

Vertebral Augmentation After Recent Randomized Controlled Trials: A New Rise in Kyphoplasty Volumes

Moungnyan Cox, MD^a, David C. Levin, MD^a, Laurence Parker, PhD^a, William Morrison, MD^a, Suzanne Long, MD^a, Vijay M. Rao, MD^a

Abstract

Purpose: In 2009, the results of two randomized controlled trials refuting the effectiveness of vertebroplasty compared with sham procedures were published in a leading journal. The purpose of the present study was to evaluate the impact of these randomized trials on subsequent volume and utilization rates of vertebral augmentation (VA) in the United States.

Methods: Using nationwide Medicare Part B databases, Current Procedural Terminology, version 4, codes for thoracic and lumbar vertebroplasty and kyphoplasty were studied from 2006 to 2013 (codes 22520 to 22525). The total volumes of procedures were determined and utilization rates were calculated. Volumes and rates by provider specialty were also studied.

Results: The total volume of VA procedures peaked in 2008 at 101,807 and thereafter fell steadily to 80,940 in 2013. The utilization rates per 100,000 beneficiaries also showed a similar trend. Radiologists performed the largest number of VA procedures in 2013 (33,618 procedures [42%]), followed by orthopedic surgeons (19,886 procedures [25%]). After 2009, vertebroplasty volumes decreased sharply. Kyphoplasty volumes increased in 2011, after an initial decrease in 2010. The divergent trend in the volumes of the two procedures persisted through 2013.

Conclusions: After the publication of the two trials' results in 2009, vertebroplasty volumes and rates decreased sharply. However, there is an emerging trend toward performing more kyphoplasty procedures, mitigating the decrease in total volume of VA procedures. Radiologists have the strongest role in performing these procedures among all medical specialties.

Key Words: Vertebroplasty, kyphoplasty, *New England Journal of Medicine*, sham, simulated, VERTOS

J Am Coll Radiol 2016;13:28-32. Copyright © 2016 American College of Radiology

PURPOSE

Vertebroplasty and kyphoplasty are percutaneous procedures used to treat painful vertebral body fractures, most commonly from osteoporosis [1]. In 2009, the results of two randomized clinical controlled trials were published in the *New England Journal of Medicine (NEJM)*, calling into question the efficacy of vertebroplasty compared with placebo [1,2]. In the randomized controlled Investigational Vertebroplasty Safety and Efficacy Trial by Kallmes et al [1], 131 patients with one to three

painful vertebral compression fractures were randomized to vertebroplasty or a sham procedure (68 versus 63 patients). There were no significant differences in pain and disability scores between the vertebroplasty group and the placebo group at one month. There were improvements in pain and disability scores in both groups, however.

In the same issue of *NEJM*, an independent study out of Australia showed findings similar to those of the Investigational Vertebroplasty Safety and Efficacy Trial. In the randomized controlled study, by Buchbinder et al [2], 78 patients with one or two compression fractures less than a year old were randomized to vertebroplasty or a simulated procedure (38 versus 40 patients). Both groups had similar improvements in pain and disability scores at one, three, and six months. There were no significant differences between the two groups with respect to pain and disability scores.

^aDepartment of Radiology, Thomas Jefferson University, Philadelphia, Pennsylvania.

Corresponding author and reprints: Moungnyan Cox, MD, Thomas Jefferson University, Department of Radiology, 1087 Main Building, 132 South 10th Street, Philadelphia, PA, 19107; e-mail: moungnyan.cox@gmail.com.

The authors have no conflicts of interest related to the material discussed in this article.

Shortly thereafter, the results of a randomized clinical trial (Vertebroplasty Versus Conservative Treatment in Acute Osteoporotic Vertebral Compression Fractures [VERTOS] II) comparing the efficacy of vertebroplasty with that of conservative treatment was published in *Lancet* in 2010, showing that vertebroplasty was superior to conservative therapy for pain relief in patients with acute, persistently painful osteoporotic fractures [3]. Vertebroplasty resulted in decreased pain compared with conservative therapy, with no adverse events.

