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Surgery *Versus* Conservative Management in Adult Isthmic Spondylolisthesis

A Prospective Randomized Study: Part 1

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Study Design. A prospective randomized study was performed.

Objective. To determine whether posterolateral fusion in patients with adult isthmic spondylolisthesis results in an improved outcome compared with an exercise program.

Summary of Background Data. In spondylolisthesis, satisfactory results have been reported with both surgical and conservative management. The evidence for treatment efficacy, however, is weak because prospective randomized studies are lacking.

Methods. In this study, 111 patients were randomly allocated to an exercise program (n = 34) or posterolateral fusion with or without transpedicular fixation (n = 77). The inclusion criteria were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability in individuals 18 to 55 years of age. Pain and functional disability were quantified before treatment and at 1- and 2-year follow-up assessments by visual analog scales (VAS).

Results. The 2-year follow-up rate was 93%. The functional outcome, as assessed by the Disability Rating Index and the pain reduction, was better in the surgically treated group than in the exercise group at both the 1- and 2-year follow-up assessments ($P < 0.01$). In the longitudinal analysis, the mean Disability Rating Index and pain improved in the surgical group ($P < 0.0001$). In the exercise group, the Disability Rating Index did not change at all, whereas the pain decreased slightly ($P < 0.02$).

Conclusions. Surgical management of adult isthmic spondylolisthesis improves function and relieves pain more efficiently than an exercise program. [Key words: exercise, functional outcome, isthmic spondylolisthesis, low back pain, physiotherapy, lumbar spinal fusion, prospective randomized clinical study] **Spine 2000;25:1711–1715**

The results from surgical management of spondylolisthesis usually have been reported as satisfactory and somewhat better than those for fusion in nonspecific low back pain, often referred to as degenerative disc disease.[3,5,8,10,11,12,16,20,22,24,25,28,31] Conservative management of spondylolisthesis includes bracing and physiotherapy. Good results have been reported with the use of a brace,[2,23] exercise programs,[6,15,21] and mixed conservative treatments.[13,17,20] However, the studies commonly have been retrospective with mixed material, limiting the validity of the conclusions. It has been shown that treatment outcome is highly influenced by the method used to measure it,[9] with better results for retrospective than prospective methods and for subjective than objective outcome measurements.[4,7,14,26] A control group of untreated, or conservatively treated patients is required because the most important symptom with the majority of spinal disorders is pain, which is subjective and difficult to quantify, and there is a tendency for spontaneous improvement with time.[29,30] In addition to this, surgery has strong placebo effects.[27] Thus, there are several reasons for considering a prospective randomized study design as a prerequisite for scientifically valid assessments of treatment efficacy in low back pain research.

The current study was designed to determine whether posterolateral fusion of isthmic spondylolisthesis results in an improved outcome as compared with an exercise program.

Patients and Methods

This article reports the clinical outcome for 111 patients with isthmic spondylolisthesis after randomized treatment to 1) posterolateral fusion *in situ*, 2) posterolateral fusion *in situ* with transpedicular Cotrel-Dubousset instrumentation (CDI), or (3) an exercise program. In this report, the outcome of surgical treatment with fusion (Treatments 1 and 2) was compared with that of an exercise program (Treatment 3). The patients all were referred to the spine units at Huddinge University Hospital (n = 81) and Linköping University Hospital (n = 30) with a radiographically verified diagnosis of spondylolisthesis.

The inclusion criteria were lumbar isthmic spondylolisthesis of any grade, at least 1 year of low back pain or sciatica, and a severely restricted functional ability in individuals 18 to 55 years of age. Patients with mild symptoms, previous spine surgery, or alcohol/drug abuse were excluded. The major problem reported by all patients was low back pain with or without sciatica. All patients completed a pain drawing. Sciatic pain was defined as pain symbols below the knee in the pain drawing. According to the pain drawing, 33 patients had only low back pain, 67 patients had low back pain and sciatica, and 8 patients had only sciatica. In three patients, the pain drawing was missing. Patients in the surgical group with sciatica were investigated with magnetic resonance imaging (MRI) or computed tomographic (CT) myelography, and the foraminal stenosis was documented. No patients showed any radiologic sign of disc prolapse or central spinal stenosis.

