EVALUATION OF POSTERIOR SPINAL FUSION WITH PEDICLE SCREWS AND RODS WITH BONE SUBSTITUTES IN GRADE I AND II SPONDYLOLISTHESIS

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ABSTRACT

BACKGROUND

Low-back pain is the commonest condition encountered day in and day out of an orthopaedic practice. Incidence of spondylolisthesis in normal population is around 5-7%. No matter what the aetiology is, patient has significant functional disability.

OBJECTIVES

To study the efficacy of pedicular screw rod system and posterolateral fusion with bone substitutes in spondylolisthesis, and to study the complications associated with this treatment modality.

METHODOLOGY

From July 2012 to September 2014, a total of 30 patients operated with posterolateral fusion were followed up and evaluated based on VAS for low back pain and Japanese orthopaedic association scoring system.

RESULTS

The mean difference between pre-operative and post-operative VAS score is 3SD with a p value of <0.001, which is strongly significant. The pre-operative and post-operative JOA score has an improvement of 73.4% with a p value of <0.001, which is strongly significant. Rate of improvement was excellent in 16.7%, good in 53.3%, fair in 23.3% and poor in 6.3% of patients; 82% of patients had bone fusion by the end of 8 months.

CONCLUSION

Pedicular screw rod system with postero-lumbar fusion with bone substitute is safe, promising and appealing technique for low-grade spondylolisthesis with early post-operative pain relief.

KEYWORDS

Spinal Fusion, Bone Substitutes, Grade I and II, Spondylolisthesis.

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INTRODUCTION.1,2

Spondylolisthesis is derived from the Greek words-Spondylos (Vertebra) and Olisthanein (To slip or fall). This most commonly describes the forward slippage of a cephalad vertebra on a caudal vertebra. Two processes-acquired and congenital-can give rise to spondylolisthesis. The acquired pathway is initiated by repetitive loading. The congenital pathway is initiated by a congenital defect in the bony hook or its process of cephalad vertebra. The symptoms associated with spondylolisthesis are caused by chronic muscle spasm as the body attempts to limit motion around a painful pseudoarthrosis of the pars interarticularis. Pain may also derive directly from impingement of the fibrous pars nonunion, as nerve endings have been identified there. Plain anterior-posterior and lateral roentgenograms document the amount of vertebral subluxation, they also reveal a pars interarticularis defect if one is present; oblique views have been used to highlight the Scottish Terrier-dog sign.

Financial or Other, Competing Interest: None. Submission 09-03-2016, Peer Review 09-04-2016, Acceptance 14-04-2016, Published 30-04-2016. Corresponding Author: Dr. Chaitanya Reddy Chintham, #1-241/195, Road No. 6N, Bhavani Nagar, Opp. Radhika Theater, ECIL 'X' Roads, Hyderabad-500062. E-mail: drccreddy@gmail.com DOI: 10.14260/jemds/2016/472 Flexion and Extension (Stress Views) can be taken to show excessive movement across the site of pseudoarthrosis in the pars interarticularis and subluxation of the vertebral body as the patient moves from flexion to extension. The Meyerding classification.³ is based on the amount of anterior subluxation of the cephalad vertebra in relation to the caudal vertebra. The slippage is graded as the percentage relative to the sagittal diameter of the inferior body. Laurent and Einola measured the anterior slip as the width of the listhesis body, while Tillard described the forward displacement of L5 as a percentage of the maximum antero–posterior diameter of S1.

Grade I:	0 – 25%.
Grade II:	25 – 50%.
Grade III:	50 – 75%.
Grade IV:	75 – 100%.
Grade V:	100% – Spondyloptosis.

Management of Spondylolisthesis.4,5,6

A trial of non-operative treatment is indicated for any spondylosis or spondylolisthesis patient who presents with no neurological compromise or with a stable chronic deficit. Therapies are aimed at relief of symptoms in short term, as symptoms tend to run a course of acute exacerbation followed by remission. NSAIDS or muscle relaxants with or without physiotherapy.

