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Original Article

Trends in vertebroplasty and kyphoplasty after thoracolumbar osteoporotic fracture: A large database study from 2005 to 2012

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ABSTRACT

Purpose: The aim of our study was to investigate the trends and incidence of vertebral augmentation procedures (VAPs) in treating osteoporotic vertebral compression fractures. **Results:** In total, 118,074 patients were analyzed. The overall incidence of VAPs was 15.2%. The incidence of VAPs was significantly higher in those 75–79 years old (20.4%), significantly higher in females than males (15.6% versus 14.9%), and most commonly performed in the South (17.7%).

Conclusion: There was a decline in the frequency of these procedures since 2008, but physicians are still performing these procedures, albeit at a much lower frequency than before 2009.

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1. Introduction

Osteoporosis can prove to be a debilitating disease, and its effects are becoming more prevalent as the proportion of the world's population made up of the elderly continues to increase. One common manifestation of osteoporosis is an

osteoporotic vertebral compression fracture (OVCF), affecting over 750,000 individuals each year,¹ the majority in women,² and most often in the thoracolumbar spine.³ OVCFs can result in severe deformity and immobility related complications, accruing an annual medical cost of over \$740 million in the U.S.^{2,3} Therapeutic options include bed rest, bracing, physical therapy, analgesia, bisphosphonates, and

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Table 1 – Diagnosis and procedure codes.

Reoperation cohort	Included billing codes
Osteoporosis	ICD-9-D-73300, ICD-9-D-73301, ICD-9-D-73302, ICD-9-D-73303, ICD-9-D-73309
Thoracic or lumbar Spine fracture	ICD-9-D-80520, ICD-9-D-80522-80526, ICD-9-D-80528, ICD-9-D-80540-80545, ICD-9-D-80548, ICD-9-D-80560-80561, ICD-9-D-73313
Percutaneous procedure	CPT-22520, CPT-22521, CPT-22522, CPT-22523, CPT-22524, CPT-22525, ICD-9-P-8165, ICD-9-P-8166

calcitonin.^{4,5} However, patients with intractable pain refractory to conservative management may opt for vertebral augmentation procedures (VAPs), including vertebroplasty (VP) and kyphoplasty (KP).

These two procedures gained popularity in the early 2000s,⁶ until 2009, when two randomized controlled trials (RCTs) questioned the efficacy of VP.^{7,8} Since, the number of patients undergoing VAPs for OVCFs began to decline, and has been reported to decline further once the *J Am Acad Orthop Surg* (JAAOS) published guidelines recommending against routine VAPs to treat OVCFs.^{9,10} No conclusions were drawn about KP, and there are evident doubts over the validity of these two RCTs,¹¹⁻¹³ leaving no consensus on the true efficacy of VAPs. Although VAPs are still being performed regularly in the U.S.,¹⁰ the recent national trends have not yet been reported. In the present study, we examined the incidence of VAPs in treating thoracolumbar OVCFs, and analyzed the U.S. demographics and trends of those undergoing VAPs before and after publication of two RCTs in 2009.

2. Materials and methods

Our study was deemed exempt from Institutional Review Board evaluation as all patient data were de-identified before being made available to us. Final data were obtained using the

standard analytical files of the Medicare data set from the PearlDiver database (PearlDiver Inc., Warsaw, IN, USA), which is a national database of insurance billing records from roughly 45 million patients each year between 2005 and 2012. We identified cohorts of patients by using Current Procedural Terminology (CPT) and International Classification of Diseases, ninth edition (ICD-9) procedure codes (Table 1).

By constructing a database algorithm and query, inclusion required a diagnosis of osteoporosis and closed thoracolumbar vertebral fracture, and 4 years of follow-up in the database. From this cohort of patients, we created a second cohort that required the patients from the first cohort to undergo a percutaneous VAP within 4 years of fracture. We selected to follow patients for 4 years to ensure that we capture any patient who underwent VAP after sustaining a vertebral fracture, although we expect most to have undergone the procedure within 1 year.¹⁴ The total number from each cohort (reported as 'total') indicates unique patients. However, because patients from one year may be included in subsequent years, individual yearly data are not exclusive. Statistical analysis was completed using GraphPad Prism statistical software version 6 (GraphPad Software Inc.). Data were analyzed using a Chi-square analysis with two-tailed *p*-values, and the significance level set at $\alpha = 0.05$. In analyses with more than 2 groups, we used the group with the highest incidence to compare all others to. To protect patient privacy, and due to contractual agreements with PearlDiver Inc., we did not report data on cohorts with less than 11 patients.

