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Pain reproduction during lumbosacral transforaminal epidural steroid injection does not affect outcome

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Abstract. *Objective*: Epidural steroid injections (ESIs) are widely used in clinical practice for the treatment of low back radicular pain. Anecdotally it has been conveyed that the reproduction of a patient's usual pain during ESI was of prognostic value as to which patients would show favorable results from the procedure, however, there is no data available to support this supposition.
Design: Retrospective.
Setting: Outpatient Spine and Sports Medicine Clinic.
Patients: Patients with lumbosacral radicular pain treated with fluoroscopically guided contrast enhanced lumbosacral transforaminal ESI.
Outcome Measures: 11-point pain intensity numeric rating scale (PI-NRS).
Results: Overall the procedure provided statistically significant pain relief in both groups A (typical radicular pain reproduced) and B (typical radicular pain not reproduced) immediately and significant pain reduction was maintained until the time of the follow-up No reduction in pain was seen in group A vs. B, although in group B there was a strong trend toward having higher pain scores at all times.
Conclusion: The reproduction of a patient's typical radicular pain during a fluoroscopically guided contrast enhanced lumbosacral transforaminal ESI does not predict a significant decrease in pain scores immediately after the procedure or at follow up.

Keywords: Transforaminal, epidural steroid injection, predictive outcome, low back pain, radicular pain

1. Introduction

Epidural Steroid Injection (ESI) is a common treatment option employed for low back radicular pain. Studies on the treatment of low back pain with epidurally administered medications began in the first half of the 20th century. Anecdotally many practitioners hold the belief that pain reproduction during interventional procedures such as ESI may be a "good" sign. This hypothesis arose perhaps as early as 1930 when Dr. William Evans first noted in a paper documenting the results of epidural injections in the treatment of sciatica that, "many of the patients experienced much pain in the distribution of the affected sciatic nerve, and as this symptom appeared to indicate that the nerve was being stretched it was thought that its presence in any particular case predicted a favourable result" [4]. Although some data exists on various spine interventions regarding pain provocation and outcomes [3,5] no data exists regarding ESI and outcome.

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Table 1
Demographics

	Maximum	Minimun
Age:	93	22
		Percent
Female	115	55.60%
Male	92	44.40%
Mean age	52.5	
Standard deviation	17.275	
N	207	100%
Group A (no pain reproduction during procedure)	62	30%
Group B (typical pain reproduction during procedure)	145	70%
Injection by Level:	N	%
T11-12	1	0.40%
L1-2	1	0.40%
L2-3	5	1.90%
L3-4	17	6.50%
L4-5	53	20.30%
L5-S1	132	50.60%
S1	52	19.90%
Total Injections	261	100%

Transforaminal epidural steroid injections (TFESIs) have become the standard at our clinic for the interventional treatment of refractory low back radicular pain syndromes. We routinely track data such as pain scores, pain reproduction and provocation, as well as basic patient demographics in our data base. To try and shed light on the question as to whether pain reproduction during TFESI is significant we performed a retrospective analysis of the data pool from our outpatient spine and sports rehabilitation center.

2. Methods

The study was approved by the University Institutional Review Board (IRB). After obtaining permission from the university IRB a retrospective chart review of 282 patients who underwent contrast enhanced fluoroscopically guided lumbosacral transforaminal epidural steroid injection (ESI) using either 2 ml of triamcinolone or betamethasone for the treatment of low back radicular pain. All patients who undergo procedures at our clinic are routinely tracked in our computer database. By protocol, pain rating on an 11-point pain intensity numeric rating scale (PI-NRS) was routinely recorded by trained nursing personnel. During the procedure, the performing physician continually monitored the patient's pain response. The patient's reported pain response during the time medications were injected into the epidural space was recorded by the performing physician in their procedure note. In the recovery area, the patient's pain rating was again collected by trained nursing personnel. At subsequent follow up visits to the clinic, patient's pain rating was again collected and was recorded in the medical record.

