

Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty sham trials?

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Introduction

- Balloon kyphoplasty (BKP) and vertebroplasty (VP) are associated with lower mortality risks than non-surgical management (NSM) of vertebral compression fractures (VCF) (Edidin 2015).
- VP versus sham trials published in NEJM 2009 (Kallmes 2009, Buchbinder 2009) sparked controversy over the effectiveness of VP, leading to diminished referral volumes (Hirsch 2016).
- This diminution in volume ran counter to trends in utilization of percutaneous interventional procedures for pain, making the association with publication of these trials very likely (Manchikanti 2016a; Manchikanti 2016b).
- We hypothesized that this lower national utilization of augmentation could lead to a greater mortality risk for VCF patients.

Methods

- BKP/VP utilization was evaluated for VCF patients in the 100% U.S. Medicare dataset (2005-2014).
- BKP/VP cohorts were those who underwent augmentation within the first year of the VCF diagnosis; those who underwent fusion surgery between the VCF diagnosis and BKP/VP were excluded.
- The NSM cohort comprised of patients who did not undergo augmentation or fusion during the study period, and those who only underwent augmentation or fusion 1+ years after the index VCF diagnosis.
- Survival and morbidity were analyzed by the Kaplan-Meier method and compared between NSM, BKP and VP using Cox regression with adjustment by propensity score and various patient/clinical factors.

Results

- 2,077,944 VCF patients were identified (n=261,756 BKP and 117,232 VP).
- BKP/VP utilization was 20% in 2005, peaked at 24% in 2007-2008, and declined to 14% in 2014.
- Adjusted mortality risk for VCF patients was 4% greater in 2010-2014 versus 2005-2009 (p<0.001).
- Overall VCF mortality risk was 85.1% at 10 years.

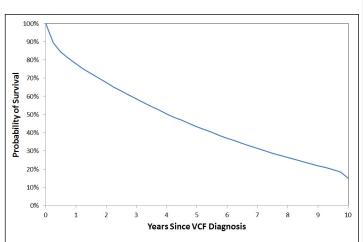


Figure 1: Ten-year survivorship of VCF patients in the Medicare population

- BKP and VP cohorts had a 19% (95% CI: 19%-19%; p<0.001) and 7% (95% CI: 7%-8%; p<0.001) lower propensity-adjusted 10-year mortality risk than the NSM cohort, respectively.
- The BKP cohort had a 13% lower adjusted 10year mortality risk than the VP cohort (p<0.001).
- BKP/VP had longer length of stay (LOS) but higher discharge to home rates (odds ratio vs. NSM: BKP 2.27, VP 1.86; p<0.001 for both) than NSM. VP had longer LOS and lower rate of discharge to home than BKP.

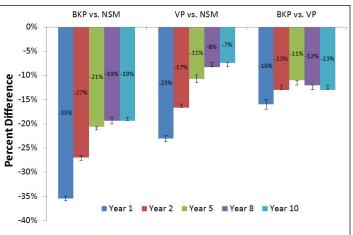


Figure 2: Difference in adjusted mortality risk of VCF patients in the Medicare population between NSM, BKP, and VP patients (all p<0.001).

Limitations

- There may be potential for selection bias due to the observational study design, which this study attempted to minimize by controlling for a large number of confounding factors and propensity scoring.
- The effects of several comorbidities were considered in the analysis, but other clinical variables or baseline health conditions, such as fracture severity, which are not captured in the database, may have potential confounding effects.

Conclusions

- Changes in treatment patterns following the 2009 VP publications led to fewer augmentation procedures.
- In turn, the five-year period following 2009 was associated with elevated mortality risk in VCF patients.
- This provides insight into the implications of treatment pattern changes and associated mortality risks.