3. Results

3.1. Baseline data

From 2005 through 2008, 118,074 patients with a diagnosis of osteoporosis experienced a thoracolumbar fracture, and had 4 years of follow up in the database. Of these patients, the 80–84 age group had the highest number of osteoporotic fractures, making up 26.5% of the total ($n = 31,253$) (Fig. 1). Of the four U.S. regions, the South had the highest number of OVCFs, making

Fig. 1 – Demographic stratification based on age.

Fig. 2 – Demographic stratification based on region.

up 34.7% of the total ($n = 41,021$) (Fig. 2). In regards to sex, more females than males suffered OVCFs (85.7%, $n = 101,207$) (Fig. 3).

3.2. VAP trends

The overall incidence of VAPs within 4 years of OVCF was 15.2% ($n = 17,996$). Table 2 shows the demographics of VAPs stratified by age, sex, and region. Within 4 years of thoracolumbar fracture, 20.4% ($n = 5487$) of those 75–79 years old underwent a VAP, which was significantly higher than all other age groups, with the exception of the 80–84 age group. The South had the highest incidence of VAP (17.7%, $p < 0.001$). The incidence of undergoing a percutaneous procedure was significantly higher in females than males (15.6% versus 14.9%, $p = 0.03$).

The number of percutaneous procedures performed in the Medicare dataset increased 35.8% from 2005 ($n = 5023$) to 2008 ($n = 7829$) (Table 3). However, this number dropped by 51% in one year, from 2008 to 2009, and by 94.5% from 2008 to 2012. The number of VAPs dropped from 546 in 2008 to 183 in 2009 in

the 65–69 age group. In 2012, of the 393 VAPs performed in the U.S., 37% ($n = 146$) were in those ≥ 85 -year-old and 25% ($n = 99$) were in those 80–84 years old. In 2012, 87.3% ($n = 343$) of the VAPs performed in the Medicare population were in females.

4. Discussion

It is well understood that OVCFs are more common in women, often attributed to hormonal changes that occur within years of menopause, resulting in rapid bone loss.^{13,15,16} However, our results showed the rate of OVCF to be 6.7 times greater in women than men, conflicting with previous reports that the rate of fracture is about 2 times greater in women.^{13,17} A meta-analysis on VP and KP by Eck et al. found the female to male ratio to be 2.1–3.2 to 1, still much lower than the numbers in our study.⁴ Although there are about 5 million more women than men covered under Medicare each year, we do not presume that this accounts for such large differences seen in our data set. It should be further noted that the Medicare data

Fig. 3 – Demographic stratification based on sex.

Table 2 – Trends of vertebral augmentation procedures after osteoporotic fractures.

	Osteoporotic thoracolumbar fracture	Percutaneous procedure	Incidence (%)	p ^a
Age ^{**}				
<65	5672	694	12.2	<0.001
65–69	10,686	1696	15.9	<0.001
70–74	17,182	3335	19.4	0.008
75–79	26,830	5487	20.4	
80–84	31,253	6353	20.3	0.7
≥85	29,615	5433	18.3	<0.001
Sex				0.03
Female	101,207	15,738	15.6	
Male	15,185	2258	14.9	
Region ^{***}				
Midwest	36,694	6000	16.4	<0.001
Northeast	21,802	2654	12.2	<0.001
South	41,021	7253	17.7	
West	19,826	2696	13.6	<0.001
Total	118,074	17,996	15.2	

^a Calculated using Chi-square.^{**} p values calculated using 75–79 age group as reference.^{***} p values compared using South region as reference.**Table 3 – Annual trends in vertebral augmentation procedures.**

