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Time to Treatment Versus Health Care Utilization in Compression Fractures Treated With Vertebral Augmentation: The Vertebral Augmentation Care Pathways Case Series

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Background: There is little data on the economics of the timing of percutaneous vertebral augmentation (PVA) for vertebral compression fractures (VCFs).

Case Report: The purpose of this case series is to compare health care utilization (HCU) costs vs the time to treatment (TTT) of the VCF. The BenchMarket Medical VCF Registry (now Talosix) was utilized. Patients receiving acute or intermediate treatment had the greatest pain and function improvement and the lowest HCU costs. Patients receiving delayed treatment had the least improvement and the highest (3-fold) HCU costs. Any TTT delay resulted in higher HCU costs and diminished benefits. The most beneficial PVA outcome and lowest HCU costs were recorded in patients whose PVA was expedited and performed within 3 months from injury.

Conclusions: This series suggests the best pain and function improvement and lowest HCU costs result from efficient, timely PVA.

Key words: Vertebroplasty, kyphoplasty, health care economics, registry, osteoporotic fracture, health care overutilization, case series

BACKGROUND

Due to the increase in osteoporosis, there are over 2 million osteoporotic fragility fractures in the United States, and the number is increasing each year (2). Studies (3,4) also suggest that 1 in 2 women and up to 1 in 4 men > 50 years will sustain an osteoporotic fragility fracture. Patients with vertebral compression fractures (VCFs) are known to require a primary care provider's (PCP) services at a rate 14 times more than the general population (5). Moreover, the medical costs attributed to VCFs exceeded $1 billion in 2005 and are predicted to reach $1.6 billion by 2025 (6). Since the 2 original trials of percutaneous vertebral augmentation (PVA) were published in 2009 (7,8), there have been numerous randomized control trials (RCTs) and meta-analyses demonstrating the effectiveness of PVA for the treat-

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ment of VCFs. In addition to an improvement in pain and function, PVA decreases mortality (9-14), and the number of patients needed to be treated with PVA to save one life is 15 (15).

Appropriate, safe, and effective treatments are the shared goals of patients on Medicare and their treating physicians and both also share a responsibility for financial stewardship. The treatment of elderly persons suffering from painful osteoporotic VCFs (POVCFs) is an opportunity to demonstrate responsible stewardship. AN Appropriate, safe, life-saving, and effective treatment of painful VCFs by PVA has been confirmed and established (1). This pilot study provides further insights into the health care utilization (HCU) costs arising from time-to-treatment (TTT) analyses of patients in the BenchMarket Medical (BMM) VCF Registry/Talosix. The primary goal of this study was to understand HCU costs and determine whether vertebral augmentation care pathways (VACPATS) can enhance care of patients experiencing VCFs.

CASE SERIES

Methods

BMM VCF Registry/Talosix

The BMM VCF Registry, now known as Talosix (Seattle, WA), established patient outcomes for PVA of POVCFs (1). Data is now available for outcomes examining patients who have undergone PVA. The BMM VCF Registry was funded by treating physicians and implemented as a collaborative between Noridian Healthcare Solutions (Noridian) and Talosix (the authorized registry vendor). Noridian is a private corporate Medicare subsidiary responsible for distributing Medicare benefits for Jurisdictions E and F, a territory including most of the Western United States, Hawaii, and Alaska. Noridian is a payor on behalf of Medicare and can determine the utility and reimbursement of medical treatments and procedures on its contractee's behalf.

The purpose of the registry was to develop evidence for selecting the right patient and right treatment at the right time and to determine the cost-effectiveness and outcomes of PVA for patients with POVCFs. Noridian had implemented a local coverage determination (LCD) (2014), which applied restrictive guidelines for authorization and reimbursement for treatments of patients with POVCFs. Nonsurgical management (NSM) was prioritized. The registry contains a total of 732 patients. Prospective observational data, including patient characteristics, diagnosis, process of care, and patient-reported outcomes (PROs) for pain and function, were collected from patients undergoing PVA. The PROs were collected at baseline, 1 month, 3 months, and 6 months following the procedure. Primary outcomes were pain improvement measured using the Numeric Rating Scale (NRS-11) and functional improvement, measured using the Roland Morris Disability Questionnaire (RMDQ). Secondary outcomes included cement leakage, new neurologic deficits, other adverse events, readmissions, and death.

The VACPATS Case Series

A case series was examined where a single Talosix site was selected in order to assess the impact of NSM on HCU for patients with VCF. Talosix requested a random sample of patients who had a VCF diagnosis code, but who did not receive PVA. A sample of 12 patients with a VCF diagnosis code was generated, but all patients eventually did receive PVA, and therefore, it is not a true NSM sample. Upon chart review of these patients, it was noted that some patients go fairly directly to surgery while others can go in and out of the system before receiving a surgical intervention.

