

## ORIGINAL RESEARCH

# Analysis of vertebral augmentation practice patterns: a 2016 update

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Accepted 20 September 2016

## ABSTRACT

**Objective** To evaluate procedure utilization patterns for vertebroplasty and kyphoplasty in the US Medicare population from 2004 to 2014.

**Methods** The analysis was performed using the Centers for Medicare and Medicaid Services database of specialty utilization files for the fee for service (FFS) Medicare population.

**Results** The FFS Medicare population increased by 28% with an annual increase of 2.5% from 2004 to 2014. Utilization of vertebroplasty procedures decreased by 63% with an average annual decrease of 9.5% from 2004 to 2014 per 100 000 FFS Medicare beneficiaries.

During the same time period, kyphoplasty procedures decreased by a total of 10%, with an average annual decrease of 1.3%. For augmentation generally (combined vertebroplasty/kyphoplasty data) there was thus an overall decrease in the rate per 100 000 Medicare population of 32% from 2004 to 2014, with an average annual decrease of 4.8%. The majority of vertebroplasty procedures were performed by radiologists whereas the majority of kyphoplasties were performed by orthopedic surgeons and neurosurgeons.

**Conclusions** There has been a significant decline in vertebroplasty and kyphoplasty procedures in the FFS Medicare population between 2004 and 2014.

## INTRODUCTION

Vertebral compression fractures are the most common type of osteoporotic fracture and are also associated with malignancy. Osteoporotic vertebral fractures affect 117 per 100 000 persons, with the primary symptom of back pain that can be debilitating.<sup>1,2</sup> These fractures are associated with a prolonged impact on health related quality of life,<sup>2</sup> and the direct management costs are estimated at more than \$1 billion per annum.<sup>3</sup> Similarly, patients with malignancy commonly develop bone metastases. Vertebral fractures in cancer patients may be due to metastases, osteonecrosis after radiation therapy, and/or osteopenia caused by systemic anticancer treatments.

In these cohorts of patients, minimally invasive percutaneous treatments, such as vertebroplasty and kyphoplasty, have become common in the USA. Initial enthusiasm was driven by multiple observational studies and comprehensive reviews showing positive results.<sup>4-7</sup> In fact, vertebroplasty increased from a rate of 43 per 100 000 Medicare population in 2001 to 85 in 2008.<sup>8</sup> Along the same lines, kyphoplasty increased from 120 per 100 000 Medicare population to 141 in 2008. However,

two randomized controlled trials of vertebroplasty for osteoporotic spinal fractures were published in the *New England Journal of Medicine (NEJM)* in 2009.<sup>9,10</sup> These trials showed lack of effectiveness of vertebroplasty compared with sham surgery, and impacted on the utilization rates of both vertebroplasty and kyphoplasty. While utilization patterns of other interventional techniques continued to demonstrate substantial increases,<sup>11-13</sup> vertebroplasty decreased from 85 per 100 000 Medicare population to 49 in 2010, and kyphoplasty decreased from 141 per 100 000 Medicare population to 121 in the year 2010.<sup>8</sup>

Since publication of these two trials in 2009, multiple additional randomized controlled trials confirmed prior observations that have demonstrated benefit for vertebroplasty and kyphoplasty for both osteoporotic and cancer related vertebral fractures compared with conservative care.<sup>14-20</sup> Recently, vertebroplasty has also been demonstrated to be effective compared with sham surgery for patients with acute fractures.<sup>21</sup> Thus our aim was to evaluate the procedure utilization patterns for vertebroplasty and kyphoplasty in the Medicare population from 2004 to 2014.

## MATERIALS AND METHODS

This analysis of data of utilization patterns of vertebroplasty and kyphoplasty procedures was performed following the reporting standards of Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidance.<sup>22</sup> Institutional review board approval was not required for this assessment as public use files available through the Centers for Medicare and Medicaid Services (CMS) database was utilized.<sup>23</sup> This analysis exclusively used non-attributable de-identified data.

## Study design

The purpose of the study was to retrospectively evaluate the utilization patterns of thoracolumbar vertebroplasty and kyphoplasty procedures from 2004 to 2014 by fee for service (FFS) Medicare beneficiaries. These physician/supplier procedure summary master files were aggregates of all Medicare part B billing claims for services performed in the USA by all providers. These data were purchased from the CMS.

## Setting

The CMS database of specialty utilization from 2004 to 2014 data files of FFS Medicare was utilized.<sup>23</sup> This is a 100% sample.



