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Postoperative Pain Following Posterior Iliac Crest Bone Graft Harvesting in Spine Surgery: A Prospective, Randomized Trial

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Abstract

Background Context: Post-operative pain at the site of bone graft harvest for posterior spine fusion is reported to occur in 6% to 39% of cases. However, the area around the posterior, superior iliac spine is a frequent site of referred pain for many structures. Therefore, many postoperative spine patients may have pain in the vicinity of the posterior iliac crest that may not in fact be caused by bone graft harvesting. The literature may then overestimate the true incidence of postoperative iliac crest pain.

Purpose: We performed a prospective study testing the hypothesis that patients will not report significantly higher visual analog scores over the graft harvest site when compared to the contralateral, non-harvested side.

Study design/Setting: Prospective, randomized cohort study

Patient Sample: Patients aged 18-75 years undergoing elective spinal fusion of 1-2 levels between L4 and S1 for spinal stenosis and spondylolisthesis were randomized to left-sided or right-sided iliac crest bone graft (ICBG) donor sites and blinded to the side of harvest.

Outcome Measures: Primary outcome was a 10-point Visual Analog Scale (VAS) for pain over the left and right posterior superior iliac spine.

Methods Bone graft was harvested via spinal access incisions without making a separate skin incision over the crest. Each patient's non-harvested side served as an internal control. Data points were recorded by patients on their study visit sheets pre-operatively and at 6 weeks, 3 months, 6 months and 1 year post-operatively.

Results: Forty patients were enrolled in the study (23 females) with an average follow-up of 8.1 months (1.5 – 12 months). Mean age was 51.7 years (23-77 years). Left and right side ICBG harvesting was performed equally between the 40 patients. The average volume of graft harvested from the left was 35.3 mL (15-70 mL) and 36.1 mL (15-60 mL) from the right. There was no statistical difference between pre-operative VAS score on the harvested side compared to the non-harvested side ($p=0.415$). Post-operatively, there were consistently higher VAS scores on the operative side; however, these differences were not statistically significant at 6 weeks ($p=0.111$), 3 months ($p=0.440$), 6 months ($p=0.887$), or 12 months ($p=0.240$). Both groups did, however, show statistically significant improvements in VAS scores over time within the

operative and non-operative sides ($p < 0.05$). Graft volume had no effect on the VAS scores ($p = 0.382$).

Conclusions: The current literature does not adequately illuminate the incidence of postoperative pain at the site of harvest and the relative magnitude of this pain in comparison to the patient's residual low back pain. This is the first study to blind the patient to the laterality of bone graft harvesting. Our randomized investigation showed that while pain on the surgical side was slightly higher, it was neither clinically or statistically different from the non-surgical side. Our conclusion supports surgeons' use of autologous bone graft, which offers a cost-effective, efficacious spinal fusion supplement.

Keywords: postoperative pain; iliac crest bone graft; bone graft harvesting

Introduction

Autologous bone graft is the gold standard in many orthopedic procedures including spinal fusion. Compared to the numerous bone substitutes currently available, autologous bone has the advantage of being osteoinductive, osteoconductive and osteogenic. Moreover, autologous bone graft avoids potential problems related to immunogenicity, disease transmission, and high cost. Due to its easy accessibility and large quantity of available cancellous bone, the posterior crest is the most common donor site for autologous bone graft harvest in posterior lumbar surgery.

Persistent postoperative pain is the most common reported complication of bone graft harvesting at this site with a reported incidence ranging from 6% to 39%.¹⁻⁷ The perception among patients and surgeons that autologous bone graft harvesting causes pain has served in part to spur the growth of the multibillion dollar bone graft substitute industry. However, the majority of these studies include patients who have undergone posterior lumbar spine fusion.⁸⁻¹¹ The area

around the posterior superior iliac spine is a frequent site of referred pain for many structures including the lumbar discs, lumbar facet joints, nerve roots, paraspinal muscles and sacroiliac joints. Therefore, many postoperative spine patients may have pain in the vicinity of the posterior iliac crest that is not in fact caused by bone graft harvesting.^{12,13} If patients and surgeons have incorrectly attributed pain in the vicinity of the iliac crest to bone graft harvesting, the literature on iliac crest pain after ICBG harvesting may overestimate the true incidence of postoperative iliac crest pain.¹⁴

