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Research Article

Randomized Control Trial of Functional Outcome between Instrumented Posterior Lumbar Interbody Fusion and Posterolateral Fusion in Degenerative and Isthmic Adult Spondylolisthesis.

Dr. Venkatasubramanian.R[1], Manoharan, M[2], Venkatram, V[3], and Ramkumar, V[3]

[1]Assistant Professor, Department of Orthopaedics, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth, Pondicherry.India

Abstract: Spondylolisthesis is a spinal condition that affects the lumbosacral vertebrae. This disease causes one of the lower vertebrae to slip forward onto the bone directly beneath it. It's a painful condition but treatable in most cases. Although spondylolisthesis can be asymptomatic, patients with degenerative and isthmic spondylolisthesis typically present with low back pain, neurologic symptoms, and/or radicular symptoms. The surgical treatment of spondylolisthesis is indicated for cases of neurogenic claudication, intractable radicular pain, severe low-back pain, presence of neurological symptoms, failure of conservative management, radiological instability, progressive worsening of the listheses, Meyerding grade III and IV listhesis, and spondylosis. The ideal surgical treatment remains controversial. We have compared the functional outcome following instrumented posterior lumbar interbody fusion and posterolateral fusion for adult spondylolisthesis in our study. The prospective study was conducted in the Department of Orthopaedics. A total of 30 patients who satisfied both the inclusion and exclusion criteria and gave informed consent were recruited for the study from January to December 2019. The patients were randomized into two groups. Of 30 patients, Group 1(n=18) underwent Posterior lumbar interbody fusion and Group 2 (n=12) underwent Posterolateral fusion. Random number generators were used for allotting the patients to the specified group. Using Oswestry Disability Index, Japanese Orthopaedic Association Score and Visual Analog Score were used for pre-operative and post-operative functional scoring. The mean age among those who received PLIF was 53.67 years and among those who received PLF was 55.17 years. Spondylolisthesis at L4-L5 comprised 66.7% among those who received PLIF and 58.3 % among those who received PLF. Neurological deficit was present in 66.7% of the participants who had received PLIF and 100% of the participants who have received PLF. Concerning those who had received PLIF as treatment, 11 patients had excellent and 7 patients had better outcome in PLIF group, 7 patients had excellent and 5 patient had better outcome in PLF group.. The mean JOAS pre-intervention score was 6.66 and 6.40 for PLIF and PLF groups, respectively. In the 6th month mean JOAS score of the PLIF group was 11.16 and that of the PLF group was 10.16. The pre-intervention mean VAS score was 6.44 and 6.50 for PLIF and PLF groups, respectively. In both, the groups over the follow-up period mean VAS score had shown a decreasing trend. Our study did not show any significant difference in functional outcome between both groups, however there seems to better short term (3 months) and mid-term (6 months) pain relief in PLIF group when compared to PLF group. Long term follow-up studies along with radiological outcome may help in establishing superiority between both procedures.

Keywords: Posterolateral Instrumented Fusion, Posterolateral Fusion, Degenerative, Isthmic, Spondylolisthesis.

***Corresponding Author**

Dr.Venkatasubramanian.R , Assistant Professor, Department of Orthopaedics, Mahatma Gandhi Medical College and Research Institute, Sri Balaji Vidyapeeth, Pondicherry.India

