Prospective Study

Do Patients Accurately Recall Their Pain Levels Following Epidural Steroid Injection? A Cohort Study of Recall Bias in Patient-Reported Outcomes

Bilal B. Butt, MD[1], David Kagan[1], Joel Gagnier, PhD[1], Ronald Wasserman, MD[1], Ahmad Nassr, MD[2], Rakesh Patel, MD[1], and Ilyas Aleem, MD[1]

From: [1]University of Michigan, Ann Arbor, MI; [2]Mayo Clinic, Rochester, MN

Address Correspondence:
Ilyas Aleem, MD
Department of Orthopedic Surgery, University of Michigan
1500 East Medical Center Drive
2912 Taubman Center, SPC 5328
Ann Arbor, MI 48109
E-mail: ialeem@med.umich.edu

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Background: Although patient-reported outcomes (PROs) have become important in the evaluation of spine surgery patients, the accuracy of patient recall of pre- or post-intervention symptoms following epidural steroid injection remains unknown.

Objectives: The purpose of this study was to: 1) characterize the accuracy of patient recollection of back/leg pain following epidural steroid injection; 2) characterize the direction and magnitude of recall bias; and 3) characterize factors that impact patient recollection.

Study Design: A prospective cohort study.

Setting: Level 1 Academic Medical Center.

Methods: Using standardized questionnaires, we recorded numeric pain scores for patients undergoing lumbar epidural steroid injections at our institution. Baseline pain scores were obtained prior to injection, 4-hours and 24-hours postinjection. At a minimum of 2 weeks following the injection, patients were asked to recall their symptoms preinjection and at 4 hours and 24-hours postinjection. Actual and recalled scores, at each time point, were compared using paired t tests. Multivariable linear regression was used to identify factors that impacted recollection.

Results: Sixty-one patients with a mean age of 61.4 years (56% women) were included. Compared to their preinjection pain score, patients showed considerable improvement at both 4 hours (Mean Difference [MD] = 2.18, 95% Confidence Interval [CI] 1.42 to 2.94) and 24 hours (MD = 2.64, 95% CI 1.91 to 3.34) postinjection. Patient recollection of preinjection symptoms was significantly more severe than actual at the 2-week time point (MD = 1.39, 95% CI 4.82 to 6.08). The magnitude of recall bias was mild and exceeded the minimal clinically important difference (MCID). No significant recall bias was noted on patient recollection of postinjection symptoms at 4 hours (MD = 0.41, 95% CI -1.05 to 0.23). Patient recollection of symptoms was also significantly more severe than actual at 24 hours (MD = 0.63, 95% CI -1.17 to -0.07), mild magnitude of bias that did not exceed MCID. Linear regression models for differences between actual and recalled pain scores reveal that for recall at 4 hours postinjection, older patients were better at recalling pain.

Limitations: Baseline pain scores were completed in person, in front of a provider. The short-term pain scores were completed while at home, and then recalled scores were obtained by phone call encounter. Telephone surveys can lead to interview bias. All patients received incentive for completion of study. It is unclear if patient incentives have any impact on patient recall. Patients were contacted 2 weeks postinjection; this time point is standard at our institution, but could vary depending on practice location. Lastly, the enrolled patients did not all share the same indication for injection, and pain was not stratified between back and leg pain.

Conclusions: Relying on patient recollection does not provide an accurate measure of preinjection status after lumbar epidural steroid injection, although patients did recall their 4-hour postinjection status. These findings support previous studies indicating that relying on patient recollection does not provide an accurate measure of preintervention symptoms. Patient recollection of postintervention symptoms, however, may have some clinical utility and requires further study.

Key words: Recall bias, injection, patient-reported outcomes, lumbar, nonoperative

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Recently, patient-reported outcomes (PROs) have increasingly been utilized in the spine literature as a marker for effectiveness of spinal interventions (1,2). Though they can generally provide information regarding pain or quality of life, their subjective nature can lead to inaccuracy of patient self-reporting, patient misinterpretations, and inability to recall response to prior interventions (3,4). A severe limitation of utilization of PROs, as a surrogate for effectiveness of an intervention, is recall bias. Recall bias is defined as a form of differential misclassification in clinical research (4,5). This risk estimate may be biased away from or toward the null hypothesis. Given this factor, recall bias is imperative to recognize for accurate interpretation of treatment effectiveness when using PROs.

