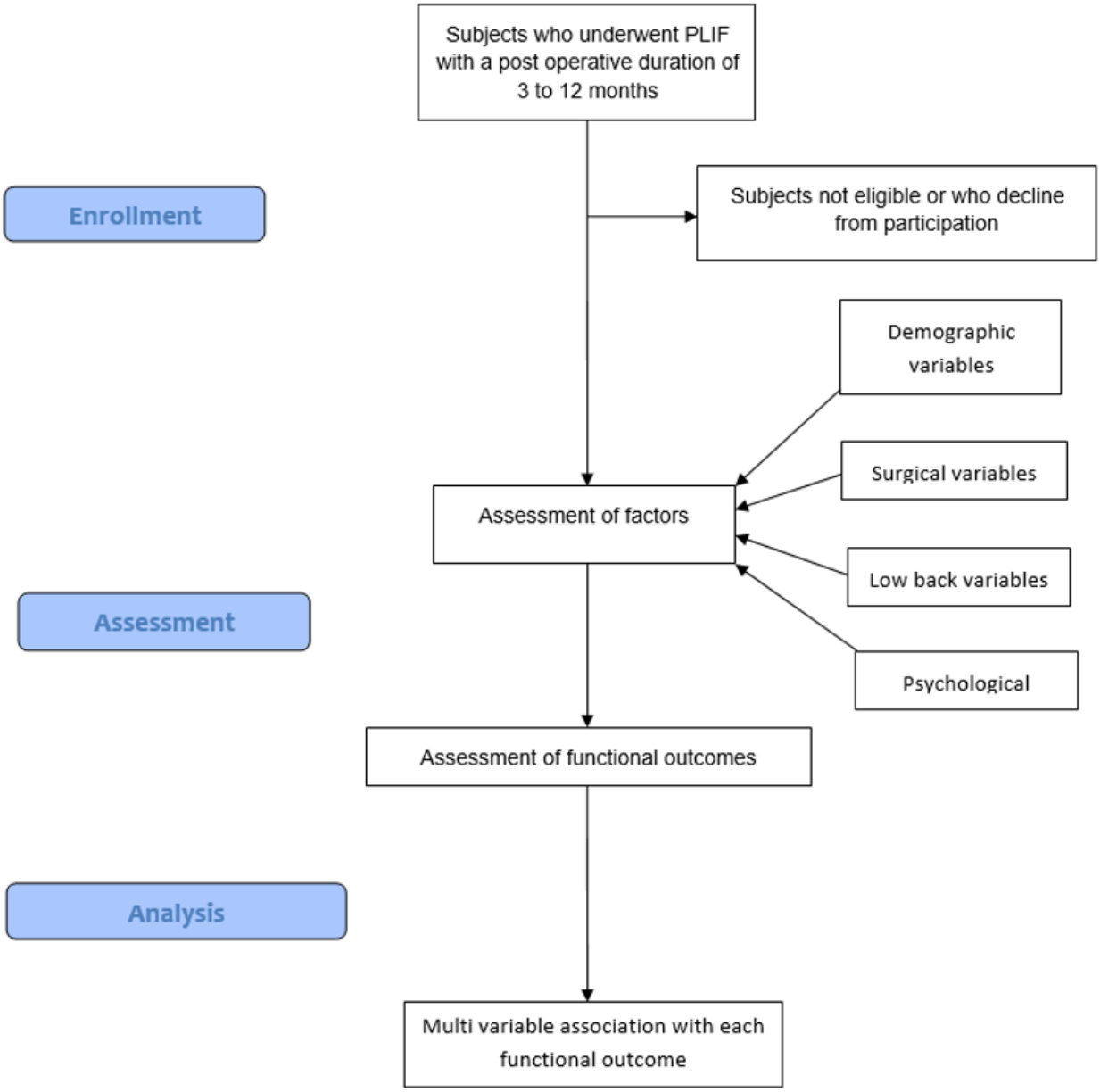
41% to 60%: severe disability

61% to 80%: crippled

81% to 100%: bed bound

Short form-12 was used to assess the Quality of life which includes 12 questions concerning physical functioning; role limitations; pain; general health perceptions; social functioning; emotional problems and general mental health. It summarizes physical and mental component summary scores. Higher the score indicates better the health status.

4.11 ALGORITHM:



4.12 STATISTICAL TOOLS

Statistical methods:

- For continuous data, descriptive statistics was presented as Mean, Standard Deviation, Median and Interquartile range - Minimum and Maximum.
- For categorical data, the number of patients and percentage were presented.
- Based on the normality of data, non-parametric spearman correlation was used to evaluate the association of factors with the functional outcomes.

