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Is Severe Pain Immediately after Spinal Augmentation a Predictor of Long-Term Outcomes?

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ABSTRACT

BACKGROUND AND PURPOSE: Severe, immediate postprocedural pain and the need for analgesics after vertebroplasty can be a discouraging experience for patients and caregivers. The goal of this study was to investigate whether the presence of severe pain immediately after vertebroplasty predicts short- and long-term pain relief.

MATERIALS AND METHODS: A chart review was performed to categorize patients regarding pain severity and analgesic usage immediately after vertebroplasty (< 4 h). "Severe" pain was defined as at least 8 of 10 with the 10-point VAS. Outcomes were pain severity and pain medication score and usage at 1 month and 1 year after vertebroplasty. Outcomes and clinical characteristics were compared between groups by using the Wilcoxon signed-rank test and the Fisher exact test.

RESULTS: Of the 429 vertebroplasty procedures identified, 69 (16%) were associated with severe pain, and 133 (31%) were associated with analgesic administration immediately after the procedure. The group experiencing severe pain had higher preprocedure median VAS rest pain scores (5 [IQR, 2–7]) and activity pain scores (10 [IQR, 8–10]) compared with patients who did not experience severe pain (3 [IQR, 1–6]; $P = .0208$, and 8 [IQR, 7–10]; $P = .0263$, respectively). At 1 month postprocedure, VAS rest and activity pain scores were similar between the severe pain group and the nonsevere pain group ($P = .16$ and $P = .25$, respectively) and between the group receiving pain medication and the group not receiving pain medication ($P = .25$ and $P = .67$, respectively). This similarity continued for 1 year after the procedure. Analgesic usage was similar among all groups at 1 year postprocedure.

CONCLUSIONS: Patients with severe pain immediately after vertebroplasty have similar long-term outcomes compared with patients without severe pain.

ABBREVIATIONS: IQR = interquartile range; VAS = visual analog scale

Spinal augmentation procedures, including vertebroplasty and kyphoplasty, have been used widely for palliation of pain-related osteoporotic and pathologic compression fractures of the spine. The literature abounds with both prospective and retrospective studies attempting to characterize many different aspects of the spinal augmentation procedures such as procedure efficacy, characteristics of fractures in success of augmentation, sequelae of spinal augmentation procedures, and a variety of other topics.[1-4] However, there is a paucity of research investigating clinical signs or symptoms directly related to the procedure as predictors of outcome after spinal augmentation.

Severe, immediate postprocedural pain; pain before hospital discharge; and the need for analgesics after vertebroplasty can be a discouraging experience for patients and caregivers. Despite the literature establishing vertebroplasty as a technique for management of painful compression fractures, the short- and long-term outcomes in patients with severe, immediate postprocedural pain, to our knowledge, have not been investigated previously. The goal of our current study is to investigate whether the presence of severe pain immediately after spinal augmentation procedures or the need for immediate postprocedure analgesics predicts short- and long-term pain relief. In addition, our study will attempt to determine whether characteristics of the patient or the procedure can predict which patients will experience severe pain immediately after the procedure.

MATERIALS AND METHODS

Study Population and Data Retrieval

Institutional review board approval was obtained before this retrospective study. A vertebroplasty patient data base maintained at

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Table 1: Vertebroplasty patient and procedure characteristics