Trial period of external spinal immobilization has long been considered a screening test for evaluating patients preoperatively for potential benefits of surgical fusion (Orthotic Devices, Body Casts, Percutaneously Placed External Fixator Devices). Corticosteroids and long acting local anaesthetic agents are of value when injected into facet joints or epidural space; 10% to 20% of patients will require surgical treatment for relief of radiculopathy and back pain. The results of fusion for back pain caused by instability in spondylolisthesis are better than the results obtained from fusion for degenerative disease and prior discectomy or for failed back syndrome.

Although spondylolisthesis is relatively common, surgical treatment is rarely undertaken. The following are considered to be the major indications for surgery:

- Symptoms of pain or neurological deficit significantly disrupt lifestyle and do not improve with conservative management (Failure of an Adequate Trial of Conservative Therapy of at least 3-4 months).
- Radiographic instability with symptoms.
- Documented progression of the slip to a greater grade.
- Patients with neurological deficits attributable to spondylolisthesis.

Aims of Surgery

- To relieve symptoms.
- To prevent progressive worsening or recurrence of symptoms.

Surgical Options

- Fusion without Decompression.
- Fusion with Decompression.
- Fusion with Instrumentation.

Bone Grafting.⁷

Autogenous cancellous bone graft provides an osteoconductive, osteoinductive and osteogenic substrate for filling bone voids and augmenting fracture-healing. The iliac crest remains the most frequently used site for bone-graft harvest. The most common complication associated with the harvest of autogenous bone graft is pain at the donor site with less frequent complications including nerve injury, haematoma, infection and fracture at the donor site.

Bone Graft Substitutes

An ideal bone graft substitute should provide three elements: Scaffolding for osteoconduction, growth factors for osteoinduction and progenitor cells for osteogenesis. Bone graft substitutes can replace autologous or allogeneic grafts or expand an existing amount of available graft material. The currently available materials including calcium phosphate ceramics, calcium sulphate, bioactive glass, biodegradable polymers, recombinant human BMPs (OP-1 and BMP-2), and autologous bone marrow cells.

AIMS AND OBJECTIVES

- To study the efficacy of pedicular screw rod system and posterolateral fusion with bone substitutes in spondylolisthesis.
- To study the complications associated with this treatment modality.

• To compare the efficacy and complications with the available literature.

MATERIALS AND METHODS

All patients of spondylolisthesis grade I and grade II who are operated upon with posterior stabilization using pedicular screw rod system. Posterolateral fusion with bone substitutes and followed up between July 2012 and September 2015.

Inclusion Criteria

- All patients in the age group of 20–75 yrs.
- Both sexes.
- Patients diagnosed with spondylolisthesis grade I and grade II with failed conservative treatment and operated with posterior stabilization using pedicular screw rod system and posterolateral fusion in our hospital.

Exclusion Criteria

- Patients of age less than 20 yrs. and more than 75 yrs.
- Patients with grade III, grade IV and grade V spondylolisthesis.
- Patients who did not have a regular followup for a minimum period of 6 months.
- Patients with any other spinal pathologies.
- Patients who have had earlier surgeries on their spine.

METHODS AND ANALYSIS OF THE RESULTS

From July 2012 to September 2014, a total of 30 patients diagnosed with Spondylolisthesis grade I and grade II and operated with posterior stabilization using pedicular screw rod system and posterolateral fusion in our hospital were included in the study. Clinical outcome was assessed based on clinical symptom score of Japanese Orthopaedic Association 3 months post-surgery and spinal fusion was then assessed by plain lumbar spine radiographs at 3, 6 and 12 months after operation.

Pre-operative Planning and Patient Selection

Patients are interviewed and epidemiologic, historical, subjective and physical findings are recorded as per the questionnaire. Routine plain roentgenograms of the lumbar spine with erect flexion and extension views are obtained and the results recorded. An MRI scan of lumbosacral spine is also done to determine the extent of the nerve root involvement. Based on all available information, a therapeutic and surgical plan is then laid out with a predetermined goal in mind for the surgery. Intraoperative findings confirm or alter the preoperative plan and modifications are made accordingly. As with any major spine surgery, patient selection, education and communications are essential for good clinical and functional results.

