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How soon after an epidural steroid injection can you predict the patient's response?

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A B S T R A C T

Background: Epidural steroid injections (ESI) are utilized for the management of radicular pain, but there are no previous published studies that detail the specific timeline of patient response to an ESI.
Purpose: To describe patients' temporal response in pain relief following an ESI.
Study design/setting: Prospective in vivo study of consecutive patients at an outpatient physical medicine and rehabilitation clinic at a single academic spine center.
Patient sample: 134 consecutive patients who received an ESI between January 2020 through June 2020.
Methods: Patients were contacted every 3 days ± 1 day for 21 days post ESI to assess pain as measured via 11-point numeric pain score and subjective percentage pain relief question.
Results: 134 consecutive patients were enrolled, with 108 (80.6 %) having follow-up data through 3 weeks post ESI. At 3 weeks, 51/108 patients (47.2 %) had reported a successful response as defined by at least 50 % reduction of their pain index. Of these 51 patients, 37 (72.5 %) reported >50 % relief on day 1, a further 11 (21.6 %) first reported >50 % relief on day 4, and the remaining 3 (5.9 %) successes first reported >50 % relief on days 13, 16, and 22. 57/108 patients (52.8 %) were non-responders, most of whom never reached the 50 % threshold at any time point. Of these non-responders, 19/57 (33.3 %) did report >50 % relief on day 1. Those patient's pain relief fell below 50 % on day 4 (12/19 patients, 63.2 %), day 7 (5/19 patients, 26.3 %), day 13 (1 patient, 5.3 %), and day 16 (1 patient, 5.3 %). A positive response or negative response at each follow up point was looked at as a predictor of a concordant three-week outcome for the population. The positive likelihood ratio at follow-up day 1, day 4, day 7, and day 10, was 2.14, 6.12, 7.97, and 40 respectively. The negative likelihood ratio at follow-up day 1, day 4, day 7, and day 10 was 0.42, 0.15, 0.16, and 0.24 respectively.
Discussion/conclusion: This is the first study to meticulously follow up patients every 72 h after ESI. A patient's response on day 4, either positive or negative, is predictive of their 3-week outcome. Sustained relief at day 7 or 10 further increases the likelihood of a positive 3-week outcome.

1. Introduction

Epidural steroid injections (ESI) are a well-established treatment for cervical and lumbar radicular pain [1,2]. In situations of transient or partial relief, repeating the ESI may also be indicated [3]. One consideration as to the timing of a repeat injection relates to allowing the body to recover from the systemic corticosteroid effects that may occur after ESI such as hyperglycemia and hypothalamic pituitary suppression [4–6]. HPA suppression may last up to three weeks post injection [6]. Others have advocated that a two week interval between injections may be reasonable [7,8]. This is in part based on the concept of allowing for a sufficient period to elapse before assessing the effectiveness of initial injection. Commonly, it has been cited that it could take up to 2 weeks for an ESI to demonstrate effect [9–11]. However, this time window was recommended either based on opinion [10], or the pre-determined follow up in the cited research used to determine if the ESI was effective at the 2 week time point [9,11]. To our knowledge, there is an absence of literature assessing exactly how soon after an ESI patients typically experience pain relief. Similarly, there is no known data that predicts if pain relief in the days following an ESI is related to pain relief at the 2-3-week window after ESI. These factors may be important in determining when or if a repeat ESI is warranted, and if so, what a reasonable time frame is to make such a decision. Similarly, from a clinical perspective, there is no literature to guide the physician in how to respond to a commonly encountered patient query, which is "how soon will I begin to feel better?". In this study, we sought to describe a patients' clinical response in terms of pain following an ESI by meticulously following consecutive patients approximately every 3 days after ESI for 3 weeks.

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2. Methods

2.1. Study design

This was a prospective study conducted at a single academic medical center. The study was approved by the Institutional Review Board at Vanderbilt University Medical Center (IRB #192319) and performed in accordance with the code of ethics of the world Medical Association (Declaration of Helsinki) for experiments involving humans.