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1. INTRODUCTION

Killianin 1857 coined the term Spondylolisthesis[1]. Spondylolisthesis is derived from the Greek word "spondylosis" (vertebra) and "olisthesis" (to slip and fall). Spondylolisthesis is defined as the forward slippage of a cephalad vertebra on a caudal vertebra. The term Spondylolysis is also derived from the Greek word "lysis" (loosening).Spondylolisthesis is present in 5% of the adult population with clinical evidence of low back pain[2]. Spondylolisthesis is the anterior displacement of one vertebra in relation to the next near lower vertebra, which can produce low back pain. Congenital, degenerative, traumatic, pathologic, and postoperative spondylolisthesis are all possible. Although spondylolisthesis can be symptom free, patients with isthmic spondylolisthesis frequently experience low back pain, neurologic symptoms, and/or nerve entrapment symptoms. They primarily affect the L3-S1 vertebral region. The lumbosacral intersection is frequently affected by isthmic spondylolisthesis. Spondylolisthesis most frequently impacts the lower lumbar spine, but it can also affect the cervical spine and, in rare cases, the thoracic spine. Degenerative spondylolisthesis primarily affects adults and is more common in women than men, with an elevated risk in the obese. Isthmic spondylolisthesis is more common in adolescents and young adults, but clinical signs may go unnoticed until adulthood. Males have a higher preponderance of isthmic spondylolisthesis. These patients are treated initially by conservative measures, failing which surgical intervention is mandatory. The majority of the patients with varying degrees of slip and disability ultimately require surgical intervention[3]. The extent of symptoms determines how isthmic spondylolisthesis is treated. Patients with somatic symptoms and mild spondylolisthesis have all been initially treated with non-surgical methods such as nonsteroidal anti-inflammatory drugs, physical therapy, and modification of pain-inducing activities, and rest for 1-2 weeks. These nonsurgical treatments, when taken in conjunction with anti-lordotic transverse reinforcement, can stand to gain in more than 75% of adults with grade I-II spondylolisthesis. Numerous studies prove that reduction of severe high-grade Spondylolisthesis is essential[4], whereas low-grade listhesis depending on the aetiology, can be managed by several methods like a posterior and posterolateral fusion in situ with or without instrumentation, posterior lumbar interbody fusion with or without instrumentation[5]. Surgeons believe reduction, posterior stabilization, and interbody fusion gives much better results. Pain control and quality of life are important outcome metrics for surgical intervention of spondylolisthesis from the patients' standpoint. Furthermore, the fusion rate and infection rate of the two strategies which may impact in such a way which procedure is suggested by the surgeon and staff. The majority of studies try comparing small groups and may lack the bio statistical ability to detect differences. In this study, we are trying to analyse the functional outcome following posterior lumbar interbody fusion in spondylolisthesis and compare it with the functional outcome following posterolateral fusion

1. MATERIALS AND METHODS

Study population

This study was conducted for one year and 6months from January 2019 - MAY 2020. Patients diagnosed with degenerative and isthmic adult spondylolisthesis. Patients diagnosed with degenerative and isthmic adult spondylolisthesis attending the Out-patient department or casualty services at our hospital and satisfying the inclusion and exclusion criteria will be the study subjects. The study was approved by the ethical committee (MGMCRI/IHEC/2018/ortho/12). The study was done in accordance with declaration of Helsinki.

Inclusion and exclusion criteria

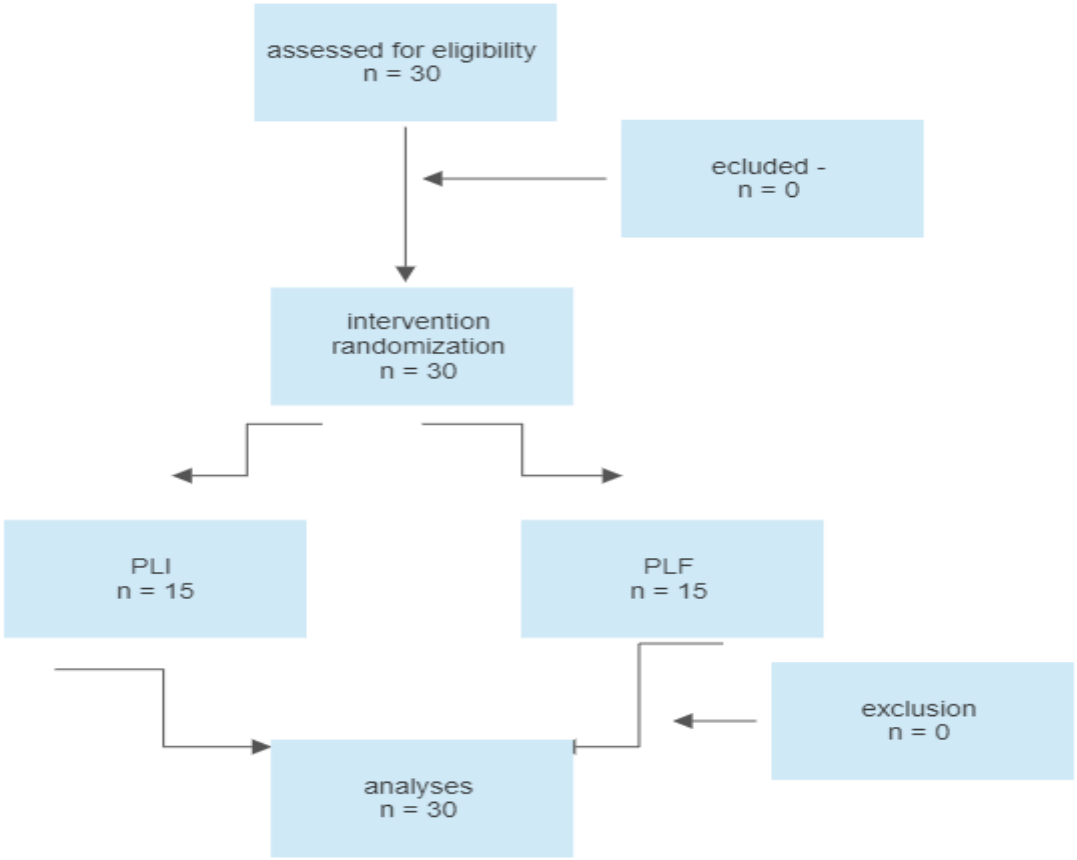
The patients presenting to the orthopedic department of the hospital willing for the study and with indication of either type of surgery – posterior lumbar interbody fusion or posterolateral fusion formed the inclusion criteria. The patients who were unwilling or with previous surgeries or with any other sensory motor deficits were excluded from the study.