Spine providers often rely on nonoperative interventions, such as epidural steroid injections for both diagnostic and therapeutic purposes (6). Irritation of the neural elements is often associated with inflammation and can manifest as pain, weakness, and/or altered sensation in a particular region of the body. Corticosteroids can be administered to these regions via a variety of methods: oral, topical, intravenous, intramuscular, and locally (7,8). These can act to downregulate the immune system and relieve these signs of nerve irritation: pain, weakness, and altered sensation in a particular distribution. While there is some debate in the literature related to which local administration method is superior: interlaminar, caudal, or transforaminal epidural steroid injection (TFESI), this is beyond the scope of this manuscript (9,10). Our institution routinely uses all 3 methods, with the most common method being TFESI. Common indications for TFESIs include radicular pain from either disc herniation and/or a fixed lesion causing spinal stenosis.

Although epidural injections are heavily utilized in clinical practice in the care of patients with spinal pathologies, the accuracy of patient recall bias following epidural steroid injections is unknown (11-14). We sought to characterize the magnitude and direction of patient recall bias in patients undergoing epidural steroid injections. We hypothesized that patient recall will have weak agreement with preinjection pain scores and symptoms at 2-week minimum following epidural steroid injections.

Methods

Study Design

We conducted a prospective cohort study of patients undergoing epidural steroid injections at a single institution. For all patients undergoing injections, all received TFESIs performed by board-certified anesthesiologists. Patients were referred to anesthesia clinics by a variety of specialties: physical medicine and rehabilitation, primary care providers, board-certified orthopedic spine surgeons, and board-certified neurosurgeons. Baseline pain scores were obtained prior to injection, and 4 hours and 24-hours postinjection (short-term postinjection survey). All baseline pain scores were obtained without any alteration to the patient's baseline pain medications. These same medications were continued postinjection as normally prescribed. The 4-hour postinjection time point was selected as a data point, as it was felt that the effect of the local anesthetic (lidocaine 1 mL of 2% or 2 mLs of 1%) would have worn off by then, thus aiding in providing the most accurate numeric pain score (NPS). At a minimum of 2 weeks following the injection, they were contacted by telephone and were asked to recall their preinjection pain scores (recall survey). We recorded gender, location of the injection, age, adjunctive therapies, mean duration of symptoms, primary location of pain, and the presence or absence of any psychological conditions. Institutional review board (IRB) approval was obtained prior to study initiation (HUM00151764). At the conclusion of the study, all patients who completed both surveys received a $5 Visa gift card for their time.

Inclusion and Exclusion Criteria

Patients were deemed eligible if they were at least 18 years of age and underwent a lumbar epidural steroid injection. Patients were not excluded based on diagnosis or indication for injection. No maximum age was identified for participation in the study. Patients were excluded if they failed to complete either the preinjection survey, the short-term postinjection survey, or the recall survey, although every attempt was made to sequentially include all patients from the time of study initiation.

Outcome Measures

A standard 11-point numeric pain scale survey was used to assess pain. Zero represented no pain, and 10 represented the worst pain imaginable.

Data Collection

Patients identified as eligible were contacted prior to undergoing epidural steroid injections. At the time of the injection, patients were given the survey forms, along with instructions, in the recovery room and an envelope to mail back in after 24 hours. They filled this form out at home, mailed it back to the Back and Pain Center, and it was then photocopied into their electronic

health record. At a minimum of 2-weeks following the injection, patients were contacted via telephone call and asked to recall their preinjection, 4-hours postinjection, and 24-hours postinjection pain scores. When called, they did not have the previously completed form in hand for reference. Only recalled pain scores were collected at the 2-week mark, not the current pain scores that they were experiencing. Telephone calls were performed using a standard telephone oral script and were performed by authors BBB and DK, who were not involved in the performance of the procedures. Other data, such as gender, age of the patient, any adjunctive therapies, mean duration of symptoms, primary location of pain, and the presence or absence of any psychological conditions, were obtained from electronic chart review, Epic electronic health records (Epic Systems Corporation, Verona WI, United States).