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**To cite:** Hirsch JA, Chandra RV, Pampati V, et al. *J NeuroInterv Surg* 2016;**8**:1299-1304.

## Measures

Services were defined as submitted, allowed, denied, and those with zero payments. Allowed services constituted total services after deletion of denied services and services with zero payments. For each procedure, total allowed services and rates per 100 000 were calculated for the corresponding year.

## Current procedural terminology codes assessed

For this study of utilization patterns, the current procedural terminology procedure codes were used for vertebroplasty procedures (22 520—thoracic percutaneous vertebroplasty; 22 521—lumbar vertebroplasty; 22 522—vertebroplasty, each additional thoracic or lumbar vertebral body) and kyphoplasty procedures (22 523—thoracic kyphoplasty; 22 524—lumbar kyphoplasty; 22 525—kyphoplasty, each additional thoracic or lumbar vertebral body). Vertebroplasty and kyphoplasty procedures were approved by CMS in January 2001 and 2006, respectively.

Vertebroplasty and kyphoplasty procedures were performed historically by various types of providers, even though the majority are performed by specialists representing radiology (diagnostic—30 and interventional radiology—94), orthopedic surgery (20), neurosurgery, pain management group (interventional pain management—09 or pain management—72), anesthesiology (05), and physical medicine and rehabilitation (25), and the remaining specialties grouped as other physicians. Site of service was also analyzed and categorized as hospital outpatient departments, hospital inpatient, ambulatory surgery centers (ASCs), and in physicians' offices (in office).

## Statistical analysis

The data were analyzed using Microsoft Access 2003 and Microsoft Excel 2003 (Microsoft, Redmond, Washington, USA); procedure utilization was calculated per 100 000 Medicare beneficiaries.

## RESULTS

### Population characteristics

Table 1 shows the growth of the US population and FFS Medicare beneficiaries along with overall utilization patterns of 312 678 vertebroplasty and kyphoplasty procedures from 2004 to 2014, and the growth rate per 100 000 FFS Medicare beneficiaries over the decade. Overall, the US population increased by 9% whereas the population over 65 years of age increased by 27% with an annual increase of 2.4% from 2004 to 2014. The elderly population over 65 years of age constituted 12.4% of the population in 2004 increasing to 14.5% in 2014. FFS Medicare beneficiaries, including those >65 years of age and also disabled individuals less than 65 years of age, increased to 28% of the US population from 2004 to 2014. Overall utilization of vertebroplasty procedures decreased by 63%, with an annual decrease of 9.5% from 2004 to 2014 per 100 000 FFS Medicare beneficiaries, whereas kyphoplasty procedures decreased by 10%, with an annual decrease of 1.3% from 2006 to 2014 per 100 000 FFS Medicare beneficiaries.

### Utilization characteristics

Table 2 show a summary of the frequency of utilization of vertebroplasty and kyphoplasty procedures in fee for service (FFS) Medicare beneficiaries from 2006 to 2014 with distribution of procedural characteristics.

As shown in table 2, the overall rate of decrease for vertebroplasty and kyphoplasty combined procedures was 32%, with an

annual decrease of 4.8% per 100 000 FFS Medicare beneficiaries from 2006 to 2014; however, vertebroplasty procedures decreased by 67%, with an annual decrease of 12.8% per 100 000 FFS Medicare population from 2006 to 2014. In contrast, kyphoplasty procedures increased from 2006 to 2009, with a slight decrease starting in 2010, an overall decrease of 10%, and an annual decrease of 1.3% per 100 000 Medicare population, starting with 126 per 100 000 Medicare population and declining to 113. However, vertebroplasty procedures were 82 per 100 000 Medicare population in 2006 and declined to 28 in 2014. Initially there appeared to be a slight shift of procedures from vertebroplasty to kyphoplasty with a stunted growth until the publication of two randomized controlled trials<sup>9 10</sup> following which the decline was rapid.<sup>8 24 25</sup> After publication of the randomized trials,<sup>9 10</sup> kyphoplasty also plateaued, with some decreases from 138 per 100 000 Medicare population in 2009, to 123 in 2010, 122 in 2011 and 2012, 119 in 2013, and finally, 113 in 2014.

