Preoperative epidural spinal injections increase the risk of surgical wound complications but do not affect overall complication risk or patient-perceived outcomes

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OBJECT A lack of information exists on the relationship between preoperative epidural spinal injections and outcomes after spine surgery. There is concern that injections might cause local changes, increasing the infection risk and surgical difficulty. Therefore, the authors explored the relationship between preoperative spinal injections and postoperative outcome.

METHODS The cohort was comprised of patients who underwent thoracic and/or lumbar arthrodesis during the years 2007–2010 and had complete (preoperatively and 3 months postoperatively) outcome scores. Patients' clinical courses were reviewed to determine the occurrence of major complications within a 30-day postoperative period. Patient-perceived outcomes were evaluated using the Oswestry Disability Index (ODI) and the SF-12 (12-Item Short Form Health Survey): mental component summary (MCS) and physical component summary (PCS) scores. Analyses were based on exposure to injections and were performed using chi-square exact tests and paired and unpaired t-tests.

RESULTS Two hundred eighty patients met the inclusion criteria: 117 patients (41.8%) received and 163 patients (58.2%) did not receive preoperative epidural spinal injections. Overall, the likelihood of complication did not differ with respect to exposure (13.7% injection vs 11.7% noninjection); however, injected patients observed a 7.4-fold risk of developing surgical wound complications over noninjected patients (5.1% vs 0.6%, $p = 0.02$).

Patient-perceived outcomes measures demonstrated no differences between groups. Three months postoperatively, the MCS and ODI scores were similar (MCS: 49.6 ± 11.6 injection vs 47.4 ± 12.8 noninjection; ODI: 35.8 ± 18.0 vs 34.4 ± 19.1). MCS or ODI score improvement (preoperatively compared with 3 months postoperatively) did not vary between groups. Injected patients maintained a 2-point lower PCS score at entry and 3 months postoperatively as compared with noninjected peers (entry: 27.6 ± 8.2 injection vs 29.5 ± 9.3 noninjection, $p = 0.09$; 3 months: 33.3 ± 8.6 vs 35.7 ± 9.0 , $p = 0.03$); the PCS score improvements between injected and noninjected groups were similar (5.7 ± 9.9 vs 6.2 ± 9.7).

CONCLUSIONS Patients exposed to preoperative epidural injections had similar complication rates to those who never received a spinal injection. However, they had a greater risk of developing wound complications. These complications had no effect on short-term improvements in outcome measures.

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KEY WORDS spinal injection; outcomes; arthrodesis; complications; infection

THE use of epidural spinal injections (ESIs) as a conservative treatment for low-back pain is increasing,^{4,7,17} although the literature reveals mixed results. Riew et al. reported that patients who received ESI were less likely than patients who received a placebo injection to request surgery during a 2-year follow-up period, and

this result continued at a 5-year follow-up.^{15,16} Others have suggested that the decision to undergo surgery is independent and/or unrelated to preoperative ESI.^{3,11,14} Despite the debate about its effectiveness, it is clear that there are a significant number of patients who undergo surgical treatment after failing to obtain satisfactory relief from ESI.

ABBREVIATIONS ASA = American Society of Anesthesiologists; BMI = body mass index; ESI = epidural spinal injection; MCS = mental component summary; ODI = Oswestry Disability Index; PCS = physical component summary; SF-12 = 12-Item Short Form Health Survey; SF-36 = 36-Item Short Form Health Survey.

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Existing literature on the relationship between preoperative ESI and postoperative outcomes is sparse. Radcliff et al. found that patients who were treated preoperatively with ESIs had lower physical function than patients who did not receive an injection.¹³ In addition, there was also a trend toward a worse outcome in Oswestry Disability Index (ODI) and 36-Item Short Form Health Survey (SF-36) physical component summary (PCS) score over a 4-year period, with patients receiving ESI demonstrating less improvement.

It is possible that ESI may cause local changes, such as epidural scarring, which may increase surgical time and/or complications. Local changes at the site of injection may account for the worse outcomes found by Radcliff et al. in patients who had ESI prior to surgery.¹³ The purpose of this study was to explore the relationship between preoperative ESIs and postoperative outcomes, including complications and patient-perceived outcome measures, in patients undergoing major spine surgery.

Methods

Patients undergoing elective thoracic and/or lumbar arthrodesis (elective defined as surgery not for a diagnosis of trauma, tumor, or infection) during the years 2007–2010 at a single institution by 3 orthopedic spine surgeons were eligible for inclusion. All data were gathered under approval of the institutional review board and were collected using an automated search engine, manually reviewing charts, and using an institutional repository. As part of our institution's protocol, all spine patients are asked to complete the ODI and SF-12 (12-Item Short Form Health Survey) questionnaires preoperatively and 3 months postoperatively. The SF-12 yields both mental component summary (MCS) and physical component summary (PCS) scores. Only patients with complete SF-12 data were included in the study cohort. Other examined variables were demographics, comorbidities, patient-reported preoperative spinal injection, and surgery-related diagnosis.