		Type of Pain			Pain Medication		
	All	Severe	Nonsevere	*P* Value	Given	Not Given	*P* Value
No. patients	429	69	360		133	296	
Patient characteristics							
Age (median, IQR)	75 (65–82)	75 (65–82)	75 (65–83)	.99	75 (65–83)	75 (65–82)	.66
Female (%)	257 (40)	41 (59)	216 (60)	.99	88 (66)	169 (57)	.09
No. with chronic, untreated fractures (%)	142 (33)	27 (39)	115 (32)	.27	59 (44)	83 (28)	.0012
No. with fractures because of malignancy (%)	74 (18)	15 (24)	59 (17)	.21	25 (20)	49 (18)	.49
Median VAS rest pain score (IQR)	4 (1–6)	5 (2–7)	3 (1–6)	.0208	3 (1–6)	4 (1–6)	.54
Median VAS activity pain score (IQR)	9 (7–10)	10 (8–10)	8 (7–10)	.0263	10 (8–10)	9 (7–10)	.0022
Median pain duration (months, IQR)	2 (1–4)	2 (1–3)	2 (1–4)	.76	1 (1–3)	2 (1–4)	.0317
No. receiving pain medication (%)	401 (99)	60 (98)	341 (99)	.56	126 (99)	275 (99)	.99
Median pain medication score (IQR)	3 (3–3)	3 (3–3)	3 (3–3)	.85	3 (3–3)	3 (3–3)	.0058
Vertebroplasty procedure characteristics							
Median cement volume (mL) (IQR)	3.5 (2.0–5.0)	3.5 (2.0–5.0)	3.2 (2.0–4.6)	.88	3.7 (2.0–5.0)	3.0 (2.0–4.5)	.15
Unilateral needle placement (%)	306 (77)	46 (74)	260 (78)	.51	89 (75)	217 (78)	.51
Median no. levels treated (IQR)	1 (1–2)	1 (1–2)	1 (1–2)	.84	1 (1–2)	1 (1–2)	.28
3+ levels treated (%)	48 (11)	11 (16)	37 (10)	.21	22 (17)	26 (9)	.0205
Complications (%)	95 (23)	17 (25)	78 (22)	.75	30 (23)	65 (22)	.99
Cement embolus (%)	19 (4)	4 (6)	15 (4)	.53	7 (5)	12 (4)	.62
Extravertebral leakage (%)	75 (17)	12 (18)	63 (18)	.87	22 (17)	53 (18)	.89

our institution was the source of data for this study. Patients in this data base have previously been included in other published studies that have not specifically examined patients with immediate postprocedure severe pain.[1,4-14] Patients who underwent a vertebroplasty procedure at our institution from 2005–2011 were included in the study. Patients were excluded if they did not have immediate postprocedure pain data within 3 hours after the vertebroplasty or at either 1 month or 1 year postprocedure.

Retrospective medical chart review was performed to confirm data base records and retrieve additional clinical information. Data recorded included preprocedure descriptors (demographics; pain severity; prescribed analgesics; number, level, and acuity of each fracture; number of chronic fractures that were not treated because they were not amenable to vertebroplasty; and benign or malignant nature of the fracture), procedural descriptors (unilateral vs bilateral transpedicular approach, number of augmentations performed, distribution of cement, and complications), and postprocedural descriptors (pain severity and medications administered within 3 hours after the procedure and at 1-month and 1-year follow-ups). Pain severity was measured at both rest and activity by using the 10-point VAS.[15] Medication scores were recorded as follows: 0 = no medications, 1 = over-the-counter analgesics, 2= non-narcotic prescription medication as needed, 3 = oral narcotic analgesic as needed, 4 = scheduled oral narcotic or analgesic patches, and 5 = intravenous narcotics.

Patients were categorized by pain and analgesic requirements within 3 hours of vertebroplasty. Patients were divided into 2 groups: those with immediate postprocedure pain scores ≥8 ("severe pain group") and those whose pain scores were < 8 ("nonsevere pain group") in the 3 hours after the vertebroplasty procedure. "Immediate postprocedure pain" was defined as that recorded before discharge from the hospital on the day of the procedure, typically 2–4 hours after vertebroplasty. Patients were also divided into whether they received pain medication in the 3 hours immediately after the procedure.

Statistical Analysis

We performed statistical analyses by using JMP (version 9; SAS Institute, Cary, North Carolina). Continuous variables were presented as median and IQR, and categoric variables were presented as percentages. Preprocedural, procedural, and postprocedural characteristics and outcomes were compared between groups by using the Wilcoxon signed-rank test and the Fisher exact test. Statistical significance was defined as $P < .05$.

RESULTS

All vertebroplasty procedures performed from 2005–2011 by 8 independent operators were identified. Of 877 total procedures performed during this timeframe, 448 (51%) procedures were excluded because they lacked 3-hour postprocedure pain data or lacked either 1-month or 1-year follow-up information on pain and medication, leaving 429 included procedures. Of these 429 procedures, 69 (16%) were associated with severe pain in the 3 hours after the vertebroplasty procedure. A total of 133 (31%) of 429 procedures were associated with administration of some pain medications in the 3 hours after the vertebroplasty procedure.