  Spearman correlation coefficient (rho),

$$\rho = 1 - \frac{6\sum d_i^2}{n(n^2-1)}$$

  where,

  d is the difference between the two ranks of each observation and

  n is the number of observations

- The linear regression was used for further analysis. All tests were two-sided at α=0.05 level of significance. All analyses were done using Statistical Package for Social Services (SPSS) software Version 21.0 (Armonk, NY: IBM Corp).

5. RESULTS

Table 1: Descriptive statistics for demographic, surgical, low back and psychological factors and functional outcomes.

Variables	Mean ± SD (range)
Age (years)	54.4 ± 11.3 (30-82)
Gender N (%)	Male: 11(39.3%) Female: 17(60.7%)
Body mass index	26.02 ± 3.2 (21.1-32)
Duration of pain before surgery (months)	40.4 ± 26.8 (6-120)
Charlson comorbidity index	0.6 ± 0.9 (0-3)
Duration of surgery (minutes)	132.7 ± 36.8 (36-210)
No. of levels fused N (%)	Single: 25 (89.3%) Double: 2 (7.1%) Multiple: 1 (3.6%)
Blood loss (ml)	73.2 ± 119.01
Duration after surgery (months)	5.2 ± 2.9 (3-12)
Low back pain (at rest)	1.8 ± 2.2 (0-8)
Low back pain (during movement)	3.7 ± 2.4 (0-9)
Radiating pain (at rest)	1.2 ± 2.01 (0-7)
Radiating pain (during movement)	2.8 ± 2.5 (0-8)
Lumbar range of motion (flexion in degrees)	25.1 ± 10.4 (12-60)
Core strength (in mmHg)	4.1 ± 1.5 (2-9)
Kinesiophobia	26.2 ± 6.4 (15-37)
SF 12	32.8 ± 6.3 (23-44)
ODI	34.6 ± 14.4 (15-60)

The characteristics of the study participants are summarized in table 1. Mean age of the study sample (n = 28) was 54.4 years (SD = 11.2). The number of males and females participated in the study were 11(39.3%) and 17 (60.7%) respectively. The mean duration after surgery for this study was 5 months. The duration of pain before surgery ranged from 6 months to 10 years. Majority of subjects who participated in this study underwent single level fusion (n = 25; 89.3%). The mean Charlson comorbidity index score was 0.6 (range 0-3). The pain intensity was found to be high in low back during movement which ranged from 0 to 9. The average pain intensity at rest both in low back and leg was approximately 1 with SD of 2. Average lumbar flexion and core strength was 25 degrees and 4 mm Hg respectively. The average kinesiophobia score was 26.25 (SD = 6.36). As shown by total score of Oswestry Disability Index (mean = 34.57; SD = 14.40), the sample presented with moderate to severe levels of functional disability.

Spearman's correlation analysis was performed to evaluate the relationship of low back factors (pain intensity, lumbar range of motion and core strength), psychological factor (kinesiophobia), demographic (age, sex, body mass index, duration of pain before surgery and Charlson Comorbidity Index), and surgical factors (duration of surgery, number of levels fused, post-operative period) with the functional outcomes (Oswestry Disability Index and Quality of life).

Table 2: Correlation of low back factors with functional outcomes.

Low back factors	ODI		SF 12	
	ρ(rho)	p value	ρ (rho)	p value
Low back pain (at rest)	0.58*	**0.001**	-0.43*	**0.02**
Low back pain (during movement)	0.65*	**0.000**	-0.55*	**0.002**
Radiating pain (at rest)	0.29	0.12	-0.18	0.34
Radiating pain (during movement)	0.58*	**0.001**	-0.36	0.05
Lumbar range of motion	-0.27	0.15	0.29	0.13
Core strength	-0.28	0.14	0.42	0.23

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

ρ (rho) – Spearman's correlation coefficient

Low back pain both at rest and during movement demonstrated a statistically significant positive correlation with ODI and a significant negative correlation with SF 12. Radiating pain during movement showed a significant correlation only with ODI. Lumbar range of motion has shown a weak correlation with the functional outcomes with p value being non-significant. Core strength has shown a moderate positive correlation with SF-12 but not statistically significant.

Table 3: Correlation of psychological factor with functional outcomes.