Operative Procedure.8

After the administration of general anaesthesia, the patient is placed on Rolton–Hall frame in prone on the operating table with hips in as much neutral as possible (An attempt to reduce the listhesis) and knees in flexion (To prevent undue stretching of nerve roots). Proper padding of the pressure points done. A standard posterior midline incision is made and the paraspinal musculature detached subperiosteally and freed to the outer margins of the transverse processes on either sides.

Haemostasis is achieved by means of bipolar electrocauterization and packing. Pedicle screw entry point and insertion as per the following steps.

Entry Point

Intersection technique is the most commonly used technique at the junction of the lateral facet and the transverse processes or intersection of the vertical line through the facet joints as a horizontal line through the transverse process.

Post-Operative Protocol

The drainage tubes were removed after 48 hours and the patient is allowed to turn in bed. The sutures are removed on 12th day. Patients were allowed to ambulate after drain removal with a lumbosacral belt and the patient is discharged with lumbosacral belt and instructed to continue followup on a regular basis. After 3 months, the lumbosacral belt is withdrawn gradually.



OBSERVATIONS AND RESULTS

In VIMS and RC Hospital, Whitefield, Bangalore, between July 2012 and September 2014, a total of 30 cases of spondylolisthesis with grade I and II were treated surgically by posterior stabilization using pedicular screw rod system and posterolateral fusion.

Pre-Operative Observations

Sex: Of the 30 patients that were followed up, there were 17 females and 13 males.



Age: All patients were in the range of 31 yrs. and 71 yrs. with an average age at the time of surgery being 46 yrs.

Duration of symptoms: The patients have a duration of symptoms ranging from 7 months to 72 months with a mean time period of 30 months.



Fig. 8

Duration of Symptoms: The patients have a duration of symptoms ranging from 7 months to 72 months with a mean time period of 30 months.



Fig. 9

Occupation: The majority of the patients were housewives followed by those doing heavy manual work.



Fig. 10

Symptoms: All the 30 patients had low back pain; Radicular pain present in 19 patients; Neurological deficits present in 3 patients; No involvement of bowel and bladder in any patient.



Previous Treatment: All patients have had some sort of previous non-operative treatment in the form of NSAID's, bed rest, physiotherapy and epidural steroid for a variable periods with an average of 15 months.



Fig. 12

Signs: Almost all patients have paraspinal muscle spasm and spinal tenderness, while some of them had palpable step. All patients had restricted and painful spinal movements.

Pre-operative Scores – VAS and Japanese Orthopaedic Association scoring system.

Average pre-operative VAS for low back pain was 7.97.

Average Pre-Operative Japanese orthopaedic Association score was 15.77. Level of Instability: 3 patients had L3-L4 instability, whereas 19 patients had L4-L5 instability and 8 patients had L5-S1 instability.



Fig. 13

Meyerding's Grade of Slip: 8 patients had grade 1 slip, 22 patients had grade 2 slip pre-operatively.



Investigations

Routine blood investigations required for the surgery. Plain Roentgenograms of Lumbosacral spine – Anteroposterior, Lateral, Oblique and Flexion and Extension views.

MRI of lumbosacral spine was done in patients having radicular pain, to identify associated lesions like intervertebral disc prolapse or spinal stenosis.

Operative Procedure

All the patients have undergone posterior stabilization with pedicular screw rod system and posterolateral fusion using bone substitutes. Decompression by laminectomy and discectomy was done in patients with intervertebral disc prolapse associated with spondylolisthesis.

Blood Loss

The patients had an average blood loss of about 250 mL-300 mL.

Complication	Our Study	Literature		
Superficial wound infection	6.7%	6%		
Deep wound infection	3.3%	1.4%		
Dural tear	3.3%	12%		
Vascular injury	Nil	Nil		
Instrumentation failure	Nil	6%		
Pedicle failure	Nil	2%		
Neurological pain	3.3%	5%		
Re-operative rate	Nil	Nil		
Table 1				

In our study, 5 of the 30 patients that is 16.7% developed complications. Intraoperatively, one patient had

Dural tear. Dural tear was treated by placing free fat graft and water tight closure of all layers.