2.2. Participants

Informed consent was obtained from all research participants. Consecutive patients who underwent an epidural steroid injection at the department of Physical Medicine and Rehabilitation at Vanderbilt University Medical Center from January 2020 through June 2020 were recruited to be enrolled in this study. Inclusion criteria were: all patients aged 18 years old or older scheduled to undergo an epidural steroid injection. Decision to undergo an epidural steroid injection was exclusively based on the clinical decision making of the referring or performing physician. Exclusion criteria were: patients who had an ESI within the previous six months or received any steroid injection within the previous two months prior to study enrollment. Patients who had a repeat ESI during their data collection, and patients with incomplete data at the day 22 follow up were subsequently excluded from the study analysis.

2.3. Epidural steroid injection procedure

All procedures were performed by fellowship-trained spine or pain physiatrists with extensive experience in performing spinal interventions. The physician performing the procedure determined the intervertebral level and laterality of injection based on clinical evaluation and imaging findings. The injections were performed according to the Spine Intervention Society guidelines [12]. Cervical, thoracic, and lumbar ESIs were included. Transforaminal, interlaminar, and caudal ESIs were included. Dexamethasone (10–15 mg) was used for transforaminal ESIs, while betamethasone (12 mg) or methylprednisolone (40–80 mg) was used for interlaminar ESIs. For all transforaminal epidural steroid injections, the injectate would have also included 1–2 mL of 1 % lidocaine. Interlaminar injections were performed with steroid diluted in sterile saline.

2.4. Outcome measure

The primary outcome of interest was the patients' self-reported percentage reduction in pain. Each patient also reported their pain prior to the procedure using an 11-point numerical rating score (NRS) from 0 to 10; with 0 describing no pain, and 10 describing excruciating pain. Each patient was contacted by phone or email the day after the ESI by an independent assessor, and every 3 days ± 1 day for 21 days post ESI to assess pain response.

2.5. Data analysis

Two by two tables were generated for each follow up time point to calculate the positive and negative likelihood ratios for the respective pain response on the specified day of follow up relative to the ultimate response on day 22. The three-week time point was used primarily as this spans the maximal time frame in which it has been postulated it may take for ESI to take effect as well as the fact that this is the maximal window in which there is consideration to defer repeating an ESI on account of potential HPA suppression. Data was analyzed by not including missing data points and with the last data point carried forward to ensure full transparency. Data and statistical analysis were performed using Microsoft excel.

3. Results

A total of 134 consecutive patients met inclusion criteria and were enrolled to participate in the study. 116 patients (86.6 %) completed follow up phone calls or emails, while the remaining 18 patients (13.4 %) did not provide follow up data. Of the 116 respondents, patients who had a repeat ESI while data was still being collected from them (n = 4) and patients with substantial incomplete data (n = 4), were subsequently excluded from the study and analysis. 108 patients (80.6 %) remained and were included in the analysis (Fig. 1). Patient ages ranged from 18 to 84, with injections performed at different levels including cervical (n = 21), thoracic (n = 1), lumbar (n = 58), and sacral (n = 21). 7 subjects had transforaminal ESI performed at 2 spinal levels. Injections were performed using multiple different approaches including interlaminar (n = 16), and transforaminal (n = 92; bilateral n = 25, left n = 42, right n = 25). Demographic and clinical information is summarized in Table 1. A positive response was defined as a patient reporting >50 % reduction in pain based on subjective pain relief question. At 3 weeks, 51 patients (47.2 %) achieved a positive response, while 57 patients (52.8 %) did not achieve a positive response (Fig. 2).

26 out of the 51 patients with a positive response (51 %) reported >50 % relief at all time points. Of these patients, 37/51 (72.5 %) first reported >50 % relief on day 1, an additional 11/51 (21.6 %) first reported >50 % relief on day 4, with the remaining 3/51 (5.9 %) first reporting >50 % relief on days 7, 13, and 16. In other words, by day 4 post ESI, 48 of the 51 patients (94 %) who had >50 % relief on day 22 had achieved that mark already (Fig. 3).

Of the 57 patients who did not achieve sustained 50 % relief, 32 patients (56 %) never reached that threshold at any time point. Although 19 of these 57 patients (33.3 %) did report >50 % relief on day 1, they subsequently first reported <50 % relief on day 4 (n = 12/19, 63.2 %), day 7 (n = 5/19, 26.3 %), day 10 (n = 1/19, 5.3 %), and day 13 (n = 1/19, 5.3 %).

