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Trends and Cost of Posterior Cervical Fusions With and Without Recombinant Human Bone Morphogenetic Protein-2 in the US Medicare Population

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Abstract

Study Design: Retrospective database review.

Objective: To analyze and report the trends and cost of posterior cervical fusions (PCFs) with and without off-label recombinant human bone morphogenetic protein-2 (rhBMP-2) in the Medicare population.

Methods: Patient records from the PearlDiver database were retrospectively reviewed from January 1, 2005, to December 31, 2012, to distinguish individuals who underwent a PCF with or without rhBMP-2. Total numbers, incidence, age, gender, geographic region, reimbursement, and length of stay were analyzed and summarized.

Results: The combined total of non-rhBMP-2 (n = 39 479; 85.51%) and rhBMP-2 PCF (n = 6692; 14.49%) procedures performed between 2005 and 2012 was 46 171. In general, the number of PCFs without rhBMP-2 consistently increased over time, while the number of PCFs with rhBMP-2 had only a slight increase from 2005 to 2012. On average, PCFs without rhBMP-2 were associated with $1197 higher cost than those with rhBMP-2, but the average length of stay was similar (6 days). From 2005 to 2012, the average cost for procedures with and without rhBMP-2 increased by $12 605 and $7291, respectively. The percentage of rhBMP-2 use peaked in 2007 and dwindled until 2010, and declined an additional 2.84% from 2011 to 2012. Multiple age, region, and gender tendencies were observed.

Conclusions: To our knowledge, this was the first study to use the PearlDiver database to report incidence and cost trends of PCF procedures. This article provides meaningful trend data on PCFs to surgeons and clinicians, researchers, and patients, as well as functions as a beacon for future research questions.

Keywords
PCF, PearlDiver database, rhBMP-2, demographic trends, reimbursement

Introduction

Neck pain and degenerative changes in the cervical spine are a growing problem among the US population.[1-4] Overall, surgery is considered the last resort after all forms of conservative treatments have been exhausted,[5-9] yet the number of cervical procedures has increased over the years.[10-16] Historically, surgeons have demonstrated a shift from posterior cervical decompression procedures in the 1960s to anterior cervical discectomy and fusion.[17-19] On the other hand, posterior cervical fusion (PCF) procedures are often a necessary consideration

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when a patient has an indication for such procedures as a failed anterior cervical fusion, prior cervical laminectomy, traumatic injury, neoplastic disease, myelopathy, or ankylosing spondylitis.[20] Previous studies using data from the Nationwide Inpatient Sample have shown that the total number of PCF procedures increased from 2002 to 2011.[21,22]

The increase in PCF procedures is also likely related to an aging patient population who are more apt to present with a greater severity of stenosis at multiple levels necessitating a posterior approach.[15,23] Prior studies have demonstrated that PCF procedures commonly occur in patients during the fifth and sixth decades of life and that the age of those who underwent a PCF has increased over the years.[15,21-23] Furthermore, the gender distribution does appear to slightly favor males.[21,22,24] However, updated data on PCF procedures from all national databases is needed.

Additionally, prior literature has lacked a geographic representation of PCF procedures. Baird and colleagues[25] did report that per 100 000 capita, inpatient cervical procedures were greatest in Maryland and Florida and least in California. However, their study only included data from Maryland, Florida, New York, and California and did not report total numbers specifically for PCF procedures nationally. With an aging population of baby boomers, the year-to-year advancements in spinal treatments, and the rising cost of health care, it is important to assess trends in cervical procedures to determine if the delivery of spinal care has changed over time and to observe the interaction of variables so the value can be improved.

The cost of a PCF procedure has increased over time.[21,22] Oglesby et al[22] demonstrated an increase of $8845 from 2002 to 2009, while Marquez-Lara and colleagues[21] reported a $12 406 increase between 2002 and 2011. At the same time, the length of hospital stay (LOS) has been shown to either remain steady[21] or decline over the years.[26] With a decreasing LOS, the predictable decrease in PCF total cost has not occurred, suggesting changes in treatment and/or reimbursement rates. Continually reporting and evaluating surgical cost is fundamental to cost-effectiveness and identifying areas or variables to lower cost and, subsequently, improve the value of spinal care.