Post-op deep wound infection was seen in 1 patient, it was treated by wound exploration, debridement and thorough wash. Superficial wound infection was seen in 1 patient, it was treated by antibiotics.



Duration of Follow-up

The patients had an average duration of follow-up of 13 months with the maximum follow-up being for 23 months and the least being for 7 months.

Post-operative Results

Post-operatively, one patient had persistent radicular pain and 2 patients had persistent low back pain at the time of their last follow-up (Fig. 6). The mean difference between pre-operative and post-operative VAS at final follow-up was 3 (SD=0.81), which is more than the minimal clinically important change.



Fig. 16





Fig. 17

Original Article

Post-operative Grade of Slip

Grade 0: 12 patients

Grade I: 18 patients

Grade II: 00 patients

Overall outcome has been graded into poor, fair, good, excellent on the basis of JOA improvement rate and VAS score in radiculopathy and neurological deficits.

Outcome	Scale % Improvement	No. of Pts.	% of Patients		
Excellent	75-100%	5	16.7%		
Good	50-74%	16	53.3%		
Fair	25-49%	7	23.3%		
Poor	<24%	2	6.7%		
Table 2					





Fusion: The establishment of fusion was strictly derived from radiographic confirmation of continuous bone traversing the grafted segments, which showed no evidence of motion on flexion – extension radiographs. Pseudo arthrosis is defined as a discontinuous or fibrous interface, but may also refer to translational motion (Typically more than 4 mm) in an apparently fused segment. 25 of the 30 patients (82%) had obtained bony fusion while 5 patients did not. The average time for bony fusion was 7 months with the earliest being 4.5 months and the latest 13 months.



Fig. 19

Ago in Vooro	Rate of Improvement				Total
Age in Years	Poor	Fair	Good	Excellent	Total
31-40	0 (0%)	3 (42.9%)	4 (25%)	4 (80%)	11 (36.7%)
41-50	0 (0%)	2 (28.6%)	5 (31.3%)	1(20%)	8 (26.7%)
51-60	1 (50%)	2 (28.6%)	6 (37.5%)	0 (0%)	9 (30%)
>60	1 (50%)	0 (0%)	1 (6.3%)	0 (0%)	2 (6.7%)
Total	2 (100%)	7 (100%)	16 (100%)	5 (100%)	30 (100%)
Table 3: Age Distribution of Patients Studied According to Rate of Improvement					

P=0.299, not significant (But Positive Association), Fisher Exact test

Candan	Rate of Improvement				Tatal
Gender	Poor	Fair	Good	Excellent	Total
Female	2 (100%)	4 (57.1%)	8 (50%)	3 (60%)	17 (56.7%)
Male	0 (0%)	3 (42.9%)	8 (50%)	2 (40%)	13 (43.3%)
Total	2 (100%)	7 (100%)	16 (100%)	5 (100%)	30 (100%)
Table 4: Gender Distribution of Patients Studied According to Rate of Improvement					

P=0.754, not significant, Fisher Exact test.

Dro on Crado	Rate of Improvement				Tatal
Pre-op Grade	Poor	Fair	Good	Excellent	Total
Grade I	1 (50%)	1 (14.3%)	3 (18.8%)	3 (60%)	8 (26.7%)
Grade II	1 (50%)	6 (85.7%)	13 (81.3%)	2 (40%)	22 (73.3%)
Total 2 (100%) 7 (100%) 16 (100%) 5 (100%) 30 (100%)					
Table 5: Pre-op Grade According to Rate of Improvement of Patients Studied					

P=0.178, not significant (but positive association), Fisher Exact test

VAS score	Pre-op	Post-op	% Change	
0	0 (0%)	0 (0%)	0.0%	
1-3	0 (0%)	2 (6.7%)	6.7%	
4-6	0 (0%)	25 (83.3%)	83.3%	
7-10	30 (100%)	3 (10%)	-90.0%	
Total	30 (100%)	30 (100%)	0.0%	
Table 6: VAS Score: Pre-Operative and Post-Operative Evaluation of Patients Studied				

Improvement of 90.0% is statistically significant with p<0.001**, Paired proportion test.