### Specialty characteristics

As shown in table 3, 75.3% of vertebroplasty procedures were performed by radiologists whereas 71.2% of kyphoplasty procedures were performed by orthopedic surgeons and neurosurgeons in 2006. There was a slight increase in utilization of kyphoplasty procedures for anesthesiology and pain management specialties from 2010 when these procedures were approved for use in ASCs, making reimbursement in this site of service possible for CMS patients. Specialty designation derives from the electronic portal through which physicians enroll in Medicare, the so called Provider Enrollment and Chain/Ownership System (PECOS), leading to significant confusion—for example, many interventional radiologists are listed as diagnostic. The same is true for interventional pain management and pain management. For that reason, we combined diagnostic and interventional radiologists in the specialty specific analysis.

Vertebroplasty utilization decreased by 2% from 2006 to 2009, and decreased by 18% from 2009 to 2010, and continued to decrease by 49% from 2010 to 2014. Kyphoplasty procedure utilization increased by 15% from 2006 to 2009, decreased by 8% from 2009 to 2010, and increased by 5% from 2010 to 2014 (table 4).

### Site of service utilization

Place of service data were available from 2008. The majority of vertebroplasty and kyphoplasty procedures (>90%) were performed in hospitals, as either outpatient (53%) or inpatient (33%) procedures. There was a slight increase in ASC settings from 1.4% in 2009 to 3.6% in 2014, as shown in table 5.

### Discussion

The present analysis shows significant change in utilization patterns of vertebral augmentation procedures over the past decade. There were substantial decreases in vertebroplasty procedures of 63% from 2004 to 2014 and a modest decrease of 10% for kyphoplasty procedures from 2006 to 2014. After the *NEJM* publications in 2009, vertebroplasty decreased by 49% from 2010 to 2014, while kyphoplasty utilization increased by 5%. This overall reduction in vertebral augmentation procedures occurred in spite of more recent positive randomized controlled trials. This suggests that the 2009 *NEJM* publications have had considerable ongoing impact on vertebral augmentation utilization rates in the FFS Medicare population.

**Table 1** Summary of the growth of the US population fee for service Medicare beneficiaries and frequency of utilization of vertebroplasty and kyphoplasty procedures in the Medicare population from 2004 to 2014

Year	US total population in thousands (% elderly)	Medicare beneficiaries in thousands (% elderly)	Vertebroplasty				Kyphoplasty				
			Services	% Change from previous year	Rate*	% Change from previous year	Services	% Change from previous year	Rate*	% Change from previous year	
2004	292 892 (12.4)	41 729 (84.7)	31 032		74	–	–	–	–	–	–
2005	295 561 (12.4)	42 496 (84.2)	35 478	14	83	12.2	–	–	–	–	–
2006	299 395 (12.4)	43 339 (83.8)	35 716	1	82	–1.2	54 657	–	126	–	–
2007	301 290 (12.6)	44 263 (83.5)	35 175	–2	79	–3.7	61 785	13	140	13.0	–
2008	304 056 (12.8)	45 412 (83.4)	36 745	4	81	2.5	63 348	3	139	2.5	–
2009	307 006 (12.9)	45 801 (83.4)	35 091	–5	77	–4.9	63 005	–1	138	–0.5	–
2010	308 746 (13.0)	46 914 (83.1)	28 949	–18	62	–19.5	57 890	–8	123	–8.1	–
2011	311 583 (13.3)	48 300 (82.8)	24 315	–16	50	–19.4	59 043	2	122	2.0	–
2012	313 874 (13.8)	50 300 (83.3)	18 764	–23	37	–26.0	61 165	4	122	3.6	–
2013	316 129 (14.1)	51 900 (83.0)	16 681	–11	32	–13.5	61 839	1	119	1.1	–
2014	318 892 (14.5)	53 500 (83.4)	14 732	–12	28	–12.5	60 656	–2	113	–1.9	–
Change (%)	9	28	–53		–63		11		–10		
GGR (%)	0.9	2.5	–7.2		–9.5		1.3		–1.3		

\*Rate, per 100 000 fee for service Medicare beneficiaries; kyphoplasty data available from 2006.  
GGR, geometric growth rate.