Positive or negative responses on a particular follow up day along with positive or negative response on day 22 were evaluated to calculate likelihood ratios. When missing data was not considered, the positive likelihood ratio of a positive response predicting the day 22 outcome was 2.14, 6.12, and 7.97 on days 1, 4, and 7 respectively (Fig. 4). When the last data point was carried forward, the positive likelihood ratio was 2.14, 5.46, and 8.01 on days 1, 4, and 7 respectively (Fig. 5). The likelihood ratio was highest at 40 or 44 depending on how data was handled on day 10.

When missing data was not considered, a negative response on that respective day predicting a negative response on day 22 via a negative likelihood ratio (with a score closer to 0 indicating a strong predictor), the results were 0.42, 0.15, and 0.16 on days 1, 4, and 7 respectively. When last data point was carried forward, the negative likelihood ratio was 0.42, 0.16, and 0.18 on day 1, 4, and 7 respectively (Fig. 5). The likelihood ratio was closest to 0, at 0.03 or 0.02 depending on how missing data was handled on day 16.

4. Discussion

Here we present the most granular data published to date on pain responses following treatment with ESI. Professional groups have recommended waiting for about 2 weeks after an ESI to assess a patient's response [7,8]. This was likely based on reference material that claimed it may take up to 2 weeks to demonstrate effect of ESI, with the main limitation being that these claims were either based on expert opinion or the first follow up time period of the respective study being 2 weeks post injection [9–11]. Overall, our success rate, defined as >50 % reduction in pain, was 47.2 %. This is largely in line with published outcomes, with one meta-analysis reporting the success rate for lumbar TFESI for degenerative conditions, which made up the bulk of our procedure, being 49 % at 4 weeks [1]. This adds external validity to our study despite it being a single institution cohort.

Fig. 1. Flow of patient number from recruitment to analysis.

Table 1
Baseline demographic and clinical information for 108 patients analyzed in the study; presented as number and (percentages).

Category	Number (%)
Age (years)	
<29	8 (7.41)
30 - 39	12 (11.11)
40 - 49	18 (16.66)
50 - 59	28 (25.93)
60 - 69	22 (20.37)
>70	20 (18.52)
Level of injection	
Cervical	21 (19.44)
Thoracic	1 (0.93)
Lumbar	58 (53.70)
Sacral	21 (19.44)
Multilevel	7 (6.48)
Steroid used	
Dexamethasone	100 (92.60)
Betamethasone	4 (3.70)
Methylprednisolone	4 (3.70)
Approach	
Interlaminar	16 (14.81)
Transforaminal	92 (85.19)
TF-Bilateral	*25 (23.15)*
TF-Left	*42 (38.89)*
TF-Right	*25 (23.15)*

The positive and negative likelihood ratios were noticeably less predictive on day 1 compared to any other time point. By day 4, the positive likelihood ratio dramatically increased to 6.12 and the negative likelihood ratio significant decreased to 0.15 by day 4. By day 7, the positive likelihood ratio increased somewhat, from 6.12 to 7.97 whilst the negative likelihood ratio essentially remained unchanged (0.15–0.16).

26 of the patients who had a positive outcome (26/51, 51 %) uniformly reported >50 % relief at all time points, and 32 of the patients who had a negative outcome (32/57, 56 %) uniformly reported <50 % relief at all time points. In other words, 50 of the patients (50/108, 46.3 %) had at least 1 day during the 3-week window in which their pain relief was not concordant with their final outcomes. It is worth noting that of the 51 patients with a positive response to ESI on day 22, 37/51 (72.5 %) first reported reaching this threshold on day 1, with an additional 11/51 (21.6 %) reaching this threshold by day 4. In total, 48 of the

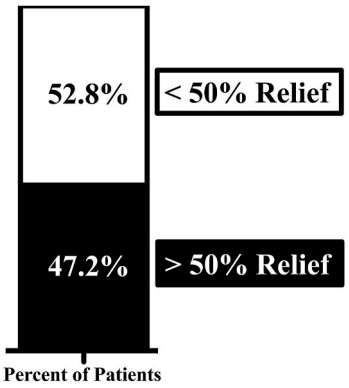

Fig. 2. Patient response after ESI with >50 % relief indicating positive response. Percentage of patients with >50 % are shown in black (number in white), and patients with <50 % relief shown in black (number in black).

