Trainee Involvement in Transforaminal Epidural Steroid Injections Associated With Increased Incidence of Vasovagal Reactions

Byron Schneider, MD, David J. Kennedy, MD, Ellen Casey, MD, Matthew Smuck, MD, Bryan Conrad, PhD, Christopher Plastaras, MD

Objectives: To evaluate whether trainee involvement (resident and fellow) during transforaminal epidural steroid injections (TFESI) results in greater rates of vasovagal reactions.

Design: Retrospective study on consecutive patients.

Setting: Single academic medical center with multiple attending physicians and trainees.

Participants: A total of 2642 consecutive subjects undergoing 4482 TFESI were analyzed from March 8, 2004, to January 30, 2009.

Main Outcome Measures: The Pearson χ^2 test was used to determine the relationship between vasovagal reactions and level of trainee involvement.

Results: A total of 4482 TFESIs were performed, with 157 (3.5%) of procedures complicated by a vasovagal reaction. An attending physician performed 2884 (64.3%) procedures without trainee involvement, with only 79 (2.7%) vasovagal reaction noted. A fellow was involved in 723 (16.1%) procedures, with 30 (4.1%) noted to have a vasovagal reaction. A resident was involved in 875 (19.5%) procedures, with 48 (5.5%) having a vasovagal reaction. Overall, trainees were involved in 1598 (35.7%) cases, of which 78 (4.9%) were complicated by vasovagal reaction. When a trainee was involved in the case, there was a greater incidence of vasovagal episodes ($P < .001$, $\chi^2 = 16.047$). Although there was a trend towards greater vasovagal rates with residents over fellows, this did not reach statistical difference.

Conclusions: Vasovagal reactions can occur with spine injection procedures and may result in premature procedure termination or other adverse events. Although this retrospective study has significant potential for bias, it appears that trainee involvement in a TFESI is associated with a greater incidence of vasovagal reaction ($P < .001$, $\chi^2 = 16.047$).

PM R 2014;6:914-919

INTRODUCTION

In 2004 there were a total of 1,637,494 epidural, spinal neurolysis, and adhesiolysis procedures performed in the Medicare population [1]. Although serious complications have been reported, in general, these types of interventions have very low complication rates [2-4]. Vasovagal reactions during spine injections frequently are cited as a common immediate adverse event, with a range of reported rates between 0% and 8.7% [5-13]. Vasovagal reactions are thought to occur via an autonomic nervous system response resulting in arterial dilation and bradycardia. In addition to the unpleasant but relatively benign symptoms of vasovagal reactions such as dizziness, diaphoresis, and nausea, vasovagal reactions also may lead to aborted procedures because of hypotension, bradycardia, and, very rarely, asystole [10,14-16].

Risk factors for vasovagal reactions during spine injections are poorly defined. Previous studies have suggested that there is an increased risk of vasovagal reactions in men and those patients younger than 65 years of age [17]. In the surgical literature, trainee involvement is a risk factor for increases in overall morbidity,

B.S. Department of Orthopaedics, Stanford University, Redwood City, CA
Disclosure: nothing to disclose

D.J.K. Department of Orthopaedics, Stanford University, Redwood City, CA. Address correspondence to: D.J.K., 450 Broadway St., Pavilion C, MC 6342 Redwood City, CA 94063; e-mail: djkenned@stanford.edu
Disclosure: nothing to disclose

E.C. Rehabilitation Institute of Chicago, Northwestern University, Chicago, IL
Disclosures outside this publication: grants/grants pending, NIH K-12 grant for unrelated research (money to institution)

M.S. Department of Orthopaedics, Stanford University, Redwood City, CA
Disclosures outside this publication: board membership, ISIS; grants/grants pending, Cytonics Corp, Seikagaku Corp (SKK) (money to institution); payment for lectures, including service on speakers bureaus, NASS Instructional Course Honoraria; travel/accommodations/meeting expenses unrelated to activities listed, NASS Airfare

B.C. Nike Sport Research Lab, Beaverton, OR
Disclosure: nothing to disclose

Author information continued on page 918.

Peer reviewers and all others who control content have no relevant financial relationships to disclose.

Submitted for publication August 7, 2013; accepted April 6, 2014.