2.1. Statistical analyses

All analyses were conducted on SPSS 13.0 (SPSS Inc., Chicago, IL). Patients were included in the analysis if they reported at least some degree of pain at baseline (See Fig. 1). Primary analyses examined the effects of injections on pain reports. As a broad measure of effectiveness, a mixed models analysis of variance was used to examine pain reporting as a function of the fixed time points (time: pre-injection, post-injection, and follow-up) and group (definitely aggravated versus not aggravated). The interaction of Group by Time was also evaluated. The present study allowed for participants to provide more than one injection series to the analysis. However, one individual's responses over time to an injection are expected to be more similar in multiple injections than across individuals, which create complex statistical dependencies that violate assumptions of analysis of variance. To account for these statistical dependencies that arise from participants providing more than one injection series to the analysis, observations were modeled as nested within injection series, with injection series nested within individuals. A first-order autoregressive error term was specified for the repeated observations, with error terms allowed to vary across participants (scaled identity). The results may be interpreted as a traditional analysis of variance.

3. Results

207 subjects underwent 261 transforaminal epidural steroid injections during a consecutive five month period. Data was gathered to assess their pre and post-procedure PI-NRS scores, whether or not their pain was provoked during the procedure, and to compare their follow up pain scores. Some patients underwent a single injection while others underwent a series of up to three. Not all subjects followed up or completed data at all time points. Follow-up self reported PI-NRS was manually extracted from the charts at the follow up visit for this data review.

Of 207 subjects, 72 had short term follow up data available (34.8%); this represented follow up data on 84 of 261 performed injections (32.2%). There were

Table 2
PI-NRS Scores as a Function of Group by Time

	Time point	Mean PI-NRS	Std. Error
Group A (no pain reproduction during procedure)	Pre-procedure	5.561	1.547
	Post-procedure	2.443	1.549
	Follow up	3.675	1.577
Group B (typical pain reproduction during procedure)	Pre-procedure	5.969	1.537
	Post-procedure	2.872	1.537
	Follow up	3.884	1.559

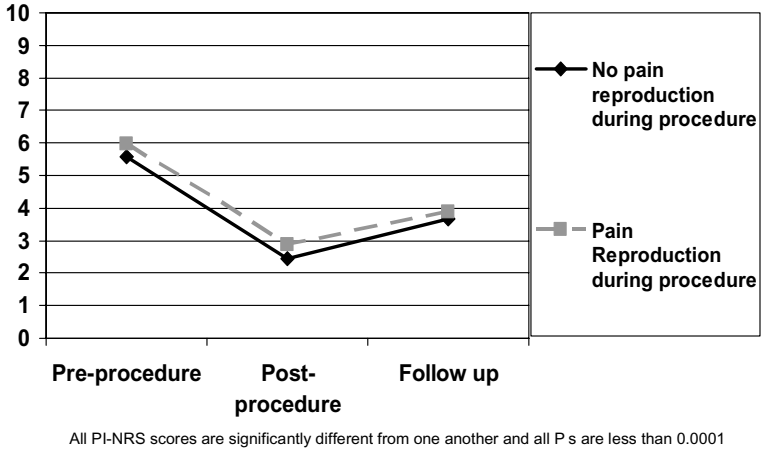

Fig. 1. PI-NRS as a function of group by time.

no significant complications. The mean time of follow up was 18.2 days ($SD = 10.9$). Correlation between the number of days of follow up and follow up pain score was near zero ($R = 0.07$, $p = 0.56$). The mean age of the patient was 52.5 years (range 22–93, SD 17.3). 55.6% were female while 44.4% were male ($F = 115$, $M = 92$, $N = 207$). 30% ($N = 624$) of the patients did not have their typical radicular pain reproduced during the injection while 70% ($N = 145$) of the patients did experience typical radicular pain reproduction during the procedure (see Tables 1 and 2).

All groups, regardless of pain reproduction, showed a statistically significant reduction of pain from pre-injection (mean 5.8) to post-injection (mean 2.7), TIME F(2,373.9) = 132.9, $p = 0.0001$. At follow up all groups reported significant increase in their pain scores (compared with immediate post-injection scores) but the follow up scores were still significantly improved from the pre-procedure scores (mean 3.8).

