

Retrospective Review

e **The Use of Advanced Imaging and Representation of Workers Compensation in Vertebral Augmentation: A Single-Center Comparison with the INVEST Trial**

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Background: Vertebral augmentation (VA) techniques have changed the paradigm of treatment during the past decade and involve injection of polymethylmethacrylate (PMMA) cement directly into a compressed vertebral body. During the summer of 2009, the INVEST trial was one of 2 randomized controlled studies that reported equivalence between vertebroplasty and a control procedure.

Objective: In this analysis, we sought to compare the subset of patients studied in the INVEST trial to a tertiary academic institution with respect to 2 variables: Workers compensation status and presence of advanced imaging prior to the procedure.

Study Design: Retrospective review of 634 procedures.

Methods: We performed a retrospective review of 634 vertebral augmentation procedures at our institution between June 2004 and August 2008, overlapping with the dataset of the INVEST trial. The primary comparison was whether patients received Workers compensation and/or advanced imaging prior to the procedure. The study was IRB approved, and in accordance with HIPAA guidelines.

Results: There were 409 patients who underwent 634 procedures between June 2004 and August 2008. Among 634 procedures, only 3 included Workers compensation. Therefore, the majority of patients (> 99%) did not receive Workers compensation compared to the INVEST trial (11 – 13%). Similarly, in 629 out of 634 procedures (99.2%), patients underwent advanced imaging comprised of magnetic resonance imaging (MRI), computed tomography (CT) or bone scan.

Limitations: We simply looked at 2 elements of the patient demographic in a time-matched fashion and compared it to the U.S. based INVEST trial. It is possible that despite our diligent efforts to review the data set, we have inadvertently excluded some patients, the incorporation of whom might have changed the statistics.

Conclusion: We reviewed our time-matched database in terms of 2 variables we thought curious in the INVEST trial. In comparison to our practice, where advanced imaging is essentially required and Workers compensation largely not seen, these aspects of the INVEST trial's population stood out.

Key words: Spinal fractures/therapy, vertebroplasty/methods, kyphoplasty, evidence-based medicine, pain management, treatment outcome

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Vertebral compression fractures (VCFs) are becoming increasingly common with an estimated annual incidence of 1.4 million worldwide (1). They are thought to cost approximately 12 – 18 billion dollars every year (2) and remain a major cause of pain, disability, and loss of independence. VCFs were previously treated conservatively with bed rest, orthotic braces, non-steroidal anti-inflammatory drugs (NSAIDs), and opioid analgesics. Vertebral augmentation has changed the paradigm of treatment during this past decade. Referring physicians, proceduralists, and patients saw people admitted for unyielding fracture-related back pain return home within a day, after vertebral augmentation with polymethylmethacrylate (PMMA) cement. The literature on vertebral augmentation largely supported these beliefs that were anticipated by the favorable anecdotal evidence. Several case series and cohort analyses, both prospective and retrospective, have demonstrated that vertebral augmentation dramatically improves fracture-related pain and disability in many patients (1,3-16).

In 2003, augmentation practitioners and Comparative Effectiveness Research experts called for a randomized controlled trial (RCT) to definitively establish the effectiveness of vertebroplasty (17). During the summer of 2009, 2 RCTs (18,19) published in the *New England Journal of Medicine* sparked a media frenzy as they reported equivalence between vertebroplasty and a control procedure. The multiple previous publications in support of the safety and efficacy of vertebral augmentation were viewed in light of their lower place on the evidentiary chain because they did not include a control procedure (3-16).