From 1990 through 1995, a total of 116 consecutive patients fulfilled the inclusion criteria. After 2 patients refused randomization, 80 patients were randomized to surgery and 34 to an exercise program. One patient randomized to fusion had surgery arranged at another hospital because of a long waiting time until surgery. Two further patients randomized to fusion improved spontaneously, so that at admission surgery was no longer considered to be

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Table 1. Demographics, Symptoms, Level and Grade of Slip, and Lifestyle Factors in Percentage (Except Age and Mean Sick Leave Period) Before Treatment in All 111 Patients With Adult Spondylolisthesis, According to Type of Randomized Treatment

	All (n = 111)	Surgery (n = 77)	Exercise (n = 34)
Mean age (yr)	39	39	37
Mean age at onset of symptoms (yr)	26	27	25
Women	49 (54)	51 (39)	44 (15)
Men	51 (57)	49 (38)	56 (19)
Low back pain only	31 (33)	27 (21)	39 (12)
Low back pain + sciatica	62 (67)	65 (50)	55 (17)
Sciatica only	7 (8)	8 (6)	6 (2)
L5 lysis	85 (94)	83 (64)	88 (30)
L4 lysis	13 (14)	14 (11)	9 (3)
L4 and L5	3 (3)	3 (2)	3 (1)
Grade 1 slip	60 (67)	61 (47)	59 (20)
Grade 2 slip	38 (42)	36 (28)	41 (14)
Grade 3 slip	2 (2)	3 (2)	0
Sick leave or disability pension	71 (79)	75 (58)	62 (21)
Mean sick leave before (months)	16	14	18
Blue collar	80 (87)	83 (63)	73 (24)
Immigrants	32 (35)	29 (22)	38 (13)
Married	74 (82)	75 (58)	71 (24)
Smokers	54 (60)	60 (46)	41 (14)
Medication for conditions other than back pain	21 (23)	23 (18)	15 (5)

Observed numbers in parentheses.

indicated. These five patients were excluded from the study. Therefore, 111 patients were entered into the study. Three patients randomized to the exercise program worsened during the first year of treatment to such an extent that it was considered ethically not correct to continue conservative treatment. These three patients underwent surgery and were excluded from the study. Two patients in the surgical group did not show up for follow-up assessment at 2 years. One of them had a second surgical procedure at another hospital because of pseudarthrosis, and the other refused further visits to the hospital. Therefore, of 114 randomized patients, final 2-year outcome data were available from 106 (93%).

The 111 patients (54 women and 57 men) who entered the study had a mean age of 39 years (range, 18–55 years). The slip was at L5 in 94 patients, L4 in 14 patients and both L4 and L5 in 3 patients. There were 67 patients with a Grade 1 slip, 42 patients with a Grade 2 slip, and 2 patients with a Grade 3 slip (Table 1).

All 77 patients who underwent surgery had a posterolateral fusion *in situ* with autologous bone transplantation harvested from the right iliac crest. No instrumentation was used in 40 patients and rigid pedicle screw fixation (CDI) in 37 patients. The noninstrumented group wore a daytime lumbar brace for 6 months after surgery. The patients who underwent surgery did not receive a postoperative exercise program.

The 34 patients randomized to the exercise program were referred to a physiotherapist with a special interest in spondylolisthesis. The exercise program was based on strength and postural training, with the emphasis on back and abdominal muscle exercises. Twelve different exercises were performed. To allow for exercises at home, 8 of the 12 exercises did not include specific training equipment. Four exercises included a pully machine and a leg press machine. The patients exercised three times a week the first 6 months, and twice a week between 6 and 12 months. The exercise program was supervised by the physiotherapist and required approximately 45 minutes.

After 1 year, the patients were instructed to continue with a home program, which consisted of the eight exercises that did not need special equipment. Two thirds of the patients complied with the full program during the first year. After the first year, it is not known to what extent the patients continued with the recommended exercises.