Statistical Analyses

We used 2-sided paired Student t tests to compare recalled pain scores to actual pain scores at both the preinjection 4-hour and 24-hour time marks. We then calculated Pearson correlation coefficients to evaluate overall concordance between actual and recalled NPS at time points of interest. Correlation coefficients of less than .35 represent a weak correlation, values between 0.35 and .70, a moderate correlation, and values more than 0.7, a strong correlation (15). We then used multivariable linear regression to determine whether age, gender, body mass index (BMI), and duration of symptoms had an effect on the change in score (Table 1). In this study, we considered the minimal clinically important difference (MCID) to be 1.4 with a standard deviation (SD) of 2.25 (16,17). We conducted a sample size calculation using SPSS (mean comparison test) to detect the minimally important difference between groups of 1.4 on the pain scale, with an SD of 2.25 (alpha = .05, power = 80%), and we determined we would need a total of 60 patients to exceed power. We considered $P < 0.05$ significant for all statistical tests. All analyses were performed using IBM SPSS Version 22 (Armonk, NY).

Results

A total of 61 patients with a mean age of 61.4 years (56% women) were included in the final analysis. Baseline characteristics of study patients are shown in Table 1. In this study, 12/61 (20%) of patients were on an opioid medication at the time of the injection. These same medications were continued postinjection as normally prescribed. No alterations to the patient's baseline pain medications were made. The average morphine milligram equivalent of these 12 patients was 17.4 mg. While the authors do not routinely use sedation for all epidural steroid injections, some patients are anxious and do receive mild sedation with midazolam. In this study, 14 patients out of 61 (23%) patients received mild sedation to allow for successful and safe injections to be performed. Compared to their preinjection pain score, patients showed considerable improvement at both 4 hours (Mean Difference [MD] = 2.18, 95% Confidence Interval [CI] 1.42 to 2.94) and 24 hours (MD = 2.64, 95% CI 1.91 to 3.34) postinjection (Table 2). Twenty-seven days postinjection was the maximum amount time for follow-up. The mean follow-up was 16.7 days ± 2.3 days.

Preinjection Recall

Patient recollection of preinjection symptoms was significantly more severe than actual (MD = 1.39, 95% CI 4.82 to 6.08) (Table 3). The magnitude of recall bias was mild and exceeded the MCID. Patient recollection of symptoms was also significantly more severe than actual at 24 hours (MD = 0.63, 95% CI -1.17 to -0.07), mild magnitude of bias that did not exceed MCID (Fig. 1). Patient recall of injection effect was also increased from actual effect (Table 2).

Table 1. *Demographics of included patients (n = 61).*

Patient Demographics	Mean
Mean Age at Injection	61.4 yrs
Men/Women	44%/56%
BMI	29.3
Duration of Symptoms (mos)	13.9
Prior Surgery (Lumbar Only)	28%
Baseline Psychological Conditions	23%

Abbreviation: BMI, body mass index.

Table 2. *Mean difference of patient therapeutic effect (actual and recall).*

(MD [95% CI])		
Preinjection vs 4 hours post	2.18 (1.42-2.94)	Actual Reported Therapeutic Effect
Preinjection vs 24 hours post	2.64 (1.91-3.34)	
Recall Preinjection vs Recall 4	3.16 (2.43-3.90)	Recall Therapeutic Effect
Recall Pre-injection vs Recall 24	3.4 (2.64-4.18)	

Mean Difference at Various Intervals.
Abbreviations: MD, mean difference; CI, confidence interval; vs, versus.