Originally, recombinant human bone morphogenetic protein-2 (rhBMP-2) was approved by the Food and Drug Administration (FDA) in 2002 for anterior lumbar interbody fusion procedures.[27,28] Thereafter, the use of rhBMP-2 in off-label situations increased.[29] Around 2006, data supporting serious complications from rhBMP-2 began to surface among the literature, which eventually prompted the FDA to release a public health announcement with regard to usage of rhBMP-2 in the cervical spine.[30] A few years after the 2008 safety alert by the FDA, the Yale University Open Data Access (YODA) project was formed to assess all refereed and unpublished data on rhBMP-2.[31] The results demonstrated that complications had been underreported and conclusions were biased at times.

Prior literature has demonstrated that the majority of PCF procedures do not include rhBMP-2.[21,24,26] However, Fineberg and colleagues[24] showed that the rhBMP-2 utilization in PCF procedures progressively rose from 0.2% to 18.9% between 2002 and 2009, although patients who received an anterior-posterior fusion were incorporated into this PCF cohort. Additionally, prior literature has reported an elevation of rhBMP-2 use until 2008[32] and 2009.[21,26] However, more longitudinal data and a thorough analysis thereof is needed to determine if a true shift in the process occurred as a result of the FDA advisory. Therefore, the purpose of this study was to analyze and report the trends and reimbursement of PCFs with and without off-label rhBMP-2 in the Medicare population.

Methods

Data Source

Data from the PearlDiver Patient Record Database (PearlDiver Technologies, Warsaw, IN) was used. The PearlDiver database is a national, commercially available database that contains medical insurance records for Medicare and several private insurance agencies.

Patient Selection

We retrospectively reviewed the patient records within the orthopedic subset of the Medicare database from January 1, 2005, to December 31, 2012. Current Procedural Terminology (CPT) codes for PCF (CPT-22590, CPT-22595, and CPT-22600) and the International Classification of Disease, Ninth Revision Procedural (ICD-9-P), codes for PCF (P-8103) and rhBMP-2 (P-8452) were used to identify patients who underwent a PCF with rhBMP-2. The absence of the ICD-9-CM 84.52 code represented patients that did not receive rhBMP-2. Additionally, P-81.02, CPT-22548, CPT-22551, and CPT-22554 were used to exclude combined anterior/posterior procedures.

Patients were divided into 2 groups: PCF patients with and without rhBMP-2. Additionally, patients were classified into demographic categories: age (<65, 65-69, 70-74, 75-79, 80-84, 85+), gender, and geographic region (Table 1). Hospital and surgeon Medicare reimbursement and LOS were also gathered for these PCF patients. For purposes of this article, Medicare reimbursement to hospitals and surgeons is considered equivalent to the cost of the procedure. Due to the nature of the PearlDiver database, institutional review board approval was not required for this study.

Data Analysis

Total numbers, incidence, age, gender, geographic region, cost, and LOS were analyzed and summarized. Medicare reimbursement was available from the ICD-9-P and CPT codes for PCF and rhBMP-2. The reimbursement amount includes what Medicare paid to hospitals and surgeons. Incidence was calculated per 10 000. In addition, a control P-chart[33] was conducted to assess the use of rhBMP-2 over time in order to explore if a special or assignable cause

Table 1. Regional Division of States.

Region	States
Midwest	IA, KS, MN, MO, NE, IL, IN, MI, WI, OH, NO, SD
Northeast	CT, MA, ME, NH, NJ, PA, RI, NY, VT
South	AL, AR, DC, DE, FL, GA, KY, LA, MD, MS, NC, OK, SC, TN, TX, VA, WV, PR
West	AK, AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, WY, HI

occurred between 2005 and 2012. Upper and lower limits were calculated using the standard formula.[33]

Results

Table 2 displays the total number of procedures, the incidence of procedures for all groups, and the percent rhBMP-2 use of PCF patients with rhBMP-2. Table 3 includes the amount of reimbursement and LOS for patients with and without rhBMP-2 as well as by age, region, and gender.

The combined total of non-rhBMP-2 and rhBMP-2 PCF procedures performed between 2005 and2012 was 46 171. The majority of PCF procedures did not include rhBMP-2 (85.51%). With the exception of a slight dip in 2006, the number of PCFs without rhBMP-2 consistently increased over time, while the number of PCFs with rhBMP-2 had a slight increase from 2005 compared to 2012. The incidence without rhBMP-2 demonstrated a small uptrend from 0.95 (2005) to 1.28 (2012), while the incidence with rhBMP-2 remained fairly steady between a low of 0.13 (2005) and a high of 0.21 (2007 and 2008; Figure 1).

