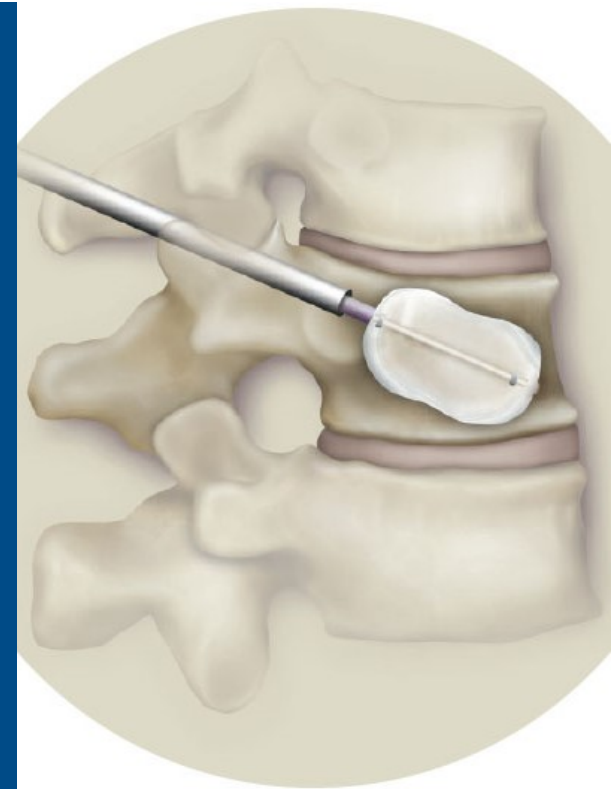


UNDERSTANDING MORTALITY AND MORBIDITY RISKS FOR PATIENTS WITH VERTEBRAL COMPRESSION FRACTURES (VCF)

CLINICAL EVIDENCE UPDATE

KEVIN L. ONG, PH.D.
EXPONENT, INC.



Medtronic
Further, Together



If noted, the relationships with Medtronic are as follows:

- (a) Grant/Research Support
- (b) Consulting Fee/Honoraria
- (c) Ownership Interest
- (d) Royalties
- (e) Intellectual Property Rights

Exponent, Inc.

(a) + (b)

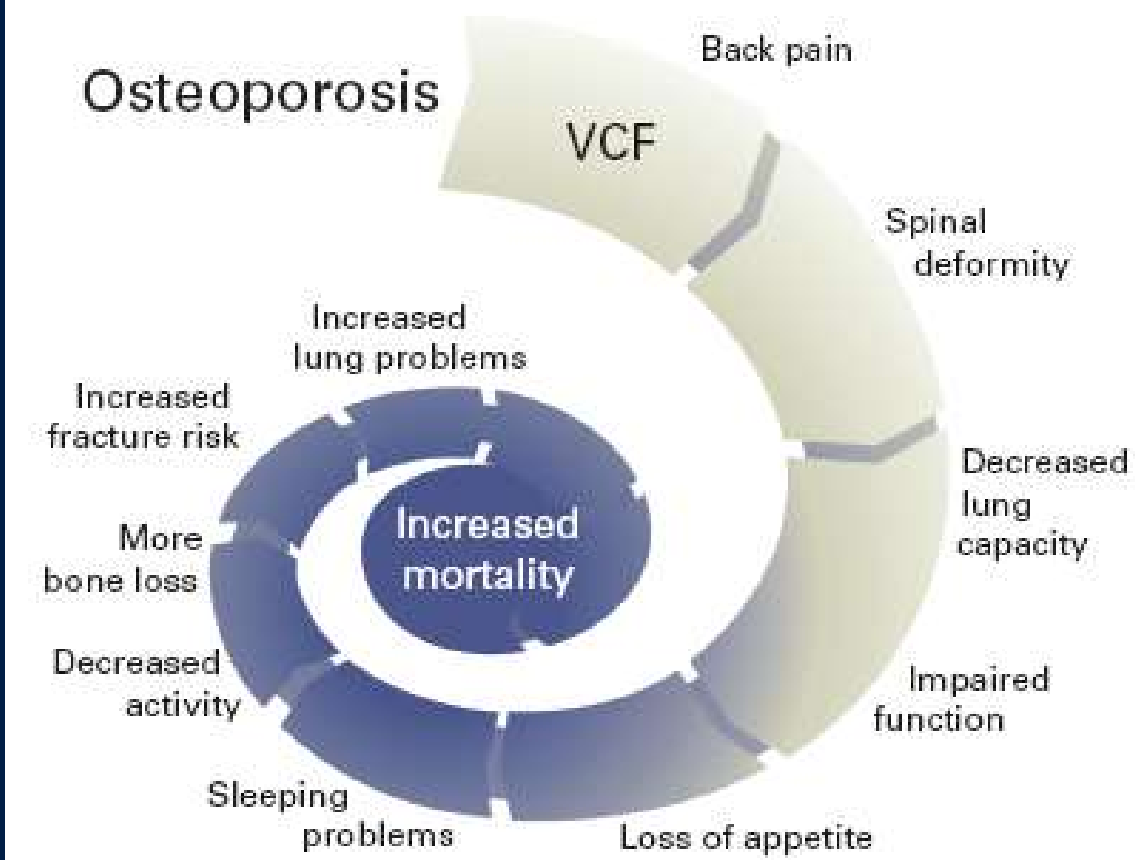
This therapy is not for everyone.