	2005	2006	2007	2008	2009	2010	2011	2012
Age								
<65	184	241	273	277	120	81	30	^a
65–69	458	573	606	546	183	99	49	13
70–74	788	1018	1042	1049	477	279	153	47
75–79	1342	1652	1799	1626	749	476	235	82
80–84	1361	1847	2090	1948	1099	611	362	99
≥85	999	1517	1964	1895	1231	928	556	146
Sex								
Female	4444	5925	6713	6282	3357	2162	1202	343
Male	579	783	902	945	482	297	179	50
Region								
Midwest	1560	2177	2546	2561	1271	837	462	125
Northeast	745	940	1048	1095	550	313	191	45
South	2050	2651	2989	3060	1460	1003	545	178
West	732	1007	1112	1182	565	309	185	45
Total	5023	6708	7615	7829	3839	2459	1381	393
Percent change from previous year	–	33.5	13.5	2.8	–51.0	–35.9	–43.8	–71.5
Percent change from 2008	35.8	14.3	2.7	–	51.0	68.6	82.3	94.5

^a Data are not reported on cohorts with less than 11 patients.

set is made up primarily of those ≥65 years of age, exemplifying the natural progression of osteoporosis in an aging population.

The overall rate of VAPs was 15.2% between 2005 and 2012. Our results revealed a rapid increase in the number of VAPs performed in the Medicare population, from 5023 in 2005 to a peak of 7829 in 2008. As VAPs grew in popularity in the early 2000s, published literature showed promising results and significant clinical improvements after both VP and KP, although most reports were in the form of single reports or case series.^{4,18–21} A small randomized trial by Voormolen and colleagues²² found that VP resulted in better short-term outcomes when compared to pain management alone.

However, the number of VAPs declined even more rapidly, from 7829 in 2008 to 3839 in 2009. This may be attributable to two RCTs published in the *N Engl J Med* (NEJM), which suggested that VP is no more effective than sham procedure in relieving pain.^{7,8} The study by Kallmes et al.⁸ was an intention-to-treat study that had significant crossover (43% of patients from sham procedure to VP versus 12% from VP to sham procedure). Further qualms about these two RCTs include the lack of inclusion of acute fractures, inconsistent inclusion criteria, small sample size, and few sites or centers.^{11,12} Another RCT also published in 2009 reported results that conflicted with the NEJM articles, although it was a study on the efficacy and safety of KP, rather than VP.⁵ KP involves general anesthesia and may include overnight hospital admissions, and thus, it is

not known whether the same conclusions can be drawn about VP and KP. Regardless, physicians still offer VAPs to their patients with OVCFs, as our data revealed more than half of VAPs performed in 2012 were in those ≥ 80 years old.

Smieliauskas et al.¹⁰ reported that the number of VAPs performed in Florida have declined since publication of the two NEJM RCTs and recommendations made against VP by the JAAOS. Their results showed a 25% decline in the number of VP performed from 2008 to 2012, and a 9% decline in the number of KP. However, their study was restricted to one state, which may not exactly reflect U.S. trends. We found that the South had the highest incidence of VAPs, but only made up 17.7% of the total. Furthermore, the PearlDiver database includes inpatient and outpatient procedures, which provides data from a mix of academic and private practice, and may be more representative of the U.S., showing a staggering 94.5% decline in the frequency of VAPs from 2008 to 2012. Our results also show the expected effects of osteoporosis on the elderly, as over half of the Medicare population who suffered an OVCF were 80 and older.

This study is not without limitations. Given the retrospective nature of the study, there are obvious biases that are avoided in a prospective study. Secondly, although our results confirm that osteoporosis is a disease of the elderly, Medicare is made up primarily of those 65 and older, precluding us from examining the U.S. population as a whole. Furthermore, ICD-9 and CPT codes are dependent on medical coders and appropriate billing. Finally, to protect patient privacy, we receive data in total numbers, and do not have individual patient data, which precludes us from various statistical analyses that can control for potential confounding factors and provide further insight on the progression of osteoporosis.

5. Conclusion

OVCFs are a cause of significant morbidity and mortality in those affected. Although there are conflicting reports on surgical versus conservative management options, the consensus has been toward conservative management. Our database affirmed this notion, showing that the number of VAPs being performed in the U.S. has significantly declined since 2008. However, physicians are still performing these procedures, and thus, larger, multicenter RCTs are warranted to gain a full understanding of VAPs and their long-term outcomes in treating OVCFs when compared to conservative management.

Conflicts of interest

The authors have none to declare.

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