During this 8-year time period, the average percent rhBMP-2 use for all PCF procedures was only 14.49%. The percentage of rhBMP-2 use increased from 2005 but peaked in 2007. A decline in percent rhBMP-2 was shown to continue until 2010 and decreased another 2.84% from 2011 to 2012 (Figure 2). The control P-chart demonstrated that rhBMP-2 use did not stay within upper and lower limits throughout 2005 to 2012 (Figure 3). When the percent rhBMP-2 use was averaged for years 2005 to 2007 (before FDA advisory) and was compared to the average for years 2008 to 2012 (after FDA advisory), the percent rhBMP-2 use did stay within statistical control.

The annual Medicare reimbursement to hospitals and surgeons for PCFs increased from 2005 to 2012 (Figure 4). The average reimbursement for procedures with and without rhBMP-2 increased by $12 605 and $7291, respectively. On average, PCFs with rhBMP-2 were associated with cost $1197 lower than those without rhBMP-2, but the average LOS was equal (6 days).

Age

Patients younger than 65 years of age consistently demonstrated the highest incidence both with and without rhBMP-2, and the oldest age group demonstrated the lowest incidence for PCFs with and without rhBMP-2. The average annual cost for PCFs with and without rhBMP-2 increased for all age groups from 2005 compared to 2012. For both groups, patients 85 years or older had the highest average cost. rhBMP-2 patients, aged 85 and over, exhibited a large cost spike between 2009 and 2010 and again from 2011 to 2012. Additionally, each year the oldest age group demonstrated the longest LOS compared to the other age groups, with the exception of 2007 (rhBMP-2 group). For all age groups, the average percent rhBMP-2 use ranged between 13.40% and 15.02%.

Region

The incidence of rhBMP-2 supplemented PCFs was highest in the Midwest and lowest in the Northeast from 2005 to 2012. The incidence of PCFs without rhBMP-2 was highest in the Northeast (2007 on) and lowest in the West. Although the average reimbursement was similar, the Northeast and West received the highest average reimbursement for PCFs with and without rhBMP-2, respectively. The lowest average reimbursement for PCFs with and without rhBMP-2 occurred in the South and Midwest, respectively. Sizeable fluctuations in reimbursement were demonstrated in the Midwest, Northeast, and West for PCFs with rhBMP-2 between 2008 and 2012. In contrast, smaller fluctuations were noticed over time for PCFs without rhBMP-2. The average percent rhBMP-2 use was consistently lower in the Northeast than in the Midwest, West, and South.

Gender

Males exhibited a higher incidence of PCFs both with and without rhBMP2 from 2005 to 2012. Two noticeable increases in incidence occurred in the non-rhBMP-2 group for both males and females from 2008 to 2009 and from 2011 to 2012. Except for 2008, males received higher reimbursement for PCFs without rhBMP-2 and also averaged 1 extra day in the hospital than females. Similarly, males who received rhBMP2 also demonstrated larger reimbursement than their female counterparts with the exceptions of 2006 and 2011. Females demonstrated a slightly higher percent rhBMP2 use than males over time.

Discussion

The aim of this study was to examine and report the trends and cost of PCFs with and without off-label rhBMP-2 in the Medicare population. Out of the 46 171 PCF procedures performed during this time period, only 14.49% used rhBMP-2, and the number of those procedures stayed fairly steady from 2007 to 2012. In contrast, PCF surgeries without rhBMP-2 steadily increased over time. With the rising annual number of spinal fusions occurring in the Unites States, an understanding of health care trends as well as patient tendencies, both currently and historically, are fundamental to aiding needed research and updating or changing policies to maximize value.

Table 2. The Total Number of Procedures, the Incidence of Procedures for All Groups, and the Percent rhBMP-2 Use of PCF Patients With rhBMP-2.