51 patients (94 %) that had a successful outcome on day 22 already felt relief by day 4. Of the 19 patients who had a negative outcome at 3 weeks but reported >50 % pain relief on day 1 of follow up (19/57; 33.3 %), 12/19 (63.2 %) already first fell below this threshold by day 4 and an additional 5/19 (26.3 %) first fell below this threshold by day 7.

Thus, the likelihood ratios after day 7 most likely represents intra-individual variability as opposed to significant trends in predicting the ultimate outcome at 3 weeks. Said differently, change in these values are most likely due to a patient with a negative response at 3 weeks having a "random" good day in terms of pain control, or vice versa. For instance, the high positive likelihood ratio of 40 on day 10 is more a result of only 1 person with a negative outcome at 3 weeks reporting >50 % relief on that day, which appears random given that at all other time points more than 1 patient satisfied this criterion. By day 13, the positive likelihood ratio had decreased back down to 23 and by day 16 was down to 11, which is much closer to the day 7 value of 7.97. Similarly, the negative likelihood ratio on day 13 of 0.11 was only slightly lower than it was on day 4 when it was 0.15.

Given the dearth of information on this topic, there is little if any other literature to discuss when considering this data. Hence, we discuss how to put this information into clinical context. Clinically, then, when posed with the question from the patient "when will I know if it is working?" our data provides some clear answers. If a patient does not experience relief within the first 4 days following an ESI, it is extremely unlikely they will experience any durable or significant relief from the ESI. This advice would have misled only 3 of the 108 patients in our study (2.7 %). While the study did not extend beyond three weeks, it is worth noting that any perceived relief that occurs or begins to occur after the 3-week mark is not likely attributable to the steroid injection and more likely represents natural history.

If a patient has experienced relief within the first 1–4 days after the ESI, it is likely they will still be experiencing relief by week 3. This would have held true for 101 of the 108 patients in this study (93.5 %). If this is stated slightly more specifically, by saying that if a patient feels relief within the first 4 days following an ESI and this relief persists out to the 1-week mark following the ESI, it is extremely likely they will still be experiencing relief by week three. This advice would have held true for

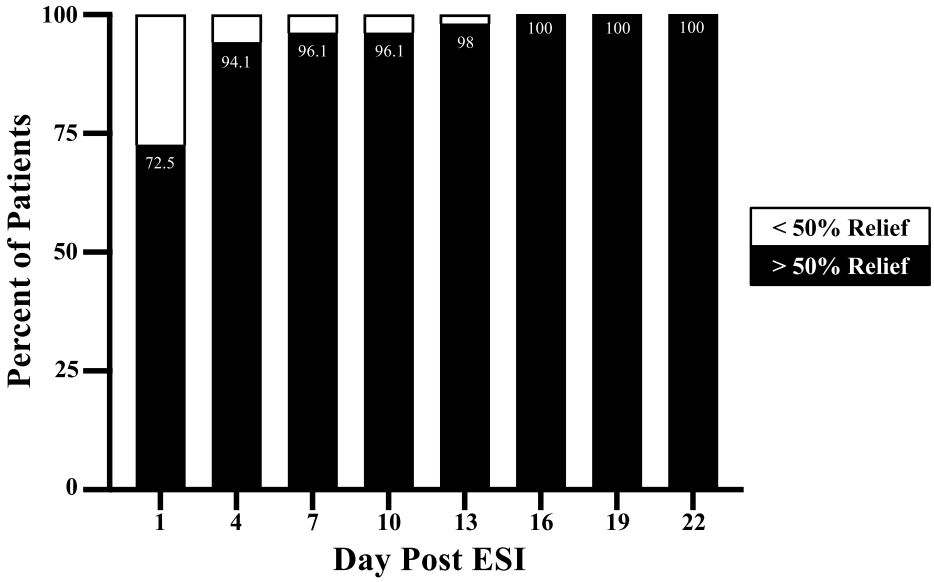

Fig. 3. Of the patients who had >50 % relief at 3 weeks, the percent of those that first reported >50 % relief by each follow up window. (Percentage numbers shown in white).