Psychological factor	ODI		SF 12	
	ρ(rho)	p value	ρ (rho)	p value
Kinesiophobia (TSK 11)	0.46	0.14	-0.53*	**0.003**

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

ρ (rho) – Spearman's correlation coefficient

Kinesiophobia (TSK 11) showed a significant negative correlation with quality of life (SF 12). A moderate positive correlation was found between kinesiophobia and ODI with p value being non-significant.

Table 4: Correlation of surgical factors with functional outcomes.

Surgical factors	ODI		SF 12	
	ρ(rho)	p value	ρ (rho)	p value
Duration of surgery	0.13	0.48	-0.14	0.45
Blood loss	0.28	0.13	0.01	0.94
Duration after surgery	-0.15	0.43	-0.02	0.89

ρ (rho) – Spearman's correlation coefficient

A weak correlation was found between surgical factors and ODI, with p value being non-significant. Blood loss and post-operative duration did not show any correlation with SF 12.

Table 5: Correlation of demographic factors with functional outcomes.

Demographic factors	ODI		SF 12	
	ρ(rho)	p value	ρ (rho)	p value
Age	-0.01	0.92	-0.09	0.63
Weight	0.16	0.39	-0.001	0.99
Height	-0.20	0.29	0.10	0.59
Body mass index	0.24	0.22	-0.18	0.35
Duration of pain before surgery	0.16	0.39	-0.001	0.99
Charlson comorbidity index	-0.12	0.52	0.03	0.87

ρ (rho) - Spearman correlation coefficient

A weak correlation was found between body mass index and the functional outcomes with p value being non-significant. Most of the demographic factors were not found to correlate with the functional outcomes.

Table 6: Regression analysis model summary with ODI score as the dependent variable

Independent predictor	R square	Coefficient (B)	95% CI	p value
Low back pain (at rest)	0.31	3.64	1.47 to 5.81	**0.002**
Low back pain (during movement)	0.50	4.28	2.58 to 5.97	**0.000**
Radiating pain (during movement)	0.34	3.31	1.45 to 5.17	**0.001**

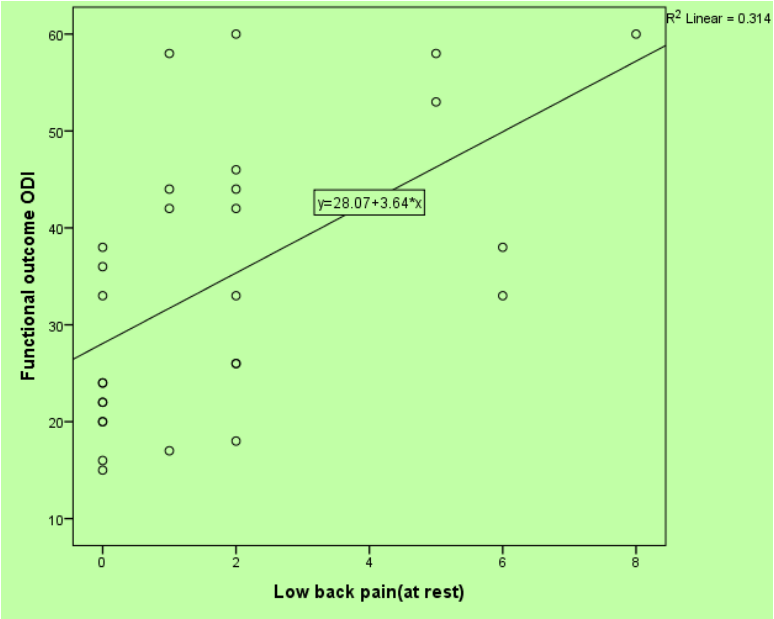
The variables that correlated significantly with the functional outcomes were considered for further analysis in the linear regression model as independent variables. Regression analysis using ODI score as the dependent variable showed that low back pain during movement accounted for 50% of variation in ODI score. It also showed that for one unit increase in LBA during movement there will be 4 units increase in ODI. Also, for one unit increase in LBA at rest and radiating pain during movement there will be 3 units increase in ODI (Table 6).