Please consult your physician. A prescription is required.

For further information, please call Medtronic Office of Medical Affairs at 1.800.876.3133

CONSEQUENCES OF VCF

Downward Spiral



- Impaired gait, poor balance (*Gold 1996, Sinaki 2004*)
- Disability, reduced quality of life (*Leidig-Bruckner 1997*)
- Reduced lung function (*Leech 1990, Culham 1994, Schlaich 1998*)
- Early satiety, gastric distress (*Gold 1996*)
- Future fracture risk (*Kado 2003*)
- Excess mortality (*Kado 1998, Kado 2004, Huang 2005*)

Consequences are independent of acute fracture pain

MORTALITY FOLLOWING VCF

Mortality rates post VCF

- 39% at 5 years (Cooper et al., 1993)
- 63% at 4 years (Johnell et al., 2004)
- 43% at 4 years (Bliuc et al., 2009)
- 69% at 5 years (Lau et al., 2008)

1479

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Mortality Following the Diagnosis of a Vertebral Compression Fracture in the Medicare Population

By Edmund Lau, MS, Kevin Ong, PhD, Steven Kurtz, PhD, Jordana Schmier, MA, and Av Edidin, PhD

Investigation performed at Exponent, Inc., Menlo Park, California

CONTROVERSY WITH AUGMENTATION

Similar outcomes for VP and control patients following VP trials (NEJM) led to call for curtailing of augmentation

The **NEW ENGLAND**
JOURNAL *of* **MEDICINE**

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A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures

Rachelle Buchbinder, Ph.D., Richard H. Osborne, Ph.D., Peter R. Ebeling, M.D., John D. Wark, Ph.D., Peter Mitchell, M.Med., Chris Wriedt, M.B., B.S., Stephen Graves, D. Phil., Margaret P. Staples, Ph.D., and Bridie Murphy, B.Sc.

The **NEW ENGLAND JOURNAL** *of* **MEDICINE**

ORIGINAL ARTICLE

A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures

David F. Kallmes, M.D., Bryan A. Comstock, M.S., Patrick J. Heagerty, Ph.D., Judith A. Turner, Ph.D., David J. Wilson, F.R.C.R., Terry H. Diamond, F.R.A.C.P., Richard Edwards, F.R.C.R., Leigh A. Gray, M.S., Lydia Stout, B.S., Sara Owen, M.Sc., William Hollingworth, Ph.D., Basavaraj Ghdoke, M.D., Deborah J. Annesley-Williams, F.R.C.R., Stuart H. Ralston, F.R.C.P., and Jeffrey G. Jarvik, M.D., M.P.H.

RESEARCH QUESTION?

RESEARCH QUESTIONS

- What is the **mortality** risk for treating VCF patients by non-surgical management (NSM), vertebroplasty (VP), and balloon kyphoplasty (BKP)?
- What is the **morbidity** risk for treating VCF patients by non-surgical management (NSM), vertebroplasty (VP), and balloon kyphoplasty (BKP)?

**CLINICAL DATA
WITH >1,000
PARTICIPANTS AND
12+ MONTHS
FOLLOW UP**

Several recent large clinical studies that followed patients for at least 12 months after vertebral compression fracture (VCF) have concluded that mortality rates following VCFs are significantly higher for patients treated conservatively versus VP or BKP, while other studies have concluded no difference. ¹⁻⁵

Majority of studies show that BKP/VP patients have lower mortality risk (up to 43% lower at up to 5 years³) than patients treated with non-surgical management.