While prior studies have retrospectively or prospectively assessed iliac crest pain after bone graft harvesting¹⁵⁻¹⁸, there are no randomized controlled and blinded studies objectively evaluating postoperative pain following ICBG harvesting. The goal of this study is to evaluate pain severity at the site of bone graft harvesting from the posterior iliac crest for use in posterior lumbar spine fusion through use of a simple visual analog pain score comparing pain at the site of harvest versus pain at the contralateral, non-harvested iliac crest.

Material and Methods

A randomized investigation with institutional review board approval was performed at a single tertiary care center with patient recruitment occurring between July 2009 and November 2013. Patients aged 18-80 years undergoing elective spinal fusion for one or two levels between L4 and S1 for spinal stenosis with or without spondylolisthesis who had failed conservative treatment and were indicated for spinal fusion were eligible for inclusion in the study. Patients falling outside the aforementioned age range or those who did not meet indications for surgery or were deemed poor surgical candidates secondary to medical comorbidities were excluded from the study. Additionally, patients requiring bilateral ICBG harvesting due to inadequate volume

from a single site, those who had previously undergone posterior ICBG harvest, patients requiring spinopelvic fixation or patients with an abnormality of either iliac crest – i.e. preexisting tumor, infection, dysplasia – precluding harvest from that site were also excluded.

Surgical technique

The standard midline approach to the posterior lumbar spine was utilized to access the iliac crest. A subcutaneous, suprafascial approach was then made to the iliac crest and the fascia was then elevated to expose the bony crest without elevating muscular attachments of the glutei. An osteotome or rongeur was used to open a cortical window in the crest and cancellous graft was harvested from between the inner and outer tables of the ilium taking care not to create a discernible defect in the outer crest. This common surgical technique first reported by Hutchinson and Dall in 1994 is comparable to a separate Wiltse incision with respect to postoperative pain and the surgeon's ability to harvest graft.^{19,20} In cases harvested via a midline incision, because there is no separate skin incision over the crest, patients could be blinded to the side of harvesting.

In minimally invasive or mini-open cases, decompression, fusion, and instrumentation were performed via bilateral paramedian Wiltse incisions. Bone graft was harvested in these cases via the Wiltse spinal access incision, again permitting patients to be blinded to laterality of harvesting.

In all cases, after bone graft harvest, the harvest site was packed with gelfoam to achieve hemostasis and the overlying fascia was closed. The harvest site was not backfilled with allograft or biologic substitute. The volume of morselized graft was measured and recorded prior to performance of the fusion.

Of note, thirteen of the 40 patients were also indicated for anterior lumbar interbody fusion which was performed through an open, retroperitoneal approach prior to the posterior portion of the procedure.

Data Collection

Basic demographic data including age, sex, body mass index, and preoperative diagnosis or diagnoses (i.e. degenerative disc disease, stenosis, spondylosis, spondylolisthesis or a combination of these) as well as number of levels fused and surgical approach was collected via chart review; presence of possible pain generators, such as loose implants, was also noted.

The primary outcome of interest was evaluated via administration of a visual analog pain scale which was recorded preoperatively, and at routine 6 week, 3 month, 6 month and 12 month follow-up. Subjects were provided with the IRB-approved data collection sheet prior to evaluation by the principal investigator. It was designed to be intuitive and able to be completed without assistance, with the intention of preventing undue influence from the surgeon or research staff administering the questionnaire. The sheet consisted of a cartoon representation of the human figure with shaded areas over the potential posterior iliac crest donor sites followed by a request to complete a visual analog pain scale for both the left and right posterior superior iliac spines (Figure 1). Patients were explicitly instructed not to include pain at the knee or groin or midline low back pain.