Table 7: Regression analysis model summary with SF 12 score as the dependent variable

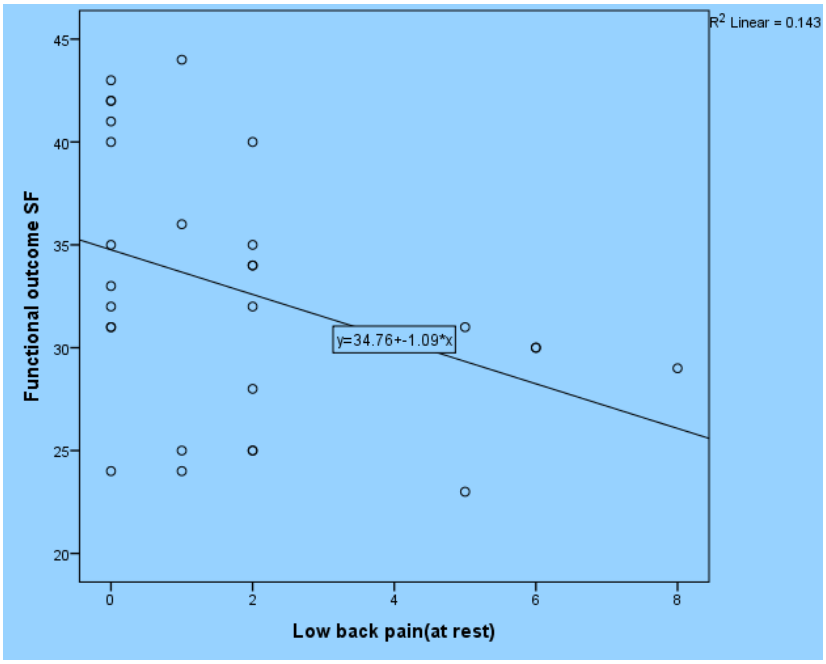
Independent predictor	R square	Coefficient (B)	95% CI	p value
Low back pain (at rest)	0.14	-1.08	-2.15 to -0.01	**0.047**
Low back pain (during movement)	0.29	-1.43	-2.33 to -0.53	**0.003**
TSK 11	0.29	-0.54	-0.87 to -0.20	**0.003**

Regression analysis using SF 12 score as the dependent variable revealed that low back pain during movement and TSK 11, each accounted for 29% of the variance in SF 12 score. It also showed that for one unit increase in either LBA at rest or during movement, quality of life reduces by one unit.

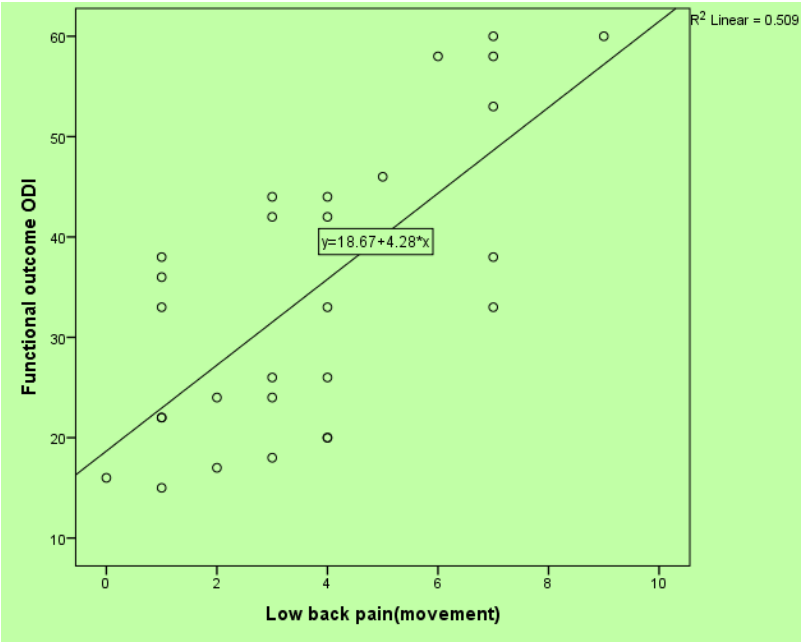
Graph 1 shows significant positive correlation between low back pain at rest and ODI