Edidin A, et al (JBMR 2011)¹

Chen A, et al. (J Bone Joint Surg Am. 2013)²

Lange A, et al. (Spine 2014)³

Edidin A, et al. (Spine 2015)⁴

McCullough B, et al. (JAMA Intern Med. 2013)⁵

Limitations

- are retrospective database analyses and are prone to selection bias;
- have variables that are not captured in the database that may explain mortality effects;
- have study designs that cannot demonstrate causality of treatment received with mortality outcomes;
- indicate to some extent that BKP (and VP) subjects have better “baseline” health, which may at least partially explain the mortality benefit.

For more information visit www.medtronic.com/bkpmortality

MEDICARE DATA

- Administered by Centers for Medicare and Medicaid Services (CMS)
- Medicare 5 or 100 percent beneficiary encrypted files (BEF)
 - 52 million enrollees in 2013
 - Typical enrollees $\geq 65y$ (83%)
 - Disabled enrollees $< 65y$ (17%)
 - Persons with end-stage renal disease



MEDICARE DATA

- Claim records from all Medicare services
 - Inpatient
 - Outpatient
 - Physician/Carrier
 - Skilled nursing
 - Hospice
 - Home health agency
 - DME

- Can be used to examine longitudinal outcomes and charges/costs/payments



DISCUSSION

EDIDIN A, ET AL (JBMR 2011)

- 100% Medicare data (2005-2008)
- Mortality risk for non-operated (NSM), balloon kyphoplasty (BKP), and vertebroplasty (VP) compared using Cox regression
- Sensitivity/subgroup analyses:
 - Patients with specific comorbidities
 - Patients who survived ≥ 1 year post-VCF
 - Instrumental variable analysis (physician and hospital preference, physician specialty, census region)

ORIGINAL ARTICLE

JBMR

Mortality Risk for Operated and Nonoperated Vertebral Fracture Patients in the Medicare Population