Data was analyzed using paired t-tests of mean VAS scores within individuals comparing pain scores at the operative versus non-operative sides. The study was powered to detect the minimum significant difference of 1.2 between control and operative sites. A secondary analysis was performed to compare VAS scores for all time points between patients with diagnoses of

degenerative disc disease, stenosis, spondylosis, and spondylolisthesis and for those undergoing combined anterior and posterior surgery or posterior surgery only.

Results

A total of 40 patients were prospectively enrolled in the study with an average follow-up of 8.1 months (1.5 – 12 months). Mean age at surgery was 52.7 years (23-78 years) and average BMI was 26.4 (18.3-38.3). Thirty two of the 40 patients (80%) enrolled in the study had complete data with pain scores at final 12 month follow-up (Table 1). Of the 8 patients without 1 year follow up 5 had VAS scores recorded at 6 months, one had three month scores, and one patient had only 6 week scores at latest follow up. Four of the patients enrolled in the study had prior discectomy (10%), three had undergone a prior decompression, and two patients were status post total disk replacement. Another patient was taken back to the OR approximately two weeks after the index surgery for extension of the fusion to L3 in the setting of severe postoperative pain secondary to adjacent level pathology.

Left and right side ICBG harvesting was distributed equally between the 40 patients. The average volume of graft harvested from the left side was 35.3 mL (15-70 mL) and 36.1 mL (15-60 mL) from the right side. Graft volume harvested had no effect on the VAS scores ($p=0.382$).

Overall, without taking into account the preoperative diagnosis or surgery performed, there was no statistical difference between pre-operative VAS score on the operative side compared to the non-operative side ($p=0.415$). Post-operatively, there were consistently higher VAS scores on the operative side; however, the mean differences (Δ) were not statistically significant at 6 weeks ($\Delta=0.866$, $p=0.111$), 3 months ($\Delta=0.500$, $p=0.440$), 6 months ($\Delta=0.073$, $p=0.887$), or 12 months ($\Delta=0.624$, $p=0.240$) (Graph1). Over the course of the study, VAS scores

at both operative and non-operative sides demonstrated statistically significant improvements over time ($p < 0.05$) compared to the initial preoperative scores. On the operative side, pain scores were significantly lower at 6 months compared to the initial postoperative visit at 6 weeks ($p = 0.015$), though this difference lost significance at final 1 year follow up ($p = 0.456$). There was no statistically significant difference in pain scores on the non-operative side at any time point (3 month, 6 month and 1 year, $p = 1.0$) compared to scores at 6 week follow-up.

With regards to specific diagnoses, there was no difference in pain scores at any time point on the harvested side compared to the non-harvested side in patients with a diagnosis of degenerative disc disease or spondylosis compared to those without these diagnoses. However, patients with spondylolisthesis (Graph 2) demonstrated significantly lower pain scores at the initial visit, 6 weeks and 3 months postoperatively compared to patients without spondylolisthesis ($p = 0.004$, $p = 0.041$, and 0.006 , respectively). Similarly, patients with stenosis (Graph 3) demonstrated a significant decrease in pain scores over time ($p = 0.002$) while those without a diagnosis of stenosis did not ($p = 0.639$), and had significant improvement in pain scores on the operative side at 6 months and 1 year ($p = 0.001$ and 0.007 , respectively). There was no difference at any time point between patients with a diagnosis of degenerative disc disease and those without DDD.

While the study was not powered to detect differences in pain scores between patients undergoing combined anterior and posterior surgery versus posterior only surgery, there was no difference in pain scores seen between these two groups at any time point.

Discussion and Conclusion

The above findings suggest that while there may be residual pain following iliac crest bone graft harvesting, it was not statistically or clinically significantly different from pain reported at the non-operative site at any time point throughout the study and was shown to improve over time.

