Pain Medicine

Pain Medicine 2015; 16: 673–679
Wiley Periodicals, Inc.

# SPINE SECTION

## *Original Research Article*

# The Use of Moderate Sedation for the Secondary Prevention of Adverse Vasovagal Reactions

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None of the authors have any personal, financial, or professional interests to disclose.

### Abstract

**Background. Vasovagal reactions can occur with spine procedures and may result in premature procedure termination or other adverse events.**

**Objective. To evaluate if moderate sedation is an effective means of secondary prevention for vasovagal reactions.**

**Methods. Prospectively collected data on 6,364 consecutive spine injections.**

**Results. Of the 6,364 spine injections, 6,150 spine injections were done without moderate sedation and resulted in 205 vasovagal reactions (3.3% [95% confidence interval {CI} 2.9–3.8%]). One hundred thirty-four spine procedures were performed on patients that had a history of prior vasovagal reaction during a spine procedure. Of these, 90 procedures were performed without moderate sedation, and 21/90 (23.3% [95% CI 15.2–32.1%]) were complicated by a repeat vasovagal reaction. None of 44 repeat injections that utilized moderate sedation experienced a repeat vasovagal reaction (0% [95% CI 0–9.6%]) ($\chi^2 = 12.17$, $P < 0.00048$). The rate of vasovagal reaction in patients with a history of prior reaction undergoing repeat injection without conscious sedation was significantly higher (23.3% [95% CI 15.2–32.1%]) than the rate in patients with no such history (3.0% [95% CI 2.6–3.5%] [$\chi^2 = 113.4$, $P < 1.78E\text{-}26$]).**

**Conclusions. A history of vasovagal reaction is a strong predictor of experiencing a vasovagal reaction on subsequent procedures. No vasovagal reactions occurred with the use of moderate sedation, including in the 44 injections in patients that had a history of vasovagal reaction during spine procedures. The overall low rate of vasovagal reactions is low, and greater benefits of moderate sedation were observed when utilized as secondary prevention of repeat vasovagal reactions.**

**Key Words. Epidural (Injection Space); Sedation; Block; Safety; Facet Joint; Fluoroscopy; Spine**

### Introduction

Spine pain is very common, with 80–90% of adults reporting low back pain at some point in their lives [1,2]. In addition to physical therapy, chiropractic care, and medical management, injections are frequently utilized as a treatment modality with good success in appropriately chosen patients [3]. The rates of lumbrosacral injections have steadily increased by 241% from 633 per 100,000 to 2,319 per 100,000 between 1994 and 2001 in the United States Medicare population alone [4]. The efficacy data of these procedures vary with positive outcomes reported between 18% and 90%, likely depending upon procedure utilized, patient selection, and outcome measures [5,6].

Vasovagal reactions during spine injections are frequently cited as a common immediate adverse event, rates of which have been reported to range between 0% and 8.7% [7–16] [17]. Typical symptoms for vasovagal reactions include lightheadedness, dizziness, palpitations, weakness, dimming or blurred vision, nausea, feeling warm or cold, facial pallor, sweating, and dilated pupils [18]. In addition to these unpleasant but relatively benign symptoms, other negative consequences of vasovagal

reactions include aborted procedures or even asystole in severe cases [11,13,19]. Males, patients under the age of 65, and higher preprocedure pain scores have been associated with increased risks of vasovagal reactions during procedures [16].

A 2012 literature review with meta-analysis found that alpha-adrenergic agonists and selective serotonin reuptake inhibitors were effective in preventing recurrence of vasovagal syncope in general but did not specifically address situational-induced vasovagal syncope [20]. In the 2009 European Society of Cardiology syncope guidelines, the only intervention that meets class I criteria for prevention of vasovagal syncope is counter-pressure maneuvers and patient education [21].

