

# Analysis of Vertebral Augmentation Procedures from 2010 to 2018: Sequela of Controversy from Randomized Control Trials and Guidelines

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## Abstract

**Background:** Vertebral fractures affect many people, especially in countries with an aging population like the United States. Vertebral augmentation procedures such as vertebroplasty or kyphoplasty can be effective treatment options that increase life expectancy. However, in the late 2000s, randomized control trials and guideline recommendations questioned the efficacy of these procedures. This study aims to evaluate current utilization trends of vertebral augmentation procedures.

**Methods:** Data were collected from the United States Centers for Medicare and Medicaid Services Physician/Supplier Procedure Summary from 2010 to 2018. Data were stratified using current procedural terminology (CPT) codes for vertebral augmentation procedures and then sub-analyzed by type of intervention, specialty performing the intervention, and location the intervention was performed.

**Results:** The number of vertebral augmentation procedures performed decreased from 228.4 per 100 000 in 2010 to 180.8 per 100 000 in 2018—a decrease of 20.9%. By specialty, spine surgeons saw the biggest decrease from 102.75 per 100 000 to 79.29 per 100 000. Finally, by location, procedures were approximately constant except for office-based procedures which saw an increase of 256%.

**Conclusion:** The number of vertebral augmentation procedures performed per 100 000 people declined. Specifically, vertebroplasties decreased while kyphoplasty remained approximately the same. By specialty, spine surgeons saw the largest decrease followed by radiologists. Finally, when analyzed by location, all locations were approximately the same except for office-based procedures which saw an increase. The stagnant trends in vertebral augmentation procedures could potentially be explained by the controversy among randomized control trials and guidelines in the late 2000s.

**Keywords:** Kyphoplasty, office-based lab, vertebral augmentation, vertebroplasty

## Introduction

Vertebral fractures annually affect approximately 750 000 people in the United States and will continue to affect more people due to the aging population.<sup>1,2</sup> Selection of optimal treatment for vertebral fractures is important because it is associated with increase in morbidity and mortality.<sup>3</sup> Management options include nonsurgical management or percutaneous interventional vertebral augmentation techniques, such as vertebroplasty or kyphoplasty. Vertebroplasty is a minimally invasive method of injecting cement into the vertebral body to treat pain and prevent further height loss. Kyphoplasty is a similar procedure but

requires balloon inflation prior to injection of cement. Treatment of vertebral fractures by vertebral augmentation procedures has been associated with an increase in life expectancy from 2.2 years to 7.3 years when compared to nonsurgical management.<sup>4</sup>

Vertebral augmentations were commonly performed for the treatment of osteoporotic compression fractures prior to the publication of randomized controlled trials by Kallmes et al<sup>5</sup> and Buchbinder et al<sup>6</sup> in the *New England Journal of Medicine (NEJM)* in 2009 and the guidelines recommended by the American Academy of Orthopedic Surgeons in 2010.<sup>7</sup> The 2 randomized control trials published in the *NEJM* indicated no benefit in pain

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relief, disability, and quality of life when repairing vertebral fractures by vertebral augmentation when compared to sham procedures.<sup>5,6</sup>

Initial assessment of the effects of published literature and guidelines on the frequency of vertebral augmentation performed by Degnan et al<sup>8</sup> suggested a correlation between the *NEJM* publications and decreased vertebral augmentation procedure volume which peaked in 2008 before decreasing 14% in 2010 and 25% by 2014. There have been multiple meta-analyses and randomized control trials published since that show the benefit of vertebral augmentation. The purpose of this study is to analyze trends in vertebral augmentation utilization since the release of the Dengen et al study.

## Materials and Methods

This study obtained data from the United States Centers for Medicare and Medicaid Services (CMS) Physician/Supplier Procedure Summary from 2010 to 2018. These public use files consist of aggregate claims of all Medicare Part claims submitted by healthcare professionals for reimbursement. The dataset can be stratified by a procedure using Healthcare Common Procedure Coding System (HCPCS) codes. Data can further be characterized by provider specialty codes, place of service, and pricing locality. This database excludes patient identifiers, providing an exemption for review by the Institutional Review Board.

The HCPCS codes for vertebroplasty and kyphoplasty were modified in 2014. To obtain data for the years 2010 to 2014, HCPCS codes 22520-22522 and 22523-22525 were used for vertebroplasty and kyphoplasty, respectively. For years 2015 to 2018, HCPCS codes 22510-22512 and 22513-22515 were used for vertebroplasty and kyphoplasty, respectively. The procedures were stratified by site of service: Office, Hospital Outpatient, Hospital Inpatient, Ambulatory Surgical Center, and others. The "Others" category included all procedures not easily categorized as being performed in Office, Hospital Outpatient, Hospital Inpatient, or Ambulatory Surgical Center.