Study design and randomization

The present study was an open-label randomized control trial. The patients was randomized into two groups. Of 30 patients. Group 1(18) underwent Posterior lumbar interbody fusion and Group 2(12) who underwent Posterolateral fusion. The random numbers were generated at the start of the study following which the patients have been recruited and numbered sequentially and allotted to their respective groups. From the patients diagnosed with adult spondylolisthesis and satisfying the inclusion and exclusion criteria, the following score have been obtained for pre-op and post -op functional outcome. 1)Oswestry Disability Index: The Oswestry Disability Index (also known as the Oswestry Low Back Pain Disability Questionnaire) is an extremely important tool that researchers and disability evaluators use to measure a patient's permanent functional disability.2) Japanese Orthopaedic Association Score. 3)Visual Analog Score: The visual analogue scale (VAS) is commonly used as the outcome measure for such studies.

2. STATISTICAL ANALYSIS

The quantitative data was entered in Microsoft Excel (2016) and analysed using Statistical Package for Social Sciences (SPSS). The data were presented in the form of numbers and percentages for qualitative variables and mean SD for quantitative variables. The dependent variables include the functional outcomes as assessed by the Oswestry Disability Index, the Japanese Orthopaedic Association Score, and the Visual Analog Scores.The student t test was used for parametric data and a p value of less than 0.05 was considered significant.



3. RESULTS

The mean age among those who received PLIF was 53.67 ± 9.84 years and among those who received PLF was 55.17 ± 8.31 years. Female comprised 92.2% among those who received PLIF and 16.7% among those who received PLF. Degeneration L4-L5 comprised 66.7% among those who received PLIF and 58.3 % among those who received PLF. Neurological deficit was present in 66.7% of the participants who had received PLIF and 100% of the participants who have received PLF.

3.1 Clinical outcomes

Concerning those who had received PLIF as treatment, 11 patients had excellent and 7 patients had better outcome in PLIF group, 7 patients had excellent and 5 patient had better outcome in PLF group.. The mean JOAS pre-intervention score was 6.66 and 6.40 for PLIF and PLF groups, respectively. In the 6th month mean JOAS score of the PLIF group was 11.16 and that of the PLF group was 10.16. The pre-intervention mean VAS score was 6.44 and 6.50 for PLIF and PLF groups, respectively. In both, the groups over the follow-up period mean VAS score had shown a decreasing trend. Our study did not show any significant difference in functional outcome between both groups, however there seems to better short term (3 months) and mid-term (6 months) pain relief in PLIF group when compared to PLF group. Long term follow-up studies along with radiological outcome may help in establishing superiority between both procedures.