**Table 2** Utilization of vertebroplasty and kyphoplasty services in Medicare beneficiaries

	Current procedural terminology	F2006	F2007	F2008	F2009	F2010	F2011	F2012	F2013	F2014	Change (%)	GGR (%)
Vertebroplasty	Medicare	43 339	44 263	45 412	45 801	46 914	48 300	50 300	51 900	53 500	23	2.7
	Change (%)	2	2	3	1	2	3	4	3	3		
	22 520	14 435	14 032	14 559	13 845	11 430	9768	7469	6725	5842	–60	–10.7
	Change (%)	–1	–3	4	–5	–17	–15	–24	–10	–13		
	Rate	33	32	32	30	24	20	15	13	11	–67	–13.0
	22 521	14 187	14 491	15 036	14 458	12 101	10 275	7709	6812	6058	–57	–10.1
	Change (%)	2	2	4	–4	–16	–15	–25	–12	–11		
	Rate	33	33	33	32	26	21	15	13	11	–65	–12.4
	22 522	7094	6652	7150	6788	5418	4272	3586	3144	2832	–60	–10.8
	Change (%)	2	–6	7	–5	–20	–21	–16	–12	–10		
Rate	16	15	16	15	12	9	7	6	5	–68	–13.2	
Kyphoplasty	Vertebroplasty	35 716	35 175	36 745	35 091	28 949	24 315	18 764	16 681	14 732	–59	–10.5
	Change (%)	1	–2	4	–5	–18	–16	–23	–11	–12		
	Rate	82	79	81	77	62	50	37	32	28	–67	–12.8
	22 523	21 096	23 690	23 960	23 550	21 680	22 044	22 662	22 921	22 258	6	0.7
	Change (%)		12	1	–2	–8	2	3	1	–3		
	Rate	49	54	53	51	46	46	45	44	42	–15	–1.9
	22 524	22 111	25 220	26 300	26 305	24 199	24 699	26 130	26 646	26 266	19	2.2
	Change (%)		14	4	0	–8	2	6	2	–1		
	Rate	51	57	58	57	52	51	52	51	49	–4	–0.5
	22 525	11 450	12 875	13 088	13 150	12 011	12 300	12 373	12 272	12 132	6	0.7
Change (%)		12	2	0	–9	2	1	–1	–1			
Rate	26	29	29	29	26	25	25	24	23	–14	–1.9	
Combined	Kyphoplasty	54 657	61 785	63 348	63 005	57 890	59 043	61 165	61 839	60 656	11	1.3
	Change (%)		13	3	–1	–8	2	4	1	–2		
	Rate	126	140	139	138	123	122	122	119	113	–10	–1.3
	Vertebroplasty and kyphoplasty	90 373	96 960	100 093	98 096	86 839	83 358	79 929	78 520	75 388	–17	–2.2
Change (%)	NA	7	3	–2	–11	–4	–4	–2	–4			
Rate	209	219	220	214	185	173	159	151	141	–32	–4.8	

GGR, geometric growth rate; NA, not available.

Notably, the significant in reduction in vertebroplasty rates from 2010 to 2014 contrasts with the slight increase in kyphoplasty rates during the same period. This likely relates to multiple factors, most importantly the lack of benefit from vertebroplasty reported in the two *NEJM* trials (78 and 131 patients).<sup>9 10</sup> The

simultaneous publication in a very high impact factor journal (*NEJM* impact factor 47.1 in 2009)<sup>26</sup> garnered significant media attention, and thus the results were widely known by both potential referring physicians and patients. This contrasts with an earlier trial of kyphoplasty compared with conservative

**Table 3** Utilization of vertebroplasty and kyphoplasty services by provider specialty in fee for service Medicare beneficiaries