Vol. 6, 914-919, October 2014
http://dx.doi.org/10.1016/j.pmrj.2014.04.003

operative time, and complications during hospitalization [18-22]. Data were collected as routine part of medical care with an electronic medical record. The goal of this article and study was to specifically examine the role of trainee involvement. A larger and more extensive multivariate analysis of this cohort has already been done and published [17]. The novel findings in this study are the effects of trainee involvement on the likelihood of a patient developing a vasovagal reaction.

METHODS

This study was a retrospective analysis of an existing prospectively collected dataset that included 2642 consecutive patients treated at a single academic medical center between 2004 and 2009. This study was institutional review board approved at Northwestern University and Health Insurance Portability and Accountability Act of 1996 compliant. Data were collected as routine part of medical care with an electronic medical record. All interventions were performed by the use of fluoroscopic-guidance in either an office-based fluoroscopy suite or ambulatory surgery center by 1 of 4 experienced attending 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. Residents and fellows in this cohort were solely physical medicine and rehabilitation trainees, as no other medical subspecialties were represented. Resident blocks consisted of 2-month rotations during the postgraduate training years 3 and 4. When present, a fellow usually participated in the procedure. Resident involvement was more variable, and the degree of trainee involvement was at the discretion of the attending physician. Trainees were noted to be involved only if they participated in the interventional portion of the procedure. This participation could be variable and range from anesthetizing the skin to completion of the procedure. The attending's involvement ranged from supervision without being gloved in to hands-on participation with the trainee.

More than 95% of the procedures were performed in an office-based fluoroscopy suite; however, monitoring in this setting was set up to mirror that received in an outpatient surgical center. During the procedure, all patients were actively monitored via continuous pulse oximetry and intermittent automatic blood pressure monitoring by a registered nurse who was positioned at the head of the bed and whose sole responsibility was to monitor the patient. Nurses also kept in verbal communication with the patients to their monitor level of consciousness and to note any symptoms such as nausea. The nurse notified the attending physician if any symptoms were noted. Patients were noted to have a vasovagal reaction by the attending physician if they had a decrease in heart rate and blood pressure in addition to one or more symptom(s) consistent with vasovagal reaction, including lightheadedness, dizziness, palpitations, weakness, dimming or blurred vision, nausea and epigastric distress, feeling warm or cold, facial pallor, and excessive sweating.

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 demographic and multiple clinical and procedural characteristics were noted, including age, gender, pre- and post-procedure 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 after the start of the procedure and before the patient was transferred from the treatment room to recovery. Termination of the procedure was at the sole discretion of the attending physician [17].

Statistical analyses were performed per injection, rather than per patient. To determine the relationship between categorical variables, the Pearson χ^2 test was used. The assumption that the sampling distribution of each variable approximated a χ^2 distribution was checked by ensuring that the expected frequencies in each cell were at least 5. In situations in which sample sizes are less than 5, the Fisher exact test was used. All statistical analysis was performed using SPSS version 20 (IBM Corp.; Armonk, NY). Significance values were set a priori at a level of $P < .05$ [17].

RESULTS

A total of 4482 TFESIs were performed in 2642 consecutive patients. An attending physician performed 2884 (64.3%) procedures without trainee involvement, and only 79 (2.7%) resulted in a documented vasovagal reaction. A fellow was involved in 723 (16.1%) procedures, with 30 (4.1%) noted to have a vasovagal reaction. A resident was involved in 875

Table 1. *Vasovagal rates per level of trainee involved with 95% confidence intervals*

	Vasovagal Reaction	No Vasovagal Reaction
Resident (total n = 875)	n = 48 5.5 ± 1.5%	n = 827
Fellow (total n = 723)	n = 30 4.1 ± 1.5%	n = 693
Resident or Fellow* (total n = 1598)	n = 78 4.8 ± 1.1%	n = 1520
Attending only* (total n = 2884)	n = 79 2.7 ± 0.6%	n = 2805

*Denotes nonoverlapping 95% confidence intervals.