In 2012, Long et al [4] published data regarding vertebroplasty volumes from 2001 through 2010, reporting a sharp decrease in vertebroplasty volumes after the studies of Kallmes et al [1] and Buchbinder et al [2], but they provided data for only one year after publication of the trials. Long et al also showed a slight decrease in kyphoplasty volumes in 2010. Manchikanti et al [5] reported similar findings in 2012.

The purpose of the present study was to evaluate the impact of these randomized clinical controlled trials on subsequent volume and utilization rates of vertebroplasty and kyphoplasty procedures in the United States.

METHODS

For our study, we used data from the national Medicare Part B Physician/Supplier Procedure Summary Master Files for 2006 through 2013. This database contains aggregated information on procedure volume, allowed billing claims, and provider specialty for each code assigned in the Current Procedural Terminology, version 4. The Medicare Part B files represent the largest database of its kind on Medicare patients and cover patients enrolled in traditional fee-for-service Medicare (37.3 million patients in 2013). This database does not include patients enrolled in Medicare Advantage plans (15.1 million patients in 2013).

The vertebroplasty and kyphoplasty procedure codes used in our study are listed in Table 1. For each of the

codes, the total volume of procedures performed was determined, and utilization rate per 100,000 fee-for-service Medicare beneficiaries was calculated. The utilization rate per 100,000 was calculated by dividing the total number of procedures for a given year by the number of hundreds of thousands of Medicare beneficiaries for that year. The utilization rates were included in the analysis because they adjust for yearly fluctuations in the total Medicare population. The total volume of procedures and utilization rate by specialty were also calculated. The specialty groups analyzed were radiologists, orthopedic surgeons (the largest nonradiologist participants in vertebral augmentation [VA]), neurosurgeons, anesthesiologists, rehabilitation medicine physicians, and all other physicians as one group. The physician groups were classified using self-identification codes. The total volume of vertebroplasty and kyphoplasty were also examined separately because of recent controversies about the similar efficacy and complication rates but unequal costs of the two procedures [6,7].

RESULTS

Table 2 shows that the total volume of VA procedures performed in 2006 was 90,772. The total volume of vertebroplasty and kyphoplasty procedures peaked in 2008 at 101,807 and thereafter fell steadily to 80,940 in 2013. The utilization rates of vertebroplasty and kyphoplasty also showed similar trends. The utilization rate was 252 per 100,000 Medicare beneficiaries in 2006. It peaked at 292 in 2008 and fell each year after 2008 to 217 in 2013.

In Figure 1, the total volume of vertebroplasty and kyphoplasty procedures was investigated separately, and it seemed that vertebroplasty volumes decreased sharply after 2009, whereas kyphoplasty procedures started to increase. In 2013, there were 63,821 kyphoplasty procedures performed in the Medicare fee-for-service population, compared with 17,119 vertebroplasty procedures in the same population during that year. As shown in Figure 2, radiologists were the predominant specialists performing vertebroplasty procedures from 2006 to 2013. All specialty groups experienced decreases in vertebroplasty volumes after 2009, a trend that was steepest for radiologists. Figure 3 shows that from 2006, orthopedic surgeons were performing more kyphoplasty procedures than any other specialty until radiologists overtook them for the first time in 2012. As of 2013, radiologists were performing the highest number of vertebroplasty and kyphoplasty procedures.

Table 1. Current Procedural Terminology, version 4, codes and descriptors for vertebroplasty and kyphoplasty

Code	Descriptor
22520	Percutaneous vertebroplasty thoracic
22521	Percutaneous vertebroplasty lumbar
22522	Percutaneous vertebroplasty additional level
22523	Percutaneous kyphoplasty thoracic
22524	Percutaneous kyphoplasty lumbar
22525	Percutaneous kyphoplasty additional

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