	F2006	F2007	F2008	F2009	F2010	F2011	F2012	F2013	F2014	Change (%)	GGR (%)
<i>Vertebroplasty (n (%))</i>											
Radiology	26 909 (75.3)	25 843 (73.5)	25 786 (70.2)	24 114 (68.7)	20 546 (71.0)	17 717 (72.9)	14 162 (75.5)	12 837 (77.0)	11 391 (77.3)	-58	-10.2
Orthopedic surgery	2914 (8.2)	3106 (8.8)	3763 (10.2)	3672 (10.5)	3101 (10.7)	2155 (8.9)	1364 (7.3)	1032 (6.2)	936 (6.4)	-68	-13.2
Neurosurgery	1831 (5.1)	1573 (4.5)	2052 (5.6)	2507 (7.1)	2108 (7.3)	1781 (7.3)	1593 (8.5)	1511 (9.1)	1546 (10.5)	-16	-2.1
Radiology and surgery	31 654 (88.6)	30 522 (86.8)	31 601 (86.0)	30 293 (86.3)	25 755 (89.0)	21 653 (89.1)	17 119 (91.2)	15 380 (92.2)	13 873 (94.2)	-56	-9.8
Anesthesiology	1713 (4.8)	1663 (4.7)	1559 (4.2)	1399 (4.0)	850 (2.9)	626 (2.6)	421 (2.2)	358 (2.1)	218 (1.5)	-87	-22.7
Interventional pain management and pain management (09 and 72)	1479 (4.1)	2123 (6.0)	2635 (7.2)	2597 (7.4)	1754 (6.1)	1552 (6.4)	886 (4.7)	701 (4.2)	462 (3.1)	-69	-13.5
PM&R	116 (0.3)	154 (0.4)	257 (0.7)	231 (0.7)	241 (0.8)	222 (0.9)	142 (0.8)	107 (0.6)	86 (0.6)	-26	-3.7
Pain management group	3308 (9.3)	3940 (11.2)	4451 (12.1)	4227 (12.0)	2845 (9.8)	2400 (9.9)	1449 (7.7)	1166 (7.0)	766 (5.2)	-77	-16.7
Other	754 (2.1)	713 (2.0)	693 (1.9)	571 (1.6)	349 (1.2)	262 (1.1)	196 (1.0)	135 (0.8)	93 (0.6)	-88	-23.0
Total	35 716	35 175	36 745	35 091	28 949	24 315	18 764	16 681	14 732	-59	-10.5
<i>Kyphoplasty (n (%))</i>											
Radiology	13 276 (24.3)	17 115 (27.7)	18 584 (29.3)	19 317 (30.7)	17 251 (29.8)	18 822 (31.9)	20 412 (33.4)	20 783 (33.6)	20 265 (33.4)	53	5.4
Orthopedic surgery	25 398 (46.5)	25 989 (42.1)	25 979 (41.0)	24 364 (38.7)	21 645 (37.4)	20 240 (34.3)	19 879 (32.5)	18 854 (30.5)	18 329 (30.2)	-28	-4.0
Neurosurgery	13 487 (24.7)	15 148 (24.5)	14 939 (23.6)	14 745 (23.4)	13 704 (23.7)	14 034 (23.8)	13 608 (22.2)	13 720 (22.2)	13 357 (22.0)	-1	-0.1
Radiology and surgery	52 161 (95.4)	58 252 (94.3)	59 502 (93.9)	58 426 (92.7)	52 600 (90.9)	53 096 (89.9)	53 899 (88.1)	53 357 (86.3)	51 951 (85.6)	0	-0.1
Anesthesiology	923 (1.7)	1142 (1.8)	1315 (2.1)	1558 (2.5)	1412 (2.4)	1438 (2.4)	1920 (3.1)	2160 (3.5)	2135 (3.5)	131	11.1
Interventional pain management and pain management (09 and 72)	532 (1.0)	1233 (2.0)	1271 (2.0)	1668 (2.6)	2461 (4.3)	2880 (4.9)	3700 (6.0)	4552 (7.4)	4664 (7.7)	777	31.2
PM&R	134 (0.2)	197 (0.3)	240 (0.4)	484 (0.8)	677 (1.2)	887 (1.5)	860 (1.4)	1035 (1.7)	1218 (2.0)	809	31.8
Pain management group	1589 (2.9)	2572 (4.2)	2826 (4.5)	3710 (5.9)	4550 (7.9)	5205 (8.8)	6480 (10.6)	7747 (12.5)	8017 (13.2)	405	22.4
Other	907 (1.7)	961 (1.6)	1020 (1.6)	869 (1.4)	740 (1.3)	742 (1.3)	786 (1.3)	735 (1.2)	688 (1.1)	-24	-3.4
Total	54 657	61 785	63 348	63 005	57 890	59 043	61 165	61 839	60 656	11	1.3
<i>Combined (n (%))</i>											
Radiology	40 185 (44.5)	42 958 (44.3)	44 370 (44.3)	43 431 (44.3)	37 797 (43.5)	36 539 (43.8)	34 574 (43.3)	33 620 (42.8)	31 656 (42.0)	-21	-2.9
Orthopedic surgery	28 312 (31.3)	29 095 (30.0)	29 742 (29.7)	28 036 (28.6)	24 746 (28.5)	22 395 (26.9)	21 243 (26.6)	19 886 (25.3)	19 265 (25.6)	-32	-4.7
Neurosurgery	15 318 (16.9)	16 721 (17.2)	16 991 (17.0)	17 252 (17.6)	15 812 (18.2)	15 815 (19.0)	15 201 (19.0)	15 231 (19.4)	14 903 (19.8)	-3	-0.3
Radiology and surgery	83 815 (92.7)	88 774 (91.6)	91 103 (91.0)	88 719 (90.4)	78 355 (90.2)	74 749 (89.7)	71 018 (88.9)	68 737 (87.5)	65 824 (87.3)	-21	-3.0
Anesthesiology	2636 (2.9)	2805 (2.9)	2874 (2.9)	2957 (3.0)	2262 (2.6)	2064 (2.5)	2341 (2.9)	2518 (3.2)	2353 (3.1)	-11	-1.4
Interventional pain management and pain management (09 and 72)	2011 (2.2)	3356 (3.5)	3906 (3.9)	4265 (4.3)	4215 (4.9)	4432 (5.3)	4586 (5.7)	5253 (6.7)	5126 (6.8)	155	12.4
PM&R	250 (0.3)	351 (0.4)	497 (0.5)	715 (0.7)	918 (1.1)	1109 (1.3)	1002 (1.3)	1142 (1.5)	1304 (1.7)	422	22.9
Pain management group	4897 (5.4)	6512 (6.7)	7277 (7.3)	7937 (8.1)	7395 (8.5)	7605 (9.1)	7929 (9.9)	8913 (11.4)	8783 (11.7)	79	7.6
Other	1661 (1.8)	1674 (1.7)	1713 (1.7)	1440 (1.5)	1089 (1.3)	1004 (1.2)	982 (1.2)	870 (1.1)	781 (1.0)	-53	-9.0
Grand total	90 373	96 960	100 093	98 096	86 839	83 358	79 929	78 520	75 388	-17	-2.2

