The Long Term Outcomes of Spinal Fusion in Adult Isthmic Spondylolisthesis

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ABSTRACT

Objective: To evaluate the long-term outcomes of spinal fusion surgery for different spinal disorders, such as isthmic spondylolisthesis.

Methods: The 67 patients, ages 18 to 55, who had adult lumbar isthmic spondylolisthesis and had experienced significant back pain for at least a year, either without or with sciatica. A one-year exercise regimen, posterolateral fusion having instrumentation or having no pedicle screw instrumentation were allotted to the patients at random. The 91 percent of patients had long-term follow-up.

Results: Longitudinal analysis: In both surgery groups, pain and functional impairment were considerably reduced at long-term follow-up compared to before treatment. In every analysed variable, there were no discernible differences between patients who had instruments and those who did not. Although the functional impairment was not improved at all in the exercise group, the discomfort did. Long-term functional impairment in the surgery group was significantly higher than it had been at the 2-year follow-up, as determined by DRI but not ODI. Between long-term and 2-year follow-up, no notable changes were seen in the exercise group. Analysis: In the follow-up of long-term there is no significant differences in between surgical and conservative groups which were seen in any outcome measurement, with the exception of the global assessment and they are significantly better for the patients of surgery. Compared to 50% of the patients receiving conservative care, 76% of patients of surgery rated all the outcomes as better or much better ($p = 0.015$). In all eight of the analysed areas, and found no differences in the long-term the life-quality measured by SF-36, but it was still much worse than for the general population.

Conclusions: When lumbar isthmic spondylolisthesis affects adults, posterior fusion yields a marginally better outcomes of long-term than exercise of a year. Patients having fusion still rate the overall outcomes as superior clearly to patients who received conservative treatment, despite the outcomes indicating that few of previously documented short-term gain are lost with time. Furthermore, one might draw the conclusion that not at all appreciable impulsive enhancement should be anticipated with time in the adult patients having the isthmic spondylolisthesis due to the long-term outcomes of patients who received conservative treatment most likely mirror the normal course. For the majority of patients, significant functional incapacity, pain, and lowered quality of the life are likely to persist for many years.

Keywords: Lumbar, Patients, Spondylolisthesis, Fusion, Functional, Posterior.

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INTRODUCTION

Prior research from two randomized studies demonstrated that lumbar spine fusion outperformed conservative therapy in terms of short-term outcomes. In the first trial to report on effectiveness of the fusion of the lumbar spine (degenerative) and use as randomized control design, we have shown that the isthmic spondylolisthesis postero-lateral fusion led to markedly better outcome at the follow-up of 2-year which is compared with the exercise regimen.[1] In contrast to patients receiving conservative treatment, pain index measured using a VAS (visual analogue scale), decreased from the 63 to the 37 on average in surgical patients.[2] The same

findings were supported by the functional index DRI (Disability Rating Index). Similar to this, patients who underwent surgery had a clearly better overall assessment of their results, with 74% rating them as the good or the excellent compared to the 26% of patients who underwent the intensive exercise regimen.

The signs and symptoms of adult isthmic spondylolisthesis are similar to those of non-specific degenerative lumbar spine conditions, making it a verifiable model (radiologically) of the accelerated spinal deterioration.[3] The SLSS (Swedish Lumbar Spine Study), whose demonstrated short-term outcomes very similar in the non-specific back pain (degenerative) with enhanced outcomes in individuals with fusion which is compared with physiotherapy, corroborated the beneficial effects of fusion upon the low back pain.[4]

We discovered no difference in the result between 1 and 2 years, indicating a steady early position. However, between the 1- and 2-year follow-up in the SLSS, a substantial rise in the low back pain and propensity toward higher leg pain were noted. This prompts the query of what fusion's long-term impact will be. There has been substantial discussion regarding the potential for subsequent accelerated deterioration in the adjacent motor segments. However, it is debatable if this phenomenon exists and whether it has clinical significance.[5,6]

Except for prospective study with a 2-year and a 5-year follow-up without non-operated control participants, the only evidence available on long-term effects are retrospective studies with questionable scientific validity.[7–9] Between the second and the fifth year of follow-up, the study noted further enhancement in sub-group of patients with posterolaterally fused bones.[10] This, however, was not shown for the entire population of fused patients; rather, it was only shown for the subset of non-instrumented fusions.