A

		Day 22	
		> 50%	< 50 %
Day 1	> 50%	37	19
	< 50%	14	37
Positive Likelihood Ratio		2.14	
Negative Likelihood Ratio		0.42	

B

		Day 22	
		> 50%	< 50 %
Day 4	> 50%	42	8
	< 50 %	6	48
Positive Likelihood Ratio		6.12	
Negative Likelihood Ratio		0.15	

C

		Day 22	
		> 50%	< 50 %
Day 7	> 50%	41	6
	< 50 %	7	50
Positive Likelihood Ratio		7.97	
Negative Likelihood Ratio		0.16	

D

		Day 22	
		> 50%	< 50 %
Day 10	> 50%	38	1
	< 50 %	12	52
Positive Likelihood Ratio		40	
Negative Likelihood Ratio		0.24	

E

		Day 22	
		> 50%	< 50 %
Day 13	> 50%	41	2
	< 50 %	5	49
Positive Likelihood Ratio		23	
Negative Likelihood Ratio		0.11	

F

		Day 22	
		> 50%	< 50 %
Day 16	> 50%	39	5
	< 50 %	1	50
Positive Likelihood Ratio		11	
Negative Likelihood Ratio		0.03	

G

		Day 22	
		> 50%	< 50 %
Day 19	> 50%	42	4
	< 50 %	1	43
Positive Likelihood Ratio		11	
Negative Likelihood Ratio		0.03	

Fig. 4. Follow up response and predictive concordant 3-week outcome when patients with missing follow up data are included in analysis. (A) Number of patients reporting a positive or negative response on day 1 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (B) Number of patients reporting a positive or negative response on day 4 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (C) Number of patients reporting a positive or negative response on day 7 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (D) Number of patients reporting a positive or negative response on day 10 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (E) Number of patients reporting a positive or negative response on day 13 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (F) Number of patients reporting a positive or negative response on day 16 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (G) Number of patients reporting a positive or negative response on day 19 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios.

106 of the 108 patients in our study (98 %). By using this latter statement in predicting a positive response, in conjunction with the prior statement in terms of predicting a negative response, 103 of the 108 patients in our study (95.4 %) would have been counseled in a predictable manner. Suffice to say, a physician does not need to wait 2 weeks to accurately determine a patient's clinical response to an ESI.

This study does not aim to discuss who is a reasonable repeat injection candidate. However, this does contest the center for Medicare services stipulation that, if a patient fails to respond well to the initial ESI, a repeat ESI (using a different approach, level and/or medication) can be considered only after 14 days from the first ESI [13]. Repeating a failed ESI must also take into account consideration for the systemic effects of steroids following ESI such as HPA suppression, which may last up to 3 weeks, with some advocating that it is best to allow the HPA suppression to recover prior to re-exposing a patient to steroids again [6].

This study predominantly utilized the non-particulate steroid dexamethasone, though 8 patients who received cervical ILESI received a particulate steroid (betamethasone or methylprednisolone). The predominance of available literature on the effect of steroid type on ESI outcome, largely suggests equivalency of particulate and non-particulate steroids when used for ESIs [14–16]. Of the 8 patients who received particulate steroids, 3 (37.5 %) had a positive outcome at 3 weeks, and all 3 of those patients were reporting 50 % relief on day 1.