Avram Allan Edidin,¹ Kevin L Ong,² Edmund Lau,³ and Steven M Kurtz²

¹Medtronic, Inc., 1221 Crossman Ave, Sunnyvale, CA 94089, USA

²Exponent, Inc., 3401 Market Street, Suite 300, Philadelphia, PA 19104, USA

³Exponent, Inc., 149 Commonwealth Drive, Menlo Park, CA 94025, USA

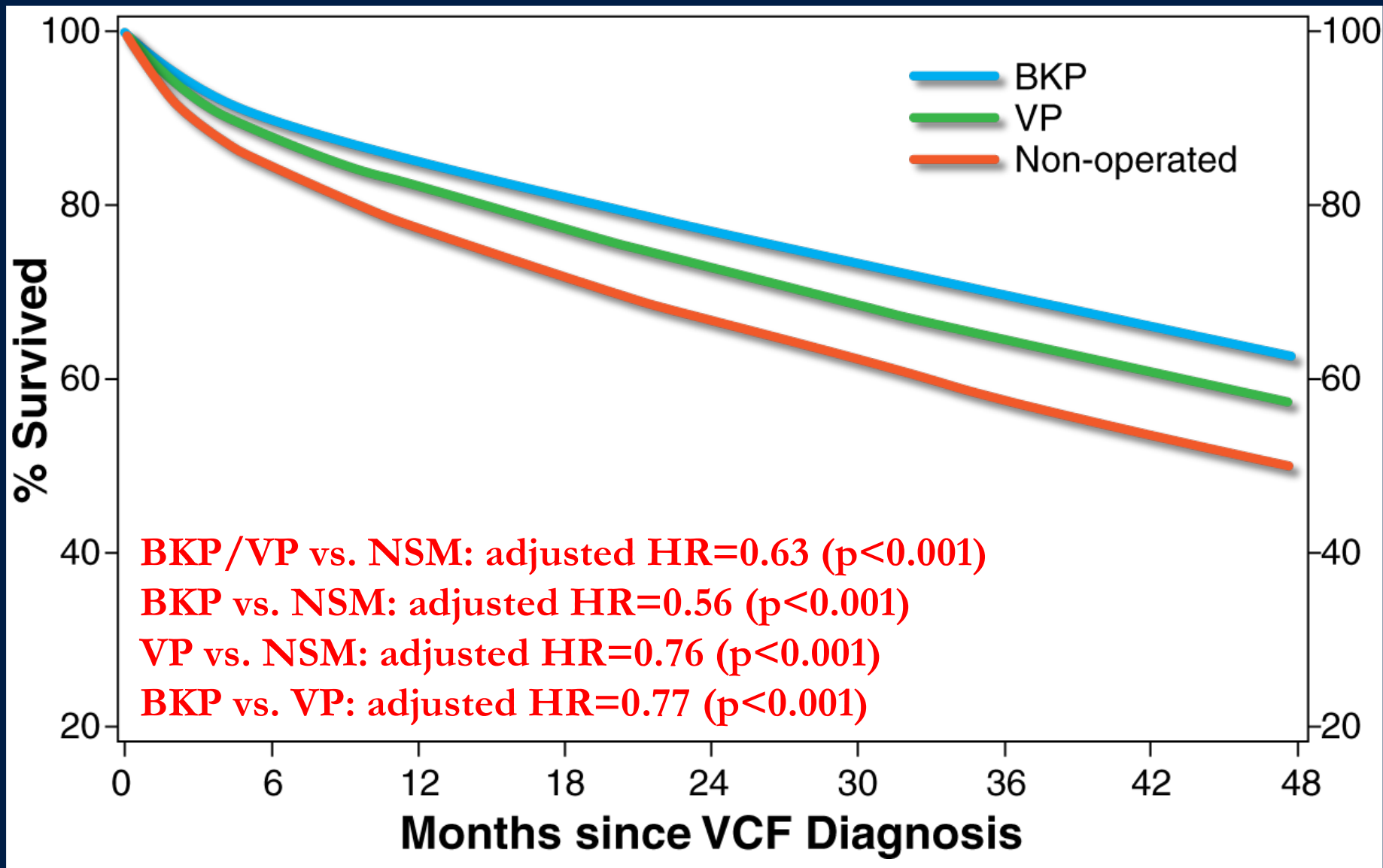
DISCUSSION

EDIDIN A, ET AL (JBMR 2011)

- N=858,978 newly diagnosed VCFs
 - N=119,253 BKP (13.9%)
 - N=63,693 VP (7.4%)
- Mortality risk: 39% (operated) vs. 50% (non-operated) at 4 years

MORTALITY BY TREATMENT

EDIDIN A, ET AL (JBMR 2011)



LIMITATIONS

EDIDIN A, ET AL (JBMR 2011)

- Retrospective database analysis and may be prone to selection bias
- Unclear whether confounded by other unmeasured selection bias
- May be confounded by other variables not considered in the analysis
- Cannot demonstrate causality of treatment received with mortality outcomes

DISCUSSION

EDIDIN A, ET AL. (SPINE 2015)

Spine

SPINE Volume 40, Number 0, pp 1-14
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HEALTH SERVICES RESEARCH

Morbidity and Mortality After Vertebral Fractures

Comparison of Vertebral Augmentation and Nonoperative Management in the Medicare Population

Avram Allan Edidin, PhD,* Kevin L. Ong, PhD,† Edmund Lau, MS,‡ and Steven M. Kurtz, PhD†

METHODS

EDIDIN A, ET AL. (SPINE 2015)

**2005-2009 Medicare dataset
(100% inpatient and outpatient files)**



**VCF diagnosis
(ICD-9-CM: 733.13 (OVCF), 805.0, 805.2,
805.4, 805.6, 805.8)**



N= 1,238,312 VCFs



Exclusion criteria:

- VCF/augmentation in previous 12 months
 - <65 y.o.
 - HMO enrollee
- Spine fusion in 12 months post-VCF



**N= 1,038,956
new VCFs**

METHODS

EDIDIN A, ET AL. (SPINE 2015)

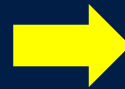
N = 1,038,956 new VCF patients



ICD-9-CM/CPT-4 codes for BKP/VP



N=141,343 BKP (13.6%)
N=75,364 VP (7.3%)
N=822,249 NSM (79.1%)



Mortality
(from denominator file)



Morbidity
(ICD-9-CM, CPT-4 codes)

METHODS - OUTCOMES

EDIDIN A, ET AL. (SPINE 2015)