Chart review was performed to identify timing of VCF recognition, timing of PVA, and any related encounters through 6 months post-PVA. All current procedural terminology codes and associated costs were collected for every appointment. All 12 patients were compliant with the Noridian LCD (2014) and satisfied authorization and treatment outcomes surveillance criteria. The HCU costs, linked to the International Classification of Diseases (ICD)-9 code for acute VCF, were tracked for all patients. All patients in this study received all treatments from a single community health care system. All HCU costs (e.g., office, hospital, emergency department [ED], imaging, skilled nursing facility, etc), arising from any site and linked to the ICD-9 code for acute VCFs, were recorded and tracked for all patients.

To further understand the impact of HCU on VCF costs, TTT was analyzed. HCU costs were separated into 3 TTT groups: acute treatment—defined as < 1 month from date of injury, intermediate treatment—defined as 3 months from injury, and delayed treatment—defined as 6 months from injury.

Since this site participates in the BMM VCF Registry, we correlated our extracted case series data with our BMM VCF Registry database. Nine of the twelve patients in this VACPATS case series were enrolled in the BMM

VCF Registry. For these 9 patients, we were able to link their NRS-11 and RMDQ scores from baseline, 1, 3, and 6 months postop to their care pathway data. The patient profiles for patients who were not enrolled in the registry will not contain the NRS-11 and RMDQ scores.

RESULTS

A total of 12 patients were included. Nine of which were part of Talosix. Patients all received PVA as treatment modality for their VCF. Talosix outcomes confirmed postmarket evidence of highly significant pain relief with mean pain score improvement of 6.5/10 points at 6 months following PVA. Function also improved significantly with a mean RMDQ score change of 11.4/24 points 6 months after surgery. Results also supported the safety and reliability of PVA.

Figure 1 depicts the time, which elapses from when a POVCF is diagnosed until when it has PVA performed the first time.

Figure 1 outlines the correlation between overall cost and time it took to receive PVA from the original VCF diagnosis—each dot represents a patient. The second chart outlines every patient's total cost broken down by general appointment types (ED, office visit (OV), physical therapy (PT), and dual-energy x-ray absorptiometry scan). There are 3 examples of a single patient profile. These are examples of an inefficient care pathway, an intermediate care pathway, and an efficient care pathway. We based these on the length of time it took for a patient to receive the PVA from the diagnosis date. The appendix figures detail additional individual patient profiles, outlining the care pathway data in the same format. Each patient profile contains the following: a chart that breaks down how many of each appointment type they had, a chart that breaks down the percentage of total care cost per appointment type, and a color-coded timeline that maps when each appointment took place.

We also examined the number of days from diagnosis to PVA, and the total cost of that care pathway. For the inefficient care pathway, 171 days elapsed from diagnosis to PVA with a total cost of $19,590. For the intermediate care pathway, 28 days elapsed from diagnosis to PVA with a cost of $9,412. For the efficient care pathway, only 2 days elapsed from diagnosis to PVA with a cost of $5,096. Days from diagnosis to PVA ranged from 1 day to 171 days for all 9 patients. All patients had dramatic improvement in pain (NRS-11) and function (RMDQ) scores. Patients receiving efficient treatment had the highest beneficial pain and functional improvements and the lowest HCU costs.