Table 3. *Mean patient-reported outcome scores at various intervals.*

Mean Patient-Reported Outcome Scores at Various Intervals			
	Preinjection Score Mean (SD)	Patient Recall of Preinjection Score Mean (SD)	Δ in Patient Recall of Preinjection and Actual Preinjection Mean (95% CI)
NPS (n = 61)	5.5 (2.3)	6.8 (2.3)	-1.4 (-1.9, -.86)*
	Actual Score of 4-Hour Mean (SD)	Patient Recall of 4-Hour Score Mean (SD)	Δ in Patient Recall of 4-Hour Pain Score and Actual 4-Hour Pain Score Mean (95% CI)
NPS (n = 61)	3.3 (.31)	3.7 (.33)	-.41 (-1.0, .23)
	Actual Score of 24-Hour Mean (SD)	Patient Recall of 24-Hour Score (SD)	Δ in Patient Recall of 24-Hour Pain Score and Actual 24-Hour Pain Score Mean (95% CI)
NPS (n = 61)	2.8 (.35)	3.5 (.37)	-.62 (-1.17, -.07)*

*Statistical significance
Abbreviations: CI, confidence interval; NPS, numeric pain score; SD, standard deviation.

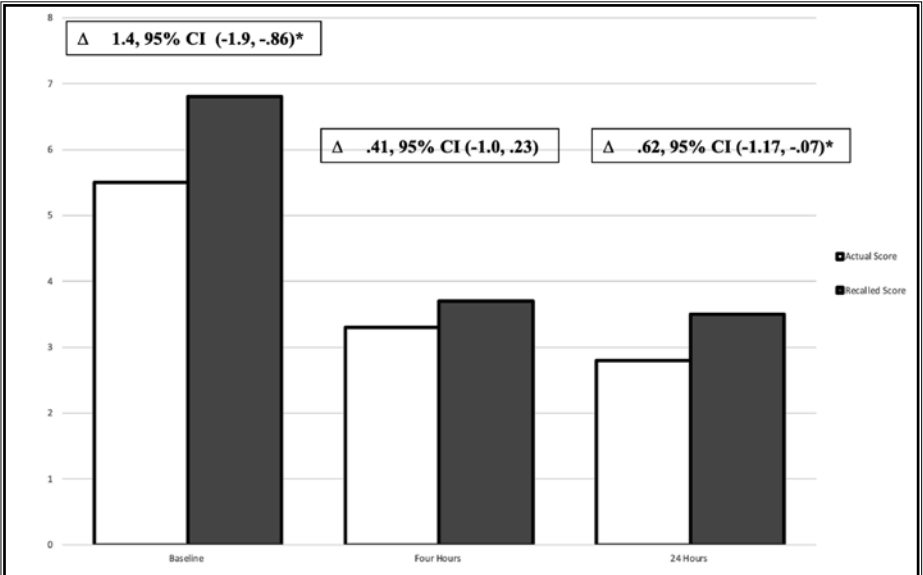

Fig. 1. *Recalled vs actual PROs as a function of time. Magnitude change of score is denoted by delta symbol. CI: Confidence Interval. Asterix denotes statistical significance.*

Postinjection Recall

No significant recall bias was noted on patient recollection of postinjection symptoms at 4 hours (MD = 0.41, 95% CI -1.05 to 0.23), see Table 3. We found moderate correlations between actual and recall scores with regards to recalled pain, at all-time points (Figs. 2, 3, 4). Linear regression models for differences between actual and recalled pain scores reveal that for recall at 4 hours postinjection, older patients were better at recalling pain ($P < 0.05$). At 24 hours postinjection, this was no longer true, and patients with elevated BMIs became better at recalling pain ($P < 0.05$). No significant differences were noted in recalled scores based on age or gender.

Discussion

Our data indicates that patient recollection of preinjection symptoms was significantly more severe than their actual symptoms (Table 3). Patients also were poor at recalling the effect of the injections, as they reported increased recalled effect as compared to actual effect. Overall patients showed considerable improvement in their pain scores at both 4 hours post-injection as well as 24 hours postinjection. Interestingly, there was no significant recall bias present at 4 hours postinjection. These findings indicate that relying on patient recollection following lumbar epidural steroid injections at the 24-hour mark does not provide an accurate measure of their true pain status, effectiveness of the injection, but does demonstrate that pain appears to improve following injections.

Pain can vary based on many factors. Patients, who reported a pain level of zero prior to undergoing an injection, likely felt like they had zero pain at that moment. That is not to say, they do not have pain, but merely saying, at that time point, they felt zero pain. Pain, as we understand it, is a complex phenomenon and, at the time of completing their preinjection survey, some patients may not have been experiencing pain at that moment and indicated so on their survey.