■ Mortality

- With or without pneumonia diagnosed in 90 days prior to death

■ Morbidity

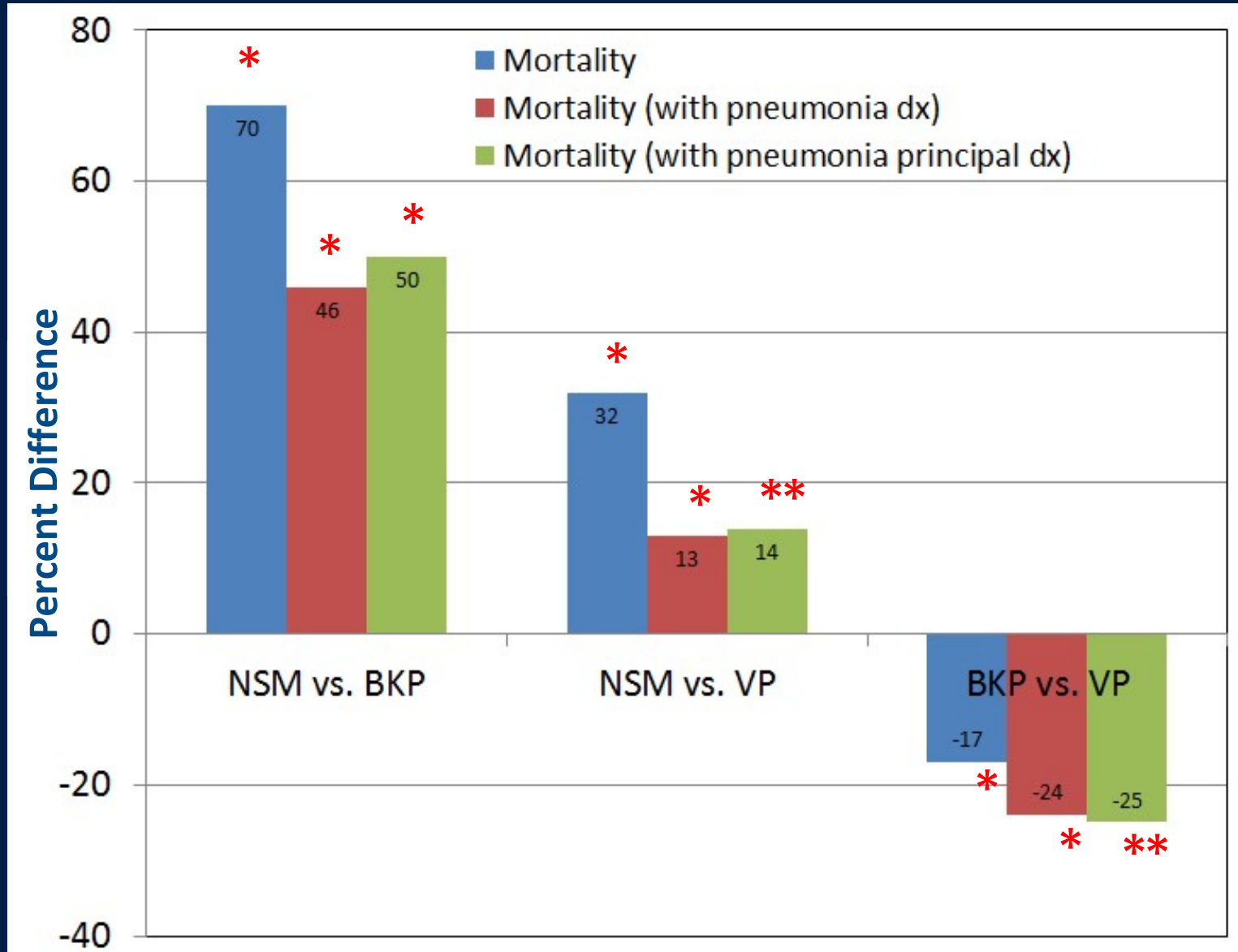
- Pneumonia
- Myocardial infarction/cardiac complications
- Pulmonary/respiratory complications
- Pulmonary embolism
- Deep venous thrombosis
- Urinary tract infection
- Infection
- Subsequent VCF with repair (fusion, augmentation, any spine fx repair)

MORTALITY – PROPENSITY MATCHED (OVCF)

EDIDIN A, ET AL. (SPINE 2015)

