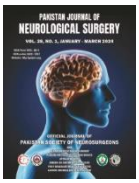

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Original Research

Comparison of Transpedicular Fixation with Fusion with Transpedicular Fixation Alone in Spondylolisthesis

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ABSTRACT

Objective: This research evaluated the clinical outcomes of two surgical methods used to treat degenerative lumbar spondylolisthesis in the short term. Fixation through the pedicles with or without inter-body fusion. Utilizing a spinal cage for first- and second-degree condition patients is one of the two methods being compared.

Materials & Methods: A total of 28 individual lumbosacral spondylolisthesis were incorporated in the research. Based on the surgical method and fixation technique employed for their care, they were split into two groups at random. Posterolateral intertransverse bone fusion, transpedicular screw fixation, and posterior lumbar decompression operations were performed on Group A. Conversely, Group B underwent posterolateral interbody fusion via the implantation of interbody cages, transpedicular screws, and posterior decompression.

Results: There existed no statistically significant association in terms of the two groups that is intraoperative and postoperative complications, clinical outcomes, and patient satisfaction, while noteworthy significance was observed about blood loss and rates of post-operative fusion.

Conclusion: Incorporating a spinal implant in conjunction with transverse body fusion results in superior fusion rates and post-operative clinical improvements, while intertransverse bony fusion alone yields comparable patient satisfaction with reduced surgical times.

Keywords: Fusion procedures, Lumbar Spine, Spondylolisthesis, Spinal fusion, Transpedicular fixation, Treatment outcome.

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INTRODUCTION

Since 1782, spondylolisthesis, a malfunction marked by the observable deformities in the lumbosacral region, vertebrae displacement, fractures, or irregularities in the pars interarticularis., has been recognized as a term used to describe the forward or backward slippage of a vertebral column concerning the segments below. Among the general population, the incidence of spondylolisthesis was 4-8% depending on several factors like age, gender, and race of the population.[1] Besides the postsurgical form, the most well-known categorization system classifies spondylolisthesis into four types i.e. 1) Isthmic, 2) Degenerative dysplastic, 3) Traumatic, and 4) Pathologic.[2]

Spondylolisthesis frequently occurs without any symptoms. Although the causes, ages, genders, and pathologies of the many varieties of spondylolisthesis vary, certain clinical symptoms are common among all types of spondylolisthesis, such as backache, pain radiating in nature, neuro claudication pain, certain deformities like kyphosis or scoliosis along with disturbance in gait.[3] "Meyerding grading system" slip degree. The upper part of the vertebra's anterior-posterior diameter is split into four sections: Less than twenty-five percent slide in Grade I, from twenty-five percent to fifty percent slip in Grade II, from fifty percent to seventy-five percent slip in Grade III, and more than seventy-five percent slip in Grade IV. Standing lateral radiographs are the most effective technique to assess slippage. The diagnosis and severity of spondylolisthesis are established using side-view X-rays of the spine. Dynamic radiographs can identify hidden movements, viewing as excessive extension and flexion. In recent years, MRI has proven useful in pinpointing the origins of radiculopathy.[4,5] It is often possible to treat isthmic spondylolisthesis conservatively. Surgery is recommended in situations when the condition is recalcitrant, and it involves a variety of neural decompression, fusion, and internal fixation procedures.[6] Surgeries are done to subside pain, overcome any neurological deficiency, and improve quality of life. Surgery decisions often consider a patient's work, sports or recreational activity, socioeconomic status, and other considerations in addition to the localized pathology's type, symptoms, and disability.[7]

The main objective of the research was to assess both the clinical and radiological effectiveness of the transpedicular fixation surgeries done for first and second-grade spondylolisthesis degenerative in nature either with interbody fusion through the lumbar cage or not.

MATERIAL AND METHODS

Study Design & Setting

This randomized trial was carried out at Khyber Teaching Hospital, Peshawar. RCT was registered with the Iranian clinical trial registry recognized by WHO. The registration number is IRCT20230907059376N3.

Inclusion Criteria

First and second-grade degenerative lumbar spondylolisthesis patients were included, who gave consent to participate in the study under ethical conditions.

Exclusion Criteria

Patients with additional lumbar spondylolisthesis types, third and fourth-grade degenerative spondylolisthesis, spondylolisthesis in conjunction with other spinal pathologies such as lumbar spine fracture and disc prolapse, and patients who responded well to nonsurgical or conservative treatment, were excluded from the study.