Table 2. *Procedural associations and rates of vasovagal reactions*

		Needle Gauge		Needle Length, inches		Fluoro Time, s		VAS (0-10)	
	N	Mean	Range	Mean	Range	Mean	Range	Preprocedure	Postprocedure
Vasovagal	157	22.12	22-25	3.7	2-5	26.6	3-112	4.94	2.48
No vasovagal	4325	22.22	20-25	3.8	1.5-8	38.9	3-655	5.92	2.28
Total	4482	22.21	20-25	3.8	1.5-8	38.3	3-655	5.91	2.67

VAS = visual analog scale.

(19.5%) procedures, with 48 (5.5%) having a vasovagal reaction (Table 1). Overall, trainees were involved in 1598 (35.7%) cases, of which 78 (4.9%) were complicated by vasovagal reactions (Table 1). When a trainee was involved in the case, the incidence of vasovagal episodes was greater ($P < .001$, $\chi^2 = 16.047$). Although there was a trend toward greater vasovagal rates with residents over fellows, this trend did not reach statistical difference. A per-month analysis of vasovagal rates also was performed (Figure 1) to determine whether the level of training of the trainee played a role in the development of a vasovagal reaction. When analyzing data on a per month basis, no differences emerged that reached statistical significance ($P < .134$).

A total of 2601 (58.0%) of the procedures were performed on female patients, and 3137 (70.0%) of the procedures were performed on patients younger than the age of 65 years. The mean fluoroscopy time was 47.3 seconds (Table 2). The range of needle gauge was 20-25, with a 22-gauge needle used most commonly (4155; 92.7%) (Table 2). Needle length ranged between 1.5 and 8 inches, with a 3.5-inch needle being used most common (3184; 71.0%) (Table 2). Needle data were unavailable for 7 of the procedures. The majority of procedures were performed without patients receiving sedation, with only 132 (2.85%) of the injections performed with the patient under moderate conscious sedation. The decision to preform conscious sedation was based upon attending preference, and trainees also were involved in these procedures.

In total, 157 (3.5%) procedures were complicated by a vasovagal reaction. Of these, 46 (29.3%) were terminated before the procedure was completed because of vasovagal reactions. None of the vasovagal reactions occurred when conscious sedation was used. The mean fluoroscopy time of procedures complicated by vasovagal reaction was 30.7 seconds versus 46.1 seconds for procedures not complicated by vasovagal reaction. Male patients accounted 63.1% vasovagal reactions, at a rate of 5.3% (Table 3). Patients younger than the age of 65 years accounted for 85.4% of the vasovagal reactions, at a rate of 4.3% (Table 4). Needle data were unavailable for 4 of the procedures with a vasovagal complication. One hundred forty-seven of the 4155 (3.5%) injections that used a 22-gauge needle resulted in a vasovagal reaction. Six of the 317 (1.9%) procedures that used a 25-gauge needle resulted in the remainder of the vasovagal reactions. One hundred sixteen of the 3184 (3.6%) procedures that used a 3.5-inch needle resulted in a vasovagal reaction whereas 36 of the 1025 (3.5%) injections that used a 5-inch needle resulted in a vasovagal reactions. A 2-inch needle had a vasovagal rate of only (0.4%), and the only place a needle less than 3.5 inches was used was with a cervical injection. There was no significant relationship found between needle gauge or needle length and vasovagal reaction. However, there was a trend toward a significant relationship demonstrating that men and patients younger than 65 years of age were associated with an increased rate of vasovagal reaction during TFESI. No patients received preprocedure oral anxiolytics. Intravenous sedation was used in only 214 subjects who received any injection from this group during the data collection period, and the rate of adverse vasovagal reactions was zero among patients that received sedation.

DISCUSSION

This study of a large consecutive cohort of more than 2600 patients who received more than 4400 TFESI provides unique findings on the association between trainee involvement and rates of vasovagal reactions. This finding is consistent with surgical literature demonstrating an association of trainee involvement and increased hospital or procedural complications [18-21]. To the best of the authors' knowledge, evidence on trainee involvement and complications during TFESIs,

Table 3. *Patient gender and vasovagal reactions*

	Male	Female	Total
VV	99 (5.3% (95% CI ± 1.0%))	58 (2.2% (95% CI ± 0.6%))	157 (3.5%)
No VV	1779 (94.7%)	2546 (97.8%)	4325 (96.5%)
	1878 (41.9%)	2604 (58.1%)	4482

CI = confidence interval; VV = vasovagal reaction.