The data were further stratified by physician category. Physicians were placed into 1 of 3 groups using provider specialty codes: radiologists, spine surgeons, and pain management. The category of radiologists consists of physicians who identify as interventional radiologists, diagnostic radiologists, and nuclear medicine specialists. The spine surgeons category consists of orthopedists and neurosurgeons. Finally, the pain management category consists of pain management specialists, interventional pain management specialists, and

anesthesiologists; given that pain management fellowships are open to all physicians, all the remaining specialties were also grouped into the pain management category.

All data were extracted and tabulated using Excel™. To determine utilization, it was necessary to adjust the absolute number of procedures performed to account for changes in CMS beneficiary enrollment from 2010 to 2018.<sup>9</sup> Final data were calculated and reported as the number of procedures performed per 100 000 CMS beneficiaries per year (PPBY).

## Results

The total number of vertebral augmentation procedures performed in 2010 was 108 876 (Table 1). Total vertebral augmentation procedure volume decreased year over year until reaching a trough in 2013 at 97 803. By 2018, procedure volume increased to 108 467, with 83.6% of procedures performed by radiologists (42 624 procedures) and spine surgeons (48 110 procedures). The changes in the number of services performed by each physician category and all physicians in total are summarized in Figure 1.

The overall calculated vertebral augmentation PPBYs decreased from 228.4 in 2010 to 180.8 in 2018—a 20.9% decrease. The changes in vertebral augmentation procedure volume from 2010 to 2018 vary between the type of vertebral augmentation (Figure 2) and physician specialty (Figure 3). Of note, vertebral augmentation procedures rose by 256% in the Office setting in 2018 when compared to 2010 (Figure 4).

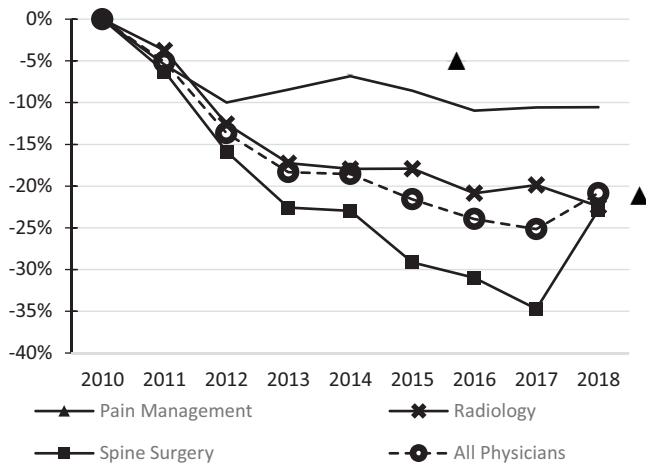
## Discussion

The data from this study suggest a decrease in vertebral augmentation utilization in the United States from 2010 to 2018, substantiating the correlation described by Degnan et al.<sup>8</sup> Although the absolute procedure count of vertebral augmentations remained stable (Figure 1), the CMS beneficiary pool increased by 26%. The PPBYs, which control for the changing population, decreased by 20.9%, indicating a decrease in utilization (Figure 2). This declining trend is contrary to what was expected given the aging population of the United States and studies demonstrating the efficacy of vertebral augmentation.<sup>4,10</sup>

Interestingly, the rate of vertebral augmentation decline was not uniform between vertebroplasty and kyphoplasty. Declining vertebroplasty procedure counts account for almost all the decline in utilization of vertebral augmentations (Figure 2). In fact, there is a 25.9% increase in absolute kyphoplasty procedure count from 2010 to 2018. However,

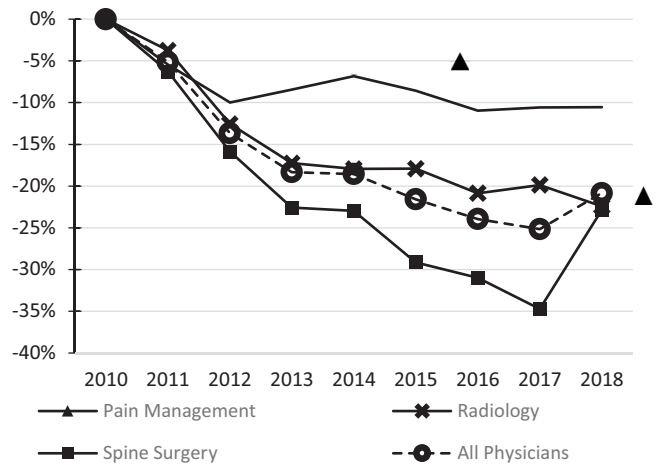
**Table 1. The Total Number of Vertebral Augmentation Procedures Billed to CMS by Procedure and Specialty from 2010 to 2018**