GGR, geometric growth rate; PM&amp;R, physical medicine and rehabilitation.

**Table 4** Percentage of change in volume of vertebroplasty and kyphoplasty procedures by provider specialty in fee for service Medicare beneficiaries

Physician specialty	2006–2009		2009–2010	2010–2014		2006–2014	
	Change (%)	GGR (%)		Change (%)	GGR (%)	Change (%)	GGR (%)
<i>Vertebroplasty</i>							
Radiology	–10	–3.6	–15	–45	–13.7	–58	–10.2
Orthopedic surgery	26	8.0	–16	–70	–25.9	–68	–13.2
Neurosurgery	37	11.0	–16	–27	–7.5	–16	–2.1
Radiology and surgery	–4	–1.5	–15	–46	–14.3	–56	–9.8
Anesthesiology	–18	–6.5	–39	–74	–28.8	–87	–22.7
Pain management	76	20.6	–32	–74	–28.4	–69	–13.5
PM&R	99	25.8	4	–64	–22.7	–26	–3.7
Pain management group	28	8.5	–33	–73	–28.0	–77	–16.7
Other	–24	–8.8	–39	–73	–28.2	–88	–23.0
Total	–2	–0.6	–18	–49	–15.5	–59	–10.5
<i>Kyphoplasty</i>							
Radiology	46	13.3	–11	17	4.1	53	5.4
Orthopedic surgery	–4	–1.4	–11	–15	–4.1	–28	–4.0
Neurosurgery	9	3.0	–7	–3	–0.6	–1	–0.1
Radiology and surgery	12	3.8	–10	–1	–0.3	0	–0.1
Anesthesiology	69	19.0	–9	51	10.9	131	11.1
Pain management	214	46.3	48	90	17.3	777	31.2
PM&R	261	53.4	40	80	15.8	809	31.8
Pain management group	133	32.6	23	76	15.2	405	22.4
Other	–4	–1.4	–15	–7	–1.8	–24	–3.4
Total	15	4.8	–8	5	1.2	11	1.3
<i>Combined</i>							
Radiology	8	2.6	–13	–16	–4.3	–21	–2.9
Orthopedic surgery	–1	–0.3	–12	–22	–6.1	–32	–4.7
Neurosurgery	13	4.0	–8	–6	–1.5	–3	–0.3
Radiology and surgery	6	1.9	–12	–16	–4.3	–21	–3.0
Anesthesiology	12	3.9	–24	4	1.0	–11	–1.4
Pain management	112	28.4	–1	22	5.0	155	12.4
PM&R	186	41.9	28	42	9.2	422	22.9
Pain management group	62	17.4	–7	19	4.4	79	7.6
Other	–13	–4.6	–24	–28	–8.0	–53	–9.0
Grand total	9	2.8	–11	–13	–3.5	–17	–2.2

GGR, geometric growth rate; PM&R, physical medicine and rehabilitation.

management (300 patients) in *The Lancet* (impact factor 30.8 in 2009)<sup>26</sup> which reported a significant benefit for kyphoplasty that was largely unnoticed by the media.