Table 4. *Patient age and vasovagal reactions*

	Younger Than 65 Years	65 Years and Older	Total
Vasovagal	134 (4.3% (95% CI ± 0.7%))	23 (1.7% (95% CI ± 0.7%))	157 (3.5%)
No vasovagal	3003 (95.7%)	1322 (98.3%)	4325 (96.5%)
	3137 (70.0%)	1345 (30.0%)	4482

more commonly performed in the setting of PM&R and anesthesia practices, has not previously been described. The overall rate of vasovagal reactions observed was 3.5%, which is consistent with previous reports [5-13]. This consistency with previously reported rates suggests good generalizability of these findings and the influence of physician experience on vasovagal rates. Trainees were shown to have a vasovagal rate nearly twice that of experienced attending physicians (4.9% versus 2.7%; $P < .001$, $\chi^2 = 16.047$). Moreover, there was a trend towards greater vasovagal rates when generally less experienced residents participated in the procedure compared to generally more experienced fellows.

This study was not designed to uncover the reason for greater vasovagal rates with trainees; thus, we can only speculate about the potential causes. Variation in technique is possibly a culprit. The attending physicians may perform the procedure more rapidly than trainees, and they may also have techniques that reduce patient discomfort. Fluoroscopy time was measured but may not be an accurate measure because it could be artificially low in any subject in whom the procedure was terminated. Experienced physicians also may be more in tune with subtle feedback from patients that cause them to alter their approach to minimize procedure discomfort. Also, trainee involvement may increase patient anxiety, leading to an increased rate of vasovagal reactions, as emotions appear to be an additional factor underlying the development of vasovagal syncope [23-25]. Potentially, the supervision of an experienced attending would mitigate this relationship; however, additional study is required to demonstrate this. Regardless, a learning curve exists for epidural needle placement. Studies have shown a learning curve among trainees for specific portions of spine procedures [26,27]; however, the connection between the technical skill learning curves and complication rates during injection procedures has not been investigated [28].

This investigation reaffirms an association of male gender and age younger than 65 years with increased rate of vasovagal events, specifically in TFESIs [29]. Needle characteristics, including gauge and length, were not shown to correlate to the development of a vasovagal reaction. In addition to the unpleasant side effects of a vasovagal reaction, nearly 30% of vasovagal events resulted in premature completion of the procedure in this cohort. By stopping the procedure before completion, no patients in this large cohort required intravenous medications or transportation to a hospital due to a vasovagal reaction. Typical treatments included placing patient in a Trendelenburg position with a cold pack on their neck.

This study had several limitations. First, because several physicians (both attending and trainee) performed the procedures, variations in technique likely existed; thus, other unknown factors could easily have affected these results. All procedures were performed in accordance with the Standards outlined by the International Spine Interventional Society [30], but this may not account for minor variations in technique or bedside manner that could affect the rate of vasovagal reactions. This variation does, however, help paint a more accurate picture of the vasovagal rate among physicians in general. Second, the exact degree of trainee involvement was not documented. For instance, a fellow at the end of training who required minimal attending supervision was classified the same as a fellow on the first day of training. These 2 trainees would obviously represent different amounts of experience, yet it is unclear whether this amount of detail would have changed this study's findings.

Another confounder is that trainee experience changes with time, such that a fellow at the end of training is much more similar to an attending whereas at the beginning of training they are closer to a resident. This dataset does not facilitate a more in-depth analysis; however, a per-month vasovagal rate was included in Figure 1. This information is difficult to interpret, given the degree of trainee involvement may vary significantly through time. The amount of trainee involvement was also variable; however, the large numbers in this cohort help with this potential source of bias. There is also large potential for bias by having the physician enter the data of complications. However, there would be no incentive for a physician to not note the occurrence of an adverse vasovagal reaction, and not entering these data presents potential liability issues. Finally, this study was a retrospective analysis; however, the original

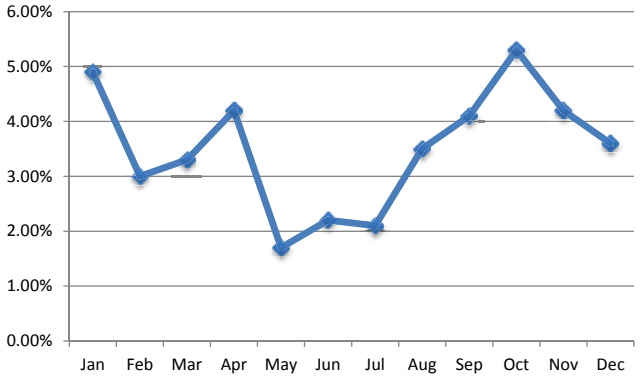

Figure 1. Vasovagal rate by month.

data were collected in a strict prospective manner using an electronic medical record with drop-down menu choices to facilitate ease of data entry at the time of the procedure.