JOA	Pre-op	3 Months	% Change		
11-15	14 (46.7%)	0 (0%)	-46.7%		
16-20	12 (40%)	4 (13.3%)	-26.7%		
21-25	4 (13.3%)	24 (80%)	66.7%		
26-30	0 (0%)	2 (6.7%)	6.7%		
Total 30 (100%) 30 (100%) 0.0%					
Table 7: JOA: Pre-operative and Post-operative					
Evaluation of Patients Studied					

Improvement of 73.4% is significant with P<0.001**, paired proportion test.

Statistical Methods

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups. Paired proportion test has been used to find the significance of proportion in paired data.

Significant Figures

- + Suggestive significance (P value: 0.05 < P < 0.10).
- * Moderately significant (P value: 0.01 <P <0.05).
- ** Strongly significant (P value: P <0.01).

Statistical Software: The statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver. 2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables, etc.



Pre-op X-Rays



Immediate Post-op X-Rays



3 Months Post-op



6 Months Post-op



18 Months Post-op





Clinical Outcome at 18 Months Follow-Up

DISCUSSION.9,10,11,12

Adult spondylolisthesis is a fascinating condition that is radiographically verifiable revealed by motion in lumbar segments. It is important to isolate the specific symptoms, signs and functional disabilities that distinguish spondylolisthesis from other types of low back pain and sciatica. It is clear that only a small minority of affected individuals ever have symptoms, but this proportion increases with severity of slip.

In our study, we examined cases of low-grade spondylolisthesis. Despite the conservative treatment previously received by these patients, their symptoms had not been resolved, dynamic radiological examinations revealed lumbar instability. Persistence of symptoms in spite of adequate conservative management constitutes the main indication in this study. Risk of progression of slip if not surgically treated is often an used surgical indication. However, it is difficult to quantify what the real risk of progressive slipping. Wiltse and Hutchinson have described a reasonable policy for the surgical treatment of spondylolisthesis that is widely accepted.

In numerous studies the mean age of the patients being treated for spondylolisthesis has ranged from 29.8 years to 53.4 years; in our study of 30 patients, the mean age of patients was found to be 46 years. The observation in this study are comparable to numerous studies established in literature. They include female preponderance in the spondylolisthesis. In our study of 30 patients 17 were females and 13 were males, that is 57% females and 43% males.

The lower lumbar vertebrae is said to be the commonest defective level. Kim et al reported that 50% of the defective levels were at L4-L5 and the ratio was similar to that found in this study, 63% of patients have L4-L5 spondylolisthesis. In our study of 30 patients, 19 patients had spondylolisthesis L4-L5, 8 patients of level L5-S1, 3 patients of level L3-L4. An effective spondylolisthesis surgery involves fusion of the fewest possible segments, minimizes dislocation, achieves adequate decompression, corrects the sagittal axis and accomplishes fusion.

combined approaches are being used. Currently, a combination of segmental screw fixation and postero-lateral fusion is most widely used method in the treatment of spondylolisthesis. Posterolateral spinal fusion is the treatment of choice most surgeons prefer for fixing an unstable spine. Posterior approach for spinal fusion is the most preferred technique, as it is more flexible and safer than anterior approach. Posterior approach permits exploration of nerve roots, intervertebral discs and defects. Watkin, Witlse and others reported a high rate of successful fusion by posterolateral technique. In our study fusion, rate achieved was 82% which is comparable to 83% fusion rate for posterolateral fusion mentioned in literature.

It is generally believed that reduction at operation is not required for patients with grade I and II of spondylolisthesis. Complication rates were reportedly higher in patients who received reduction at operation. In our study, there were 8 patients of grade I and 22 patients of grade II preoperatively. Following stabilization there were 20 patients of grade I and 10 patients of grade II, reduction was not done, following stabilization grade of slip got reduced.

