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Predictive factors of the effectiveness of caudal epidural steroid injections in managing patients with chronic low back pain and radiculopathy

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Abstract

Study Design—Retrospective clinical outcome analysis

Objective—To evaluate and determine if demographic, comorbid factors or physical examination findings may predict the outcome of caudal epidural steroid injections in managing patients with chronic low back pain and radiculopathy

Summary of Background Data—The caudal epidural approach is commonly utilized with patients who are on anticoagulation or who have had prior lumbar surgery to treat L5 or S1 radiculopathies.

Methods—A retrospective review of 136 patients undergoing an initial caudal epidural steroid injection for radiculopathy from January 1, 2006 to August 30, 2013. The patients were assessed prior to their injections for their pain levels: visual analog scale (VAS), presence of lumbar paraspinal and sciatic notch sensitivity, pain with provocative maneuvers, motor weakness, and sensory loss. The patients were then reassessed following their injection for their VAS pain levels, percentage improvement and duration of pain relief.

Results—Stepwise regression was used to determine if demographic, comorbid factors or physical examination signs were predictive of percentage improvement or length of relief following an injection. Among these variables, duration of symptoms was found to be negatively significantly related with a p-value of 0.032 for percentage of improvement. For each week of the duration of symptoms, the percentage of improvement decreased by 0.07%. Regarding physical examination findings, presence of pain with lumbar extension was negatively and significantly related to length of relief duration with a p-value of 0.0124. The mean length of relief duration is

38.37 weeks for individuals without painful lumbar extension and 14.68 weeks for individuals with painful lumbar extension

Conclusions—The mean length of relief following a caudal injection is reduced by 62% in patients who exhibit pain with lumbar extension.

INTRODUCTION

Low back pain is the leading cause of disability in the world and is the second most common reason for physician office visits, with an estimated lifetime prevalence between 40% and 70%.¹ Most episodes of low back pain are acute, but about 30% of cases will develop significant recurrences or chronic pain, lasting over three months.^{1,2} Conservative approaches to chronic low back pain include pain medications, for mild to moderate pain, as well as strengthening exercises. When such measures do not lead to improvement, more invasive modalities such as epidural injections and surgery may be considered.

An epidural steroid injection (ESI) is the most commonly used procedure in pain clinics in the United States, but despite its widespread use, there is still significant controversy surrounding the efficacy of the treatment.^{1,3-5} The medication can be delivered to the epidural space by a caudal, interlaminar or transforaminal approach. The caudal approach uses the sacral hiatus as a landmark and the needle is placed in the sacral canal and advanced to the level of the second sacral foramen. The caudal approach is the preferred approach in anticoagulated patients as it reduces the risk of bleeding complications including epidural hematoma. It is also commonly used in patients with previous lumbar spine surgeries to reduce the risk of dural puncture and spinal headache.

The purpose of an ESI is to deliver the medication in close approximation to the inflamed nerve roots, by influencing the local inflammatory and neurochemical mediators.⁶⁻⁷ Although, it is generally recognized that caudal ESI are beneficial in well-selected patients there is variation regarding its efficacy and duration of effectiveness.⁸⁻¹⁷ There is some evidence that in general, patients with lower back pain, older age, workers' compensation, longer duration of pain before consultation, more days of reduced activity, and depression are associated with increased time to recovery, but little else in terms of prognostic indicators are known.¹⁸

Classic teaching in medical schools promote the idea that the majority of diagnoses can be made simply with taking a good patient history and performing a complete physical examination. However, the relationship between physical examination signs, duration of symptoms and severity of symptoms and its potential predictive value on outcomes associated with caudal ESI have not been studied.