To the best of the authors' knowledge, there is no literature with positive findings on the prevention of situational-induced vasovagal reactions. Moreover, the use of conscious sedation to prevent vasovagal reactions during spine procedures has not been formally evaluated. Cicala et al. reported no vasovagal reactions in 191 cervical epidural injections that were all performed with 2- to 4-mg midazolam prior to every procedure [7]. Diehn et al. reported a vv rate of only 0.4% in a cohort of 6,878 cervical, thoracic, and lumbar transforaminal epidural steroid injection (TFESI) with over 99% of injection being performed without sedation [17]. Conversely, Karaman et al. specifically noted that "sedation was not given routinely" in their cohort of 1,305 lumbar TFESIs and reported a higher rate (8.7%) of vasovagal reactions. The use of conscious sedation for spinal procedures varies between providers ranging from none to routine use [20]. The published rates of vasovagal reactions vary, as does the use of conscious sedation. This prospective cohort evaluates that relationship.

## Methods

This study is a retrospective analysis of an existing prospectively collected dataset including 6,364 consecutive spine injections performed on 3,529 consecutive patients. The data were pulled from a larger cohort so that only spine injections were included which were defined as TFESIs, interlaminar epidural steroid injections, caudal epidural steroid injections, zygoepophyseal intraarticular joint injections, medial branch blocks, radiofrequency neurotomies, third occipital nerve blocks, intradiscal injections, and sacroiliac joint injections. All procedures were performed at a single academic medical center between 2004 and 2008. This study was institutional review board approved and HIPAA compliant. All interventions were performed using fluoroscopic guidance in either an office-based fluoroscopy suite or ambulatory surgery center by one of four experienced physicians with and/or without trainee involvement. The attending physicians were all board certified in Physical Medicine and Rehabilitation and had additional subspecialty certification in either Sports Medicine or Pain Medicine. During the procedure, all patients were actively monitored via continuous pulse oximetry and intermittent automatic blood pressure recording by a registered nurse positioned at the head of the bed. When done, moderate sedation typically consisted of 1–4 mg of midazolam and 25–100 mg of IV fentanyl. Patients were noted to have a vasovagal reaction by the attending physician if they had a decrement in heart rate and blood pressure and one or more symptoms consistent with a vasovagal reaction, including lightheadedness, dizziness, palpitations, weakness, dimming or blurred vision, nausea, epigastric distress, feeling warm, feeling cold, facial pallor, and/or excessive diaphoresis.

Per standard protocol, immediately after the intervention, the treating physician entered all data into a single database using pre-set drop-down menu choices to facilitate standardized reporting. Baseline demographics, and multiple clinical and procedural characteristics were noted, including age, gender, pre and postprocedure pain scores, type of procedure and target level(s), needle gauge, needle length, fluoroscopy time, termination before completion, and complications. Each of the following complications was included in the drop down menu choices: vasovagal reaction, intravascular injection, hypertension, intolerable pain, tachycardia, dural puncture, and allergic reaction. Vasovagal reactions were noted only if the reaction occurred following the start of the procedure. Procedure termination was at the sole discretion of the attending physician.

Statistical analyses were done per injection, rather than per patient. To determine the relationship between categorical variables, Pearson's chi-squared test was used. The assumption that the sampling distribution of each variable approximated a chi-squared distribution was checked by ensuring that the expected frequencies in each cell were at least five. All statistical analysis was performed using SPSS version 20 (IBM Corp., Armonk, NY, USA). Significance values were set *a priori* at a level of $P < 0.05$.