The Investigational Vertebroplasty Efficacy and Safety Trial (INVEST) by Kallmes et al (18) was one of the 2 blinded RCTs that garnered media attention. In this study, patients with painful osteoporotic vertebral compression fractures were assigned to either vertebroplasty or a simulated procedure. The authors concluded that improvements in pain and disability were similar across the 2 treatments arms, thus calling into question the true effectiveness of vertebral augmentation. Much of the critique of the INVEST trial has derived from patient workup and inclusion criteria. Although the authors of this report acknowledge that not all investigators agree with the premise that patient characteristics influence outcomes of vertebral augmentation, many practitioners agree that patient demographics such as age, gender, level of functioning, etc., can influence the results of vertebral augmentation. For instance, a

retrospective cohort study found age and gender to be independent predictors of pain improvement (3). Another retrospective study reported that use of chronic oral steroids was a significant risk factor in the development of additional symptomatic VCFs, many of which required further intervention (20).

The investigators have attempted to address these concerns in a variety of forums (21). We view such dialogue as helpful and believe that a benefit of discussion of any study is in aiding the design of next generation trials.

In this analysis, we sought to compare the subset of patients studied in the INVEST trial by Kallmes et al (18) to a tertiary academic institution with respect to 2 variables: Workers compensation status and presence of advanced imaging prior to the procedure.

Workers Compensation

In the Kallmes et al study population, the percentage of patients who were treated as part of a Workers compensation claim was higher than we would have expected based on our own practice, 9 out of 68 in the vertebroplasty group (13.2%) and 7 out of 63 (11.1%) in the control group (18). In clinical investigations of medications and procedures for the treatment of pain, patients who are involved in Workers compensation claims are commonly excluded due to secondary gain considerations that hamper evaluation of their pain syndrome (22). Indeed, occupational status has been demonstrated to influence response to pain therapies (23,24). Moreover, patients who receive Workers compensation payments are more likely to have an unsatisfactory outcome after surgery compared with patients who do not receive them (25). The association between litigation and compensation and poor outcomes has been observed for over a century, leading to the coining of terms such as “railway spine” in the nineteenth century (26).

Imaging

Similarly, obtaining advanced imaging prior to vertebral augmentation might best be considered the standard of care in our practice. By advanced imaging we specifically mean magnetic resonance imaging (MRI), computed tomography (CT), or bone scan. The recently published research reporting standards for augmentation by Radvany et al (27) reiterate that imaging protocols and grade of the fracture be described in detail for high quality studies, although these standards came out after the publication of the

INVEST results. In the INVEST trial data, MRI or bone scan were only indicated for fractures of uncertain age to look for bone edema and increased vertebral body uptake respectively (18). At a later date, Buchbinder and Kallmes (21) together reported that "although the presence of a fracture line was a possible inclusion criterion in the Australian trial, all participants had fracture edema present on magnetic resonance imaging (MRI) or, as indicated in our published protocol, if MRI was unable to be performed, a computed tomography scan, to determine the position and extent of the vertebral fractures, and a positive bone scan with increased uptake in a distribution compatible with recent vertebral fracture were required." With respect to the INVEST trial, Buchbinder et al (28) has reported that 90% of patients underwent pre-procedure MRI and the number may be higher. This suggests that pre-intervention advanced imaging was not a uniform standard. Based on the quote above regarding the Australian study and Dr. Kallmes's perception that the vast majority of INVEST patients underwent advanced imaging, the investigators in both studies would appear to agree that advanced imaging comprises a critical portion of the workup for VCFs and to have made efforts to include them.

METHODS

We performed a retrospective review of 634 vertebral augmentation procedures at our institution between June 2004 and August 2008, overlapping with the dataset of the INVEST trial by Kallmes et al (18). Patients were identified through an electronic database and through paper records as described previously (3). The database captured pertinent variables such as age, gender, vertebral levels treated, and insurance information. The retrospective study was IRB approved, and data collection and analyses were conducted in accordance with Health Insurance Portability and Accountability Act guidelines.

The primary comparison in this analysis was whether patients received Workers compensation and/or advanced imaging prior to the procedure. First, the operative note from the electronic medical record (EMR) was reviewed with attention paid to the patient's insurance carrier. Second, as a confirmatory check, a contemporaneous history and physical note was studied to look for the patient's occupational status and whether this was related to the fracture in any way.