We can assure you all patients who were offered epidural injections were experiencing pain at the time of the injection enrollment. Unfortunately, our study could not account for real time changes in pain score, or fluctuations in pain with certain activities.

The findings of this study shed light on the issues providers may encounter when patients return to their clinics following lumbar epidural steroid injections. These results are consistent with several other studies assessing patient recall bias both in the spine literature and other material (1,2,12,13,18-21). In a prospective cohort study of patients undergoing lumbar spine surgery, we previously noted that patient recollection of preoperative status at least one-year postoperative was significantly more severe than their actual preoperative status (2). Similar findings (1) were also found in a prospective cohort of cervical spine patients undergoing surgical intervention. Interestingly, it was found that a significant number of patients flipped their predominant presurgical symptoms from either arm to neck pain or neck to arm pain on recall. Dawson et al (18) noted in their cohort of patients with back pain followed closely for 10 years that severity of pain is not recalled with the same accuracy when compared to other qualities, such as frequency and location of pain, and the activities which amplified their pain. These findings are similar to our findings in which patients did not recall pain severity accurately. While it is becoming

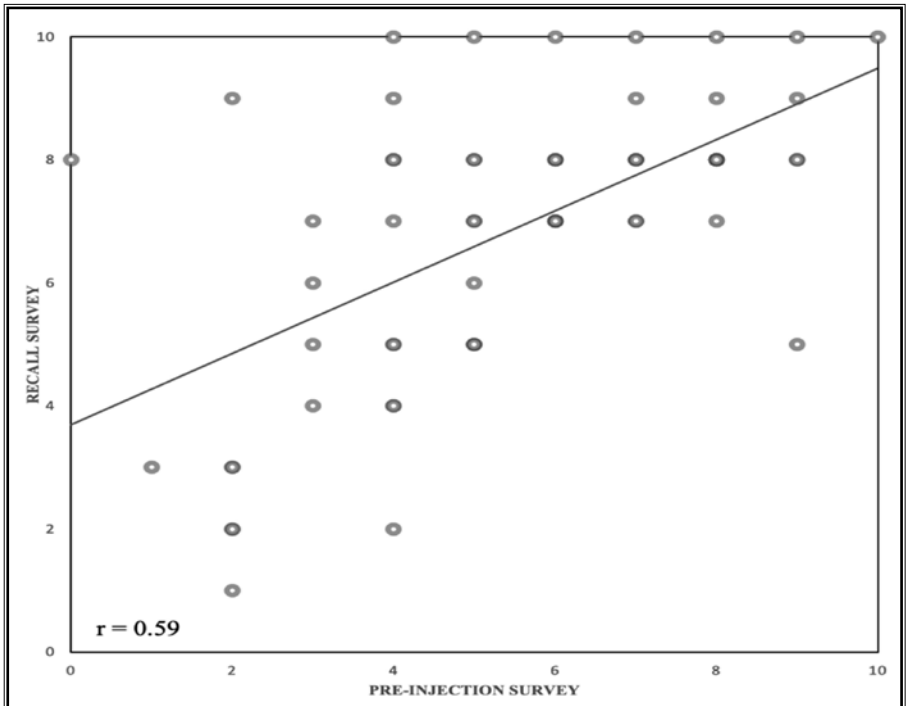

Fig. 2. *Scatter plot of recalled vs actual preinjection pain scores with line of best-fit showed moderate correlation (r = 0.59).*