## Results

A total of 6,364 spine injections were performed in 3,529 consecutive patients. Two hundred fourteen of the 6,364 (3.36%) injections were performed with moderate sedation (Figure 1). Within this cohort, there was not a single incidence of vasovagal reaction in 0/214 (0% [95% confidence interval {CI} 0–2.1%] [$\chi^2 = 7.37$ $P < 0.0066$]) (Figure 1). Two hundred five of the 6,150 (3.3% [95% CI 2.9–3.8%]) spine injections performed without moderate sedation resulted in a vasovagal reaction (Figure 1). Sixty-six of the 205 (32.4% [95% CI 26.2–38.9%]) vasovagal reactions resulted in termination of the procedure prior to completion. A total of 6,230 injections were performed on patients without a history of prior vasovagal reaction. Of these, 184 of the 6,060 (3.0% [95% CI 2.6–3.5%]) performed without moderate sedation resulted in a first instance of a vasovagal reaction in a patient without prior history of such (Table 1). None of the 170 performed with moderate sedation resulted in vasovagal reactions (0% [95% CI 0–2.6%] [$\chi^2 = 5.32$, $P < 0.02$]) (Table 1).

**Table 1** Vasovagal reactions with and without moderate sedation in patients with no history of prior vasovagal reaction

| | Vv | No vv | Total |
|---|---|---|---|
| No sedation | 184 | 5876 | 6060 |
| Sedation | 0 | 170* | 170 |
| Total | 184 | 6046 | 6230 |

*$\chi^2 = 5.32$ ($P < 0.02$).
vv = vasovagal reaction.

**Table 2** Vasovagal reactions with and without moderate sedation in patients with a history of prior vasovagal reaction during prior injection

| | Vv | No vv | Total |
|---|---|---|---|
| No sedation | 21 | 69 | 90 |
| Sedation | 0 | 44* | 44 |
| Total | 21 | 113 | 134 |

*$\chi^2 = 12.17$ ($P < 0.00048$).
vv = vasovagal reaction.

Of the 6,364 injections, 134 were subsequent injections on patients with a documented vasovagal reaction during a previous spine injection. Ninety of the 134 were performed without moderate sedation (Figure 2). Twenty-one of the 90 injections were complicated by repeat vasovagal reaction (23.3% [95% CI 15.2–32.1%]) (Table 2). Forty-four of these 134 (32.8% [95% CI 25.5–41.2%]) injections performed on patients with a history of vasovagal reaction during spine procedure were performed with moderate sedation (Figure 2). None of these 44 injections resulted in a vasovagal reaction (0% [95% CI 0–9.6%] [$\chi^2 = 12.17$, $P < 0.00048$]) (Table 2).

Without the use of moderate sedation, the rate of vasovagal reaction during a spine procedure was 7.77 times higher in patients with a history of previous vasovagal reaction during spine procedure compared with the rate in patients without prior history of vasovagal reaction ([23.3% [95% CI 15.2–32.1%] vs 3.0% [95% CI 2.6–3.5%] [$\chi^2 = 113.4$, $P < 1.78E\text{-}26$]) (Table 3).

## Discussion

This study of a large consecutive cohort of over 3,500 patients undergoing over 6,300 spine injections provides many unique findings regarding the use of moderate sedation and its relationship on vasovagal reactions. Vasovagal reactions during spine injections are a common immediate adverse event. The overall rate of vasovagal reaction of 3.3% in this cohort is within reported previously reported rates that range between 0% and 8.7% [7–17]. Aside from the use of moderate sedation, no other vasoactive drugs were utilized in any of the injections to prevent or treat vasovagal reactions. In addition to the unpleasant but almost always relatively benign symptoms of vasovagal reactions, having to prematurely abort a spine injection is problematic to the practitioner and the patient.