Surgical Procedure

Under general anesthesia, with preoperative

antibiotic prophylaxis, and while the patient lying on a spinal frame in such a position that the abdomen of the patient was free and the spine was curved to access the interlaminar gaps, the surgical procedure was performed. The surgical procedure is carried out as Alexander has stated.

Allocation of the Participants

A total of 28 sample sizes was selected for patients on the assumption that transpedicular fixation with interbody fusion has a 60% success rate in patients having degenerative spondylolisthesis.[8] Patients from several research centers were enrolled between November 2021 and December 2022. Patients were grouped based on the center and randomly assigned using a computer-generated permuted-block system. Allocations were kept in envelopes that were opaque, coded, and sealed by a data manager who was not engaged in the patient selection or allocation process. Following randomization, the prepared envelope was opened, the patient was told of the assigned intervention, and the necessary preparations were made for the assigned intervention. Blinding the patients to the treatment group was not possible.

Outcomes

Before surgery, the assessment process involved gathering medical history, doing a neurological exam, and determining the intensity of pain through two tools i.e. Oswestry Disability Index (ODI) along with Visual Analogue Score (VAS). Additionally, imaging examinations included dynamic plain X-ray, computed tomography (CT), and MRI.

The afflicted location, intraoperative blood loss, and method of fixation were all included in the surgical data. Following surgery, the presence of discomfort and any potential neurological impairment were evaluated. All intraoperative and postoperative complications were also recorded.

Data Collection Procedure

Data collection along with patient assessment both clinically as well as radiologically was done after surgery was done for the patient as well as after three months and one year of surgery.

Analysis

With the help of SPSS version 25, statistical analysis was carried out. While qualitative data were reported as total number and percent, descriptive statistics for quantitative data were written as the mean and SD. We used the Shapiro Walk test to determine whether continuous data were normal. An Independent T-test was done to compare the intensity of pain on the visual analog scale (VAS). The surgical results of the comparison between the two groups were conducted utilizing an unpaired Student's t-test. The chi-square test is employed to investigate the variations among categorical variables. P value <0.05 was considered significant.

RESULTS

From November 2021 and December 2022, a total of 48 surgical candidates were approached for this clinical trial, 10 candidates did not fulfill the criteria of inclusion, 10 candidates refused to take part in the study, and the remaining 28 candidates were randomized into two groups.

Characteristics at Baseline

14 patients were assigned randomly to group A, receiving transpedicular fixation surgery alone and 14 patients were assigned to group B, receiving transpedicular fixation combined with interbody fusion. Baseline measurements are mentioned in Table 1. Group A average age was 50.97±6.34 years. The average age of group B, however, was 52.33±5.73 years. Ten (71%) of the 14 patients in group A were female, whereas the others were all male. In contrast, group B included