All patients completed a questionnaire concerning their symptoms, functional disability, and pain before treatment, then at the 1- and 2-year follow-up assessments. Functional disability was quantified by the Disability Rating Index (DRI), which is composed of 12 functional visual analog scales (VAS) that assess dressing, outdoor walking, climbing stairs, sitting for a longer time, standing bent over a sink, carrying a bag, making a bed, running, light work, heavy work, lifting heavy objects, and participation in exercise/sports.[19] The mean of the 12 functional visual analog scales provides the DRI. The form is self-administered according to oral instructions. On the VAS, the patient marks on a 100-mm scale his or her ability to perform the respective activity using anchor points 0 (without difficulty) to 100 (impossible). Pain was quantified as "pain right now" by one VAS and as "worst pain last week" by another VAS, using anchor points 0 (no pain) to 100 (intolerable pain). The mean of the two pain visual analog scales provides the pain index.

In addition to the DRI and pain scales, the observer and the patients classified the overall outcome into "much better," "better," "unchanged," or "worse." The patient also answered the question: "Would you go through the treatment again now that you know the result?" and the working status was documented.

At follow-up evaluation, the patient was not seen by the operating surgeon, but by an independent orthopedic surgeon, the main surgeon's assistant, or the physiotherapist leading the exercise program. Some patients who underwent surgery were seen at follow-up evaluation by the physiotherapist, whereas other patients who received the exercise program were at seen at follow-up assessment by a surgeon to avoid bias.

Randomization Procedure. Randomization without stratification was used. For each patient, three different notes were each marked with one of the three different treatment methods, and one note was blindly chosen by the attending nurse in the outpatient ward. This procedure gave each patient the same chance to become part of each treatment group. The type of treatment was unknown to the patient and the physician until after the patient had given consent. The randomization resulted in a similar distribution of age, symptoms, level and grade of slip, and lifestyle factors between the two groups (Table 1).

Statistical Methods. The sample size sufficient to detect a clinically relevant difference in functional outcome, if it existed, was calculated according to Altman.[1] The risk of a Type 1 error was set at 5% (significance level, 0.05). A Type 2 error risk was set at 10% (90% power). The standard deviation of the DRI was 18, and the clinical difference of relevance was set at 15, resulting in a necessary sample size of 30 in each group.

To test for differences between variables based on VAS, the nonparametric Mann Whitney *U* test was used for unpaired data (*i.e.,* comparisons between the two groups), and the Wilcoxon signed-rank test was used for paired data (*i.e.,* comparisons within each group). In addition to the nonparametric tests, 95% confidence intervals, based on the standard error of the mean, also were given. The χ^2 test or Fisher's exact test was used to determine differences in the distribution of symptoms between groups. McNemar's test was used to compare the proportion of individuals at

Table 2. Mean Values of Disability Rating Index and Pain Index Before Treatment and at 1- and 2-Year Follow-Up Assessments for the Surgical Group and the Exercise Group

	Before (n = 106)	1 Yr (n = 98)	2 Yr (n = 106)	*P*
Surgery				
DRI	48 (43.9–52.3)	29 (23.0–34.6)	29 (23.5–34.9)	<0.0001
Pain index	63 (58.5–67.7)	35 (28.7–42.2)	37 (29.6–43.8)	<0.0001
Exercise				
DRI	44 (38.2–50.3)	45 (36.4–53.7)	44 (36.5–50.9)	0.53
Pain index	65 (57.3–71.9)	54 (44.7–63.7)	56 (48.7–63.8)	0.024

CI = confidence interval, DRI = Disability Rating Index.
The worst possible status is 100, and the best possible status is 0. The *P* value refers to the comparison between the pretreatment score and the score at 2-year follow-up assessment in each group.
95% CI in parentheses.

work before and after treatment in each group. The χ^2 test for trend was used to compare ordered categories such as overall outcome. The Yates continuity correction was used in the χ^2 analysis. All *P* values less than 0.05 were considered statistically significant. The study was approved by the Medical Ethical Committee of Huddinge University Hospital.