	Year								
	2005	2006	2007	2008	2009	2010	2011	2012	Total Average
Total count (rhBMP-2/non-rhBMP-2)	541/4039	742/3964	940/4129	973/4621	915/5133	859/5375	921/5735	801/6483	6692/39 479
Incidence (rhBMP-2/non-rhBMP-2)	0.13/0.95	0.17/0.91	0.21/0.93	0.21/1.02	0.20/1.10	0.18/1.13	0.19/1.17	0.16/1.28	0.18/1.06
<65 (years)	0.21/1.40	0.26/1.26	0.29/1.27	0.27/1.34	0.27/1.58	0.28/1.51	0.27/1.67	0.23/1.70	0.26/1.47
65-69 (years)	0.11/0.90	0.14/0.84	0.19/0.91	0.16/0.83	0.18/1.00	0.15/1.03	0.17/1.09	0.12/1.21	0.15/0.98
70-74 (years)	0.14/0.96	0.17/0.96	0.24/0.98	0.21/0.93	0.20/1.14	0.17/1.20	0.20/1.20	0.17/1.26	0.19/1.08
75-79 (years)	0.13/0.98	0.18/0.97	0.22/0.96	0.23/0.98	0.21/1.21	0.19/1.23	0.19/1.21	0.17/1.43	0.19/1.12
80-84 (years)	0.11/0.87	0.18/0.88	0.20/0.82	0.17/0.85	0.19/1.01	0.16/1.06	0.18/1.03	0.16/1.20	0.17/0.96
85+ (years)	0.04/0.44	0.10/0.46	0.12/0.49	0.10/0.45	0.10/0.54	0.12/0.62	0.09/0.69	0.08/0.70	0.09/0.55
Midwest	0.16/1.02	0.23/0.94	0.30/0.98	0.28/1.03	0.26/1.19	0.28/1.13	0.25/1.13	0.22/1.29	0.25/0.09
Northeast	0.07/0.99	0.09/0.97	0.12/1.04	0.11/1.15	0.11/1.25	0.09/1.35	0.12/1.36	0.10/1.42	0.10/1.19
South	0.15/1.07	0.18/1.02	0.22/0.99	0.23/1.08	0.21/1.14	0.18/1.16	0.21/1.24	0.17/1.33	0.19/1.13
West	0.12/0.72	0.19/0.75	0.22/0.77	0.23/0.88	0.20/0.93	0.17/0.98	0.17/1.05	0.15/1.18	0.18/0.91
Male	0.12/0.77	0.15/0.73	0.18/0.74	0.16/0.72	0.17/0.88	0.15/0.89	0.17/0.91	0.15/1.03	0.16/0.83
Female	0.13/1.17	0.20/1.15	0.25/1.18	0.23/1.16	0.23/1.38	0.22/1.42	0.21/1.49	0.17/1.58	0.20/1.32
rhBMP-2 (%)	11.81	15.77	18.54	17.39	15.13	13.78	13.84	11.00	14.49
<65 (years)	13.01	16.98	18.76	16.91	14.68	15.55	13.94	12.00	15.02
65-69 (years)	10.67	13.83	16.88	16.34	15.21	12.98	13.70	9.34	13.40
70-74 (years)	13.07	14.68	19.46	18.25	14.94	12.49	14.22	11.73	14.66
75-79 (years)	11.60	15.97	18.24	18.92	15.03	13.47	13.78	10.86	14.55
80-84 (years)	10.82	17.12	20.00	16.46	15.95	13.21	14.62	12.01	14.91
85+ (years)	9.17	18.21	19.03	18.34	15.95	16.02	11.75	10.28	14.61
Midwest	13.40	19.95	23.30	21.40	17.92	20.16	18.17	14.49	18.52
Northeast	6.81	8.27	10.08	9.06	8.36	6.52	8.01	6.32	7.84
South	12.10	14.88	18.11	17.54	15.78	13.42	14.41	11.23	14.55
West	14.77	20.25	22.20	20.98	17.51	14.48	13.84	11.17	16.43
Male	10.03	14.70	17.36	16.82	14.03	13.14	12.46	9.76	13.35
Female	13.84	17.07	20.00	18.18	16.48	14.59	15.62	12.51	15.83

Abbreviation: rhBMP-2, recombinant human bone morphogenetic protein-2.

Table 3. The Amount of Reimbursement and LOS for Patients With and Without rhBMP-2 as Well as by Age, Region, and Gender.