Overall characteristics were very similar between the severe pain/pain medication groups and their respective control groups (Table 1). The severe pain group had significantly higher preprocedure median VAS rest pain scores (5 [IQR, 2–7]) compared with the nonsevere pain group (3 [IQR, 1–6]) ($P = .0208$). Median VAS activity pain scores were also significantly higher in the severe pain group (10 [IQR, 8–10]) compared with the nonsevere pain group (8 [IQR 7–10]) ($P = .0263$). The patient group that received pain medication immediately after the procedure also had higher median VAS activity pain scores (10 [IQR, 8–10]) compared with the group that did not receive pain medication (9 [(IQR, 7–10]) ($P = .0022$). There was a higher percentage of patients in the pain medication group with chronic fractures who were not treated because they were not amenable to vertebroplasty compared with the control group (59 [44%] of 133 vs 83 [28%] of 296; $P = .0013$). Patients in the pain medication group

Table 2: Postvertebroplasty pain and medication usage at 1-month and 1-year follow-ups

		Type of Pain			Pain Medication		
	All	Severe	Nonsevere	*P* Value	Given	Not Given	*P* Value
One-month follow-up							
No. patients (% lost to follow-up)	399 (7)	68 (1)	331 (8)		123 (8)	276 (7)	
No. patients with pain scores	369	61	308		113	256	
Median VAS rest pain score (IQR)	0 (0–3)	2 (0–3)	0 (0–3)	.16	0 (0–2)	0 (0–3)	.25
Median VAS activity pain score (IQR)	4 (0–6)	3 (0–5)	4 (0–6)	.25	3 (0–6)	4 (0–6)	.67
No. patients with pain medication scores	383	60	323		119	264	
Median pain medication score (IQR)	3 (0–4)	3 (0–4)	3 (1–4)	.17	3 (1–4)	3 (0–4)	.33
Change in pain medication score from prevertebroplasty							
Unchanged (%)	99 (26)	12 (20)	87 (27)	.34	31 (26)	68 (26)	.99
Improved (%)	167 (43)	21 (35)	146 (45)	.16	52 (43)	115 (44)	.99
Worsened (%)	117 (31)	27 (45)	90 (28)	.0097	36 (31)	81 (31)	.99
One-year follow-up							
No. patients (% lost to follow-up)	307 (28)	46 (33)	261 (28)		100 (25)	207 (30)	
No. patients with pain scores	288	44	244		93	195	
Median VAS rest pain score (IQR)	0 (0–2)	0 (0–3)	0 (0–2)	.0247	0 (0–3)	0 (0–2)	.43
Median VAS activity pain score (IQR)	3 (0–6)	4 (0–6)	3 (0–6)	.17	3 (0–6)	3 (0–6)	.78
No. patients with pain medication scores	176	29	147		59	117	
Median pain medication score (IQR)	3 (1–4)	3 (1–4)	3 (1–4)	.30	3 (1–4)	3 (1–4)	.65
Change in pain medication score from prevertebroplasty							
Unchanged (%)	63 (36)	9 (31)	54 (37)	.67	25 (42)	38 (32)	.24
Improved (%)	63 (36)	9 (31)	54 (37)	.67	23 (39)	40 (34)	.62
Worsened (%)	50 (28)	11 (38)	39 (27)	.26	11 (19)	39 (33)	.0514

also had a shorter median duration of pain before the procedure compared with the control group (1 month [IQR 1–3] vs 2 months [IQR 1–4]; $P = .0378$). There was no difference in the percentage of patients who had 3 or more levels treated between the severe pain group and the nonsevere pain group ($P = .21$). However, there was a higher percentage of these patients in the pain medication group compared with the control group (22 [17%] of 133 vs 26 [9%] of 296; $P = .0205$). All other clinical and procedural characteristics were similar between the severe pain group and the nonsevere pain group and between the pain medication group and the no-pain-medication group.