As a result, although there is some data supporting fusion as a successful treatment for determined low back pain, the outcomes are not significant, and it is unknown if the improvement will last over time. The goal of the current study was to ascertain the quality of life (QOL) and global outcome (outcome) long-term effects of posterolateral lumbar spine fusion on pain and functional impairment.

PATIENTS AND METHODS

The outcomes of the long-term of same patient material are reported in the current investigation. In total, 67 patients who were between the ages of 18 and 55 and had lumbar isthmic spondylolisthesis of any grade, at least a year's worth of low back pain, either with or without sciatica, and significantly limited functional ability met the inclusion criteria.

Previous spine surgery, substance addiction, or just mild symptoms were prohibited. Low back discomfort, whether associated with sciatica or not, was the predominant complaint of all patients. Exercise, posterolateral fusion with and without the transpedicular fixation are randomly allocated to three groups of the patients. All of the patients were sent to the Khyber Teaching Hospital Peshawar's Orthopaedic and spine unit.

The method employed was randomization without stratification. The attending nurse at the outpatient ward randomly selected one of the three notes labelled with one of the three distinct treatment modalities for each patient. Each patient receives an equal chance in each therapy group thanks to the process. Only after the patient gave consent did the doctor and the patient learn what kind of treatment was being administered. The distribution of symptoms, age, grade and level of slip, and the lifestyle characteristics amongst groups was similar as a result of the randomization shown in Table 1.

Outcome Measurements

By using the VAS (pain index), the work status and DRI before the treatment, at follow-up of long-term, 1 year, and at 2 years, functional, and pain disability were measured. At long-term and two years follow-up, the patient completed the global assessment and classified findings as significantly better, better, unchanged, or worse. At long-term and two years follow-up, the ODI was attained. Only during the follow-up of long-term was SF-36 acquired. The questionnaires of SF-36 and ODI were included to the same surveys that were utilized at 1 and 2 years and mailed to the patients.

With anchor points of 0 for no pain and 100 for excruciating agony, pain was measured using two VAS scales: one for "pain right now" and one for "worst pain last week." The pain index was determined by averaging the two pain scores.

Table 1: Demographics, grade and level of the slip, symptoms, and the percentage of life-style factors (except sick-leave period and age), before the treatment.

All	Instrumented	Non-instrumented	Exercise
Mean age on onset of symptoms in (26 years)	29	25	25
Mean age (39 years)	39	39	37
Men (51)	43	55	56
Women (49)	57	45	44
Low back pain only and sciatica (62)	62	68	55
Sciatica only (7)	8	8	6
Low back pain only (31)	30	25	39
Levels L4 + L5 (3)	3	3	3
Level L4 (13)	14	15	9
Level L5 (85)	84	83	88
Grade (3) slip (2)	3	3	0
Grade (2) slip (38)	43	30	41
Grade (1) slip (60)	54	68	59
Before treatment mean sick leave (16)	14	15	18
Disability pension or sick leave (71)	84	68	62
Immigrants (32)	27	30	38
Medication except for back pain (21)	16	30	15
Married (74)	76	75	71
Blue collar (80)	75	90	73
Smokers (54)	57	63	41

DRI is a valid and reliable tool for disease-specific functional outcomes that includes 12 items of VAS, including dressing, going outside, sitting for an extended period of time, climbing stairs, bending over a sink, carrying a bag, making a bed, running, doing light work, doing heavy work, lifting objects, and engaging in sports or exercise[13]. The DRI is calculated using the average of the 12 functional VAS components. Oral instructions are followed while completing the form on your own. In the VAS, the patient rates their level of ability to carry out each task using anchor points on a scale of 0 to 100, with 100 being impossible.