CONCLUSIONS

Vasovagal reactions have an overall occurrence rate of 3.5% in TFESIs, with increasing rates found in male patients and in patients younger than 65 years of age. Although there is a potential for bias, this study does appear to demonstrate that when a trainee is involved in a TFESI, there is nearly twice the rate of vasovagal reaction. A similar association, although not statistically significant, was a trend seen towards vasovagal reactions having a greater incidence with resident involvement compared with fellow involvement. Fortunately, no serious complications occurred during any of the more than 4000 injections. Further investigation is needed to evaluate whether trainee involvement is associated with increased rate of other complications during TFESIs and other similar procedures. Trainee involvement in an essential element of physician training and should not be discouraged despite the findings in this study.

REFERENCES

1. Manchikanti L. Medicare in interventional pain management: A critical analysis. Pain Physician 2006;9:171-197.
2. Kennedy DJ, Dreyfuss P, Aprill CN, Bogduk N. Paraplegia following image-guided transforaminal lumbar spine epidural steroid injection: Two case reports. Pain Med 2009;10:1389-1394.
3. DePalma MJ, Stout A, Kennedy DJ. Corticosteroid Choice for Epidural Injections. PM R 2013;5:524-532.
4. O'Brien D, Cohen I, Kennedy DJ. Compounding pharmacies: A viable option, or merely a liability? PM R 2013;5:974-981.
5. Cicala RS, Westbrook L, Angel JJ. Side effects and complications of cervical epidural steroid injections. J Pain Symptom Manage 1989;4:64-66.
6. Karaman H, Kavak GO, Tufek A, Yldrm ZB. The complications of transforaminal lumbar epidural steroid injections. Spine 2011;36:E819-E824.
7. Manchikanki L, Malla Y. A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. Pain Physician 2012;15:131-140.
8. Botwin KP, Gruber RD, Bouchlas CG, Torres-Ramos FM, Freeman TL, Slaten WK. Complications of fluoroscopically guided transforaminal lumbar epidural injections. Arch Phys Med Rehabil 2000;81:1045-1050.
9. Huston CW, Slipman CW, Garvin C. Complications and side effects of cervical and lumbosacral selective nerve root injections. Arch Phys Med Rehabil 2005;86:277-283.
10. Florida N. Quality assurance for interventional pain management procedures in private practice. Pain Physician 2008;11:43-55.
11. Waldman S. Complications of cervical epidural nerve blocks with steroids: A prospective study of 790 consecutive blocks. Reg Anesth 1989;14:149-151.
12. Ahmed SU, Tonidandel W, Trella J, Martin NM, Chang Y. Peri-procedural protocols for interventional pain management techniques: a survey of US pain centers. Pain Physician 2005;8:181-185.
13. Pobiel R, Schellhas K, Eklund J, et al. Selective cervical nerve root blockade: Prospective study of immediate and longer term complications. Am J Neuroradiol 2009;30:507-511.
14. Wieling W. Reflex syncope in children and adolescents. Heart 2004;90:1094-1100.
15. Botwin K, Gruber R, Bouchlas C, et al. Complications of fluoroscopically guided caudal epidural injections. Am J Phys Med Rehabil 2001;80:416-424.
16. Stauber B, Ma L, Nazari R. Cardiopulmonary arrest following cervical epidural injection. Pain Physician 2012;15:147-152.
17. Kennedy DJ, Schneider B, Casey E, et al. Vasovagal rates in flouroscopically guided interventional procedures: A study of over 8,000 injections. Pain Med 2013;14:1854-1859.
18. Bukur M, Singer MB, Chung R, Ley EJ, Malinoski DJ, Margulies DR, et al. Influence of resident involvement on trauma care outcomes. Arch Surg 2012;147:856-862.
19. Davis SS Jr, Husain FA, Lin E, Nandipati KC, Perez S, Sweeney JF. Resident participation in index laparoscopic general surgical cases: Impact of the learning environment on surgical outcomes. J Am Coll Surg 2013;216:96-104.
20. Kiran RP, Ahmed Ali U, Coffey JC, Vogel JD, Pokala N, Fazio VW. Impact of resident participation in surgical operations on postoperative outcomes: National Surgical Quality Improvement Program. Ann Surg 2012;256:469-475.
21. Raval MV, Wang X, Cohen ME, et al. The influence of resident involvement on surgical outcomes. J Am Coll Surg 2011;212:889-898.
22. Scarborough JE, Bennett KM, Pappas TN. Defining the impact of resident participation on outcomes after appendectomy. Ann Surg 2012;255:577-582.
23. Arthur W, Kayne G. The pathophysiology of common causes of syncope. Postgraduate Med J 2000;76:750-753.
24. Buodo G, Sarlo M, Poli S, et al. Emotional anticipation rather than processing is altered in patients with vasovagal syncope. Clin Neurophysiol 2012;123:1319-1327.
25. Chen-Scarabelli C, Scarabelli TM. Neurocardiogenic syncope. BMJ 2004;329:336-341.
26. Smuck M, Abbott Z, Zemper E. Interpretation of contrast dispersal patterns by experienced and inexperienced interventionalists. PM R 2009;1:55-59.
27. Visco CJ, Kennedy DJ, Chimes GP, et al. Programmatic design for teaching the introductory skills and concepts of lumbar spine procedures to physiatry residents: a prospective multiyear study. Am J Phys Med Rehabil 2013;92:248-257.
28. Mayer EK, Ihm JM, Sibell DM, Press JM, Kennedy DJ. ACGME Sports, ACGME Pain, or Non-ACGME Sports and Spine: Which is the ideal fellowship training for PM&R Physicians interested in musculoskeletal medicine? PM R 2013;5:718-725.
29. Kennedy DJ, Segal NA. Conclusion. PM R 2012;4(5 Suppl):S174-S175.
30. Derby MD, Dreyfuss P, Endres S, et al. Educational Guidelines for Interventional Spinal Procedures [cited 2012 Dec 26]. Available at: http://www.indianapainsociety.org/fileuploads/ClinicalGuidelines/AAPMRIPMGuidelines2008.pdf. Accessed April 29, 2014.