We also created a database of the most recent imaging (MRI, CT, bone scan, outside imaging) prior to the

intervention. If the patient had imaging at an outside institution, the paper charts were reviewed in regard to this specific issue.

RESULTS

Patient Demographics

There were 409 patients who underwent 634 procedures between June 2004 and August 2008. The average age was 74.8 years. Women represented the majority of the population (n = 300, 73.3%) as has been observed in other studies involving VCFs.

Among our database of 634 procedures, only 2 patients received Workers compensation; one patient underwent 2 procedures yielding a total of 3 procedures (0.5%, Table 1) involving Workers compensation.

The 2 patients who received Workers compensation were 73 and 78 years old. Further, one of these patients referred for vertebral augmentation in the setting of Workers compensation had undiagnosed multiple myeloma (MM). During his initial office visit, MM was suspected and a biopsy was obtained at the time of the augmentation procedure. Biopsy confirmed the suspected pathology.

Of the 634 procedures performed at our institution, 629 (99.2%) underwent advanced imaging comprised of MRI, CT, or bone scan. In the remaining 5 procedures, outside imaging was documented in 4 instances; however, the paper charts revealed no further information on the imaging modality. One procedure had no documented imaging. Therefore, the type of advanced imaging was documented 99.2% of the time (Table 2).

Among 634 procedures performed at our institution, there were 470 MRIs, 165 CT scans, and 78 bone scans obtained pre-treatment as illustrated in Fig. 1.

Table 1. *Workman's compensation results.*

Procedures without Workman's Comp	Procedures with Workman's Comp
631	3

% Procedures without Workman's Compensation: 99.5% (631/634)

Table 2. *Imaging results.*

Procedures with Advanced Imaging	Procedures without Documented Imaging
629	5

% Procedures with Advanced Imaging: 99.2% (629/634)

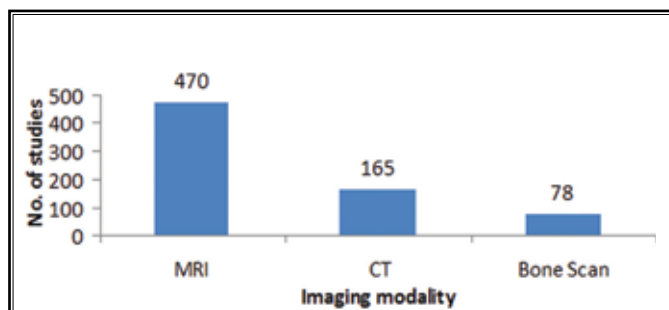


Fig. 1. Imaging distribution. Patients received a combination of advanced imaging (MRI, CT, or bone scan) prior to vertebral augmentation.

Some patients received a combination of procedures.

Discussion

The long-awaited RCTs undertaken by Kallmes (18) and Buchbinder (19) are commendable. Prior to the *New England Journal of Medicine* articles, experience, evidence, and much of the literature attested to the safety and efficacy of vertebral augmentation in appropriately selected patients. This seeming disconnect between the 2 RCTs and previous data provides us with a tremendous opportunity for exploration and an opportunity to inform future research on vertebral augmentation.

The FREE (1) and Vertos II (29) randomized controlled trials are often cited in support of vertebral augmentation due to their high place on the evidentiary ladder. Both have proven the efficacy of kyphoplasty and vertebroplasty respectively, compared to conservative treatment. However, blinding is critical in reducing bias and this is not possible in a trial that compares a procedure to medical management. The INVEST trial demonstrated equivalence between blinded augmentation and sham procedures, i.e., both the vertebroplasty and the control group had reductions in disability and pain. This suggests that the response may be attributable to the placebo effect, a matter that could not be addressed in either the FREE or Vertos II trials.