3.2 Radiological outcomes

The radiological outcomes like decreased slippage are difficult to quantify. The next problem is any radiological improvement without clinical outcomes is not going to be beneficial. A combined and synchronized analyses of radiological and clinical outcomes were not part of our study

Table1: DI Index comparison between PLIF and PLF

ODI	PLIF	PLF	P value	5	41.7	
	N	%	N	%		0.725
Pre ODI	41-60%	10	55.6	7	58.3	0.880
	61-80%	6	33.3	3	25.0	
3 months	0-20%	3	16.7	0	0	0.233
	21-40%	9	50.0	9	75.0	
	41-60%	6	33.3	3	25.0	
6 months	0-20%	11	61.1	7	58.3	0.879
	21-40%	7	38.9	5	41.7	

Table11: Mean JOAS Score Among the Study Participants.					
JOAS	groups	Mean	SD	N	P value
Pre-intervention	PLIF	6.66	1.18	18	0.708
	PLF	6.50	1.16	12	
1st month	PLIF	8.33	1.28	18	0.177
	PLF	7.66	1.30	12	
3rd month	PLIF	9.83	1.38	18	0.094
	PLF	9.00	1.12	12	
6th month	PLIF	11.16	1.38	18	0.033
	PLF	10.16	0.83	12	

Table 12: Mean Vas Score Among the Study Participants Over the Follow Up Period.						
VAS	groups	mean	SD	N	T value	P value
Pre-intervention	PLIF	6.44	1.09	18	0.145	0.885
	PLF	6.50	0.91	12		
1st month	PLIF	5.44	1.14	18	1.580	0.125
	PLF	6.16	1.33	12		
3rd month	PLIF	3.88	1.07	18	2.112	0.044
	PLF	5.00	1.80	12		
6th month	PLIF	2.44	0.85	18	2.929	0.007
	PLF	3.66	1.43	12		

3.3 Pre-op and follow up xrays(PLIF)

48 year male

Degenerative spondylolisthesis L5 S1 Neurology- Intact
Procedure – PLIF

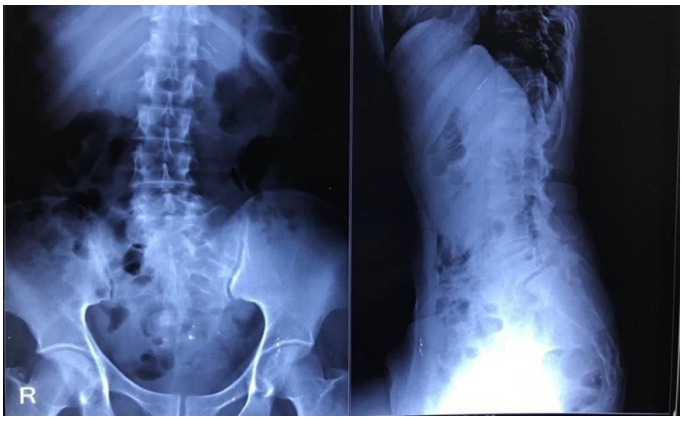
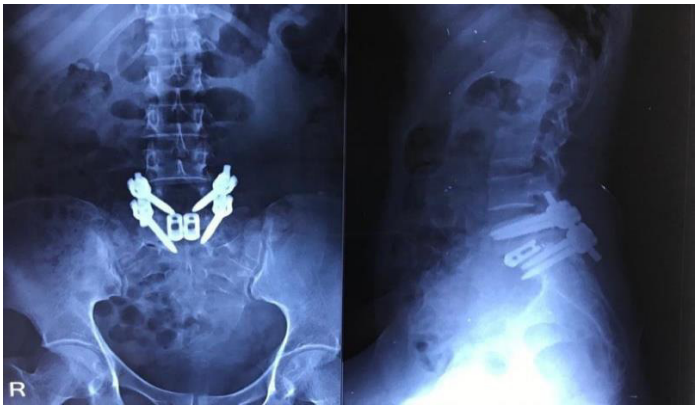


Fig 1 : Pre op Xray



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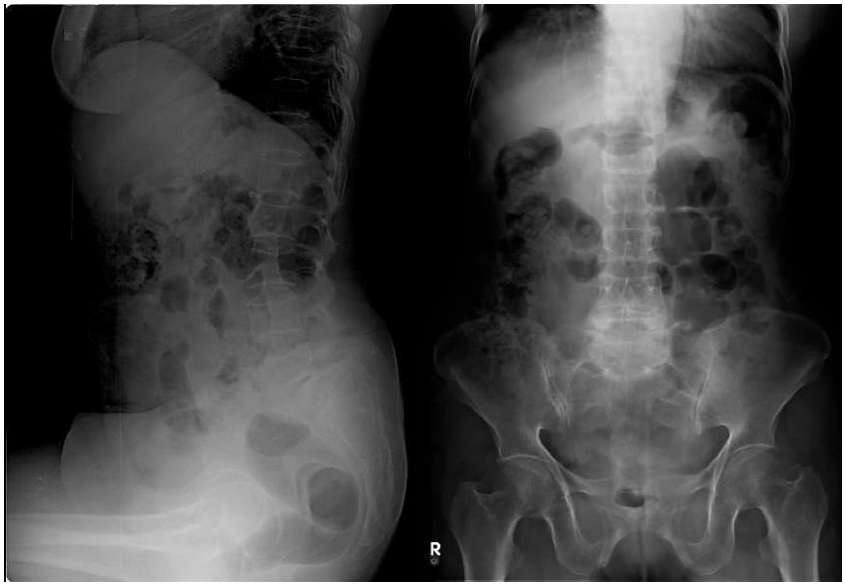
AP VIEW LATERAL VIEW