No significant difference was observed between group A, no pain reproduction, (mean pre-injection of 5.6, post-injection 2.4, and follow up 3.7) vs. group B, typical pain reproduction, (mean pre-injection 6.0, post-injection 2.9, follow up 3.9), GROUP F(1,383.8) = 1.79, $p = 0.182$. Regardless of the time period, Group B showed a trend of reporting higher pain scores at all time points, (mean PI-NRS 4.242, std error 1.5) as compared to group A, (mean PI-NRS 3.893, std. error 1.5), although this did not reach statistical significance.

The procedure did not provide differential pain relief as a function of group, as the procedure provided equivalent pain relief in both groups which was equivalently maintained until the time of the follow-up visit (mean follow up PI-NRS 3.8, a reduction of 2.0), GROUP by TIME F(2,361.3) = 0.08, $p = 0.92$. Figure 1 displays the pain reporting of both groups as a function of time.

4. Discussion

Using a retrospective analysis we investigated data from an outpatient spine and sports rehabilitation center and studied the phenomena of pain reproduction during TFESI as it relates to procedure outcome as measured on an 11-point PI-NRS both before and immediately after the procedure as well as at short term follow up. Although the results of our study are limited by many

factors such as its small size, retrospective design, and poor follow up rate, the data is nonetheless useful and worthwhile to study as it can prompt further research with more rigorous follow up with functional outcome measures.

We show, for the first time to the best of these authors' knowledge, that the reproduction of a patient's typical pain symptoms during TFESI is not indicative of significantly improved pain scores immediately post-procedure or at follow up when compared to those persons who did not have a reproduction of their typical pain in our select sample. We did see a trend in that those patients who perceived a reproduction in their pain tended to have higher pain scores just prior and immediately after the procedure as well as at follow up. This has been reported by previous authors using discography in an attempt to isolate the generator of pain in spine pathology. In 2004, Carragee and Hannibal reported that patients who underwent painful injections on discography were more likely to have complaints of chronic pain and emotional distress [1].

Unfortunately, we have no measure of emotional distress in our data. It is possible, that these higher pain scores could be a function of a decreased pain threshold in these subjects. Alternatively, it is also possible that subjects with higher baseline pain scores have more severe findings radiographically. Unfortunately, radiographic measures were not in our data set. Subjects with high pain scores also could have more of an inflammatory mechanism of their pain which could potentially be a source of the greater likelihood of pain provocation during the procedure based on pressure effects of injectate.

Although follow up was low there are many reasons for this. Foremost at the time of the study patients were generally referred for the procedure from either their primary care physician or other treating specialist. After receiving their injection, many of the patients followed up with their referring physician. Unfortunately, because we did not have access to these records our follow up data was somewhat limited.

Our failure to record and present functional status measurements, overall health scores, and measures of emotional distress may all limit the utility of the current study. As previously reported by Caragee psychological factors were predictive of a pain response in discography [2,3]. With our small sample size even a low number of persons in this category could be enough to skew the data.

Shortcomings of this study include the small size (207 patients), inconsistent follow up (generally shorter than 4 weeks but ranging from 1–6), retrospective design, lack of radiographic data, functional status measures, overall health scores, and emotional distress measures.

5. Conclusion

There is no statistically significant difference in pain scores immediately after lumbosacral transforaminal epidural steroid injections in those people who had pain reproduction during their injection in our select sample. Our study shows in a statistically significant way that the reproduction of a patient's typical radicular pain during epidural steroid injection is not indicative of a good or better outcome than no pain reproduction during the injection in our data set. There was, however, a strong trend seen in those persons who had a reproduction of their typical radicular pain during their procedure to have higher mean pain scores before injection, after injection, and at follow up. In our small select subset of short term follow up data, subjects who had their typical pain provoked during the injection were not more likely to have had reduced pain scores. It is important to note that our sample captured the effect of ESI only in the people who chose to follow up, which is a select subset of people and represents a sample bias.

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