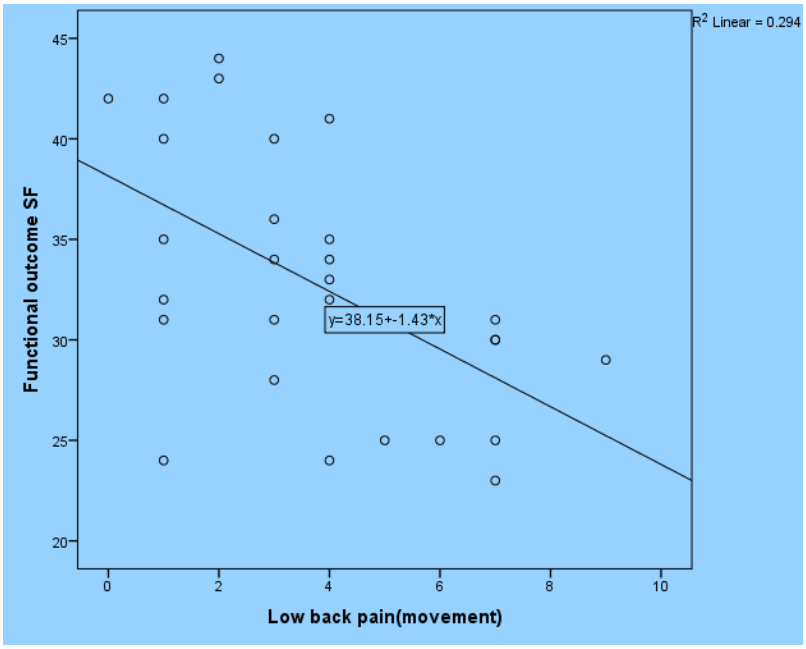
Graph 2 shows significant negative correlation between low back pain at rest and SF12



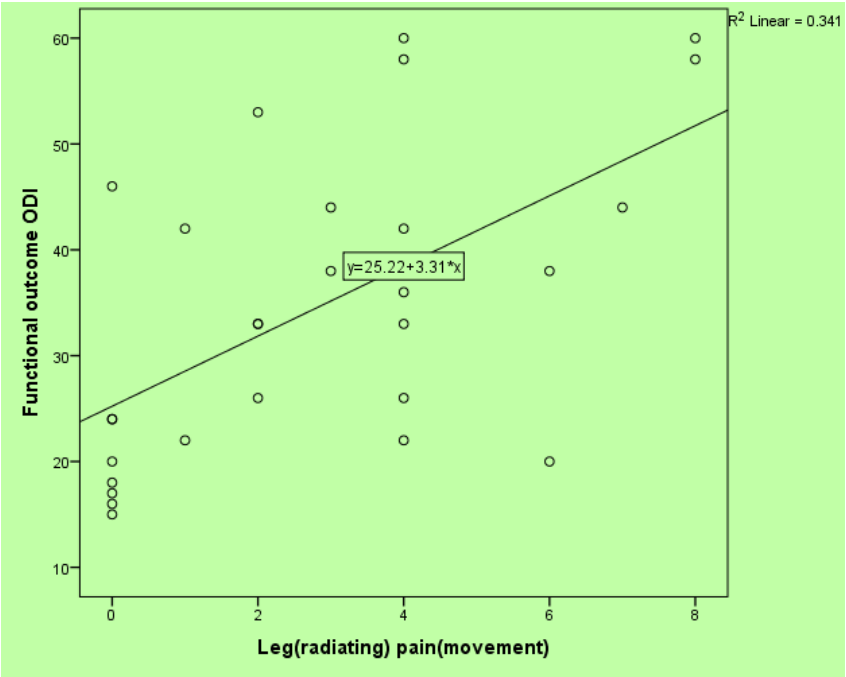
Graph 3 shows significant positive correlation between low back pain during movement and ODI



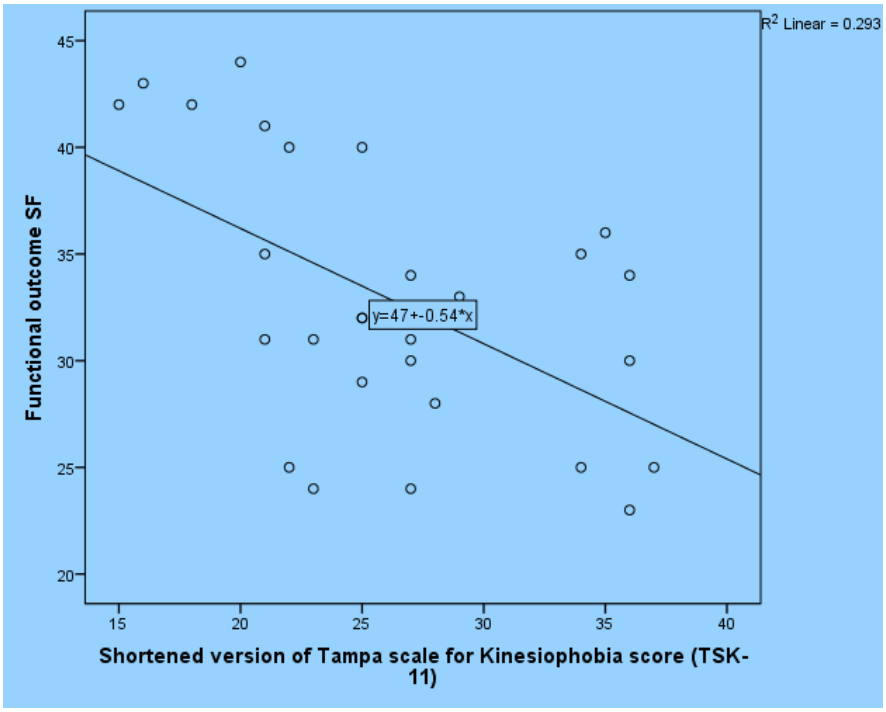
Graph 4 shows significant negative correlation between low back pain during movement and SF 12