Posterolateral fusion is relatively a safer technique with less complication rate. Superficial wound infection of 6% was documented in literature to 6.7% seen in our study. Superficial wound infection was attributed to improper skin closure. Deep wound infection of 1.4% was documented in literature to 3.3% seen in our study. Deep wound infection was attributed to the use of bone substitutes. Dural tear of 12% was documented in literature to 3.3% seen in our study. Dural tear was seen while doing discectomy. Persistent neurological pain of 5% is documented in literature to 3.3% seen in our study. It is attributed to reduction of vertebral slip or to bone graft used. Vascular injury, instrumentation failure, pedicle failure and re-operative rate is documented complications in literature and not seen in our study.

In our study patients had early postoperative pain relief when compared to patients who had PLF with autogenous bone graft. This is attributed to donor graft site pain in autogenous bone grafting technique. Younger and Chapman in a series of 243 iliac crest bone-graft procedures found that early pain (Occurring within three months after graft harvest) at the donor site has been reported to occur in 2.8% to 37.9% and 2.5% of patient reported long-term graft-site pain as their most common complaint.

Jacobs et al reviewed the outcome of 684 trails and selectively included 29 studies in their meta-analysis to determine which fusion technique achieved the best clinical and radiological results in adult patients with low-grade listhesis; 8 randomized controlled studies, 4 prospective and 17 retrospective case studies, fusion was found to be superior to non-operative treatment for low-grade listhesis. As in our study where 16.7% had excellent outcome, 53.3% had good outcome, 23.3% had fair outcome and only 6.7% had poor outcome.

SUMMARY

• This is a prospective study of 30 patients who underwent posterior stabilization with pedicular rods and screws with bone substitutes for grade I and grade II spondylolisthesis.

To achieve these goals, anterior, posterior and

- Majority of patients were from the age group of 30-50 years, which accounts for 62% of patients in our study.
- The youngest patient is of 31 years and the oldest patient being 71 years with a mean age of 46.5 years.
- In our study female preponderance was noted, 17 (56.7%) females and 13 (43.3%) were males.
- All the patients in our study had low back pain and has undergone prior conservative treatment.
- In our study of 30 patients, 5 patients had complications, and all the complications were treated accordingly.
- There was 90% improvement rate for pre-op and post-op VAS score with a significant p value of <0.001, the mean difference of pre-op and post-op VAS score is 3.
- Improvement of 73.4% was noted pre-op and 3 months post-op JOA score with a significant p value of <0.001.
- In our study of 30 patients, 25 patients had union, but only 2 patients had poor results. This signifies that short-term outcome was good in our study.
- Within the specified time of this study, complete radiological outcome could not be assessed, thus requiring a long-term follow-up.
- In our study of 30 patients, the final outcome was excellent in 5 patients, 16 patients had good outcome and 7 had fair results.
- Surgical fixation of grade I and grade II spondylolisthesis using pedicular screw rod system with bone substitutes is safe, promising technique with good functional outcome.

CONCLUSION

Low-back pain is the commonest condition encountered dayto-day in an orthopaedic practice. There are various reasons for low back pain, but the most common one is spinal instability (Spondylolisthesis). They have a prevalence rate of 5-7% in adult population. Surgical and non-surgical treatment options are well documented in literature for the treatment of spondylolisthesis. In general patients with highgrade spondylolisthesis were advised surgery and patients with low-grade spondylolisthesis were advised conservative treatment. In patients with postero-lumbar fusion using bone substitutes have relieved low back pain to a significantly greater extent than in patients with postero-lumbar fusion with autogenous bone graft in early post-operative period, which may be attributed to use of iliac crest bone graft.

There was a difference in relation to the number of patients who had achieved fusion and to the number of patients who had a good functional outcome. In our study of 30 patients, 25 patients had fusion and 5 patients had no fusion, but only 2 had poor results. Short term functional outcome was good in the study, but radiological outcome needed long-term follow-up.

In conclusion, pedicular screw rod system with posterolumbar fusion with bone substitute is safe, promising and appealing technique, especially in low-grade listhesis. Early post-operative pain relief, availability, sterility and reduced morbidity favours bone substitutes over autogenous bone graft.

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