Of the 6,364 injection, 214 (3.36%) were performed with moderate sedation. Of these 214 injections, no adverse events were noted. This is consistent with other reports of

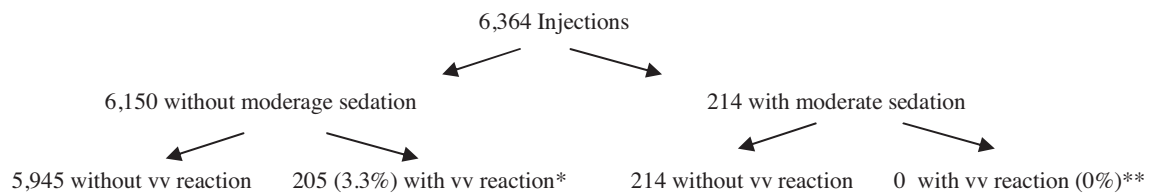


**Figure 1** Breakdown of all consecutive injections with and without moderate sedation. *3.3% (95% CI 2.9–3.8%); **0% (95% CI 0–2.1%)—nonoverlapping confidence intervals. vv = vasovagal reaction.

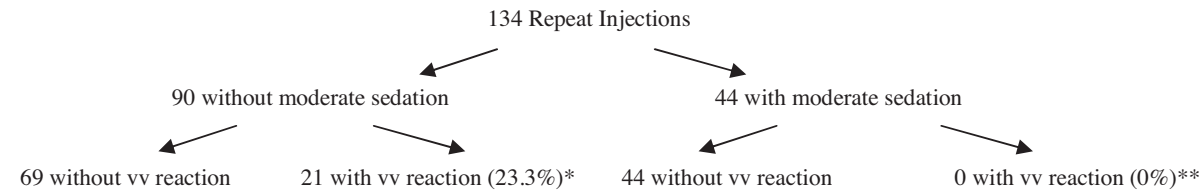


**Figure 2** Repeat injections in patients with a history of prior vasovagal reaction during previous injection. *23.3% (95% CI 15.2–32.1%); **0% (95% CI 0–9.6%)—nonoverlapping 95% confidence intervals. vv = vasovagal reaction.

**Table 3** Vasovagal rates in procedures without sedation in patients with and without a history of vasovagal reaction

| | Vv | No vv | Total |
|---|---|---|---|
| No vv history | 184 | 5876 | 6060 |
| Positive vv history | 21 | 69* | 90 |
| Total | 205 | 5945 | 6150 |

*$\chi^2 = 113.4$ ($P < 1.78E-26$).
vv = vasovagal reaction.

there being low rates of adverse events associated with conscious sedation in outpatient spine procedures [22]. Elsewhere, the use of conscious sedation for spinal procedures varies between providers ranging from none to routine use [21]. Diehn et al. reported the use of conscious sedation in only seven out of 6,878 TFESIs [17]. Conversely, Schaufele et al. reported that 49.2% of the almost 2,500 procedures in the study utilized conscious sedation [22]. Other studies have reported that when given the choice, 50–58% of patients elected to receive sedation for spine injections [23,24]. A survey performed by Cucuzzella et al. found that 17% of patients request moderate sedation prior to a first injection, and 28% request moderate sedation for second injections [25]. It has also been reported that sedation is utilized during spinal procedures more frequently for cervical rather than lumbar injections [23,26]. Moderate sedation is often offered for spine procedures for a variety of reasons, including relieving anxiety, decreasing pain, and expediting procedures that require the patient not to move [27]. The majority of patients that request preprocedure sedation are satisfied with their decision [24]. Alternatively, in a survey of patients undergoing TFESI, of whom over 99% were not offered conscious sedation, over 80% of respondents reported to probably or definitely refer a family member/friend, and 96% rated their care good or better [17]. The use of moderate sedation to prevent vasovagal reactions has not been published to the best of the authors' knowledge.