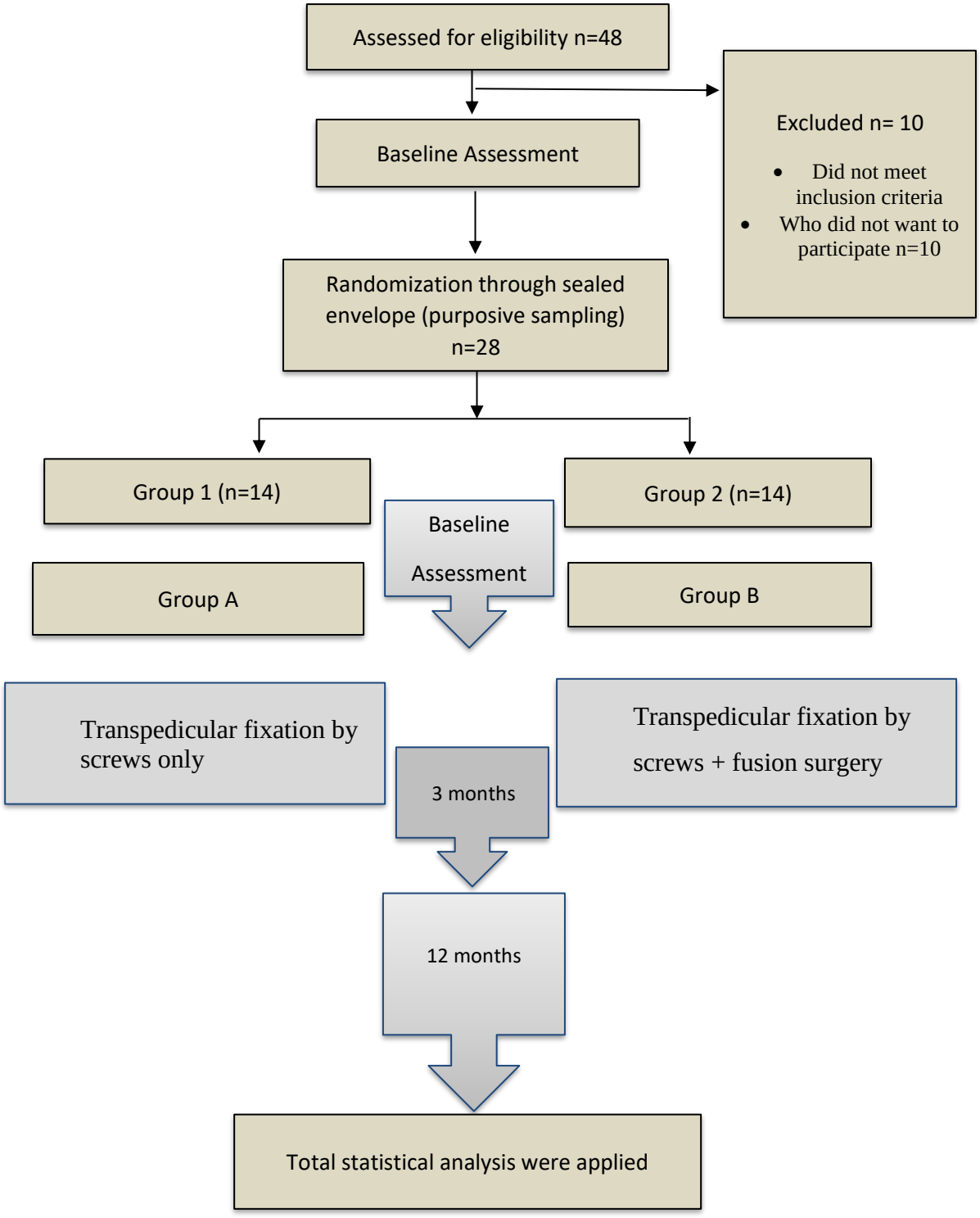

Figure 1: Consort Diagram.

8 (57%) female members, while the rest were male.

Effect on Pain and Disability Index

The average VAS (visual analog scale) for preoperative back pain in group A was 8.35,

identical to group B. The group A patients being investigated had a mean preoperative leg (VAS) of 6.3. The average results preoperative ODI of the examined participants was 71.3 in group A and 80.6 in group B. At three months after surgery, VAS and ODI both significantly decreased.

Complications after Surgery

The estimated blood loss in group A was 577.40 ± 93.26 cm^3, which was less than the 700.00 ± 91.21 cm^3 loss in group B. Regarding postoperative fusion rates, group A included a total of 14 patients, with 6 (43%) achieving grade II, 8 (57%) achieving grade III, and none achieving grade I. On the other hand, group B saw 4 (29%) receive a grade I and 10 (71%) report a grade III. Complication detail is mentioned in Table 2.

DISCUSSION

According to the study's findings, women made

Table 1: Characteristics at Baseline.

Variables	Transpedicular Fixation n=14	Transpedicular Fixation + Fusion n = 14	P value
Age (in years) Mean ± S.D	50.97 ±6.34	52.33 ±5.73	0.342
Gender			
Male	4 (29%)	6 (43%)	0.321
Female	10 (71%)	8 (57%)	
BMI	25.9 ± 5.7	26.1 ± 2.6	0.763
ODI baseline	71.30 ± 7.31	80.60 ± 7.27	0.004*
VAS baseline for back pain	8.35 ± 2.02	8.35 ± 1.02	0.112
VAS baseline for radicular pain	6.30 ± 0.60	5.65 ± 0.54	0.005*
Levels			
1 level	4 (29%)	6 (43%)	0.321
2 level	10 (71%)	8 (57%)	
Grade of Spondylolisthesis			
I	6 (43%)	6 (43%)	0.678
II	8 (57%)	8 (57%)	

*Significant association

Table 2: After Surgery Complains.