Fig 2 - 6th month post op X ray

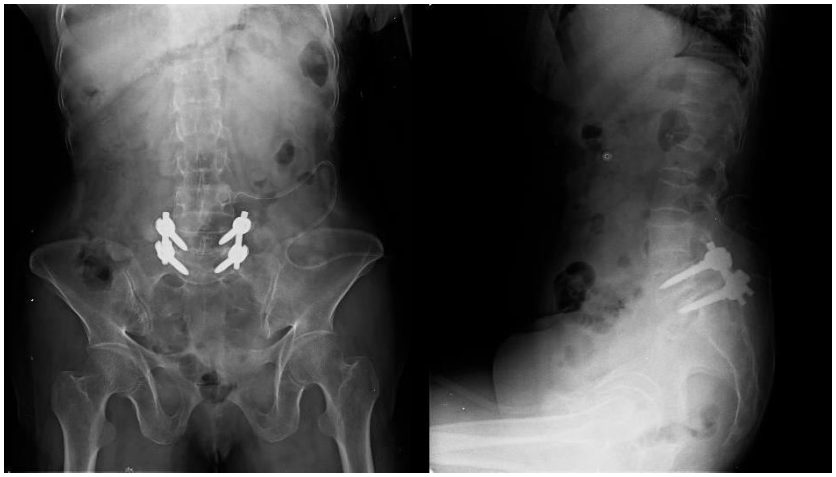
Case capsule : 56-year female- Degenerative Spondylolisthesis L4 L5 Neurology- Sensation decreased over L5 S1 Procedure – PLF