METHODS

Subjects

The medical charts of patients who underwent their initial caudal ESI for management of chronic low back pain and radiculopathy from January 1, 2006 to August 30, 2013 were reviewed, after approval by the Pennsylvania State Institutional Review Board (protocol

43025EP). The patients who underwent the caudal approach were almost exclusively patients with prior history of lumbar surgery(ies) or on anticoagulation. All patients were evaluated in an academic clinic by a single practitioner following the spine patient protocol for their complaints of low back pain with radiculopathy. Patients were examined completely before any review of their diagnostic studies to avoid bias in determining a diagnosis.¹⁹ All patients prior to their injection had a lumbar magnetic resonance imaging (MRI) study performed within 6 months of their injection. The study was reviewed by a neuroradiologist and a pain specialist, in regards to its pathology and evidence of a radiculopathy involving the L5 or S1 levels. Patient history included evaluation of their pain history detailing the duration of their symptoms and assessment of their pain levels, lowest pain and highest pain level by means of the visual analog scale (VAS). Physical examinations were performed on every patient with an emphasis on the presence of sensitivity to palpation of the lower lumbar paraspinal region, tenderness to palpation of the area overlying the greater sciatic notch, reproduction of pain with flexion or extension of the lower lumbar spine, motor or sensory deficits and supine straight leg raise testing.²⁰ Specific protocols of the Spine Center were also followed when selecting patients for injections, only patients with radicular pain underwent injections. Radicular pain was defined as pain that radiated from the lower back and followed a dermatomal pattern of either L5 or S1 involvement into the legs. A total of 149 patients underwent a caudal epidural injection during this time period and complete data and follow-up were available for 136 patients. Their demographic information and pain history is summarized in Table 1 and their comorbid information and physical examination findings are summarized in Table 2.

Procedures

All injections were performed at an outpatient surgical center and were done by a single practitioner. They were done under fluoroscopic guidance with use of a c-arm (GE OEC 9800 Plus/9900 Elite, GE Healthcare, Wauwatosa, Wisconsin, USA). The injections were performed by anesthetizing the overlying sacral skin and injection tract with 4ml of Lidocaine 1% (Hospira Inc., Lake Forest, Illinois, USA) via a 25 gauge 1 ½ inch spinal needle (BD Medical, Franklin Lakes, New Jersey, USA) and then placing a 25 gauge 3 ½ inch spinal needle (BD Medical, Franklin Lakes, New Jersey, USA) in through the anesthetized sacral hiatus and advancing into the sacral canal under lateral fluoroscopic guidance. The superior endpoint of the needle tip was not advanced beyond the S2 level (Figure 1). Aspirations for blood were performed and if negative for blood, the patient was then injected with 5 ml of preservative free 0.9% sodium chloride (Hospira Inc., Lake Forest, Illinois, USA) and 40mg/ml of methylprednisolone acetate injectable suspension, USP (Pharmacia & Upjohn Co, Division of Pfizer Inc., New York, New York, USA).

Outcome measures

Following the injection patients were scheduled for follow-up visits, typically 4 weeks post injection and thereafter if their pain returned. At their follow up visit their percentage improvement in pain and current lowest and highest VAS pain scales since their injection were assessed. A reduction in pain of greater than 30% of their pre-injection level of pain was used to determine a successful response to an injection. The return of pain was

documented in their charts. The end of improvement was defined as when VAS returned to its pre-injection level.

Statistical Analysis

The SAS version 9.3 statistical package (SAS Institute INC., Cary, North Carolina, USA) was used for the statistical analysis. Stepwise regression was used to choose the significant variables first with percentage of improvement as the response variable and then length of relief duration as another response variable. The relationship between the various demographic/comorbid factors and the response variables: percentage of improvement and length of relief duration was evaluated by correlation analysis. Additionally, the relationship between the presence of physical examination signs and the response variables was similarly evaluated by correlation analysis.

RESULTS

The patients' response to their injections is summarized in Table 3. We evaluated if demographic and comorbid factors were predictive of a patient's percentage of improvement or their length of relief duration following an injection. The demographic and comorbid factors considered were age, sex, duration of symptoms, pre-injection low VAS pain score, pre-injection high VAS pain score, diabetic status and underlying depression. When the response variable was the percentage of improvement, duration of symptoms was found to be negatively significantly related to percentage of improvement with a p-value of 0.032 which was marginally significant. The relationship between duration of symptoms and its influence on percentage of improvement was also evaluated. For each week of the duration of symptoms, the percentage of improvement was expected to decrease 0.07%. When the response variable was length of relief duration, both the duration of symptoms and pre-injection low VAS pain level were found to be negatively related to the length of relief duration, but neither were significant at $\alpha=0.05$. The correlation analysis results are summarized in Table 4.