The 10-item ordinal ODI scale, the validated tool (disease-specific) for the evaluation of the spinal diseases, with the six response options for each[14]. The overall score runs from zero to hundred, with 100 being the worst degree of disability. The categories include the pain severity, self-care, mobility (including the capacity to lift objects), sleep, sex life, social interaction, and travel. For each category, the severe disability is 5, whereas normal function is 0. The ODI (0-100) is calculated as the sum of the 10 components multiplied by 2.

The patients evaluated the overall results, categorising them as "better," "unchanged," "much better," or "worse." The state of the work was recorded. The questionnaire SF-36 has 36 questions divided into eight areas, was used to calculate QOL. These domains are: physical function, role physical, bodily pain, general health, social function, role emotional, mental health, and vitality. A profile of the results is shown.

A pain sketch was completed by each patient[16]. In the pain drawing, the sciatica was identified as the symbols of pain below knee. About 33 patients had only low back pain, 67 had low back pain and sciatica, and 8 had only sciatica, according the pain sketch. Three patients had no pain drawings done. Patients with sciatica in the surgery group underwent MRI or CT-myelography examinations to determine whether there was evidence of nerve root compression. No individuals had any radiographic evidence of central spinal stenosis or disc prolapse.

Statistical Method

According to Altman, the right sample size was determined to be able to spot any differences in outcomes that would be clinically significant[17]. The probability of the type I mistake had been setted to 5 percent. (Level of significance, 0.05). The error of type II was setted at 10 percent. The clinical difference of significance had established at 15, and

the DRI's standard deviation was 18, therefore a sample size of 30 people in each group was required.

For longitudinally comparisons within each group or for the paired data, the Wilcoxon signed the rank test, and comparisons between two groups, or non-parametric Mann-Whitney-U-test are utilized for the unpaired data, to analyze differences in between the DRI, ODI, pain index, and the SF-36. Using standard error of mean as basis, 95 percent confidence intervals are also provided in addition with nonparametric tests. The chi-square test was performed to compare the work ability and overall results of the groups. After collapsing the significantly improved and the better categories into one and the worse and unchanged categories into another cell, the overall result was evaluated. The four cells of the overall result were preserved when using the chi-square test for trend to compare treatments. The chi-square calculation included the Yates continuity correction. Statistics were judged significant at $P < 0.05$.

The Ethical Committee of Khyber Teaching Hospital Peshawar gave its approval to the study.

RESULTS

Cross-sectional analysis

There were no appreciable differences in between the patients of surgery having postero-lateral fusion without and with instrumentation at follow-up of long-term in terms of pain index, global evaluation, DRI, ODI, SF 36, or the ability of job shown in Table 2 and Table 3. In order to strengthen the study's design, surgical patients were assessed collectively.

11 patients (14%) in the surgical group underwent multiple lumbar spine operations due to the following conditions: removal of implants due to potential local irritation in 7 patients, the two injuries of the root of nerve in the instrumented fusions, the one discectomy and one pseudarthrosis. There were neither early nor late profound infections.

In the follow-up of long-term, there were no appreciable differences in pain index, ODI, DRI, or job ability between patients who underwent surgery (combined surgical group) and those who underwent conservative treatment (Table 4). Similar to this, no discernible changes between the surgical and conservative groups were found in any of the eight SF-36 areas.

Table 2: Proportion of patients at work, Mean pain index, ODI, and DRI.

Long-term	Instrumented	Non-instrumented	p
At-work	52%	50%	0.9
DRI	30	36	0.31
Pain index	36	45	0.27
ODI	27	30	0.79

The surgical group, however, fared far better in the overall evaluation. This held true both before and after the collapse of the better and much better in one, and the worse and unchanged into other cell where $p = 0.015$, as well as for the various categories that were examined as independent cells ($0.02 < p < 0.05$). (Table 5). The significantly better patients in the surgery group had significantly lower mean pain index, ODI, and DRI ratings than significantly better patients in group of exercise. Compared to the significantly better surgical and conservative groups, where the mean ratings for pain, DRI, and ODI were 18, 13, and 8 respectively, respectively. For pain and DRI, the differences were not statistically significant, but for ODI ($p = 0.078$), they were nearly so.