Graph 5 shows significant positive correlation between radiating pain during movement and ODI



Graph 6 shows significant negative correlation between kinesiophobia and SF 12



6. DISCUSSION

The purpose of our present study was to investigate the association of low back factors with functional outcomes in subjects who underwent posterior lumbar interbody fusion with a post-operative duration between 3 to 12 months. In addition, we also aimed at investigating the relationship of psychological, demographic and surgical variables with the functional outcomes. The findings of our study suggest that post-operative low back pain (both at rest and during movement), radiating pain during movement and kinesiophobia can influence the functional outcomes after posterior lumbar interbody fusion.

In this study, we selected a few variables from different perspective, namely demographic, surgical, low back and psychological variables. Amongst these, some of the variables like lumbar range of motion, core strength and kinesiophobia were not included in the previous studies as the factors that contribute to the changes in functional outcomes. The low back variables chosen for this study were based on the findings in previous research [46].

Low back factors that were found to have a significant positive correlation with Oswestry Disability Index included low back pain both at rest and during movement and radiating pain during movement. Additionally, low back pain during movement has shown to account for 50% of variation in Oswestry Disability Index score. Whereas, lumbar range of motion has shown a weak correlation with ODI. In a previous study by Ruiz et al[36], the authors found Oswestry Disability Index to be a better predictor of the motion parameters than the Visual Analogue Scale. In the present study, lumbar range of motion

showed a weak correlation probably because of adjacent segmental hypermobility that happens after spinal fusion[47].

A significant negative correlation was found between kinesiophobia and quality of life, which means, as the fear factor increases, the quality of life reduces. It has also been found that kinesiophobia accounted for 29% of the variance in SF 12 score. In a study by Ulug et al, kinesiophobia was found to have an impact on the quality of life in patients with low back pain[48]. But the association of kinesiophobia with the functional outcome was not investigated in any of the spinal fusion studies. Identification of the psychological variable as one of the contributing factors to the outcome emphasizes identification of the fear of movement or fear of reinjury in the subjects after spinal fusion surgery and also inclusion of fear avoidance model in the post-operative rehabilitation guidelines.

Abduljabbar et al[24] found that estimated blood loss and duration of surgery had a significant association with the ODI score. Our present study did not show any significant association of the surgical variables with the functional outcomes. This might be because of the retrospectively collected surgical data from the medical records and also because of the uncertainty about the method of blood loss measurement. Also, in our study, majority of the subjects, nearly 89% (n=25) had undergone single level fusion, two subjects underwent double level and only one subject underwent multiple level fusion. This variation might have also influenced the results of our study.

Jiang et al[49] performed a meta-analysis and found that obesity seemed to be associated with higher risk of surgical site infection, venous thromboembolism, more blood loss, and longer surgical time. However, obesity was not evaluated with the functional outcomes. A 2018 study[50] has showed that non-obese patients had better physical well-

being in the mid-term although obese patients experienced a comparable improvement in clinical scores. Also, obesity had no impact on patients' ability to return to work. In our study, body mass index measurement was taken post operatively unlike the other studies where it was taken at the time of surgery, which would have influenced the results.

The extraneous variables like premorbid status, participants' pain tolerance and motivation level would have also influenced the outcome of this study. In this line of thought, it would probably be useful to have a homogenous group that would help to disentangle the predictors associated with functional outcomes after posterior lumbar interbody fusion. Also, the cross-sectional nature of our study hinders in comparing long term outcomes and thereby makes it impossible to draw final conclusion on the predictors and mediators of the functional outcomes.

Nevertheless, the results of our present study are relevant from a clinical perspective. The strength of our study includes incorporation of various dimensional factors like demographic, surgical, low back and psychological factors. Also, identification of some of the potentially modifiable variables like pain, core strength, lumbar range and kinesiophobia from a physiotherapist perspective.