Fig 3 showing Functional status after 6th month



Lateral view AP view

Fig 4 - Pre-op X ray



AP VIEW LATERAL VIEW

Fig 5 - Immediate Post op X ray

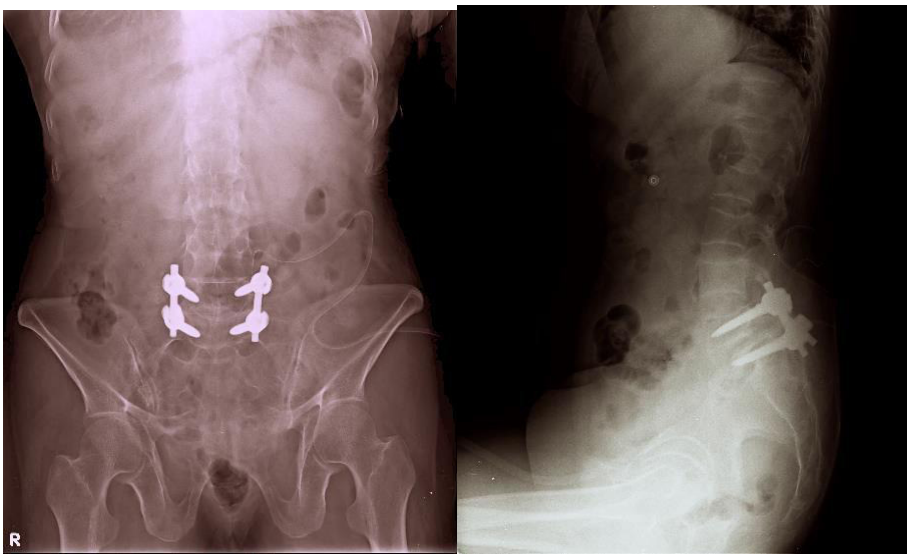


Fig 6 - 6th month post op X ray

Fig 7 showing Functional Outcome after 6 months

4. DISCUSSION

Symptomatic spondylolisthesis is often associated with backpain due to spinal instability and presents with varying degrees of neurological deficits. Treatment of choice in such a scenario is surgical stabilization and fusion of the unstable spinal segment. Various approaches are described for the same. However, no single approach has been described as the gold standard. This forms the basis of our research question. A literature search revealed 6 similar studies which shall be detailed in relation to our study in following discussion. In our study the mean age of patients in PLIF group was 52 years and in PLF group was 56 years. The mean age is higher in comparison to the existing studies as shown in table (14). The higher mean age in our study could be attributed to the predominance of degenerative spondylolisthesis (n=27) over Isthmic spondylolisthesis (n=3). In the studies which included both types of spondylolisthesis only Dantas et al reported a higher percentage of patients with degenerative spondylolisthesis[51]. Sharkawi et al and Cheng et al had a greater number of patients with Isthmic spondylolisthesis[52,53]. Female patients were much higher (n=23) in comparison with male patients (n=7) in our study. This is similar to the gender distribution in the studies done by Ekman et al, Musluman et al, Sharkawi et al and Dantas et al[54,55,52,51]. However, Cheng et al and Madan et al had a slightly higher proportion of males in their studies[53,56]. L4-L5 was the most common level involved in our study (63%) PLIF had 66.7% and PLF had 58.3%. This pattern of involvement is similar to Cheng et al (74%) and Madan et al (65.9%)[53,56]. Only Ekman et al reported a greater percentage of L5 slip (80%)[54]. 80% of our patients had some degree of neurological deficit prior to surgical intervention. Madan et al reported neurological deficit in 77% of their sample population[56]. Other studies reported neurological deficits ranging from 40-60% of their study sample. None of the other studies in scientific literature quantified the extent of neurological improvement in the form of an appropriate score. Ours was the only study which used a comprehensive scoring system in the form of Japanese Orthopedic Association Score (JOAS) to assess the neurological outcome post-operatively. Neurological recovery in our study was found to be marginally better in PLIF group. This was in contrast to the outcomes reported with respect to neurological recovery in similar studies where both PLIF and PLF had comparable results. VAS was used in our study to quantify the severity of pain pre-operatively and to assess improvement post operatively. Both PLIF and PLF groups showed improvement in postoperative VAS scoring but the extent of pain relief was significantly better in PLIF when compared to PLF. This difference was obvious even as early as 3rd month of follow up. Musluman et al also showed significant improvement in VAS scores in PLIF group[55]. In fact, this improvement was specific to back pain in their study. VAS scoring for leg pain did not show any significant difference between both groups. We did not distinguish back pain and leg pain in our VAS scoring. However, Cheng et al showed no statistical difference in VAS scoring at their final follow up at 4 years[53]. Oswestry disability were assessed preop, 1st month, 3rd month and 6thmonth. Eleven patients in PLIF group and seven patients in PLF had excellent outcome and seven patients in PLIF and Five patients in PLF group had better outcome. This difference between the two groups was not significant.. This is similar to studies done by cheng et al, Ekman et al and Dantas et al, where no significant difference in both groups[53,54,57]. Meta-analysis done by Yong-ping et al which included two RCT and two NRCT and one retrospective[58]. Conclusion from the analysis similar to our results, Pain relief is significantly better with PLIF. Functional outcome is similar in both approaches. See figures 1 – 7)Fusion rates(not assessed in our study) better with PLIF. They recommended separate scales for pain relief and functional outcome assessment in PLIF and PLF patients so as to correctly gauge their advantage and disadvantage over each other.

5. CONCLUSION

Short term follows up did not show any significant difference in functional outcome between both groups, however there seems to be better pain relief in PLIF group at the end of 6month.Larger sample study and longer follow up needed to estimate superiority of one approach over another in terms of radiological outcomes. However, from our study we recommend PLIF over PLF for its clear superiority in providing better short term and medium-term pain relief.

6. LIMITATIONS

Small sample size, Lack of radiological evaluation outcome in all cases due to short follow-up period and COVID pandemic interfering with the follow-up of older cases, Different surgeons operated, Pain in terms of back vs leg was not differentiated in follow up.

7. AUTHOR CONTRIBUTION STATEMENT

VeR data collection
VR – data collection
MM – supervision
VV – manuscript and communication

8. CONFLICT OF INTEREST

Conflict of interest declared none.

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