	Year								
	2005	2006	2007	2008	2009	2010	2011	2012	Average
rhBMP-2: Reimbursement ($) (LOS)	15 424 (6)	16 660 (6)	16 908 (5)	18 915 (5)	21 078 (5)	22 731 (5)	24 069 (6)	28 029 (6)	20 603 (6)
<65 (years)	13 220 (5)	15 527 (5)	16 820 (5)	18 419 (6)	21 770 (5)	22 444 (5)	21 997 (5)	26 465 (6)	19 861 (5)
65-69 (years)	13 098 (4)	15 208 (5)	15 068 (4)	16 097 (4)	18 172 (4)	21 637 (5)	21 728 (5)	28 255 (6)	18 908 (5)
70-74 (years)	17 150 (7)	20 691 (7)	16 254 (5)	17 038 (5)	19 375 (4)	22 992 (5)	25 345 (6)	26 715 (6)	20 601 (5)
75-79 (years)	17 596 (6)	15 151 (5)	17 040 (5)	22 813 (6)	22 331 (6)	20 495 (5)	26 499 (6)	29 723 (6)	21 388 (6)
80-84 (years)	16 624 (7)	17 597 (7)	19 459 (7)	19 633 (6)	25 625 (7)	22 614 (5)	24 617 (7)	26 203 (7)	21 738 (6)
85+ (years)	19 467 (11)	16 472 (9)	19 757 (7)	21 458 (7)	22 715 (8)	31 105 (8)	30 901 (9)	38 247 (8)	25 175 (8)
Midwest	14 942 (6)	17 253 (6)	16 943 (5)	18 538 (5)	20 266 (5)	20 808 (5)	25 868 (6)	29 773 (7)	20 681 (5)
Northeast	17 348 (7)	16 703 (5)	18 318 (7)	19 484 (5)	21 849 (5)	27 011 (6)	23 609 (6)	32 957 (7)	22 407 (6)
South	15 132 (6)	15 136 (6)	16 665 (5)	18 419 (6)	18 527 (5)	23 497 (6)	22 223 (6)	23 502 (5)	19 225 (6)
West	15 702 (6)	18 583 (6)	16 600 (5)	20 062 (5)	27 026 (6)	22 582 (5)	25 479 (5)	31 582 (6)	22 182 (6)
Male	17 357 (7)	16 595 (6)	17 177 (5)	19 631 (6)	22 413 (5)	23 225 (5)	23 666 (6)	28 179 (6)	21 106 (6)
Female	13 887 (5)	16 736 (6)	16 629 (5)	17 861 (5)	19 787 (5)	22 161 (5)	24 473 (6)	27 885 (6)	20 099 (5)
Non-rhBMP-2: Reimbursement ($) (LOS)	16 941 (6)	18 676 (6)	19 457 (6)	21 049 (6)	23 163 (6)	23 825 (6)	23 763 (6)	24 232 (5)	21 800 (6)
<65 (years)	18 149 (6)	17 760 (6)	20 318 (6)	20 785 (6)	21 816 (5)	23 774 (6)	23 943 (5)	23 140 (5)	21 584 (6)
65-69 (years)	15 579 (5)	16 512 (5)	17 839 (5)	17 254 (4)	21 159 (5)	22 306 (5)	21 249 (5)	24 016 (5)	20 095 (5)
70-74 (years)	15 634 (5)	18 230 (6)	18 888 (6)	21 184 (6)	23 472 (6)	22 722 (6)	23 297 (5)	22 745 (5)	21 133 (5)
75-79 (years)	17 066 (7)	21 099 (7)	20 778 (6)	22 999 (7)	24 066 (6)	24 410 (6)	25 676 (6)	25 282 (6)	22 980 (6)
80-84 (years)	19 298 (7)	19 643 (7)	19 298 (7)	24 822 (7)	25 050 (7)	25 099 (7)	24 496 (6)	25 582 (6)	23 207 (7)
85+ (years)	16 544 (8)	22 779 (9)	21 129 (8)	23 565 (8)	29 228 (8)	28 997 (8)	27 861 (7)	28 380 (7)	25 613 (8)
Midwest	15 235 (6)	16 991 (6)	17 108 (5)	19 640 (6)	21 598 (6)	23 251 (6)	22 918 (6)	22 437 (5)	20 250 (6)
Northeast	19 194 (7)	19 823 (7)	20 104 (7)	21 606 (6)	23 715 (6)	24 920 (6)	25 065 (6)	25 601 (6)	22 956 (6)
South	16 119 (6)	18 490 (6)	19 531 (6)	19 565 (5)	22 298 (6)	22 922 (6)	23 028 (6)	22 715 (5)	20 893 (6)
West	18 940 (6)	20 098 (6)	21 717 (6)	25 555 (6)	26 545 (6)	25 095 (5)	24 765 (5)	27 880 (5)	24 432 (6)
Male	17 631 (6)	20 157 (7)	21 243 (7)	19 760 (5)	24 624 (6)	25 200 (6)	24 464 (6)	25 634 (6)	23 082 (6)
Female	16 129 (6)	16 839 (6)	17 233 (5)	23 075 (6)	21 303 (5)	22 018 (5)	22 834 (5)	22 468 (5)	20 205 (5)

Abbreviations: LOS, length of stay (days); rhBMP-2, recombinant human bone morphogenetic protein-2.