■ Results

The surgically treated group reported a significantly lower DRI ($P = 0.004$) and pain index ($P = 0.002$) at the 2-year follow-up assessment than the exercise group (Table 2). At the 2-year follow-up assessment, 11 of the 12 functional scores were significantly better in the surgical group than in the exercise group. The score for running was the only score that was not significantly lower in the surgical group (44) than in the exercise group (55) ($P = 0.13$). Among all 106 patients that completed the 2-year follow-up assessment, 34 of the 37 patients with a DRI lower than 20, and 28 of the 29 patients with a pain index lower than 20 were treated surgically.

In the longitudinal analysis, the pain index and DRI before treatment and at the 2-year follow-up assessment were compared (Table 2). The mean DRI improved from 48 (range, 7–83) to 29 (range, 0–79) in the surgical group ($P < 0.0001$), but remained unchanged in the exercise group, which had a DRI of 44 (range, 6–75) before treatment and 44 (range, 15–84) at the 2-year follow-up evaluation. The mean pain index improved in both groups, from 63 (range, 10–98) to 37 (range, 0–96) in the surgical group ($P < 0.0001$), and from 65 (range, 32–96) to 56 (range, 17–87) in the exercise group ($P = 0.024$).

In the surgical group, 75% of the patients were on sick leave or disability pension before treatment, as compared with 46% at the 2-year follow-up assessment ($P < 0.0001$). The decrease was less in the exercise group, with 61% not working before treatment compared with 45% at the 2-year follow-up assessment ($P = 0.23$). However, there was no significant difference in the proportion of individuals working in the two treatment groups at the 2-year follow-up assessment.

Both the patient and the observer rated the overall outcome at follow-up evaluation significantly better for the surgical group ($P < 0.01$) (Table 3). To the question, "Would you go through the treatment again now that you know the result?" 78% answered "yes" in the surgical group as compared with 67% in the exercise group ($P = 0.43$).

Table 3. Overall Outcome in the Surgical and Exercise Groups at Minimum 2-Year Follow-Up Assessment Classified by the Patients and Observers

	Surgery		Exercise	
	Patients (%)	Observers (%)	Patients (%)	Observers (%)
Much better	55	56	13	9
Better	19	17	30	14
Unchanged	11	24	35	64
Worse	15	4	22	14

In the surgical group, three major operative complications occurred. In 2 of the 37 patients who underwent surgery with transpedicular fixation, an L5 root injury occurred with permanent sequelae. Dermatomal pain developed in both patients, and one experienced permanent extension weakness of the foot. One noninstrumented patient became permanently blind in one eye. No complications occurred in the exercise group.

A worst case analysis was performed. At the 2-year follow-up assessment, the two patients who dropped out of the surgical group leaving no outcome data were assigned the most pessimistic outcome: the highest possible DRI (100) and pain index (100). This resulted in a mean DRI of 31 in the surgical group as compared with 44 in the exercise group ($P = 0.010$). The mean pain index increased to 38 in the surgical group as compared with 56 observed in the exercise group ($P = 0.004$).

■ Discussion

The current study shows that the outcome of adult isthmic spondylolisthesis is better with posterolateral fusion *in situ* than with an exercise program. The results of the study are in agreement with those of previous studies, which have shown a satisfactory clinical outcome from both anterior and posterolateral fusion in spondylolisthesis, with an average "excellent or good" outcome rate of 77%.[28] There are no controlled studies comparing surgical treatment with conservative treatment, so the natural history, regression to the mean, and the profound placebo effect of surgery have not been controlled previously.[27,29,30] The lack of scientifically solid evidence resulted in the recommendation by the Quebec Task Force on Spinal Disorders in 1987 that surgery was contraindicated in low back pain without confirmed nerve root compression.[18] The current randomized controlled study shows, for the first time, that low back pain can be treated successfully by fusion.