While rates of vasovagal rates and rates of moderate sedation utilization during spine procedures have previously been explored, we believe this report to be the first to demonstrate that the rate of vasovagal reactions with moderate sedation in those with a history of previous vasovagal reactions. While vasovagal events have been reported even with the use of conscious sedation [22], none was found in this cohort of 212 injections using moderate sedation. Cicala et al. also reported that among 191 cervical epidural injections performed with 2- to 4-mg midazolam, no vasovagal reactions occurred [7]. However, Cicala et al. used moderate sedation universally, and as such, it is more difficult to state that conscious sedation was the only or strongest contributing factor to the low vasovagal rate. Moreover, Cicala et al. only reported on cervical injections, which have been shown to have a lower rate of vasovagal reactions compared with lumbar injections [16,28]. Other much larger cohorts of epidural injections that did either specified that moderate sedation was not used or failed to report that moderate sedation was routinely used have also reported vasovagal rates during spine injections to be almost 0% [29]. Of note though, our cohort includes a variety of spine procedures in addition to epidural injections. This cohort was part of a larger cohort that was previously published which investigated the rates of vasovagal reactions in various procedures and found that medial branch blocks had the highest rate of vasovagal reactions [16]. While the utilization of conscious sedation was somewhat higher in some injections, such as a utilization rate of 7.6% in medial branch blocks and 9.5% in medial branch radiofrequency ablations, it was still small enough to not significantly affect the previously published vasovagal reaction rates of the various injections. For example, when only including patients that did not receive conscious sedation, the rates of vasovagal reactions in medial branch blocks was 5.5%, medial branch radiofrequency ablations was 1.5%, and TFESIs was 3.6%, all of which are similar to the previously reported rates that included all patients of 5.1%, 1.4%, and 3.5%, respectively.

Using our overall rate of vasovagal reaction of 3.3%, we would have expected seven vasovagal reactions to have occurred within the subgroup of 212 injections that were performed with moderate sedation. While our data analysis and interpretation are limited by it not being a double-blind, randomized, prospective study, we do believe it does provide more unique and convincing evidence that, in general, moderate sedation appears to have a significant preventative effect on vasovagal reactions during spine procedures.

The above findings of this study are not to suggest that moderate sedation should be used universally for primary prevention of vasovagal reactions; there are many potential complications with the use of conscious sedation. These include flu-like symptoms, itching, nausea and vomiting, nonpositional headache, subjective weakness, increased pain, dysesthesia, hypotension, venous thrombosis, pulmonary emboli, cardiac arrhythmia, respiratory compromise, hospitalization, and even death [22,27,30]. Sedation may reduce a patient's ability to report adverse phenomena during procedures such as paresthesias, cardiovascular symptoms, and CNS symptoms [15,31]. This lack of response could theoretically increase potential for steroid injection into the spinal cord [32].

Perhaps more clinically applicable data are gleaned when evaluating the subset of 134 injections (in 88 different patients) that were performed on subjects with a previous history of vasovagal reaction during spine injections. Without the use of moderate sedation, the rate of vasovagal reactions during spine procedures in this group was 7.7 times higher when compared with the vasovagal rate in patients with no prior history of vasovagal reaction (23.3% [95% CI 15.2–32.1%] vs 3.0% [95% CI 2.6–3.5%] [$\chi^2 = 113.4$, $P < 1.78E-26$]). This provides evidence that a history of vasovagal reaction is a strong predictor of

experiencing a vasovagal reaction on subsequent procedures. This finding, in turn, makes the persistence of a 0% vasovagal rate (0/44) with the use of moderate sedation in this subgroup even more robust. Using a vasovagal rate of 23.3% for patients with a history of vasovagal reactions, the anticipated number of vasovagal events in the group of 44 with a history of vasovagal reactions that underwent subsequent injections, but with moderate sedation, is 10.26 events. This translates to a number needed to treat for the use of moderate sedation as secondary prevention of vasovagal reactions of only 4.3. Conversely, if used as primary prevention in all patients, the number needed to treat would be 33.3.

The safety of moderate sedation has been studied. In a review of interventional radiology procedures utilizing moderate sedation, the complication rate related to sedation was 4.2%. The most common of these was respiratory complication [30]. In a review of dentistry cases utilizing conscious sedation, a total of 1,468 cases were reviewed, and 19 adverse events were noted in 17 patients, the most common of which was IV infiltration [33]. Schaufele et al. reported no statistically significant difference in the rate of complications during spinal procedures between those using moderate sedation and those done without [22].