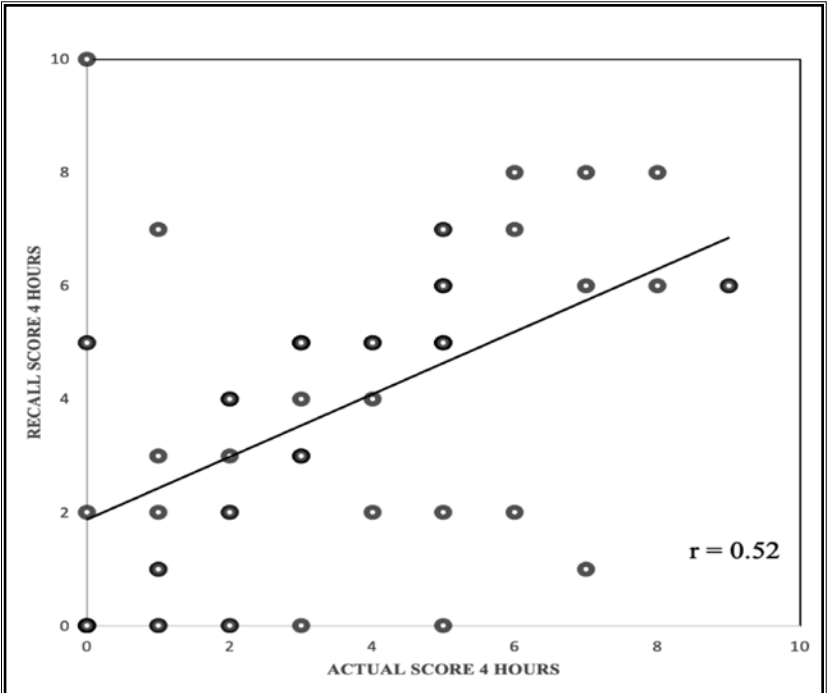

Fig. 3. *Scatter plot of recalled vs actual 4-hour pain scores with line of best-fit showed moderate correlation (r = 0.52).*

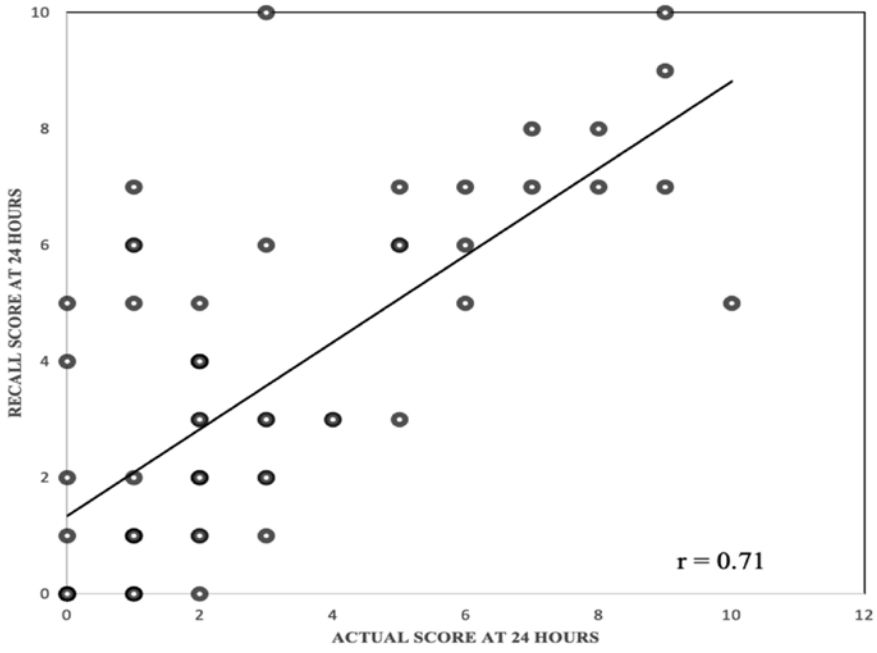

Fig. 4. *Scatter plot of recalled vs actual 24-hour pain scores with line of best-fit showed moderate correlation (r = 0.71).*

increasingly evident that spine intervention patients do not appear to recall their pain and symptoms well, other studies have demonstrated fairly accurate recall in other anatomic locations and populations (4,11,14,22).