One notable finding was the decrease in preoperative versus 6 week postoperative pain scores. Working from the assumption that iliac crest bone graft harvesting is a major pain generator, it would be expected that patients would have no ICBG harvest site pain preoperatively, pain scores would peak in the immediate postoperative period and would gradually decrease over time. However, we observed that the **harvest site** pain scores were in fact highest on average at preoperative testing, decreased significantly at both the operative and non-operative sites by 6 months and was maintained at 1 year postoperatively. This finding would suggest, as have other studies, that patient assessment of donor site pain may be overestimated and possibly confounded by pain generated by residual lumbar disc disease or radiculopathy.^{14,21-23} Furthermore, immediate postoperative surgical site pain may have served as a distractor, preventing patients from being able identify the harvest site as a major pain generator, leading to an overall decrease in harvest site pain at the 6 week time point. It is also possible that preoperative diagnosis plays a role in the level of baseline low back and iliac crest pain based on observed differences among the various diagnoses, e.g. significantly higher preoperative, 6 week and 3 month pain scores in patients with spondylolisthesis compared to those without, though it should be noted that the current study was not powered to detect pain differences between the various diagnoses. The current literature does not adequately illuminate the incidence of post-operative pain at the site of iliac crest bone graft harvest with respect to the

relative magnitude of this pain in comparison to the patient's low back pain prior to and following spinal surgery. Further investigation into these differences is merited.

One of the strengths of this study is its design and simple study question. To our knowledge, this is the first randomized investigation evaluating donor site pain following posterior iliac crest bone graft harvesting. It sought to answer a simple question using a validated, intuitive instrument and was powered to detect the minimal clinically significant difference for the visual analog scale.^{14,24} Questionnaires were administered without influence from research staff or the study investigators and patients remained blinded to their operative side throughout the study. Use of internal controls also provided insight into the potential influence of residual postoperative pain which may be a contributor to a falsely elevated assessment of donor site pain

Loss to follow-up may be considered a weakness of this study as only 32 of the original 40 patients enrolled in the study had pain scores recorded at 1 year postoperatively. However, when including the 5 patients with at least 6 month follow-up, there are sufficient numbers to adequately power the study at 6 months (initial power analysis n=36). While we cannot draw definitive conclusions regarding the difference in pain scores between operative and non-operative sides at 1 year as this time point was not adequately powered due to loss of follow-up, we would not expect the trend of improvement in pain scores to significantly reverse. However, we did see a trend toward an increase in pain at the harvest site. While, this may be attributed to a resolution of midline or surgical site pain and a relative increase in pain generated from the graft harvest site, the duration of the study and loss to follow up at 1 year prevents meaningful conclusions regarding this trend. Longterm follow-up may serve to clarify this finding. Taking into account the mean difference in pain scores between groups after 6 months (0.073, p=0.887),

we can conclude that there was no difference in pain between operative and non-operative sides up to 6 months postoperatively. Studies have focused on the incidence of pain in the immediate postoperative period and its possible contribution to delayed hospital discharge, increased opioid use, and cost associated with increased length of stay.²⁵ Attention has also been turned to the efficacy of administration of local anesthetic via local injection or at the time of surgery or placement of an indwelling local catheter at the iliac crest bone graft harvest site to decrease morbidity in the immediate postop period and beyond.^{25,26} While our study followed patients for 1 year after surgery, it was not designed to evaluate pain in the immediate postoperative period. A recent prospective study evaluating donor site pain following anterior ICBG harvest for ACDF found that preoperative opioid use contributed significantly to pain in the immediate postoperative period, which may be attributed in part to opioid hyperalgesia.¹⁵ Several of the patients in the study were noted to be taking opioid medications prior to surgery, though the exact duration and amounts were not known precluding any evaluation of its contribution to donor site pain in a given individual.

This is the first study to blind the patient to the laterality of bone graft harvesting, effectively addressing the Hawthorne effect. In the future, similarly designed studies might help to determine the major contributors predisposing individuals to postoperative donor site and general sacroiliac or crest pain – i.e. smoking history, perioperative opioid use, or preoperative diagnosis.