The findings of this study identified important low back and psychological variables that contribute to the functional outcomes. Future longitudinal studies are needed to identify the prognostic variables that determine the functional outcomes. Ultimately, the information provided by the study may be useful in designing an appropriate post-operative regimen following spinal fusion.

7. CONCLUSION

A cross sectional study design was used to find the association of low back factors with the functional outcomes in persons who underwent posterior lumbar interbody fusion with a post-operative period between three months and 1 year.

Low back pain both at rest and during movement demonstrated a significant positive correlation with functional disability and a significant negative correlation with the quality of life. Radiating pain during movement and kinesiophobia showed a significant correlation with functional disability and quality of life respectively. Demographic and surgical factors did not show any association with the functional outcomes.

Outcomes after posterior lumbar interbody fusion may vary widely with many inter-related factors. The factors identified in our study may aid in the development of an appropriate post-operative regimen that would target the potentially modifiable variables. Also, kinesiophobia should be continuously assessed in the clinical settings to recognize the obstacles that may affect patient's compliance towards a rehabilitation program in persons who underwent posterior lumbar interbody fusion.

8. LIMITATIONS AND RECOMMENDATIONS

Limitations:

- Small sample size.
- Cross-sectional study design.

Recommendations:

- Future studies with large sample size can be done to validate the findings.
- The association of the factors with the functional outcomes after posterior lumbar interbody fusion can be evaluated in a longitudinal study design with adequate follow up.
- Stratification of samples based on the different types of spondylolisthesis and the number of levels fused would demonstrate a better understanding of the factors associated with the functional outcomes.
- Electromyography or pressure biofeedback can be considered to assess core muscle activation in future trials.

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APPENDIX-1

Consent Form

Study Title: Factors associated with functional outcomes in persons who underwent Posterior Lumbar Interbody Fusion – A cross-sectional study.

Subject's Name: _____

Date of Birth / Age: _____

Hospital no: _____

(i) I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study 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. [ ]

(iii) I understand that the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signatory's Name: _____ Date: ____/_____/_____

Signature: _____

Name of the Investigator: _____ Date:_____/_____/_____

Investigators Signature: _____

Name of the witness & address: _____

Signature of witness: _____

APPENDIX-2

PARTICIPANT INFORMATION SHEET

Study title: Factors associated with functional outcomes in persons who underwent Posterior Lumbar Interbody Fusion – A cross-sectional study.

As being a person who underwent posterior lumbar interbody fusion surgery, you are requested to participate in our study which aims to find out the factors associated with the functional outcome of this kind of surgery. Please take time to read the following information regarding this research. You are requested to ask questions and clarify doubts related to this study as you read this information form. Take time to decide whether or not to be part of our study.

Why should we study about the factors' association?

This study will help us to identify the factors associated with the functional ability after the surgery. By identifying the factors, we will be able to predict and work on those factors that would improve the functional ability.

If you take part what will you have to do?

General demographic data such as name, age, gender, height, weight and the information related to your surgery will be recorded. Then your low back pain severity, muscle strength, movement and fear of movement will also be measured. Along with this your functional ability and the quality of your present life will be evaluated.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you but if you do develop any side effects or problems due to the study, these will be treated at no cost to you. We are unable to provide any monetary compensation, however.

Will your personal details be kept confidential?

All the information shared by the participants will remain strictly confidential at all times and will be reviewed and will be available only to professionals involved in this study.

Contact for further information:

Please contact: Winrose W,

Ph: 9840368498,

Email id: rosewin.w@gmail.com

APPENDIX - 3

DATA COLLECTION FORM

Topic: Factors associated with functional outcomes in persons who underwent Posterior Lumbar Interbody Fusion – A cross-sectional study.

Subject no:

Name:

Hospital number:

Diagnosis:

Surgery:

Date of surgery:

Demographic factors

- Age:
- Gender:
- Height (m):
- Weight (Kg):
- Duration of pain before surgery:
- Comorbidities (Charlson Comorbidity Index Score):

Surgical factors

- Duration of surgery:
- Number of levels fused: Single/Double/Multiple
- Blood loss:
- Duration since surgery:

Low back factors

• Pain intensity (low back and leg)- Visual Analogue Scale

Pain intensity	Low back pain	Leg(radiating) pain
At rest		
During movement		

• Lumbar active range of motion

Flexion (in degrees)

• Core strength

Trial 1 (in mm Hg)	Trial 2 (in mm Hg)	Average (in mm Hg)