Rates of loss to follow-up were similar between the severe pain group and the nonsevere pain group and between the pain medication group and the no-pain-medication group at 1 month and 1 year after the procedure (Table 2). At 1 month postprocedure, VAS rest and activity pain scores were similar between the severe pain group and the nonsevere pain group ($P = .16$ and $P = .25$, respectively) and between the pain medication group and the no-pain-medication group ($P = .25$ and $P = .67$, respectively). However, a significantly higher percentage of patients had worsened medication scores (ie, from a score of 1 for over-the-counter narcotics to a score of 3 for prescription narcotics) in the severe pain group at 1 month compared with the nonsevere pain group (27 [45%] of 60 vs 90 [28%] of 323; $P = .0097$). At 1 year postprocedure, VAS rest and activity pain scores were similar between the severe pain group and the nonsevere pain group and between the pain medication group and the no-pain-medication group. Medication scores at 1 year were statistically similar between all groups, though the severe pain group still demonstrated a higher percentage of patients with worsened medication scores compared with the nonsevere pain group (11 [38%] of 29 vs 39 [27%] of 147; $P = .26$).

DISCUSSION

This study demonstrated that severe, postprocedure pain after spine augmentation did not predict greater pain severity at either 1 or 12 months after the procedure compared with patients not experiencing severe, postprocedure pain. This equivalence in pain outcomes was present, though the patients with severe, immediate postprocedure pain presented with greater baseline pain compared with the control group. We did observe that patients with severe pain were more likely to have a worsened medication score, indicating a need for stronger analgesics, at 1 month and 1 year postprocedure compared with patients who did not have severe pain. This finding may explain why patients with severe pain reported similar levels of pain at 1 month and 1 year postprocedure compared with patients without severe pain; however, we could not confirm if or how frequently patients were taking these analgesics. Taken together, these findings are highly relevant to spinal augmentation practitioners, as they can reassure patients that severe, postprocedure pain does not mean that their medium-term and long-term pain outcomes will be suboptimal.

In addition to providing prognostic clarity, our study can also be used to identify which factors, if any, will predict the occurrence of severe, immediate postprocedure pain. The only factor noted to correlate with such pain was the severity of baseline pain, but that parameter alone likely will not provide substantial guidance. Among the numerous factors that logically might predict immediate pain severity—including numbers of treated levels, unipedicular or bipedicular approaches, cement leakage, or chronic fractures that were untreated because they were not amenable to vertebroplasty—none correlated with severe, immediate pain. Patients who had 3 or more levels treated were more likely to receive pain medication immediately after the procedure compared with patients who had fewer levels treated; however, the

incidence of reported severe pain was similar between these 2 groups.

Previous studies have evaluated the predictive value of early pain severity after spine augmentations. In a study of 181 vertebroplasty procedures, Hodler et al[16] described that immediate postprocedural pain relief was the best predictor of midterm outcome of vertebroplasty. Weill et al[17] showed that pain reduction achieved initially remained stable in 73% of their patients after 6 months. Heini et al[18] also found stable results after 1 year. Our current study expands on this prior literature by offering larger patient cohorts and detailed analysis of potential factors that might influence long-term outcomes.

Our study had several limitations. First, a large number of patients were excluded from the study on the basis of incomplete records at 3 hours postprocedure or at 1 month or 1 year postprocedure. It is unclear how this may have affected the findings of the study. Second, although pain is the most common complaint and can be debilitating, the use of the subjective pain scoring (0–10) was likely a suboptimal evaluation tool of the effectiveness of vertebroplasty.[19-22] In some cases in our study, pain at the puncture site continued for a few days after the procedure; therefore, VAS scores may have improved further if they had been evaluated later.[20] Better functional assessment of patient response to vertebroplasty is likely necessary, as subjective assessment of pain scales is subject to substantial interobserver and intraobserver variability. Third, as with most studies on vertebroplasty, there was a potential for bias when patients are evaluated at follow-up. It is possible that the nurse or physician administering the follow-up questions could have influenced the responses of the patients. Furthermore, it is possible that responses to the follow-up questions were occasionally provided by family members or health care providers who interacted with the patients on a daily basis, particularly with cases in which the patient was unable to give responses because of disability or dementia.[1] Fourth, although we could identify new prescriptions for analgesics after the procedure, we could not confirm if and how frequently patients were actually taking this medication. Finally, new fractures during the follow-up interval may have confounded pain outcomes. A number of patients who had immediate postprocedure relief had recurrent pain symptoms at the short- or long-term follow-up secondary to factors such as new metastatic lesions or development of new compression fractures.

CONCLUSIONS

Patients with severe pain after vertebroplasty have similar long-term outcomes and improvements compared with patients with no severe pain. Patient and procedural characteristics did not predispose patients to having immediate severe pain after vertebroplasty.

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