All major complications occurring within the 30-day postoperative period were recorded. The definition of "complication" varies in the literature; we chose to explore complications that impact the patient's longer-term prognosis or quality of life. For instance, urinary tract infections requiring a simple course of antibiotic therapy were excluded, but acute renal failure requiring acute medical management or long-term follow-up was included as a major medical complication. Major medical complications included death, myocardial infarction, congestive heart failure, stress-induced cardiomyopathy, acute renal failure, pulmonary embolism, cardiac arrhythmia, ileus requiring a nasogastric tube, cerebrovascular accident, pneumonia, unplanned reoperation, and hardware failure. Surgical wound complications included hematoma, seroma, and infection requiring an unplanned reoperation.

Statistical analyses were carried out using SAS System, version 9.3. Descriptive statistics were calculated for the full cohort and were based on exposure status (preoperative injection or no injection). The mean outcome scores were calculated for each group: preoperatively, 3 months postoperatively, and improvement (the difference between

surveys). Independent t-tests were used to examine differences in patient-reported outcome scores (MCS, PCS, and ODI) between groups, and dependent t-tests were used to evaluate differences in the same group (injected or not injected) at baseline and 3 months postoperatively. Chi-square and Fisher exact tests were used to assess the association between injections and postoperative complications.

Results

The cohort was comprised of 280 patients (103 males and 177 females). There were 117 patients exposed to preoperative ESIs and 163 patients not exposed to injections. Age, sex, body mass index (BMI), and preoperative comorbidity status (represented by the American Society of Anesthesiologists [ASA] score) did not differ ($p > 0.10$ for all) between those who received and those who did not receive an injection (Table 1). The overall proportion of major complications was 12.5%, and the proportion of surgical wound complications was 2.5%.

Preoperatively, there were no significant differences between groups in patient-perceived pain and function (Table 2). Three months postoperatively, MCS and ODI scores did not differ between groups, although the injected patients had a 2.3-point lower PCS score 3 months postoperatively compared with noninjected patients ($p = 0.03$). The patient-perceived improvements in all outcome scores (MCS, PCS, and ODI) were similar between exposure groups. Three months postoperatively, the proportion of patients reaching a clinically meaningful difference in ODI scores (defined as an improvement of > 10)⁵ was approximately equivalent in injected (51.5%) and noninjected (55.4%) patients.

Sixteen (13.7%) of 117 patients who received ESI ex-

TABLE 1. Patient demographic and clinical characteristics*

Variable	Injection (n = 117)	No Injection (n = 163)	Total (n = 280)
Age (yrs), mean $\pm$ SD	57.8 $\pm$ 13.3	56.9 $\pm$ 15.6	57.3 $\pm$ 14.7
Sex			
M	43 (42)	60 (58)	103
F	74 (42)	103 (58)	177
BMI (kg/m ²), mean $\pm$ SD	29.2 $\pm$ 5.6	28.8 $\pm$ 6.4	28.9 $\pm$ 6.1
<25	29 (38)	47 (62)	76
25–30	41 (43)	55 (57)	96
30–35	29 (44)	37 (56)	66
>35	18 (43)	24 (57)	42
ASA score			
1 or 2	104 (57)	79 (43)	183
3 or 4	57 (60)	38 (40)	95
No. of vertebral levels			
1	41 (47)	46 (53)	87
2	25 (42)	35 (58)	60
3–5	24 (49)	25 (51)	49
≥ 6	27 (32)	57 (68)	84

* Values represent the number of patients (%) unless otherwise indicated.

TABLE 2. Self-reported outcome scores for patients who were exposed and those who were not exposed to ESI

Survey Group	Injection		No Injection		p Value
	No. of Patients	Mean $\pm$ SD	No. of Patients	Mean $\pm$ SD	
MCS score	117		163		
Preop		48.77 $\pm$ 10.77		46.44 $\pm$ 12.48	0.10
3 mos postop		49.59 $\pm$ 11.65		47.44 $\pm$ 12.81	0.15
Improvement		0.83 $\pm$ 11.38		0.99 $\pm$ 11.67	0.90
PCS score	117		163		
Preop		27.61 $\pm$ 8.24		29.47 $\pm$ 9.33	0.09
3 mos postop		33.33 $\pm$ 8.60		35.65 $\pm$ 9.01	0.03*
Improvement		5.72 $\pm$ 9.87		6.19 $\pm$ 9.67	0.69
ODI score	99		130		
Preop		43.81 $\pm$ 14.05		45.29 $\pm$ 18.17	0.50
3 mos postop		35.82 $\pm$ 18.04		34.36 $\pm$ 19.07	0.56
Improvement		8.00 $\pm$ 17.04		10.93 $\pm$ 16.80	0.19

* Statistically significant difference between groups.