The subsequent publication of multiple randomized controlled trials demonstrating significant benefit for vertebroplasty and/or kyphoplasty has not counterbalanced the earlier *NEJM* publications. Since 2009, a total of 1187 patients have been included in 8 randomized controlled trials of vertebroplasty and/or kyphoplasty that showed significant benefit of vertebral augmentation.<sup>14–21</sup> However, these studies were published in journals with a wide range of significantly lower impact factors (as low as 1.31)<sup>26</sup> at the time of their publication, and thus were largely unnoticed by the media. In addition, all kyphoplasty randomized controlled trials to date have been positive, in contrast with vertebroplasty. In this context, it is not surprising that rates of vertebroplasty declined significantly without a similar decline in kyphoplasty.

Importantly, there is no significant difference in reduction of pain and disability between vertebroplasty and kyphoplasty, which are the primary goals of vertebral augmentation. In a meta-analysis of prospective comparative studies of vertebroplasty and kyphoplasty, Chang *et al*<sup>27</sup> included 1429 patients

from 20 studies and found that there was no difference in the reduction of pain and disability between the two techniques. Similar findings were reported in another meta-analysis of 845 patients.<sup>28</sup> A recent systematic review of both vertebroplasty or kyphoplasty for cancer related vertebral compression fractures by Ontario Health Technology concluded that both vertebroplasty and kyphoplasty significantly and rapidly reduced pain intensity in cancer patients with vertebral compression fractures.<sup>29</sup> These findings are not unexpected as kyphoplasty is essentially an extension of the vertebroplasty procedure—that is, with an additional step of inflation of a balloon tamp within the vertebra prior to cement injection. Nonetheless, the results also reveal that while radiologists are performing less vertebroplasties, they are performing a higher percentage of kyphoplasties compared with earlier time periods.

Vertebral augmentation has gone through several elements of a complex life cycle. In the 1990s, early US based neurointerventional investigators started performing percutaneous vertebroplasty at the University of Virginia.<sup>30</sup> The regional/national experience at that time largely grew out of providers that had a unique interaction with that pioneering group. In 1997, when their seminal article on augmentation was published,<sup>30</sup> interest

**Table 5** Vertebroplasty and kyphoplasty services by place of services for fee for service Medicare beneficiaries from 2008 to 2014

PLCR	F2008	F2009	F2010	F2011	F2012	F2013	F2014	Change (%)	GGR (%)
<i>Vertebroplasty n (%)</i>									
ASC	1342 (3.7)	1489 (4.2)	1043 (3.6)	642 (2.6)	534 (2.8)	438 (2.6)	347 (2.4)	-74.1	-20.2
Outpatient	16 266 (44.3)	15 865 (45.2)	13 430 (46.4)	11 534 (47.4)	10 095 (53.8)	9585 (57.5)	8479 (57.6)	-47.9	-10.3
Inpatient	14 296 (38.9)	13 184 (37.6)	10 804 (37.3)	8753 (36.0)	6737 (35.9)	5813 (34.8)	5247 (35.6)	-63.3	-15.4
Office	4841 (13.2)	4553 (13.0)	3672 (12.7)	3386 (13.9)	1398 (7.4)	845 (5.1)	659 (4.5)	-86.4	-28.3
Total	36 745	35 091	28 949	24 315	18 764	16 681	14 732	-59.9	-14.1
<i>Kyphoplasty n (%)</i>									
ASC	283 (0.4)	909 (1.4)	1721 (3.0)	2322 (3.9)	1953 (3.2)	2205 (3.6)	2192 (3.6)	674.6	40.7
Outpatient	24 084 (38.0)	29 666 (47.1)	28 749 (49.7)	31 465 (53.3)	32 264 (52.7)	32 185 (52.0)	31 357 (51.7)	30.2	4.5
Inpatient	38 862 (61.3)	32 296 (51.3)	27 224 (47.0)	25 190 (42.7)	22 960 (37.5)	20 904 (33.8)	19 300 (31.8)	-50.3	-11.0
Office	119 (0.2)	134 (0.2)	196 (0.3)	66 (0.1)	3988 (6.5)	6545 (10.6)	7807 (12.9)	6460.5	100.9
Total	63 348	63 005	57 890	59 043	61 165	61 839	60 656	-4.2	-0.7
<i>Combined n (%)</i>									
ASC	1625 (1.6)	2398 (2.4)	2764 (3.2)	2964 (3.6)	2487 (3.1)	2643 (3.4)	2539 (3.4)	56.2	7.7
Outpatient	40 350 (40.3)	45 531 (46.4)	42 179 (48.6)	42 999 (51.6)	42 359 (53.0)	41 770 (53.2)	39 836 (52.8)	-1.3	-0.2
Inpatient	53 158 (53.1)	45 480 (46.4)	38 028 (43.8)	33 943 (40.7)	29 697 (37.2)	26 717 (34.0)	24 547 (32.6)	-53.8	-12.1
Office	4960 (5.0)	4687 (4.8)	3868 (4.5)	3452 (4.1)	5386 (6.7)	7390 (9.4)	8466 (11.2)	70.7	9.3
Total	100 093	98 096	86 839	83 358	79 929	78 520	75 388	-24.7	-4.6