In conclusion, our study showed that while pain on the surgical side was slightly higher, it was neither clinically or statistically different from the non-surgical side at 6 months. This conclusion supports surgeons' use of autologous bone graft, which offers a cost-effective, efficient spinal fusion supplement.

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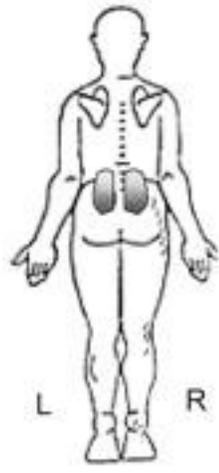
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Table 1: Patient Demographics

	n	%
Gender		
Female	22	0.55
Male	18	0.45
Age, mean +/- SD	52.7 +/- 18.9	
BMI, mean +/- SD	26.4 +/- 5.0	
Graft volume, mean +/- SD	36.5 +/- 15.1	
Surgical levels		
1	32	0.8
2	8	0.2
Approach		
Posterior only	27	0.675
Combined	13	0.325
Diagnosis		
Degenerative Disc Disease	22	0.55
Stenosis	30	0.75
Spondylosis	12	0.3
Spondylolisthesis	21	0.525
Single Diagnosis	9	0.225
Multiple Diagnoses	31	0.775
Prior Surgery	9	0.225

Figure 1: Example Data collection sheet.

6. Please make a mark on the visual analog scales below indicating the amount of pain you are experiencing in the shaded region indicated on the drawing below. Please make separate marks for the amount of pain you feel on the right and left sides.

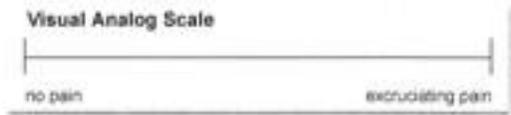


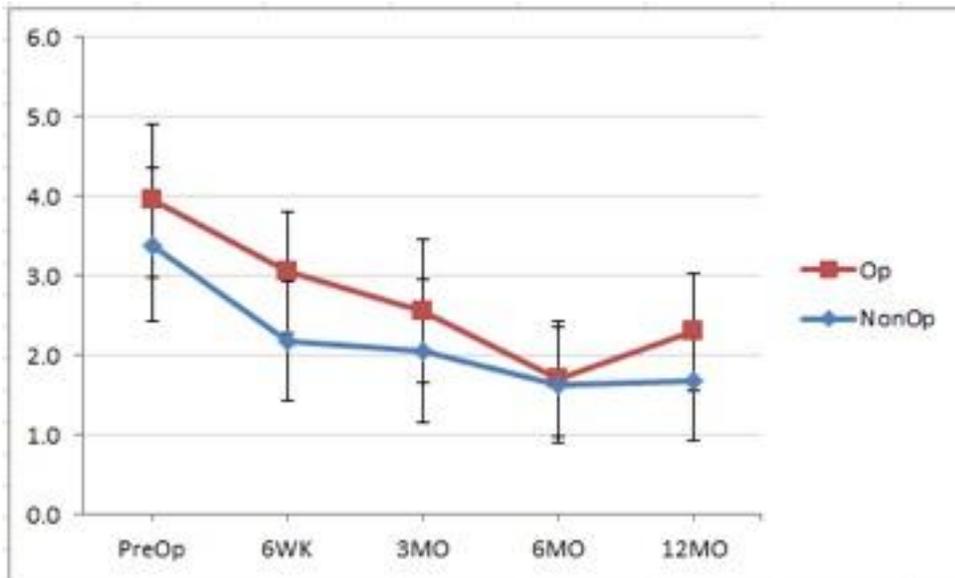
The shaded regions represent a region on your lower back and buttocks including the side of your hip. Do not include pain in your groin or knee in this mark. Please only include pain that is clearly on one side or the other. Do not include pain that is directly in the middle of your low back.