The conservative group have 9 patients who underwent surgery later has no appreciable variations in long-term outcomes from the conservative group as a whole. Additionally, the overall outcomes were unaffected by the exclusion from conservative group of these nine patients. Long-term follow-up revealed no significant changes, with the exception of overall result, from the surgical group. The follow-up time variation had no effect on the outcome.

Longitudinal Analysis

The Long-term follow-up following initiation of the study

Before the treatment to the follow-up of the long-term, the DRI mean in surgical group lowered from the 48 - 33 where $p < 0.001$, and the index of pain decreased from the 63 - 40 where $p < 0.0001$. In the surgery group, 25% of participants had jobs prior to the trial, compared to 51% after it had ended ($p < 0.0001$) shown in Table 4.

In the longitudinal study, there were no differences between patients who had been instrumented and those who had not; all scores rose in line with each other for both groups.

The pain index decreased from 65 to 49 in the conservative group while DRI mean went from the 44 - 38 where p = 0.13, improving non-significantly. Long term, there was an increase in the percentage of the patients who worked in conservative group, from the 38 – 46 percent (NS).

Table 3: Global outcomes in the non-instrumented and the instrumented group.

	Non-instrumented	Instrumented
Unchanged	22	9
Much better	44	33
Worse	12	9
Better	22	49

The follow-up of long-term and 2-year

The mean DRI of the group of surgery significantly worsted between the follow-up of the long-term and 2-years, going from the 29 - 33 where p = 0.049. The ODI and pain index both showed similar but non-significant marginal deteriorations shown in Table 4. Between the follow-ups of 2-year and the long-term, the overall assessment remained constant. Patients who were instrumented and those who weren't didn't vary in any way. Between the follow-up of the long- and short-term, all scores in group of conservation aside from ODI improved non-significantly. ODI goes from the 28 - 31 (NS), worsening shown in the Table 4.

DISCUSSION

The randomized study of long-term on the lumbar fusion that contrasted surgical with nonsurgical therapy. Patients who underwent surgery and had fusion performed better than the conservative group across the board at the average follow-up of the nine years. The 76 percent of the patients in the surgical group rated their outcomes as very good or the excellent compared to 50 percent in conservative group where p = 0.015. The changes were negligible and not statistically significant for the other examined factors. As a result, only the global outcome variable showed a significant long-term difference, as opposed to study of short-term of the same patient material, in which fusion was substantially superior to the treatment conservation for all of the variable quantity examined.[11]

Table 4: Percentage of patients at work, Mean value of DRI, ODI and pain index.

		Long-term	Pre-treatment	2-year	1-year	p
Exercise	At-work	46%	38%	55%	48%	n.s.
	ODI	31	-	28	-	0.887
	DRI	38	44	44	45	0.131
	Pain index	49	65	56	54	0.013
Surgery	At-work	51%	25%	54%	46%	<0.001
	ODI	28	-	26	-	0.223
	DRI	33	48	29	29	<0.0001
	Pain index	40	63	37	35	<0.0001

The decreased discrepancies between the groups were the combined result of the two trends in between follow-up of long- and short-term: conservative group showed a tiny improvement that was not significant, whereas the group of surgical showed a slight variation that was only significant for DRI.[12] The outcomes for group of exercise representing the natural course of the disorders of the lumbar spine due to exercise regime only one year lasted, and few of the patients are likely to have modified their regular habits of exercise after programme was discontinued. Despite a little spontaneous improvement over time in the conservative group's scores, it cannot be completely ruled out that these results merely represent the phenomena of "regression toward the mean." Due to the fact that persistent low back pain is a fluctuating illness and that all study participants were enrolled while their symptoms were at their worst, the group will generally do better over time during follow-up exams that are not scheduled in response to the degree of symptoms.

Even though 1 year of exercise accompanied by an average of 8 years without regular treatment significantly reduced pain (from VAS 64 to 49), there was still a great deal of disability and pain over the long-term, are evidenced by the fact that only the half of patients were able to work and had subpar QOL. According to the study's findings, symptomatic isthmic spondylolisthesis typically doesn't undergo

any significant alterations over the course of time. Therefore, it is unrealistic to assume that individuals with incapacitating low back pain who meet the criteria for fusion will have a gradual improvement of their symptoms over time.

