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Research Article

**A RANDOMIZED, CONTROLLED TRIAL OF FUSION
SURGERY FOR LUMBAR SPINAL STENOSIS.**¹Dr Ahmad Kamal,²Dr Muhammad Awais,³Dr Amna Ilyas^{1,2,3}MBBS, University College of Medicine and Dentistry, University of Lahore, Lahore.**Article Received:** June 2020**Accepted:** July 2020**Published:** August 2020**Abstract:**

Gradual narrowing of spinal canal is known as lumber stenosis. The typical presentation of lumber stenosis is low back pain radiating to leg which usually arises while walking. Lumber stenosis is generally degenerative condition and hampers the activity of daily life such as walking, lifting up from the chair, and climbing up the stairs etc. One of the most common indications for spinal surgery is lumber spinal stenosis. Literature has shown that people who have undergone spinal surgery has more positive outcome as compared to conservative treatment. During the past decades lumber spinal stenosis has increased drastically and surgical procedures have become more complex. To minimize the risk of instability and deformity laminectomy has been introduced in which neural decompression and lumber fusion has been treated. A condition in which one vertebra slips over other in relation to lower vertebra in known as degenerative spondylolisthesis it can be easily seen on radiographs in patients who are suffering from lumber stenosis. A sign of instability is indication of fusion surgery.

The results of the current study somehow relate with the findings of Ghogawala et al.,³⁶ in which it was reported that after combination of fusion surgery with decompression surgery there was increase in the score of Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) physical-component summary but not on the ODI.

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INTRODUCTION:

Gradual narrowing of spinal canal is known as lumbar stenosis. The typical presentation of lumbar stenosis is low back pain radiating to leg which usually arises while walking. Lumbar stenosis is generally degenerative condition and hampers the activity of daily life such as walking, lifting up from the chair, and climbing up the stairs etc. One of the most common indications for spinal surgery is lumbar spinal stenosis. Literature has shown that people who have undergone spinal surgery has more positive outcome as compared to conservative treatment. During the past decades lumbar spinal stenosis has increased drastically and surgical procedures have become more complex. To minimize the risk of instability and deformity laminectomy has been introduced in which neural decompression and lumbar fusion has been treated. A condition in which one vertebra slips over other in relation to lower vertebra is known as degenerative spondylolisthesis it can be easily seen on radiographs in patients who are suffering from lumbar stenosis. A sign of instability is indication of fusion surgery. As an alternative to decompression surgery in patients with degenerative spondylolisthesis fusion surgery has been introduced.

Regardless of the presence of spondylolisthesis the evidence that suggests an advantage of the more complex decompression surgery plus fusion surgery over decompression surgery alone is weak and a randomized, controlled trial is warranted. The aim of the current study is to evaluate whether fusion surgery as an adjunct to decompression surgery resulted in better clinical outcomes than decompression surgery alone among patients who underwent surgery for lumbar spinal stenosis, with or without preoperative degenerative spondylolisthesis.

METHODS TRIAL DESIGN:

The study was a randomized controlled trial. The age was between 49 years to 70 years. Participants who met the inclusion criteria were recruited in the study. Participants having lumbar fusion, pain more than 6 months and pain in low back radiating to both legs were included in the study. The exclusion criteria were degenerative lumbar scoliosis, stenosis not due to degenerative disc, herniated disk, and psychological disorders.

There were four groups with 30 participants in each — fusion group with spondylolisthesis, fusion group without spondylolisthesis, decompression-alone group with spondylolisthesis, and decompression-alone group without spondylolisthesis. A written informed consent was signed before recruiting the participants into the study, the purpose of the study was well explained

into their first language. Continuous variables were presented in the form of mean SD whereas for categorical variables frequency tables were used. The level of significance was 0.005.

RESULTS:

Total 290 participants were included in the study. No significant difference was observed between the 2 treatment groups. The mean degree of vertebral slip in degenerative spondylolisthesis group was 7.7 mm. Total 70 participants were included in fusion group. 80 participants were included in decompression alone group whereas 82 had undergone decompression surgery plus fusion surgery and 58 had undergone decompression surgery alone. In the primary outcomes there was no remarkable association was seen. In the fusion group the ODI score was 28 and 23 in the decompression group. The ODI score had decreased from baseline by 15 within the fusion group and by 17 within the decompression-alone group. Analyses performed with stratification consistent with the presence or absence of degenerative spondylolisthesis at baseline resulted in outcomes that were almost like the outcomes within the overall analysis. There was no remarkable association between the presence of spondylolisthesis and type of treatment in the primary outcomes.