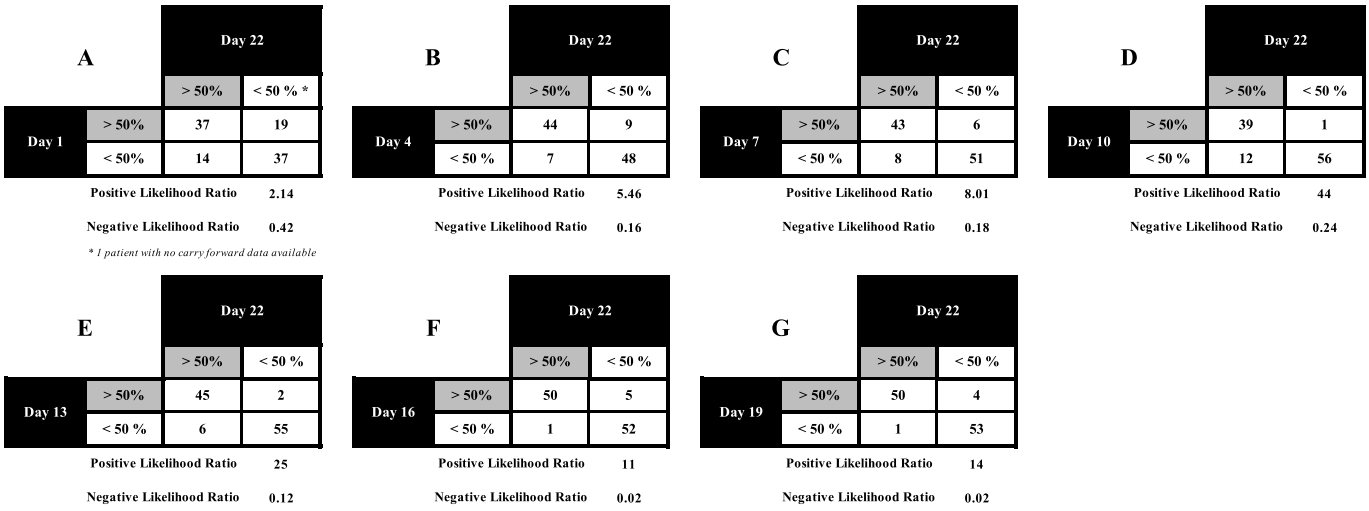

Fig. 5. Follow up response and predictive concordant 3-week outcome when last reported data point is carried forward and included in analysis. (A) Number of patients reporting a positive or negative response on day 1 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (B) Number of patients reporting a positive or negative response on day 4 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (C) Number of patients reporting a positive or negative response on day 7 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (D) Number of patients reporting a positive or negative response on day 10 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (E) Number of patients reporting a positive or negative response on day 13 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (F) Number of patients reporting a positive or negative response on day 16 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios. (G) Number of patients reporting a positive or negative response on day 19 with concurrent positive or negative response on day 22 along with positive and negative likelihood ratios.

While the study is underpowered to statistically analyze a difference between the steroids, this suggests the inclusion of these 8 patients in the study did not materially affect the results.

The strengths of this study include the prospective nature of the study, large number of patients analyzed, frequency of follow up, and response rate among participants of 80.6 %. It is also a relative strength that this study included all consecutive patients that received an ESI in our practice, as opposed to having a strict inclusion and exclusion criteria. Thus, when also considering that our success rates are consistent with current published outcomes, this is likely very representative of what can be expected in most clinical practices that perform ESI in general accordance with published indications and proper technical performance.

This study is limited in that we did not have a large enough cohort to evaluate other potential variables that may impact clinical response to ESI such as type of steroid used, or type of epidural injection performed, as sub-groups were too small to meaningfully analyze. Patients were screened pre-procedure for the use of oral steroids and our clinical practice was to reschedule patients if that screen was positive, but this was not a formal exclusion criterion of the study. We did not track post-injection utilization post-injection, new prescriptions were not typically prescribed on the day of the procedure but we are unable to account for any effect patients weaning off medications may have had. 80 % of patients would have been classified the same (responder or non-responder) whether the primary outcome was patient reported pain relief or calculated relief via NRS scores. The results may have differed slightly if the alternative measure of pain was considered the primary measure of success. Further research into the interchangeability of patient perceived pain relief versus calculated pain relief scores is warranted. Being able to predict outcomes at a longer period of follow up such as 3 months would have also improved this study.

5. Conclusion

After review of published literature, this is the first study to our knowledge where patients have been meticulously followed every 72 h after ESI. Our findings show that a patient's response on day 4, either positive or negative, is predictive of their 3-week outcome. Sustained relief at day 7 or 10 further increases the likelihood of a positive 3-week outcome.

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Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

Byron Schneider reports a relationship with International Pain and Spine Intervention Society that includes: board membership, funding grants, and travel reimbursement. Byron Schneider reports a relationship with Carelon that includes: consulting or advisory. Byron Schneider reports a relationship with State Farm Insurance Companies that includes: consulting or advisory. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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