Psychological factor

• Shortened version of Tampa scale for Kinesiophobia score (TSK 11)=

Functional outcomes:

• Oswestry Disability Index score (%)

(Total scored/Total possible score) x100 =

• Quality of life - SF 12 score =

Charlson Comorbidity Index
Scoring

Condition	Variable name	Points	Notes
Myocardial infarction	MI	1	
Congestive heart failure	CHF	1	
Peripheral vascular disease or bypass	PVD	1	
Cerebrovascular disease or transient ischemic disease	CVA	1	CVA only
Hemiplegia	PLEGIA	2	If hemiplegia, do not count CVA separately
Pulmonary disease/ asthma	COPD	1	
Diabetes	DM	1	DM only
Diabetes with end organ damage	DMENDORGAN	2	If end organ damage, do not count DM separately
Renal disease	RENAL	2	
Mild liver disease	MILDLIVER	2	
Severe liver disease	SEVERELIVER	3	
Gastric or peptic ulcer	ULCER	1	
Cancer (lymphoma, leukemia, solid tumor)	CANCER	2	Nonmetastatic cancer only
Metastatic solid tumor	METASTASES	6	If Metastatic, do not count cancer separately
Dementia or Alzheimer's	DEMENTIA	1	
Rheumatic or connective tissue disease	RHEUMATIC	1	
HIV or AIDS	HIV	6	
Hypertension	HBP	1	
Skin ulcers/ cellulitis	SKIN ULCER	2	
Depression	DEPRESSION	1	
Warfarin	WARFARIN	1	

SHORTENED VERSION OF TAMPA SCALE FOR KINESIOPHOBIA

1 = strongly disagree
2 = disagree
3 = agree
4 = strongly agree

1. I'm afraid that I might injure myself if I exercise	1	2	3	4
2. If I were to overcome it, my pain would increase	1	2	3	4
3. My body is telling me I have something dangerously wrong	1	2	3	4
4. People aren't taking my medical condition seriously enough	1	2	3	4
5. My accident has put my body at risk for the rest of my life	1	2	3	4
6. Pain always means I have injured my body	1	2	3	4
7. Simply being careful that I do not make any unnecessary movement is the safest thing I can do	1	2	3	4
8. I wouldn't have this much pain if there wasn't something potentially dangerous going on in my body	1	2	3	4
9. I can't do all the things normal people do because it's too easy for me to get injured	1	2	3	4
10. Pain lets me know when to stop exercising so that I don't injure myself	1	2	3	4
11. No one should have to exercise when he/she is in pain	1	2	3	4

OSWESTRY DISABILITY INDEX

Section 1 – Pain intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2 – Personal care (washing, dressing etc)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but manage most of my personal care
- ☐ I need help every day in most aspects of self-care
- ☐ I do not get dressed, I wash with difficulty and stay in bed

Section 3 – Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives extra pain
- ☐ Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently placed eg. on a table
- ☐ Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned
- ☐ I can lift very light weights
- ☐ I cannot lift or carry anything at all

Section 4 – Walking*

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 1 mile
- ☐ Pain prevents me from walking more than 1/2 mile
- ☐ Pain prevents me from walking more than 100 yards
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5 – Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6 – Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7 – Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

Section 8 – Sex life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9 – Social life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests eg, sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10 – Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

SHORT FORM – 12 QUESTIONAIRE

1. In general, would you say your health is:
   _____ Excellent (1)
   _____ Very Good (2)
   _____ Good (3)
   _____ Fair (4)
   _____ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
   _____ Yes, Limited A Lot (1)
   _____ Yes, Limited A Little (2)
   _____ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
   _____ Yes, Limited A Lot (1)
   _____ Yes, Limited A Little (2)
   _____ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
   _____ Yes (1)
   _____ No (2)

5. Were limited in the KIND of work or other activities:
   _____ Yes (1)
   _____ No (2)

SF-12® Cont'd:

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
   _____ Yes (1)
   _____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:
   _____ Yes (1)
   _____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
   _____ Not At All (1)
   _____ A Little Bit (2)
   _____ Moderately (3)
   _____ Quite A Bit (4)
   _____ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
   _____ All of the Time (1)
   _____ Most of the Time (2)
   _____ A Good Bit of the Time (3)
   _____ Some of the Time (4)
   _____ A Little of the Time (5)
   _____ None of the Time (6)

SF-12® Cont'd:

10. Did you have a lot of energy?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)

11. Have you felt downhearted and blue?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)