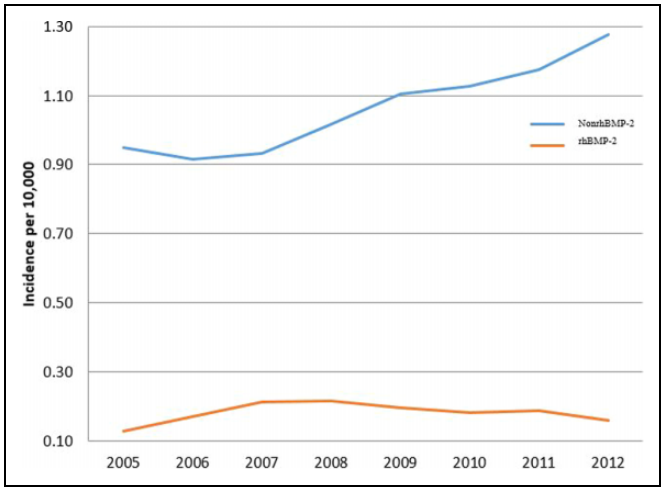

Figure 1. Incidence of PCFs with and without rhBMP-2 from 2005 to 2012. PCF, posterior cervical fusion; rhBMP-2, recombinant human bone morphogenetic protein-2.

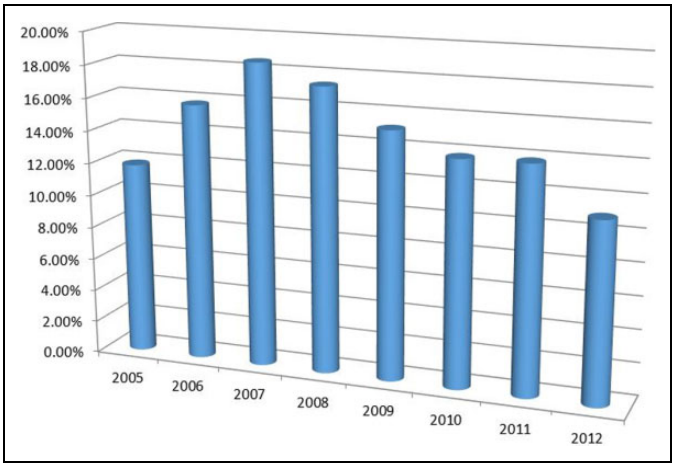

Figure 2. Percent rhBMP-2 use in PCFs from 2005 to 2012. PCF, posterior cervical fusion; rhBMP-2, recombinant human bone morphogenetic protein-2.

Incidence

PCF procedures without rhBMP-2 demonstrated a slight, steady increase from 2007 to 2012, theorizing a potential upward shift, but more data is needed to confirm this theory. Our data agrees with prior work[21,22,26] that the number and incidence of PCF surgeries have increased over the years (2002-2011). Those studies used the Nationwide Inpatient Sample database, whereas in the present study, the

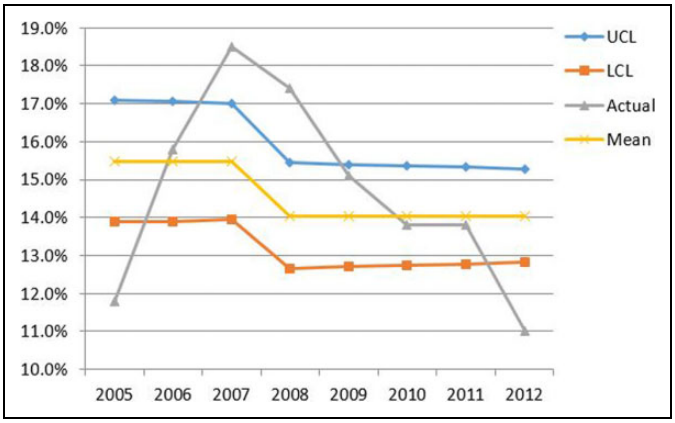

Figure 3. Control P-chart of rhBMP-2 use in PCFs over time. The mean is based on calculations before (2005-2007) and after (2008-2012) the 2008 FDA advisory. PCF, posterior cervical fusion; rhBMP-2, recombinant human bone morphogenetic protein-2; FDA, Food and Drug Administration; UCL, upper control limit; LCL, lower control limit.