The two *New England Journal of Medicine* trials have been greeted with varied responses; some have criticized the study design (30,31), while others commented on the procedural technique (32). For example, Bono et al (31) note that the acuity of fractures has long been thought to influence the results of augmentation. Some define acute fractures as being less than 4 - 6 weeks old and argue that the natural history of VCFs makes it difficult to distinguish treatment effect. In the INVEST trial, only fractures less than

a year old were included.

In analyzing the US-based INVEST trial, we were struck that the percentage of patients receiving Workers compensation seemed high compared to our own experience. While Buchbinder and Kallmes stated that their study participants are likely to be representative of typical patient populations seen in routine care (21), such as in the FREE trial, there is no mention of Workers compensation in the FREE data and patients with high-energy trauma were specifically excluded (1). We undertook a retrospective review of our own patient population from the exact period of the INVEST trial. Indeed, patients receiving Workers compensation are far less common in our cohort (0.5% vs. 11 - 13%) with one of the 2 patients having an unsuspected diagnosis of MM. As previously noted, occupational status has been shown to affect response to pain therapies and to predict poor outcomes after surgical procedures. For this reason, receiving Workers compensation payments is often an exclusion criterion for trials of pain therapies. Though Workers compensation was present in both cohorts, we note that a far higher percentage of study patients were receiving these payments compared to patients seen in routine practice by our group. In our series, osteoporotic and malignant fractures comprised the vast majority of patients.

Similarly, we are heavily reliant on advanced imaging as one of the cornerstones of our diagnostic workup and treatment paradigm. MRI has the additional advantage of detecting other spine conditions, malignancies, and vertebral levels that may contribute to the pain syndrome such as spinal degenerative disease (27). Patients routinely undergo a history and physical examination with attention paid to correlating symptoms with fracture site and acuity. As such, our retrospective review confirmed our upfront impression that we utilize advanced imaging in the vast majority of patients; greater than 99% of procedures (Table 2). In the study by Kallmes et al (18), patients underwent MRI or a bone scan only to date fractures of uncertain age as fractures greater than one year old did not meet inclusion criteria. Gray et al (33) further detail these methods and the inclusion criteria require that patients undergo either MRI or X-ray prior to augmentation. We rarely use diagnostic x-ray in this context in our

practice. Although 90% of patients underwent pre-procedure MRI in the INVEST trial per Buchbinder and Kallmes (21), it was not a uniform standard.

The simultaneous publication of the 2 RCTs represents a seminal moment for providers. It is the opinion of the authors that these articles should provide an impetus and direction for future trials. Trial design for augmentation is complex at many levels. For example, it is intuitive to practitioners that physical examination should be correlated to historical and imaging data. Rigorous data does not exist to inform the validity of that statement.

Interventional providers are calling for further studies to examine appropriate populations and endpoints (34) and have created a standardized framework in order to bring greater uniformity to vertebroplasty reporting (27). The importance of optimizing treatment for VCFs is heightened in light of a recently published Medicare database that observed decreased mortality rates for operated patients compared to their conservatively managed cohorts (35). It should be noted that there are limitations to review of any such database and in the aforementioned article by Edidin et al (35), all authors disclose Medtronic as their employer.

Our analysis should be viewed in the context of

its limitations. We simply looked at 2 elements of the patient demographic in a time-matched fashion and compared it to the US-based INVEST trial. Workers compensation was present in both the treatment and control arm of the INVEST trial and one might presume that advanced imaging was equally distributed between both arms as well. We further acknowledge the limitations of our report include all those typical of retrospective single-arm cohort reviews. Most importantly, it is possible that despite our diligent efforts to review the data set, we have inadvertently excluded some patients, the incorporation of whom might have changed the statistics.

CONCLUSION

We reviewed our time-matched database in terms of 2 variables we thought curious in the INVEST trial. In comparison to our practice, where advanced imaging is essentially required and Workers compensation largely not seen, these aspects of the INVEST trial's population stood out.

We present this data in the hope of informing future trial design.

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