Footnotes Continued From Page 914.

C.P. Department of Physical Medicine and Rehabilitation, University of Pennsylvania, Philadelphia, PA

Disclosures related to this publication: consulting fee or honorarium, 2010 National Council on Strength and Fitness Job Analysis Task Force, Elite Rehabilitation Solutions LLC, CMEInfo, Pennsylvania Neurosurgical Society, AAPM&R, North American Spine Society, 18th European congress of Physical & Rehabilitation Medicine: Science & Art in Physical & Rehabilitation Medicine, Excel Physical Therapy; support for travel to meetings for the study or other purposes, Pennsylvania Neurosurgical Society, AAPM&R, North American Spine Society, 18th European congress of Physical & Rehabilitation Medicine: Science & Art in Physical & Rehabilitation Medicine, 2010 National Council on Strength and Fitness Job Analysis Task Force; other, Senior Medical Consultant for TLG Associates

Disclosures outside this publication: board membership, 2010 National Council on Strength and Fitness Job Analysis Task Force; consultancy, Senior Medical Consultant for TLG Associates; grants/grants pending, ISIS (money to institution); payment for lectures, including service on speakers bureaus, Elite Rehabilitation Solutions LLC; patents, ownership of copyright of the RICPLAS

This journal-based CME activity is designated for 1.0 AMA PRA Category 1 Credit™ and can be completed online at www.me.aapmr.org. This activity is FREE to AAPM&R members and available to non-members for a nominal fee. For assistance with claiming CME for this activity, please contact (847) 737-6000.

CME Question

Which vasovagal symptoms will abort an interventional procedure?

a. diaphoresis
b. palpitations
c. hypotension
d. diplopia

Answer online at me.aapmr.org