Patients receiving delayed treatment had the lowest

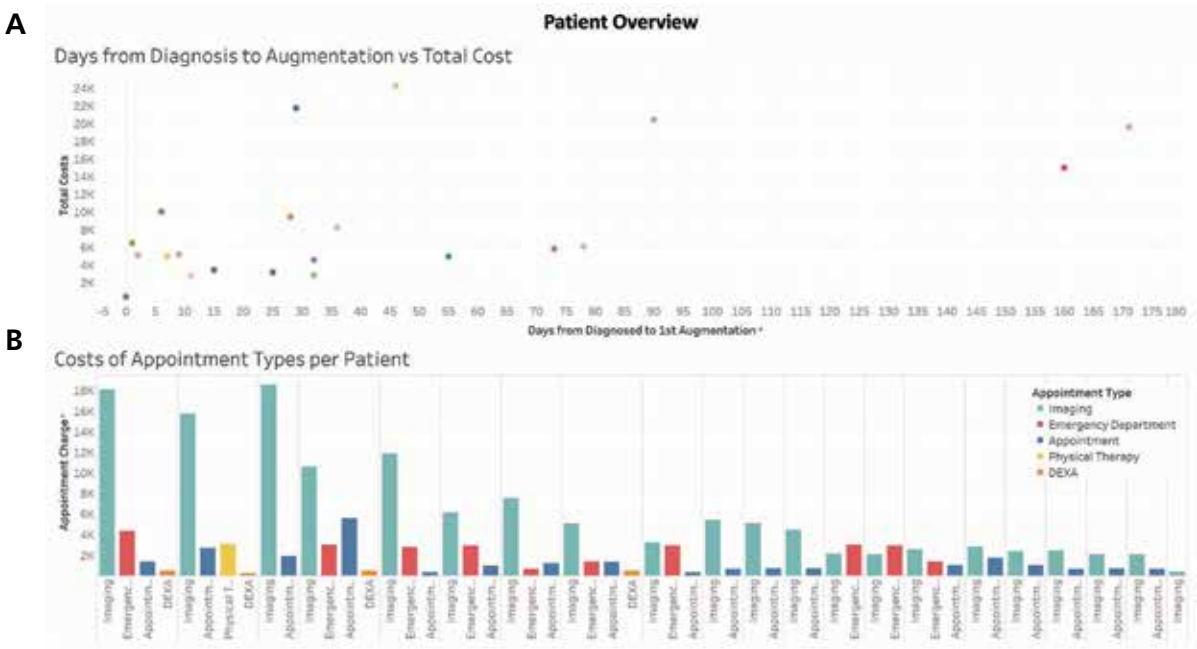

Fig. 1. A) Correlation between the overall cost and time to percutaneous vertebral augmentation (each dot represents a patient). B) Each patient's cost broken down by appointment type.

beneficial pain and functional improvements and the highest (3-fold) HCU costs. Any regulatory or TTT delay resulted in higher HCU costs and diminished beneficial treatment outcomes. The most beneficial PVA treatment outcomes and lowest HCU costs were recorded in patients whose treatment was expedited.

DISCUSSION

The BMM VCF Registry, now known as Talosix, established patient outcomes for PVA of POVCFs. In-depth analysis of a subset of patients from this registry showed that efficient PVA treatment for VCF led to improved outcomes and the lowest HCU costs. The HCU costs demonstrated in this case series and the beneficial PVA outcomes documented reflect the results of the LCD decision and its management. This is the largest registry for POVCFs to date and has a similar outcome to the SWISSspine registry, a mandated, nationwide registry for PVA, which analyzed 625 consecutive cases from 2005 to 2012 (16). It was specifically created to address reimbursement of PVA and led to permanent coverage of the procedure by basic health insurance in Switzerland. Registry data provides insight in a "real-world" fashion as it tracks all patients who undergo a therapy and their outcomes. The BMM VCF Registry and the VACPATS case series corroborate a body of evidence, which provide evidence basis for cement PVA, including the Vertebroplasty for Acute Painful Osteoporotic Fractures, Vertebroplasty Compared With a Sham-Procedure for Painful Acute Osteoporotic Vertebral Fractures, and Vertebroplasty vs Active Control Intervention for Chronic Osteoporotic Vertebral Compression Fractures RCTs (17-19).

From this study, a linear relationship between time to PVA and cost per fracture was identified. This is largely due to the increased number of radiological exams, ED evaluations, hospital stays, and OVs each patient seeks to address the VCF. Repeat imaging and visit costs were largely due to repeat visits for a similar chief complaint. The cost-effectiveness of PVA is based on 5 factors. First, the impact of time considering that only 20% of POVCFs are treated with PVA or balloon kyphoplasty (BKP), another 20% are not diagnosed, 40% are diagnosed but not referred to an interventionalist, and 20% are seen by an interventionalist but not treated by PVA. The second factor to consider is the impact on quality of life (QoL) as post-PVA, there is a 4-fold greater improvement in QoL at one month vs NSM. Additionally, there is an offset time of the treatment effect as patients showed improved mobility of an increased 136 days without limitations at 2 years vs NSM. Also, a reduction in the number of in-bed days in hospital likely contributed to the cost-effectiveness of PVA as Medicare inpatients treated with NSM spend a mean length of stay of 7.38 days vs 3.74 for PVA patients, 62% of NSM patients are readmitted within 30 days vs 35% of PVA patients, and 59.9% of PVA patients are discharged home vs 24.3% of NSM patients. Lastly, there is also a mortality benefit with treatment with a 43% reduction in mortality for PVA vs NSM.