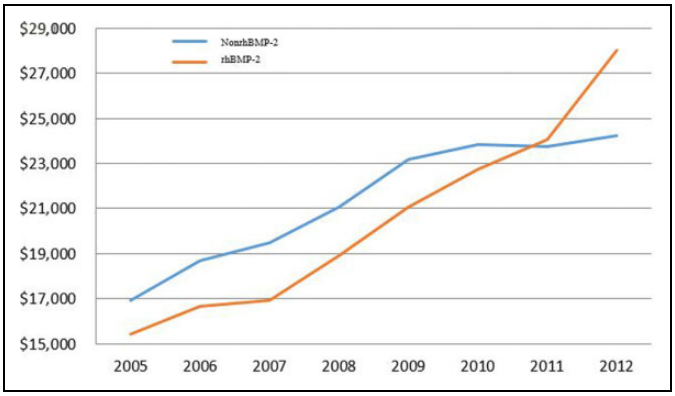

Figure 4. Annual reimbursement for PCFs with and without rhBMP-2 from 2005 to 2012. PCF, posterior cervical fusion; rhBMP-2, recombinant human bone morphogenetic protein-2.

PearlDiver database was utilized. Previous literature has demonstrated pre- to postoperative improvements in neurological function and patient outcomes of patients who underwent a posterior cervical surgery.[34-37] Other possible reasons for the increase in PCF procedures may have included factors such as longer life spans that lead to the need or desire for maintaining or repairing function, population growth, improvements in technology, and better patient access to fellowship trained spine surgeons.

Despite rhBMP-2's strong bone forming characteristics, it appears that rhBMP-2 is not overwhelmingly used for PCF surgeries. The greater incidence of PCF procedures without rhBMP-2 was consistent with previous literature.[21,24,26] The cervical spine is more vascular than the thoracic and lumbar spines,[42–44] which helps the posterior cervical region be a good environment for fusion. Prior literature has reported strong fusion rates (94.2% to 100%) for PCF procedures without rhBMP-2.[38–41]

Cost and LOS

The increase in cost over time was comparable to published data,[21,22,26] which reported increased hospital reimbursement over time. Additionally, in previous studies the LOS has been shown to either stay steady[21] or decline from year-to-year.[26] In the present study, the LOS remained fairly steady (1-2 day difference) other than the rhBMP-2 (70-74; range of 4-7 days) and 85 plus (range of 7011 days) age groups. Increasing cost through time, and stable or decreasing LOS are trends consistent both with the healthcare market and previous literature.

PCF procedures without rhBMP-2 demonstrated a higher cost than PCF procedures with rhBMP-2, with the exception of costs associated with such procedures in 2011 and 2012. Between 2007 and 2010, the average LOS was 1 day longer for patients who underwent a PCF procedure without rhBMP-2. The longer LOS for the non-rhBMP-2 patients may have been due to the procurement of iliac crest bone graft, or it may merely be by virtue of summary data being rounded up or down. Fineberg and colleagues[24] reported the average charge of a PCF with rhBMP-2 was $6272 more than without rhBMP-2, with no difference in LOS between the 2 groups. They concluded that the cost of the rhBMP-2 was the most likely explanation for the $6272 difference between the groups. It is important to note that they reported charges, not cost, which may explain why the present results disagree with their findings.[24] Additionally, in the present study, there was a significant increase in reimbursement for patients with rhBMP-2 from 2011 to 2012 in comparison to the prior year ($24 069 to $28 029). The current study design does not include data on factors influencing cost including reimbursement rates and rhBMP-2 cost. These noticeable data points warrant further investigation.

Percentage BMP Use

Our data suggests that the FDA advisory and/or the YODA findings may have had an impact on a clinician's choice of using rhBMP-2 since percent rhBMP-2 use peaked in 2007 and declined slightly thereafter (1.15% to 2.84%). Our analysis is similar to previous findings of rhBMP-2 progressively rising until 2008[32] and 2009,[21,24,26] but these studies reported data from 2002 to2011. More longitudinal data is needed along with future work designed to specifically examine these outside influences.

The control P-chart for rhBMP-2 use also demonstrated that there may have been special or assignable causes from 2005 to 2012 since some of the data points did not stay within the upper and lower limits (Figure 3). When the pre- and post-FDA audit mean percent rhBMP-2 use was determined and administered, the percent rhBMP-2 use did stay within the upper and lower limits. Only common cause variations were observed. At this point, it is imperative to understand that from a statistical standpoint, the use of rhBMP-2 is not an established process. Many more data points (years) are needed to determine whether or not

the use of rhBMP-2 process was statistically altered by a special or assignable cause such as the FDA advisory or YODA.