All outcome variables studied were better in the surgical group than in the exercise group at the follow-up evaluation. The differences between the groups were

significant for pain, functional disability, and overall outcome, but not for working ability. However, only the surgical group showed a significant increase in the number of working individuals. Therefore, both the subjective data (pain, DRI) and the objective outcome data (work status) uniformly show a better result with surgery than with the exercise program.

One variable, however, did not show a significant difference between the types of treatment: the question "Would you go through the treatment again now that you know the result?" This question was answered affirmatively by a similar proportion of patients in both groups. The reason for this similarity presumably has a psychological background. In retrospect, individuals going through substantial treatment and receiving positive attention from caregivers are more likely to look on their own efforts and those of their caregivers as worthwhile, justifying their decision to take part in the treatment program. The similar results between the groups reflect the drawback of retrospective analysis in general. The fact that despite the poor outcome of the exercise group, two thirds of the patients would "go through the same treatment again knowing the result" strongly suggests that such questions are not valid in analysis of treatment efficiency.

In contrast to the current study, previous retrospective studies have reported good results from conservative treatment of spondylolisthesis, notably, however, in adolescents and young adults.[2,6,13,17,21,23] Perhaps the exercise program in the current study did not produce similar results because the patients were older and had longer periods of disability. Therefore, the natural history of these patients was not as good.

The best results of conservative treatment have been reported in patients with acute onset of pain and spondylolysis. In these patients, the lysis probably have a potential for healing. Steiner and Micheli[23] reported excellent or good results at 78% with the use of a modified Boston brace in patients with a mean age of 16 years. Similarly, Blanda et al[2] reported excellent results from brace treatment of spondylolysis, but not spondylolisthesis.

In the current study, we cannot exclude a suboptimal exercise program was performed. In a controlled randomized study of 44 patients with spondylolisthesis, O'Sullivan et al[15] recently reported good results in patients treated with specially designed exercise training, although the dropout rate in that study was high. A possible, but unlikely, explanation for the observed better outcome after surgery also may maintain that exercise prevents spontaneous improvement. However, the fact that the results in the exercise group did not change after one further year of less frequent, unsupervised exercises rather suggests that exercises do not affect the disorder over the long-term, either positively or negatively. The placebo effect of both surgical and nonsurgical treatment are well known.[27] In this study, the exercise group received more attention than the surgical group, suggesting placebo effects of the same magnitude in the two groups, particularly at the 2-year follow-up assessment.

Differences in questionnaire design significantly influence the results of outcome studies.[9] A wide variety of assessment methods are available for measuring functional disability in patients with back pain. In this study, VAS was used for quantification of pain and functional disability. The Disability Rating Index has been shown to have a high reliability as well as a good compliance and discriminative power between different diagnostic categories, with sensitivity for small changes.[19] The DRI has been validated for patients with neck/shoulder pain, arthritis of hip and knee, and low back pain. Comparisons over time in the same individuals may be difficult because the VAS reflects relative rather than absolute disability. However, comparison between randomized groups is not invalidated by this shortcoming. Data based on VAS are in general, but not always, analyzed by nonparametric methods.[26] In this study, the same result was obtained by the nonparametric approach (Mann-Whitney) and a parametric approach (confidence intervals based on standard error of the mean).

Few patients were lost to follow-up evaluation, as compared with most previous studies, and the number of dropouts (5) does not invalidate the conclusions drawn. Furthermore, because patients who spontaneously improved before surgery were lost from the surgical group, and because three patients in the exercise group were lost as a result of deteriorating symptoms during treatment, the conclusions from the study are rather strengthened. In addition, even a worst case analysis confirms the results showing a significantly better result for the surgical than for the exercise group.

In conclusion, posterolateral fusion can now be considered a method, documented by evidence-based medicine standards, that reduces pain and functional disability in adult isthmic spondylolisthesis.

■ Key Points

- This prospective randomized study compares conservative and surgical treatment in 111 patients with isthmic spondylolisthesis.
- Using a scientifically valid method, it has now been shown, for the first, that fusion improves low back pain with or without sciatica in adult isthmic spondylolisthesis.

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