Given that the radiologic follow-up has not yet been finished, the reason for the minor decline in the surgical group's result over time can only be hypothesised.[13] Several researchers have reported adjacent segment deterioration following lumbar fusion.[14–17]

Although the current findings do not support the idea that adjacent segment degeneration could have a negative impact on the outcome of fusion over the long term, such a possibility cannot be ruled out. It's possible that the adjacent segment-degeneration slowly lowers benefits of the fusion, and that the follow-up even longer will reveal that fused patients do worse than individuals who receive conservative treatment.

When isthmic spondylolisthesis in children under the age of 20 was examined between conservatively and surgically treated patients, the study found no difference degeneration in the neighboring segment 15 years after lumbar fusion on average.[18] However, the study observed twice as the high prevalence of the degenerative alterations at the levels above the prior operation when comparing fused and non-fused individuals surgically treated for the degenerative disc disease.[19] However, there was no distinction in the results between the groups. Similarly, the study found no association between the radiological state and symptoms and a significant frequency of instability of neighbouring segment (45 percent) on the average 33 years the following lumbar fusion.[20] The similar observation was also reported by in study, who found that over the course of the 10 years following the anterior lumbar interbody fusion of adult isthmic spondylolisthesis, degenerative alterations of adjacent segment occurred in more than the 50 percent of the patients without any association to clinical outcome. The issue is still debatable because no randomised controlled study has examined the issue of neighbouring segment degeneration following fusion and its potential therapeutic implications. It couldn't be ruled out that worsening of the symptoms in surgical group are result of declining effect of placebo, barring increased degenerative processes. Instead to the ratings for the pain, QOL, and disability measures, the overall outcome shows rather obvious variations between the groups. Specific to disease (DRI, ODI, and VAS) along with the QOL questionnaires may not have important disorder-related features, or these variables may not be change-sensitive. The difference in the groups was well-pronounced in the global outcome evaluation, which is where we discovered the similar tendency in our report of prior short-term using identical patient material. Global outcome was proposed as a measurement of crucial outcome in degenerative lumbar spine by a study after demonstrating how well it matches various validated outcome metrics.[21] We both believe that, if the study design is randomised, the global result could be the most significant outcome measurement. With the global result as the only end point, it does not appear to be viable to evaluate the treatment effects from nonrandomized research.

Table 5: Global outcome in exercise and surgical group.

	Exercise	**Surgery**
Unchanged	27	13
Much better	27	39
Worse	23	10
Better	23	37

In contrast to DRI and VAS-pain, one could anticipate that the more comprehensive questionnaires, such as the SF-36 and the ODI, which include various aspects of daily life, would more accurately represent overall results. However, in the current investigation, this was not the case.

The scores of SF-36 of patients who underwent both conservative and surgical treatment were notably lower than the average score for the typical Swedish population in each of the eight categories. Thus, neither long-term natural progression nor surgical intervention appears to restore normal QOL in the adult degenerative spine. We can only hypothesise as to why the global outcome is not expressed in the SF-36, but one apparent argument is of course that QOL may be an inadequate measure to capture the more nuanced variations between various treatments' impacts on individuals with low back pain.

The state of the economy as a whole affects employment status, in Sweden in early 2000s was fewer favourable with greater unemployment rates in mid-1990s. This made it challenging to interpret how things have changed over time. No differences in employment status were seen in short-term 2 years analysis; 46 and 45 percent of participants in conservative and surgical groups, respectively, were employed. Remarkably, this percentage remained

relatively consistent throughout time, with 51 percent and 46 percent of workers in each group. Even though only the surgical group's gain in work capacity relative to pretreatment was statistically significant, the study does not show any meaningful effects of lumbar fusion on work ability. But among surgical patients in the study of Swedish lumbar spine, the more patients returned to the workforce.[22]

We underline the importance of careful patient selection, yet numerous outcome measures only the demonstrated non-substantial differences when compared with normal course. It should be noted that patients in better group amongst the fused patients performed significantly better on the DRI, ODI, and pain tests than the similarly performing patients in group of conservation.