We also analyzed if the presence of physical examination signs during the patients initial examination were predictive of either their percentage of improvement or length of relief duration. Stepwise regression analysis was used to choose the significant variables first with percentage of improvement as the response variable and then the patient's length of relief duration as the response variable. When the response variable was percentage of improvement, motor weakness and pain with lumbar extension were associated with a reduction in percentage of improvement, but neither were significant at $\alpha = 0.05$. When the response variable was length of relief duration, the most significant variable is painful lumbar extension with a p-value of 0.0125.

The length of relief duration was 38.20 weeks for individuals without painful lumbar extension and 14.68 weeks for individuals with painful lumbar extension. Thus, the length of relief duration was negatively impacted with painful lumbar extension and effectiveness of the length of relief was reduced by 62%. This decrease is tempered by the wide range of relief duration of between 0 and 350 weeks.

DISCUSSION

Demographic factors

The literature regarding the predictability of a lumbar or caudal ESI is somewhat limited and conflicted. Among demographic factors relative youth and female gender were found to be associated with a more favorable response following a lumbar epidural injection, while body mass index, electrodiagnostic abnormalities and MRI findings were not predictive.²¹ Yet other studies have not shown different responses following an ESI among the sexes.²²⁻²³ Our results with reviewing outcomes of the caudal epidural injections do not show either gender or age to be a predictor of outcome.

Comorbid factors

Studies that specifically evaluate depression and caudal ESI outcomes are also lacking in the literature. Depression and its influence on lumbar surgical outcomes has been shown to impact outcomes and is associated with lower improvements in disability or quality of life following a discectomy.²⁴ In addition extreme values on psychologic scales have been shown to be associated with treatment failure following a lumbar ESI.²⁵ Underlying depression did not show a significant reduction in efficacy rate. It should be noted that our patient group were receiving medication treatment for their depression. Regarding underlying diabetes our finding support, previous results in the literature which showed no predictive difference in diabetics following cervical or lumbar ESI.^{22, 26}

Duration of Symptoms

The duration of pain prior to the injection did have an impact on the response rates and is consistent with prior findings in the literature.²⁵ Our analysis was able to determine the significance of this factor, defining such a relationship. To our knowledge this is the first time this relationship has been quantified. We found for each week of radicular pain prior to an injection there is a 0.07% reduction in the percentage of improvement. This again supports the importance for prompt diagnosis and efficient treatment.

Physical Examination factors

Additionally, another focus on the analysis was to determine if physical examination findings could be predictive in regards to the efficacy of a caudal ESI. Specifically, the presence of sensitivity to palpation of the lower lumbar paraspinal region, tenderness to palpation of the area overlying the greater sciatic notch, reproduction of pain with flexion or extension of the lower lumbar spine, motor or sensory deficits and supine straight leg raise testing. Much has been written in the literature regarding the diagnostic value of the physical examination in patients with chronic radiculopathy.²⁷⁻³¹ These studies do not support a consistent physical examination finding. Among the physical examination tests the straight leg raise has been extensively evaluated in the literature. The sensitivity of SLR in patients with lumbar disc herniations is felt to be between 36-52%.³²⁻³ Others have suggested the presence of associated hamstring tightness may lead to false positives for the test further impacting on the sensitivity of the test.³⁴ We did not find the presence of the straight leg raise to have any impact on the likelihood of a response or the duration of the response. Prior

investigation suggested a normal straight-leg raise test prior to treatment predicted no benefit at one year.³⁵ Our analysis did not show any predictability in regards to motor or sensory deficits, lumbar paraspinal sensitivity to light touch, palpation of the sciatic notch or reproduction of pain with flexion. It did show a reduction in the length of relief in patients who have pain with lumbar extension. The length of relief duration of patients who exhibit pain with lumbar extension is 62% less than in individuals who do not exhibit extension pain with lumbar extension on physical examination. The finding was statistically significant, but relatively moderate, given the range of relief duration to be 0-350 weeks.

Limitations of this study are inherent to a retrospective review of clinical data, although the elements are the same as a prospective study design.³⁶ The injection criteria and imaging studies would not have differed if the study had been set up as a prospective study. When compared to other prospective studies our response rates were very comparable to previously reported with 79% of patients obtaining greater than 50% of pain relief for 12 months or longer.¹⁶ Our response rate was not felt to be related to technical factors of giving the injection, but more likely to be related to the strict inclusion criteria for subjects including both clinical findings and radiologic evidence to support a L5 or S1 radiculopathy and the predominance of radicular greater than axial pain. Another limitation was relying on VAS change in pain scores and patient self-reported percentage improvement in pain to determine successful outcomes following the injection.