The following is an illustrative example of a typical patient with a VCF. An elderly, thin woman trips over a rug in her house, falling from standing height on a wood floor. She goes to her PCP and complains of 9/10 pain in her back and an inability to do almost anything to take care of herself. The PCP diagnoses her with a muscle strain and sends her home with cyclobenzaprine. The pain persists for days, she returns to her PCP who orders a radiograph (XR), which does not identify the VCF. She returns home, unable to perform activities of daily living. After several days, she goes to the ED as her pain persists and another XR once again does not pick up the VCF. A magnetic resonance imaging (MRI) study of her spine is ordered and shows an acute VCF. The ED physician discharges her with opioid analgesics and a referral to an orthopedic surgeon. The orthopedic surgeon considers offering her surgery, but decides she is too fragile to undergo a fusion. He orders her a thoracolumbosacral orthotic brace and sends her home; however, she stops wearing it after a few days as it is uncomfortable. She returns to her PCP who renews her prescription of opioid analgesics and completes paperwork to obtain a home health aide and home PT. He prescribes vitamin D and calcium for her osteoporosis. Despite this, she continues to have pain, is debilitated for several weeks, and returns to her PCP, where she is weaker and he orders another MRI, showing the same acute VCF with no new findings. He increases her opioid analgesics, starts gabapentin, and sends her home. She develops pneumonia and is hospitalized for a week, then recovers. As 6 months have passed since her initial fracture, she asks for a second opinion, and is finally sent to an interventionalist. Without any of the previous MRI results, the interventionalist orders a new MRI, which once again shows the same fracture. He does PVA of her POVCF, she gets pain relief, and is able to return to her previous level of function. This is a typical example of a patient and all the likely associated costs with delayed treatment. Early treatment provides

a coefficient reduction in cost to late treatment for the parameters that were measured. Other costs, which were not tracked and were likely impacted by treatment, include home health, transportation, prescription drugs, early requirement for assisted living, and home durable medical equipment.

Interestingly, Talosix showed a gross underdiagnosis and undertreatment of osteoporosis. By definition, all of the patients in the trial should have a diagnosis of osteoporosis as defined by the American Association of Clinical Endocrinologists 2016 Guidelines. Of the 732 patients, 84% had a reported osteoporosis diagnosis. Further, only 12% (73) of patients were undergoing pharmacological treatment, the vast majority of with bisphosphonate therapy, and despite treatment, similar fracture risk was seen at 5 years compared with control. Parathyroid hormone analog was only used in 1% (6) of osteoporotic patients and calcium and vitamin D supplementation was limited as was the use of osteoporosis-specific imaging to track disease. Primary care for osteoporosis would likely have the greatest effect on cost reduction and patient outcome for VCF.

Medicare cohort analysis shows a 100% lack of treatment in some states and Medicare database shows mortality from lack of treatment. The treatment of patients with painful VCFs with PVA has been performed for over 30 years and, in addition to clinical experience, there have been high-quality RCTs and meta-analyses supporting both PVA and BKP (9-14). Mortality has also been shown to improve in patients with VCF who are treated by PVA (20). Despite the copious amount of supporting data, conflicting results from 2 sham-controlled trials (7,8) have created confusion as to the indications and value of these treatments.

The BMM VCF Registry's pain and functional improvements are impressive and sustained. This is the largest study that documents the real-world beneficial results of cement augmentation for VCFs. Safety of cement augmentation was demonstrated. Recent publications (10-12) with as-treated on-label evidence similarly reported a significant reduction of pain and improved function and QoL for Medicare patients treated with PVA. In a postmarket study, there was also a significant improvement in the patients' ability to provide self-care and a significant reduction in opioid usage as well as statistically significant improvements for all primary and secondary endpoints at every measured time point throughout the entire study (10-12). Despite this high level of evidence, there remains a paucity of well-designed and well-implemented prospective observational trials and registries that are well-maintained and include representative patient populations. A few registries show basic safety and efficacy data (16) as well as illustrate modifiable factors that can improve PVA outcomes, but data from larger longitudinal analyses from well-designed registries is not well-represented in the literature. The magnitude of pain relief found in the BMM VCF registry compares very favorably to recent studies. The NRS-11 score reduction (Pain delta ~ 6.5) is profound and represents a real-world result, from patients treated in uncontrolled and heterogeneous ways. The results of this study are similar to the results of the Fracture Reduction Evaluation (FREE) trial and the Vertebroplasty vs Conservative Treatment in Acute Osteoporotic Vertebral Compression Fractures (Vertos II) trial, which showed 3.5 and 5.7 point reductions in pain, respectively (21,22). The BMM VCF registry pain reduction scores also compare very favorably to 2 recent meta-analyses that showed mean pain reduction scores of 5.1 and 4.55, respectively (23,24). Additionally, the mean reduction of disability scores (RMDQ delta ~ 11) was equally impressive and comparable to findings in the FREE trial and in Vertos II with mean reductions in RMDQ scores of 8.0 and 9.6, respectively (21,22). The mean percentage reductions in disability in both of these studies were 17.7% and 36.3%, respectively, compared to 48% reduction in disability for all patients within the BMM VCF Registry (23,24).