ASC, ambulatory surgery center; GGR, geometric growth rate; PLCR, place of service.

further increased and early generation vertebroplasty kits were soon developed. Over the next 20 years, multiple cohort studies and systematic reviews of these studies supported the use of vertebral augmentation.<sup>6 7 31 32</sup> and multiple professional medical societies supported their use.<sup>33</sup> In 2009, the *NEJM* trials were published which showed lack of effectiveness of vertebroplasty compared with placebo.<sup>9 10</sup> However, limitations of these trials included the inclusion of fractures up to 12 months old, and periosteal infiltration of local anesthetic, an active control, that may have resolved pain that primarily arose from the adjacent structures in more chronic fractures.<sup>34 35</sup>

Since the *NEJM* trials were published, there have been multiple additional randomized controlled trials supporting the use of both vertebroplasty and kyphoplasty for osteoporotic and cancer related fractures.<sup>14-21</sup> Meta-analyses including the *NEJM* trials were also supportive of vertebral augmentation.<sup>36 37</sup> These led to multiple international society guidelines supporting the use of vertebral augmentation,<sup>38-40</sup> and endorsement of vertebroplasty for both osteoporotic and cancer related fractures by the National Institute for Health and Care Excellence that advises the National Health Service of England and Wales.<sup>41 42</sup> Most recently, the Vertebroplasty for Acute Painful Osteoporotic fractures (VAPOUR) trial was published in *The Lancet*.<sup>21</sup> VAPOUR was a multicenter randomized controlled trial designed to assess the efficacy of vertebroplasty for osteoporotic fractures in a subgroup of patients with recent (<6 weeks) onset severe pain. Notably, the placebo procedure was subcutaneous local anesthetic infiltration, closer to conservative medical management. This trial showed strong benefit to performing vertebroplasty, and also demonstrated that conservative medical therapy is not without risk; two medically managed patients developed spinal cord compression from further collapse of their fractures.<sup>21 43</sup> The effects of this trial on procedure utilization rates will become evident in the next few years.

There are many limitations to our analysis. Firstly, we reviewed the CMS database, which excludes Medicare Advantage patients. In addition, there are private payer insurers that reimburse for this procedure that are by definition not included in this analysis. In addition, there may have been

miscoding of procedures, and other limitations to using claims based data.<sup>44</sup> Nonetheless, Medicare is the largest health care payer in the USA for vertebral augmentation, providing a reliable dataset to evaluate procedure utilization.

## CONCLUSION

There was an overall decline in vertebroplasty and kyphoplasty procedures in the FFS Medicare population between 2004 and 2014, and particularly since 2009. Our analysis suggests that the *NEJM* publications have had a considerable long term impact on utilization of vertebral augmentation procedures in the Medicare population. We look forward to assessing the impact of the recently published VAPOUR trial in future analyses.

**Contributors** JAH and LM constructed the study, analyzed/synthesized the data, and crafted the original manuscript. VP organized the data. RVC, ALB, and JDB edited the preliminary draft and provided meaningful editorial suggestions. All authors take responsibility for the final manuscript.

**Competing interests** JAH has an ongoing consulting relationship with Medtronic and in the past 36 months consulted for Carefusion. Both companies make products for vertebral augmentation. JB: shareholder in Medtronic and Stryker; research support from Merit/DFine and Medtronic.

**Provenance and peer review** Not commissioned; internally peer reviewed.

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