In light of containing health care costs the need to demonstrate an efficacious approach to patient care, we have explored factors that may predict a successful response to a caudal ESI by analyzing pertinent patient premorbid findings and physical examination signs. We analyzed data over a seven plus year period on 136 patients whereas many studies on ESI have been rendered insignificant due to low sample size. To our knowledge this is the first time that an existing physical examination prior to a caudal ESI injection has been shown to be a predictor in the outcome of a caudal ESI.

CONCLUSIONS

Our findings do suggest patient parameters and physical examination signs which may be predictive of a caudal ESI response. Age, sex, underlying depression, diabetes and VAS pre-injection pain scores did not have an effect on either the response rate or length of duration following a caudal injection. Patients with longer duration of symptoms were found to be less likely to respond to a caudal injection. Although physical examination is an important component to patient evaluation and diagnosis, the only relationship which impacted upon outcome was the presence of painful lumbar extension and this finding resulted in a 62% reduction in the mean length of relief duration. Additional studies exploring the full impact on physical examination signs and ESI responses may be a necessary and should be an important focus in the future.

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Figure 1.
Fluoroscopic image of a caudal epidural steroid injection

Table 1

Demographic and comorbid information on subjects (n=136)

Demographic	
Age (years) Mean (SD) range	65.75 (16.19) 23 to 95
Gender	
Male n(%) 62 (45.59%)	Female n(%) 74 (54.41%)
Symptom Duration (weeks) Mean (SD) range	63.76 (89.15) 1 to 520
Pre-low pain VAS Mean (SD) range	2.91 (2.80) 0-10
Pre- High pain VAS Mean (SD) range	8.62 (1.79) 3-10

Table 2

Comorbid and physical examination information on subjects (n=136)

Comorbid Factors	Present n (%)	Not present n (%)
Diabetic status	16 (11.8%)	120 (88.2%)
Diabetic status	36 (26.5%)	100 (73.5%)
Physical examination factors		
Sensitivity to palpation of lumbar spine	27 (19.9%)	109 (80.1%)
Tenderness at sciatic notch	49 (36.0%)	87 (64.0%)
Pain with lumbar flexion	34 (25.0%)	102 (75.0%)
Pain with lumbar extension	26 (19.1%)	110 (80.9%)
Motor weakness	8 (5.9%)	128 (94.1%)
Sensory loss	41 (30.2%)	95 (69.8%)
Supine straight leg raise	18 (13.2%)	118 (86.8%)

Table 3

Response variables information on subjects (n=136)

Percentage of improvement (%)	
Mean (SD) range	57.49 (35.19) 0 to 100
Duration of Relief (weeks)*	
Median (interquartile) range	53.01 (67.05) 0 to 350

* Since duration of relief is skewed, we report median and interquartile range instead of mean and standard deviation

Table 4

Correlation analysis summary table (n=136)

	Improvement%		Relief duration	
	Correlation coefficient	p-value	Correlation coefficient	p-value
Demographic factors				
Age	0.03597	0.6742	0.07738	0.3652
Gender	−0.01971	0.8179	−0.07140	0.4036
Comorbid factors				
Pre-low pain	−0.02660	0.7559	−0.15218	0.0737
Pre-high pain	−0.01750	0.8380	−0.06274	0.4631
Diabetic	−0.02779	0.7454	−0.00919	0.9145
Depression	−0.02394	0.7796	−0.07272	0.3949
Symptom Duration	−0.18197 *	0.0320	−0.13904	0.1026
Physical examination factors				
Palpation	−0.07227	0.3978	−0.09169	0.2830
Sciatic Notch tenderness	−0.00093	0.9914	0.03979	0.6419
Flexion	0.09486	0.2666	−0.04066	0.6347
Extension	−0.12610	0.1391	−0.18329 *	0.0308
Motor weakness	−0.07837	0.3591	0.08652	0.3112
Sensory loss	0.04344	0.6116	−0.05367	0.5303
SLR	−0.02794	0.7440	−0.02732	0.7496

* Significant at $p < 0.05$.