While lumbar epidural steroid injections have been noted to provide pain relief (6,23), for those patients with a variety of spinal pathologies no study, to the authors' knowledge, has demonstrated improved perceived analgesic effect due to poor patient recall. Our data demonstrates this finding with patients recalling increased analgesic effect of the lumbar epidural steroid injection. This finding potentially can change a spinal provider treatment algorithm when choosing the next steps following an injection. Interestingly, we have already demonstrated that patients are unable to recall their pain following an injection, but injection analgesic effect was not the primary outcome focus of this study, yet it appears that patient's perception of effect was, in fact, magnified. Pre-injection NPS provide practitioners with information that will often lead to alterations in our decision-making process. These scores are routinely obtained at our institution not only prior to injections, but prior to any intervention. We most commonly ask patients questions, such as "how much pain are you in right now" and "how much pain are you currently experiencing." The data collected did just that, only prior to them undergoing an injection. The interpretation of a patient's own pain perspective can change with time and other factors (e.g., expectations).

This is the challenge with studying recall bias after interventions. Patients may unknowingly recalibrate their own pain standards just before or just after an intervention due to an anticipated response. This is termed "response shift," and as an attempt to overcome this challenge in some populations, recall adjustment calculations and sensitivity analysis should occur (24-26). One of the recommendations from this study is also the use of a pain diary, in which patients document their pain levels twice daily for 2 weeks following the injection. The diary would capture day-to-day fluctuations and mitigate some of the effects of recall bias as patients would be capturing their pain levels in real time. Further research here can help clarify this finding as it was unexpected.

Our study data demonstrated that patients who are older were able to recall their preinjection pain scores fairly accurately. These findings are consistent with the literature. Marsh et al (22) concluded that patients 55 years and older can accurately recall their preoperative health status 6 weeks following a total hip arthroplasty.

Strengths and Limitations

The present study has several limitations. First, patients undergoing lumbar epidural steroid injections were asked to complete their baseline pain score in person, in front of a provider. The short-term pain scores were completed by themselves while at home, and then recalled scores were obtained by phone call encounter. This variation in the setting of form completion can change the stress levels patients were

under in providing a response to a question (27). Also, it has been shown that telephone surveys can lead to interview bias, which can skew data. Secondarily, patients were aware of the study incentive prior to enrolling into the study per IRB rules. Patient incentives have been shown to increase involvement in survey studies (28), it has also been demonstrated that with financial incentives patients have improved recall (29). Our incentive of 5 dollars may have elevated the already poor recall accuracy. Our study called for patients to recall their pain following epidural steroid injections at a minimum of 2 weeks following the injection. This time period was chosen as this is the standard time of a follow-up visit at our institution. Some studies have demonstrated improved patient recall, when the follow-up interval was one day following the intervention to 7 days following the intervention (30,31). It is possible patients undergoing injections could have better recall if they were contacted sooner after the intervention. Our study did not collect any information on recall at the 1-to-2-month time point. We believe that this would provide valuable information in future studies.

The goal of this manuscript is not to attempt to evaluate the efficacy of TFESIs, but rather shed light on the patient's inability to accurately recall their pain accurately after undergoing an injection. Traditional PROs focused on both pain and functional outcomes. The authors understand that patient perception of pain symptoms can vary based on many factors. Most commonly, level of disability, impact of disease, comorbidities, psychosocial factors, and the patient's own perception of their pain. This perception can be a plausible reason as to why recalled pain is more severe, but we feel that this manuscript is adding to the literature to allow for more research to further evaluate patient recall of symptoms after other interventions.

Lastly, the enrolled patients did not all share the same indication for injection, and pain was not stratified between back and leg pain. While this limitation could have affected the magnitude of response to the injection and potentially the next step in the treatment algorithm, the scope of this study was looking at the ability to recall pain scores so this should not have been a significant factor.

Conclusions

Patient recollection of preinjection pain 2 weeks following a lumbar epidural steroid injection was significantly more severe than their actual preinjection status. These findings indicate that relying on patient recollection of preoperative symptoms does not provide an accurate measure of injection efficacy. However, patients did recall their 4-hour postinjection status accurately in this cohort of patients. Patient recollection of post-intervention symptoms, therefore, may have some clinical utility and requires further study. These findings further support the use of pain diaries in these patients. It is imperative for spine providers to understand the potential effect of recall bias, and attempt to obtain true baseline scores, and to use patient input as one of many metrics, including a pain diary, in determining the next steps of treatment for spinal pathologies.

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