Variables	Transpedicular fixation n=14	Transpedicular fixation + fusion n=14	P value
Loss of blood cm3	577.40 ± 93.26	700.00 ± 91.21	<0.001*
Variation in VAS for back pain	5.25 ± 0.55	4.65 ± 0.79	0.003*
Variation in VAS for radicular pain	4.70 ± 0.41	4.05 ± 0.22	0.001*
ODI variation	41.70 ± 4.23	44.10 ± 3.67	0.223
Complication after surgery	1	4	
Tear of dura	1	2	0.323
Infection in wound	0	1	
Injury of root	0	1	
Fusion rate after surgery			
Grade1	0 (0%)	4 (29%)	0.001*
Grade2	6 (43%)	0 (0%)	
Grade3	8 (57%)	10 (71%)	

*Significant association

up the vast majority of participants. Ghogawala et al, found a female ratio of 68% and a male ratio of 32%, which is similar to the findings of our study.[9] Our study's mean age was 50.97 years for group A and 52.33 years for group B, which is younger than the average age of comparable studies with matching designs. Men's and women's mean ages were reported by Jacobsen et al. to be 68 and 71 respectively.[10] The intensity of pain on VAS for both groups in our study was 8.35. According to Kim et al., back pain was rated as a VAS 7, which is consistent with the results of our study.[11] Following up, there was no contrast in the two groups' improvement in the V.A.S for lower limb pain. This is consistent with the results of Liu et al, who found that the postoperative V.A.S ratings for the legs and lower spine did not differ significantly.[12]

In current research findings, we discovered a highly significant difference between the mean score done preoperatively for the Oswestry Disability Index (ODI) of the examined candidates in groups A and B of 71.3 and 80.6, respectively. This is a little bit more than the 65 findings from Delawi et al, Rezk et al's investigation, which showed the mean preoperative ODI 75, is consistent with this.[13,14]

In group B, we saw four issues: two dural rips, there was one instance of root injury and an occurrence of a deep wound infection. In group A, we found just one patient with a dural tear. Moussa AA et al. observed problems with TPIF in five persons (twenty-five percent) of these, 2 participants had CSF leaks, which accounted for forty percent of all complications, along with faulty screws, case shifting, and secondary myelomeningocele (each in a single incidence), all of which were documented.[15] Among the patients in group A, who took part in this trial, the average blood loss during operation was 577.40 milliliters. It was found that Group B contained 700 ml. The total blood loss during posterolateral fusion was 280 ml, compared to 450 ml during inter-body fusion, according to McAfee et al.[16]

In our observation, 43% of the patients achieved grade-II fusion, 57% of patients reached grade III, and none of the patients reached grade I. By comparison, group B patients obtained a grade I in 29% of cases and a grade III in 71% of cases. Similar to our findings, Rao et al. found that utilizing pedicle screws for fixation resulted in early stabilization and a greater rate of fusion following PLIF than using posterior-lateral nail fusion alone. They also found that interbody fusion was effective in upgrading the fusion rate.[17]

CONCLUSION

Utilizing a lumbar inter-body fixation in conjunction with posterolateral inter-transverse fusion has been shown to enhance fusion numbers, even though intertransverse bone fusion alone yields similar outcomes regarding patient satisfaction rate and post-operative good clinical results with shorter surgery timeframes.

RECOMMENDATIONS

Prolonged observatory studies are recommended to address the limitation of the current research, which only focuses on short-term outcomes. This approach would allow for a more comprehensive evaluation of both surgical procedures' sustained effectiveness and durability, providing insights into potential complications over an extended recovery period. Studies comparing efficacy should expand to include patients with varying degrees of spondylolisthesis severity and other demographic characteristics. Quality of life, pain ratings, and functional improvement are examples of patient-reported outcome measures that we may use to provide essential insights into the subjective experiences and satisfaction levels of patients undergoing either surgical technique. Cost-effectiveness studies of direct and indirect costs of rehabilitation and follow-up care are needed to obtain a comprehensive knowledge of

the economic consequences of each surgical procedure.

LIMITATIONS

The small sample size of 28 patients in the trial may limit the validity of the results, highlighting the need for larger sample sizes in further studies Again, short-term the strength of the study limits the ability to conclude long-term outcomes and potential conclusions. Because the study relies on a single-center design, which may introduce bias, a multicenter study with varying patient populations is recommended to improve external validity.

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Additional Information

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Human Subjects: Consent was obtained by all patients/participants in this study.

Conflicts of Interest: In compliance with the ICMJE uniform disclosure form, all authors declare the following:

Financial Relationships: All authors have declared that they have no financial relationships at present or within the previous three years with any organizations that might have an interest in the submitted work.

Other Relationships: All authors have declared that there are no other relationships or activities that could appear to have influenced the submitted work.

Data Sharing Statement: For data sharing, interested researchers can contact the corresponding authors.

AUTHORS CONTRIBUTIONS

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Muhammad Idris Khan	1. Study design and methodology.
2.	Adnan Munir	2. Paper writing, data collection, and calculations.
3.	Sajjad Ullah	4. Analysis of data and interpretation of results.
4.	Sajjad Ullah	5. Literature review and referencing.
5.	Farooq Sherzada	6. Editing and quality insurer.