If the decision to utilize conscious sedation is made after discussion with the patient, there are a number of things that should be done to minimize any associated risk. First, physicians should avoid heavy sedation so that the patient is able to communicate any changes in their pain or neurologic function. Most patients in this cohort only required small doses of midazolam (1–2 mg) and fentanyl (25–50 mg). Second, the physician must be familiar with the pharmacology of the medications used. A compelling advantage of using fentanyl and midazolam are their reversibility [30]. When midazolam and fentanyl are used together, they have a synergistic effect [34]. Many of the complications associated with sedation and analgesia can be avoided if adverse drug responses are detected and treated in a timely manner. Early detection of hypoxemia with oximetry also decreases the likelihood of adverse outcomes. In addition, monitoring vital signs at least every 5 minutes reduces likelihood of adverse events [27]. The Practice Guidelines for Sedation and Analgesia by Nonanesthesiologists contain numerous other recommendations to optimize the safe use of moderate sedation [27].

Lastly, two subjects within our cohort serve as two case reports that uniquely demonstrate how robust of a preventative effect moderate sedation can be in preventing vasovagal reactions in people at greater risk. A 47-year-old male in the cohort underwent three bilateral L5-S1 TFESIs. The first injection was performed without moderate sedation and was complicated by vasovagal reaction. His second injection was performed with moderate sedations and no vasovagal event occurred, while his third injection was again performed without conscious sedation and again complicated by vasovagal reaction. Another 59-year-old male underwent five L5-S1 TFESIs over the collection period. The first was performed without moderate sedation and complicated by vasovagal reactions and early termination of the procedure. The following three were performed with moderate sedation, and no complications were noted. The final injection was performed without moderate sedation and was unfortunately complicated by vasovagal reaction once again. Both patients, while not providing scientifically or statistically valid evidence, are good examples of the benefit effect moderate sedation can have on certain individuals.

There are several limitations to this study. First, since several physicians (both attending and trainee) performed the procedures, variations in technique likely existed. Trainees have been shown to have increased risk of vasovagal reactions in TFESIs [28]. However, variation in technique likely did not contribute to the 0% vasovagal rate with the use of moderate sedation as all procedures were done in accordance with the standards outlined by the International Spine Interventional Society that were current during the collection period [35]. Also, other data such as the usage rate of moderate sedation are severely limited in its external validity given that all data were collected at a single academic institution. Most importantly, this study was a retrospective analysis. However, the data were collected in a strict prospective manner utilizing an electronic medical record with drop-down menu choices to facilitate ease of data entry at the time of the procedure. Analysis of data from large cohorts does allow for discovery of phenomenon that may otherwise be significantly more difficult to find using a prospective double-blind, randomized, control trial. Nonetheless, the finding that moderate sedation appears to be an effective means of secondary prevention of vasovagal reactions during spine injections in individuals at higher risk for such reactions was not the hypothesis at the onset of data collection. While the data in this study are compelling, ideally, it should be used to perform a more controlled prospective and randomized study that would be able to further evaluate the apparent causal effect moderate sedation has on prevention of vasovagal reactions in higher-risk populations during spine procedures.

## Conclusions

A history of vasovagal reaction is a strong predictor of experiencing a vasovagal reaction on subsequent procedures, with the rate of repeat vasovagal being over seven times higher (23.3%) than the vasovagal rate in those without such history (3.0%). The use of low-dose moderate sedation may be an effective measure to prevent the recurrence of an adverse vasovagal reaction in a select patient population. Given the known risks of moderate sedation and the overall low likelihood of a vasovagal reaction, the routine use of conscious sedation as a primary prevention for vasovagal reactions is not necessary. Greater benefits were observed when conscious sedation was used for prevention of repeat vasovagal reactions in an at risk population.

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