Data and results from RCTs and meta-analyses have long been regarded as the primary basis of assessing treatment effect. While this is appropriate, it is also important to remember that these treatments were delivered by specific providers in a standardized way for patients with very specific inclusion/exclusion criteria. The same treatment provided across the eligible patient population in real-world practice is often not as controlled as in RCTs. Therefore, other methods of assimilating evidence must weigh into the body of information necessary to assess a particular treatment or types of treatments. The BMM VCF Registry data results not only compare favorably with the results from prominent RCTs and high-quality meta-analyses, but they exceed the magnitude of improvements in pain, function, and disability of previously reported results. They also exceed observational data previously reported from the SWISSspine registry by Hubschle et al (16) who reported a 4.0-point reduction in pain that remained present up to one year.

The majority of studies on PVA report significant improvements in pain, function, and QoL when comparing PVA with NSM (17-21), but these improvements have not been compared to the real-world results of prospective observational trials nearly as often. The results from the BMM VCF Registry reported significant improvements in pain and function that are at least as good or better than the results of the best quality RCTs, and these results may be a better representation of the type of outcomes that patients receive when they are treated in real-world practices across the United States. The registry data demonstrates significant improvement in every domain of health status measured and supports a pathway of early treatment of VCFs with PVA.

Several strengths exist with this study. First, the real-world setting and the large number of patients within the data set allow for external validity of the findings. Additionally, the indications for PVA were well-defined and controlled by the insurance approval process and patients had imaging demonstrating an acute or subacute VCF and concordant physical examination pain, with over 95% had some attempted nonoperative care. Despite these strengths, several limitations exist. First, follow-up was inadequate after 3 months. Additionally, we did not evaluate any XR studies to independently confirm results. Adverse events were self-reported, and therefore likely to be underreported although insurance data was available to identify significant complications.

After VCF, all of the patients included in the study would be considered to have osteoporosis by current guidelines. However, only 84% of patients had a prior diagnosis of osteoporosis, although the majority of those patients were being treated with pharmaceutical agents. We believe that improved screening and primary treatment of osteoporosis is needed to prevent VCFs, and thus, the need for PVA. Patients sustaining VCFs utilize health services as indicated by the hospital readmission rate of 5% within the first month. Secondary fracture prevention programs, such as Own The Bone (American Academy of Orthopedic Surgery), can reduce the risk of secondary fractures, and thus, further hospitalizations. The use of an insurance registry to assess PROs is unique. In the future, further efforts to improve follow-up and define adverse events are needed. As more patients are added, subgroup analyses evaluating risk factors for poor outcomes, recurrent fractures, and complications can be performed.

The BMM VCF Registry delivered economic efficiencies for the clinical practices, reliable compliance with payer evidence needs, and real-time reporting of PROs for the clinicians via a dashboard statistics review made available through BMM. Registry enrollment provided clinicians the assurance they would avoid clawback of payments for those deemed to be noncompliant with the evidence requirements. Even though this was not a true NSM assessment, it still provides insight into the potential impact on both the patient and a health care system, when PVA is delayed. Additionally, full access to medical charts could allow for granular data collection that could strengthen the pilot study findings.

The VACPATS case series data from the 12 patients show a clear signal that there is both an economic impact on the system and a clinical impact on the patient, when augmentation is delayed. However, a sample of 12 patients is not a large enough sample to make definitive claims. Further work could expand the case series to include a large enough sample for the development of standardized care pathways and protocols for VCF patients.

CONCLUSIONS

The BMM VCF Registry delivered validated outcomes data in support of a "coverage with evidence development" decision. This registry data platform accommodated the heterogeneity of VCF disease and allowed the heterogeneity in treatments to be accurately measured. The BMM VCF Registry contained standardized definitions, outcome metrics, and time points for surveillance. PVA for VCFs resulted in highly significant improvements in pain and functional scores for this vulnerable population. Further, registry enrollment was shown to demonstrate "real-world" outcomes and deliver impactful insights for the patients, physicians, and payers. Larger studies are needed. The VACPATS case series indicates the best treatment outcomes and lowest HCU costs result from efficient, timely care. Using this framework, there may be merit in exploring the importance of integrating a standardized care pathway, as there may be a significant cost impact when a VCF diagnosis is not put on a standardized care pathway.

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