Age

The highest incidence of PCF procedures with and without rhBMP-2 seen in the <65-year-old age group was comparable to data of previous studies, which reported that patients who underwent a PCF procedure were mainly in their 50s and 60s.[15,21-23] The lowest incidence of PCF procedures with and without rhBMP-2 was demonstrated by the oldest age group. For senior patients, evaluating one's comorbidities is an important determinant when selecting the right treatment. PCF has been suggested to be a more invasive surgery.[45]

The amount of cost was greater in 2012 compared to 2005 for all age groups (Table 3). Comparable to the overall cost, the 85 and older age group did not consistently demonstrate a direct relationship between cost and LOS. Furthermore, the LOS stayed steady for the <65-year-old age group, but in general, cost increased over time, which indicates advances in treatment and changes in reimbursement rates, which is in accordance with the health care market. Yet, the >85 years of age group both with and without rhBMP-2 demonstrated an average longer LOS and the highest average cost. Typically, older individuals do have more comorbidities, and thus an increased chance of complications that could lead to additional care.

On average, rhBMP-2 use was comparable for all age groups. These findings suggest that age did not influence the use of rhBMP-2. We hypothesize that other factors such as patient characteristics (osteoporosis, smoking status), surgeon's preference and diagnosis (multilevel), indication for surgery (revision), and the ability to extend autograft more strongly determined the bone graft of choice than age directly.

Region

The incidence of PCF procedures did demonstrate some regional differences. Factors such as patient preference and complexity and regional lifestyle differences may be possible theories for the lack of symmetry. Interestingly, overall, the average reimbursement was fairly comparable between regions as well as the average LOS. Investigations designed to explore reasons for geographic similarities and differences in cost of a PCF procedure are needed so value for these procedures can be fine-tuned.

The data demonstrated a considerably lower percent rhBMP-2 use in the Northeast compared to the other 3 regions while the Midwest (2007-2012) showed the highest rhBMP-2 use. This pattern was similar to previous research on regional differences and the usage of rhBMP-2 in lumbar spinal fusions.[46,47] Examining surgeon preferences, variation of surgical indications among surgeons, the number of surgeons in a particular region, and a surgeon's training may be good future research questions to help identify regional elements and motives in spinal care.

Gender

The higher incidence of males undergoing a PCF procedure is in agreement with prior PCF and trend studies.[21,22,24] In the current study, though the rhBMP-2 male (n = 3369) and female (n = 3229) groups were fairly even, the male (21 858) non-rhBMP-2 group had 4692 more patients than the female group (n = 17 166). This may also be the case in previous literature.[21,22,24]

Overall males were shown to receive higher reimbursement and had a 1-day longer LOS. Elucidating contributing or influencing factors of reimbursement rates between men and women goes beyond the scope of this article; thus, further understanding and investigation of contributing or influencing factors of reimbursement rates between the genders is warranted.

On average, rhBMP-2 use was comparable for males and females (1.36% to 3.81% difference). Like age, the current findings suggest that gender did not influence the use of rhBMP-2. This data distribution was congruent with prior research on sex differences and the usage of rhBMP-2 in lumbar spinal fusions.[46]

Limitations

The main limitations of this study concern the retrospective collection of summary data from a large, public database and reliance on accurate medical coding. Clinical details such as diagnoses and surgical elements were not included and basic means and standard deviations for variables were not possible. Last, our sample only included Medicare patients. Nonetheless, to our knowledge, this is the first study to use the PearlDiver database to analyze and report trends and cost on PCF procedures with a large, heterogeneous sample with no industry support.

Conclusions

In general, the number and incidence of PCF procedures increased over time from 2005 to 2012. Only a small percentage of PCF procedures included rhBMP-2. The average cost for a PCF procedure increased from 2005 to 2012. Interestingly, PCF procedures without rhBMP-2 demonstrated greater cost than with rhBMP-2 from 2005 to 2010. Percent rhBMP-2 use demonstrated a peak in 2007, and then gradual, slight declines through 2012, which could have been influenced by outside forces (FDA advisory, YODA). A number of age, region, and gender differences were noticeable and require further investigation. This article provides valuable trend data on PCFs for surgeons and clinicians, researchers, and patients, and also serves as a guide for future research questions.

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