Left Side

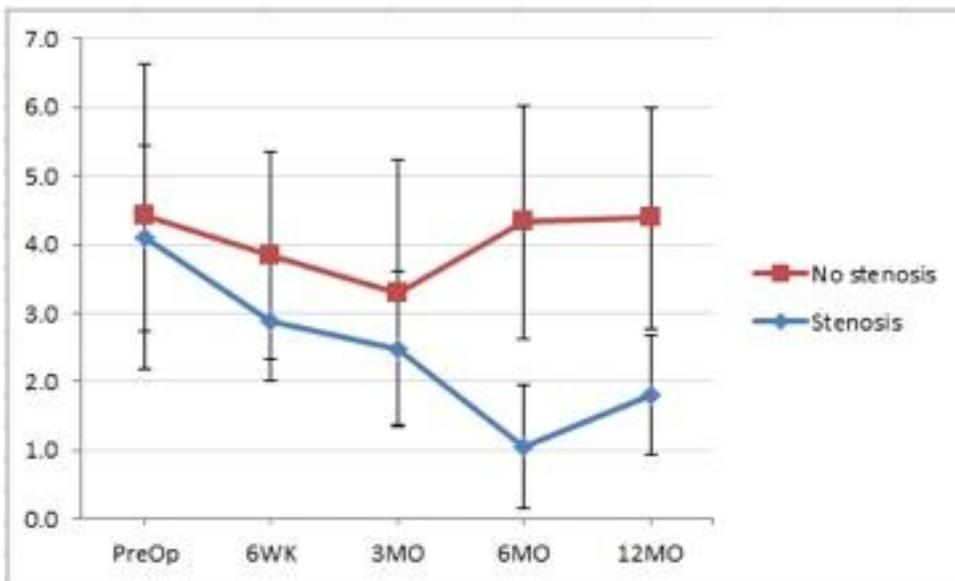


Right Side

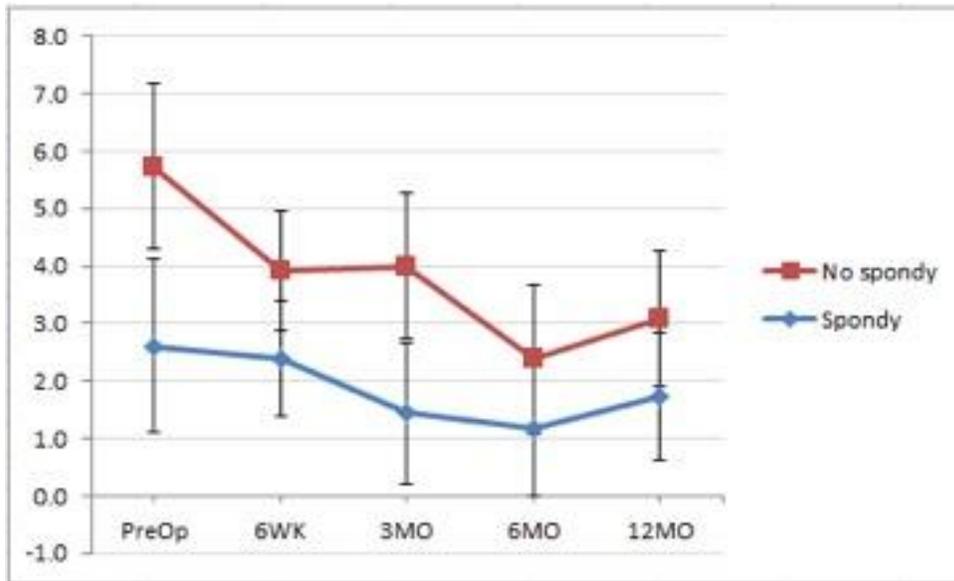




Graph 1: Mean pain scores at donor site (Op) and the contralateral iliac crest (NonOp) for all patients at all study time points



Graph 2: Mean pain scores in patients with (Spondy) and without (No Spondy) a diagnosis of spondylolisthesis



Graph 3: Mean pain scores in patients with and without a diagnosis of stenosis