Procedure	Specialty	2010	2011	2012	2013	2014	2015	2016	2017	2018
Vertebroplasty	Radiology	23 248	20 752	16 806	15 060	14 216	13 373	12 433	12 430	11 146
	Spine surgery	6692	5434	4217	3607	3736	3469	3277	3010	3440
	Pain management	5673	4388	3178	2399	2054	1868	1782	1443	1622
	Total	35 613	30 574	24 201	21 066	20 006	18 710	17 492	16 883	16 208
Kyphoplasty	Radiology	20 403	22 349	23 848	24 670	26 373	28 350	28 864	30 472	31 478
	Spine surgery	42 284	41 660	39 672	38 100	39 013	36 930	37 131	36 203	44 111
	Pain management	10 576	11 370	12 403	13 968	15 103	15 432	15 514	16 381	16 670
	Total	73 263	75 379	75 923	76 738	80 489	80 712	81 509	83 056	92 259



**Figure 1.** The number of vertebral augmentations from 2010 to 2018 was stratified by type of vertebral augmentation and specialty performing the intervention.

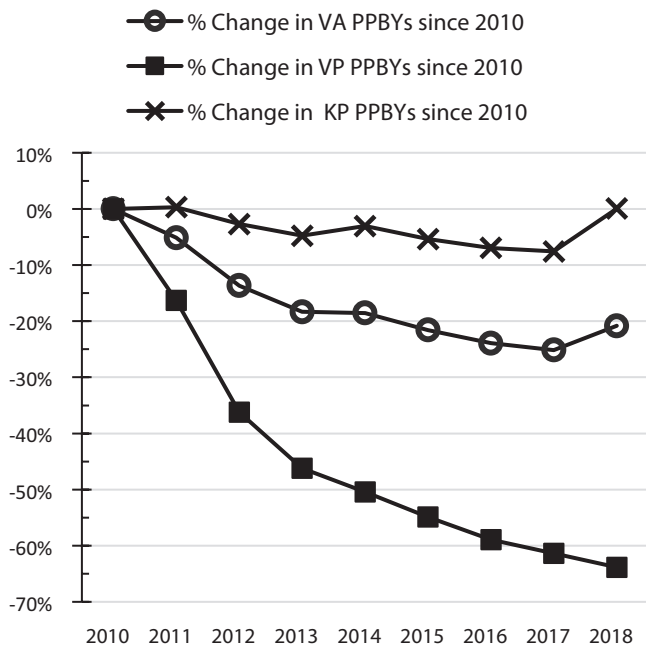
kyphoplasty PPBYs are marginally improved by 0.05% during the same period. This trend may be explained due to society guidelines and literature reports published in 2009 and 2014 which state that kyphoplasty may be more effective at restoring vertebral height and lead to improved outcomes in vertebral compression fractures.<sup>11,12</sup> Furthermore, the decrease in vertebral augmentation utilization by specialty was not uniform. Spine surgeons experienced the greatest decrease in PPBYs, followed by radiologists (Figure 3). Finally, the number of procedures performed at each site of service did not vary significantly except for the office-based setting where there was a 256% increase from 2010 to 2018 (Figure 4). This trend is consistent with the high growth of other office-based procedures such as endovascular therapies.<sup>13-15</sup> Extrapolating from these trends, one possible explanation for the rise of vertebral



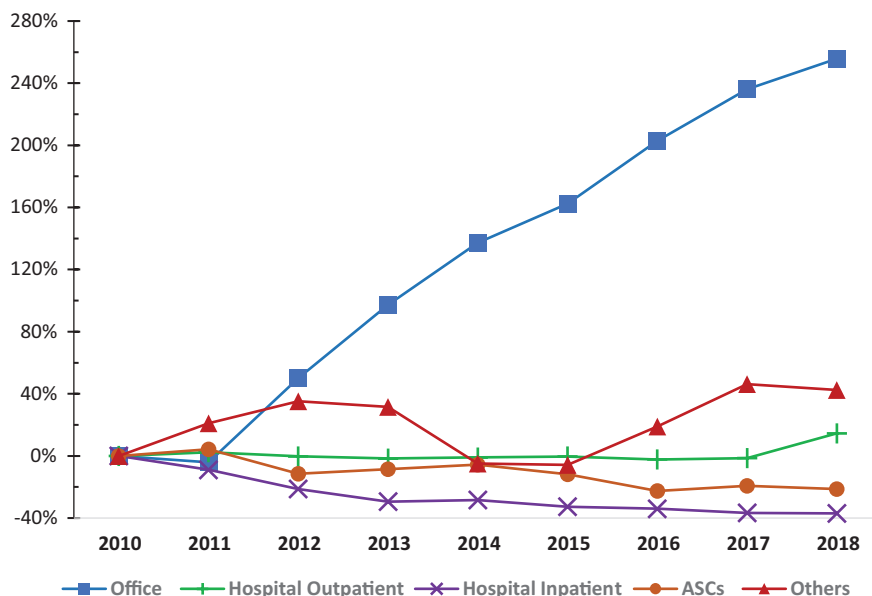
**Figure 3.** The percentage change in vertebral augmentation per 100 000 CMS beneficiaries per year from 2010 to 2018 was stratified by physician specialty.