perienced a postoperative complication as compared with 19 (11.7%) of 172 patients in the noninjected group ($p = 0.71$). However, 6 (5.1%) of 117 patients who received injections experienced a surgical wound complication: 3 deep wound infections and 3 hematomas and/or seromas. In contrast, only 1 (0.6%) of 172 noninjected patients experienced a similar complication: a deep wound infection ($p = 0.02$). This difference represents a 7.4-fold increased risk in surgical wound complications between exposed and unexposed groups ($p = 0.02$). The surgical wound site complications were identified in the acute postoperative period (< 30 days), and patients were taken back to the operating room to undergo an incision and drainage procedure. Patients who experienced infections underwent 2 or 3 additional surgeries for washout and were treated with a course of antibiotics, with no recurrence of infection at the surgical site. The noninfected patients had 1 additional procedure to address the hematoma or seroma.

Discussion

There is an increasing use of ESIs in the treatment of low-back pain.^{4,7,17} During a 7-year period spanning 1994–2001, the Medicare population observed a 300% increase in epidural injections.⁷ A meta-analysis on the effectiveness of lumbar interlaminar epidural injections demonstrated variability in the effectiveness of the injections based on patients' diagnoses, ranging from good in treating radiculitis secondary to disc herniation to fair in treating radiculitis secondary to spinal stenosis, as well as axial pain without disc herniation.¹ Despite the debate, the use of injections appears to have increased due to the ubiquitous nature of spinal conditions in the general population and the belief that an injection is a relatively safe method of treating persistent or debilitating spinal pain.^{2,8–10,13,18} Certainly, patients' desire to exhaust conservative treatments prior to undergoing surgical intervention likely contributes to the increasing rate of injections.

It is possible that injections could alter the tissues in a surgical field, resulting in greater complication rates and potential worsening of surgical outcomes. Similar to our

findings, a study by Radcliff et al. found no difference in baseline SF-36 outcomes scores between injected and noninjected patients.¹² Postoperatively (averaged over a 4-year period), they found patients treated with injections had nearly an 8-point lower magnitude of improvement in SF-36 physical function scores than noninjected patients. Although we found that the postoperative SF-12 PCS score was lower in the injection group, the group also had lower preoperative PCS scores and the actual improvement in PCS scores did not differ between the groups.

The findings in this paper suggest that preoperative spinal injection does not affect function or disability after surgery. Regardless of exposure to preoperative injections, patients demonstrated similar improvement from severely disabled preoperatively to moderately disabled postoperatively.⁶ In addition to similar improvements in perceived disability, the proportion of patients reaching clinically meaningful difference in ODI scores was comparable in injected and noninjected patients.

Preoperative injections seem to affect the prevalence of postoperative surgical wound complications. Our study does not elucidate the pathophysiological relationship between spinal injections and wound complications. Epidural injections have been proposed to potentially lead to epidural scarring, increased vascularization, introduction of bacteria, or promotion of degenerative changes at the injection site. Any of these aforementioned changes may increase the complexity of the surgery, resulting in a greater probability of developing a wound complication. In our study, patients exposed to spinal injections were at a 7.4-fold greater risk of developing surgical wound complications in the acute postoperative period; despite that, the overall complication rates were similar between the groups. The role of injections in patients' surgical course is limited to postoperative surgical complications, as suggested by our findings.

The retrospective cohort study design limited the level of detail pertaining to the preoperative spinal injection. We were only able to report ESIs as a dichotomous variable (event occurred yes/no). Given the opportunity, we would

have investigated the temporal relationship between injection and surgery, number of preoperative injections, and the specific type of injection administered in an attempt to elucidate the potential pathophysiological mechanism occurring at the injection site in response to this common preoperative treatment. Our study was also limited by the short follow-up period for patient-perceived outcome measures; differences between exposure groups that evolved over a longer period of time could not be captured by our data set. It is important to emphasize the acute postoperative nature of our findings given our limited follow-up in outcome measures. Despite limited information on the nature of the spinal injection and the short follow-up period, we are unaware of any other study with an exposure group of greater than 100 patients. The large cohort and similarity between groups demonstrate the external validity of our findings, since attempted conservative treatment is often a nonmodifiable preoperative risk factor in patients presenting to a tertiary medical center.

Conclusions

This study demonstrates that patient-perceived outcome for surgery does not differ between those who have received epidural injections and those who have not. However, surgeons should be aware of patients' preoperative exposure to injections, since these patients are at greater risk for acute surgical wound complications.

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Author Contributions

Conception and design: Yoo, Munch, Ching, Hart. Acquisition of data: Zusman. Analysis and interpretation of data: Yoo, Munch, Ching, Hart. Drafting the article: Zusman. Critically revising the article: all authors. Reviewed submitted version of manuscript: Zusman, Munch, Ching, Hart. Approved the final version of the manuscript on behalf of all authors: Yoo. Statistical analysis: Zusman. Study supervision: Yoo.

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