While this was not significant finding statistically, it is consistent with our clinical experience. This may be due to the small number of substantially better patients in the conservative group (n = 7). Patients who are fused are far more likely to be completely asymptomatic. According to numerous investigators, the difficulty for the surgeon is in choosing fusion candidates who will have such superior long-term outcomes. Sadly, there aren't many tools available to make such predictions today.

The study's main limitation is the small number of patients who underwent conservative treatment; this issue is made worse by the fact that 9 of the conservative group's 29 patients ultimately underwent fusion surgery. Of course, this might have an impact on the conservative group's outcomes. However, the outcomes were unaffected by whether these patients remained comprised in their initial group of treatment or not, in accordance with intention to principle of treat analytic. Additionally, results for these nine patients were not noticeably poorer than for clean conservative group's patients. By maintaining these nine fused patients in the conservative group that was analyzed using the intention to treat the principle was not "improved falsely," and one must draw the conclusion that source of the error does not overturn the findings.

The meagre patient material is yet another source of mistake. The minimum clinically significant difference for the study was determined to be the treatment difference of the 15-DRI which points back in late 1980s. Therefore, rather than highlighting potential tiny changes in outcome, the research study was created to discover the clinically undeniable differences in the effects of treatment. The calculated sample size for study with at least the 90 percent power at 5 percent level of significance was 30 people for each of the three groups. The power of the analysis is increased because all the analysis reveals no significant differences between the two groups of surgery. Along with the final follow-up of the 71 patients that were surgically treated and the 29 the conservatively managed patients, comparisons between surgical and conservative treatment have 95 percent power. When we only have twenty-patients in conservative group after excluding 9 patients in conservative group, the power will drop to the 89 percent.

Of course, it could legitimately favor that scores that differ by less than 15 points may have some significance for the patient, and power of current study might not enough to identify such of the smaller changes. As a result, there is a possibility that the study won't be able to show even slight variations between treatments because it only has a 70% power to detect differences of 10 points at the 5% level. When research study was planned, it is anticipated that prospective effects of treatment would be more pronounced as measured by pain and functional scores than what has actually happened. Since the fusion's effect on widely used measurements of outcome has recently been demonstrated to be somewhat negligible[1,3,8], bigger patient materials were needed if modest variations in the effects of the treatment are of the interest.

The majority of randomised controlled trial (RCT) studies found no difference in clinical outcome between lumbar spine fusions with and without instruments.[23] However, we discovered that both patients with and without instruments had a comparable long-term prognosis, which is consistent with earlier short-term trials. Although the cause of the disagreement between the two Scandinavian research studies is not known, the methodological considerations need caution when drawing conclusions from subgroup analysis, especially when the research's patient population is somewhat small, as it was in the Danish study. Furthermore, the primary Danish patient material, which is made up of mixed diagnoses, did not reveal any differences between instrumented and non-instrumented individuals. As a result, it is now possible to extend the earlier data that there are no benefits of the short-term of the instrumentation on the outcome of the two or one level of lumbar fusion to the long-term scenario. However, we couldn't find any proof that instrumentation had a bad long-term effect. Pedicle screws have been shown to negatively impact neighbouring level facet joints, while instrumentation

has been shown to negatively impact nearby segments by stiffening the fused area.[24]

There is a clear need for alternate therapy models given the exercise's and fusion's modest rates of improvement. Although there isn't enough proof to support them, disc prosthesis procedures have become more and more common in recent years. There is only a RCT on the surgery of disc replacement, and at 6 months, it did not demonstrate any superiority over fusion.[25]

CONCLUSION

In conclusion, fusion in the isthmic spondylolisthesis has limited but beneficial long-term effect due to the much better overall results of fused patients compared to those who underwent conservative treatment. But the study also demonstrates a little weakening of the fusion effect over time. Additionally, it is abundantly obvious from the results that instrumentation has no discernible good or negative impact on long-term outcomes. The study further demonstrates that natural course of symptomatic spondylolisthesis doesn't involve a spontaneous improvement but somewhat a long-term handicap that affects many aspects of life.

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