augmentation procedures in this setting could be that office-based procedures are reimbursed at lower rates than hospitals, reducing the cost to CMS and other payors. Unfortunately, the literature is limited regarding patient outcomes on vertebral augmentations performed in office settings, though one study does suggest that kyphoplasty is safe and effective.<sup>16</sup>

One possible explanation for the decrease in vertebral augmentation procedures could be due to the controversy in the literature and society guidelines about their efficacy. According to Degnan et al<sup>8</sup> vertebral augmentation procedures reached peak volume in 2008 prior to the release of the sham trials published in *NEJM* by Kallmes et al<sup>5</sup> and Buchbinder et al<sup>6</sup> in 2009. Recently, 2 Cochrane-based meta-analyses by Buchbinder et al<sup>17,18</sup> in 2015 and 2018 continue to support claims from the *NEJM* sham trials. However, these randomized control trials have been criticized for fundamental design flaws and it is important to consider reporting bias when evaluating the Cochrane studies. For example, in the Cochrane meta-analysis, the authors provide recommendations based on the 2009 sham trials while disregarding several pro-vertebral augmentation trials compared to nonsurgical management.<sup>17-19</sup> Furthermore, multiple meta-analyses and randomized control trials have been published indicating the superiority of vertebral augmentations when compared to conservative treatment.<sup>10,20-25</sup> It is also important to note that other factors may contribute to the decline in vertebral augmentation interventions. For example, although the United States population is aging, the BMI of the population is also rising. Since the underlying etiology of vertebral fractures is osteoporosis, having a higher BMI is interestingly protective against osteoporosis<sup>26</sup> and therefore could be associated with decreased vertebral fractures. Additionally, since the 2000s, medical therapy for the treatment has improved with the development and widespread use of new medications such as bisphosphonates,<sup>27</sup> delaying or eliminating the need for vertebral augmentation. Therefore, other considerations for the decline in vertebral augmentation could be the rise of obesity and the improvement of medical therapy. Further research could help clarify the primary reason for the decline, but it would be unsurprising if it was due to a combination of the 3 causes discussed.



**Figure 2.** The percentage change in vertebral augmentation per 100 000 CMS beneficiaries per year from 2010 to 2018 by specialty stratified by type of vertebral augmentation.



**Figure 4.** The percentage change in vertebral augmentation per 100 000 CMS beneficiaries per year from 2010 to 2018 was stratified by the site of the procedure.

This study has multiple aspects that make it uniquely strong, but like any study, it has some limitations. One strength of this study is the dataset size as CMS is the largest payor in the United States healthcare market and primarily covers those over age 65. Additionally, this retrospective claims-based study does not rely on random sampling and directly benefits from utilizing 100% of CMS claims data from 2010 to 2018. A limitation of this study is that physician specialty is self-reported to CMS using pre-designated provider codes during the billing process. Occasionally provider specialty codes are not reported or provider codes that are not easily categorizable are used. This may potentially skew some of the data under the "Pain Management" category. However, less than 1% of the total procedure count was considered difficult to categorize by this study's criterion, so the effect is negligible. In addition to these limitations, our data did not have access to patient characteristics or demographics. Further studies evaluating aspects such as rurality, socioeconomic status, race/ethnicity, and geographic location would be beneficial. Finally, this study can only suggest a correlation, but cannot establish causality.

## Conclusion

In conclusion, although vertebral augmentation procedures are effective, there continues to be diminished utilization except for Office settings. This is paradoxical to what one would expect in an aging population like in the United States, where rates of osteoporotic compression fracture are higher. One possible explanation for this paradoxical trend is randomized controlled trials published in the *NEJM* continue to impact physician clinical decision making. Considering the benefits of these procedures, we suggest physicians consider performing vertebral augmentation procedures when indicated.

**Ethics Committee Approval:** This database excludes patient identifiers, providing an exemption for review by the Institutional Review Board.

**Informed Consent:** N/A.

**Peer-review:** Externally peer-reviewed.

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