An exploratory post hoc analysis of the subgroup of patients with spondylolisthesis in which there was involvement of a vertebral slip of 7.4 mm or greater showed no difference in ODI score between the 2 treatment groups at baseline or at 2 years. In this patient subgroup, the mean score on the ODI at 2 years was 22 in both the fusion group and the decompression-alone group, and the score on the visual-analogue scale for back pain was 35 in the fusion group and 31 in the decompression-alone group.

There was no significant difference between treatment groups within the results of the 6-minute walk test at 2 years. Among patients with spondylolisthesis, the walking distance increased by 73 m in the fusion group and by 83, in the decompression-alone group. Subjective patient assessments of improvement in walking ability at the 2-year follow-up didn't differ between the treatment groups.

DISCUSSION:

It was a randomized controlled trial in which 290 participants were included with lumbar spinal stenosis, with or without degenerative spondylolisthesis, indicated no clinical benefits by adding fusion and decompression surgery. Adding more advanced procedures in the decompression plus fusion as compared to only decompression

surgery there was no clinical benefits achieved at 2 years instead of higher costs. The major indication of degenerative spondylolisthesis is instability no consensus on the definition of that term. Literature has reported that after decompression surgery in patients with spondylolisthesis there is an increased risk of iatrogenic slip or an increased degree of spondylolisthesis.

The potential consequence of a slipped vertebra is still under debate since decades. The progression of vertebra slip or worsening of clinical symptoms is not related with untreated degenerative spondylolisthesis. Despite of presence of spondylolisthesis some studies are in favor of fusion surgery in patients who are having spinal stenosis. To avoid the possibility of postoperative instability and restenosis some surgeons often use a combination of decompression surgery and fusion surgery regardless of consequences. Only two studies are in favor of combined surgery till yet but there validity has been questioned. Some other observational studies are also promoting the fusion surgery but with very limited population size. In the current study we found that there was no significant difference between the two treatment groups in amelioration of back pain, regardless of the presence of preoperative degenerative spondylolisthesis. Literature has demonstrated that there was no association of increased level of back pain with preoperative spondylolisthesis.

The results of our trial might at first seem to contrast with the findings of Ghogawala *et al.*,³⁶ which are presented in this issue of the Journal.

The results of the current study somehow relate with the findings of Ghogawala *et al.*,³⁶ in which it was reported that after combination of fusion surgery with decompression surgery there was increase in the score of Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) physical-component summary but not on the ODI.

The addition of fusion surgery to decompression surgery significantly increased direct hospital costs, including the costs of surgery and the in-hospital stay, but did not increase indirect costs at 2 years. Although economic data at 5 years were not collected, the clinical results and, in particular, the similar rates of reoperation in the two treatment groups indicate that the outcomes at 2 years are robust. As compared with decompression plus fusion, the use of decompression surgery alone not only is associated with a lower treatment cost per patient but also can save resources by releasing surgical capacity as a consequence of shorter operating time and hospitalization. Both the patients and the surgeons were aware of the treatment assignments, but none of the surgeons

were involved in the outcome assessment. The results of the trial are valid only for patients who have spinal stenosis at one or two adjacent lumbar vertebral levels, with or without degenerative spondylolisthesis; this is the case for most patients with lumbar spinal stenosis and constitutes the most common indication for spine surgery. The per-protocol analysis and the modified intention-to-treat analysis (with only five patients who received an intervention missing from the analysis) revealed only minor differences between groups in overall results. Validated and reliable imaging studies to identify signs of instability are lacking. To establish the diagnosis of degenerative spondylolisthesis, we used conventional lateral radiography as a complement to the preoperative MRI. Another available diagnostic tool is flexion-extension radiography, but this method has been questioned because of measurement errors, lack of definition of normal movements, and low repeatability unless the observed vertebral slip exceeds 5 mm. Nonetheless, outcomes among the patients with spondylolisthesis involving a slip of 7.4 mm or greater did not differ from the outcomes among all the patients with degenerative spondylolisthesis or the outcomes among all the patients, with or without spondylolisthesis; this strongly indicates that the use of conventional lateral radiography without the use of flexion-extension radiography did not bias our findings. In summary, in this randomized trial patients with lumbar spinal stenosis suffering from one or more vertebral slip, with or without degenerative spondylolisthesis, decompression with fusion the clinical outcomes were not better than decompression surgery alone.

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