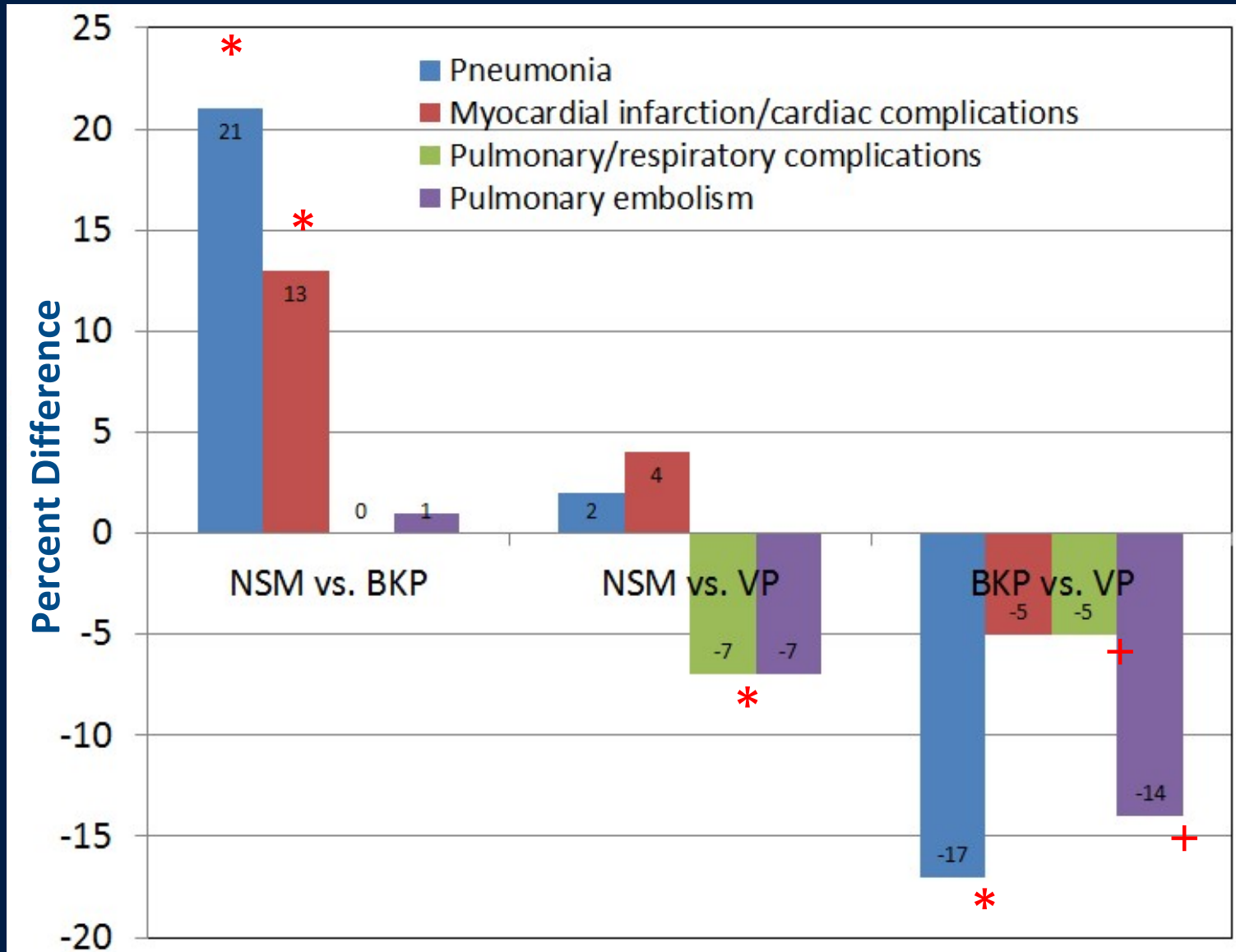
| Outcome | Cohort | KM risk (@48 months) |
|--|--------------|----------------------|
| Mortality | BKP | 45.4% (44.8-46.0%) |
| | Non-Operated | 51.5% (51.1-51.8%) |
| | VP | 48.5% (47.8-49.2%) |
| | Non-Operated | 51.0% (50.6-51.4%) |
| | BKP | 44.8% (44.1-45.5%) |
| | VP | 48.6% (47.9-49.3%) |
| Mortality (with pneumonia diagnosis) | BKP | 9.4% (9.0-9.8%) |
| | Non-Operated | 10.4% (10.1-10.6%) |
| | VP | 10.6% (10.1-11.1%) |
| | Non-Operated | 10.4% (10.1-10.7%) |
| | BKP | 9.1% (8.6-9.5%) |
| | VP | 10.6% (10.1-11.1%) |
| Mortality (with pneumonia principal diagnosis) | BKP | 4.0% (3.8-4.3%) |
| | Non-Operated | 4.6% (4.5-4.8%) |
| | VP | 4.7% (4.4-5.1%) |
| | Non-Operated | 4.8% (4.6-5.0%) |
| | BKP | 4.0% (3.7-4.4%) |
| | VP | 4.7% (4.4-5.1%) |

RELATIVE MORBIDITY (OVCF) PROPENSITY MATCHED AND ADJUSTED FOR COMORBIDITIES



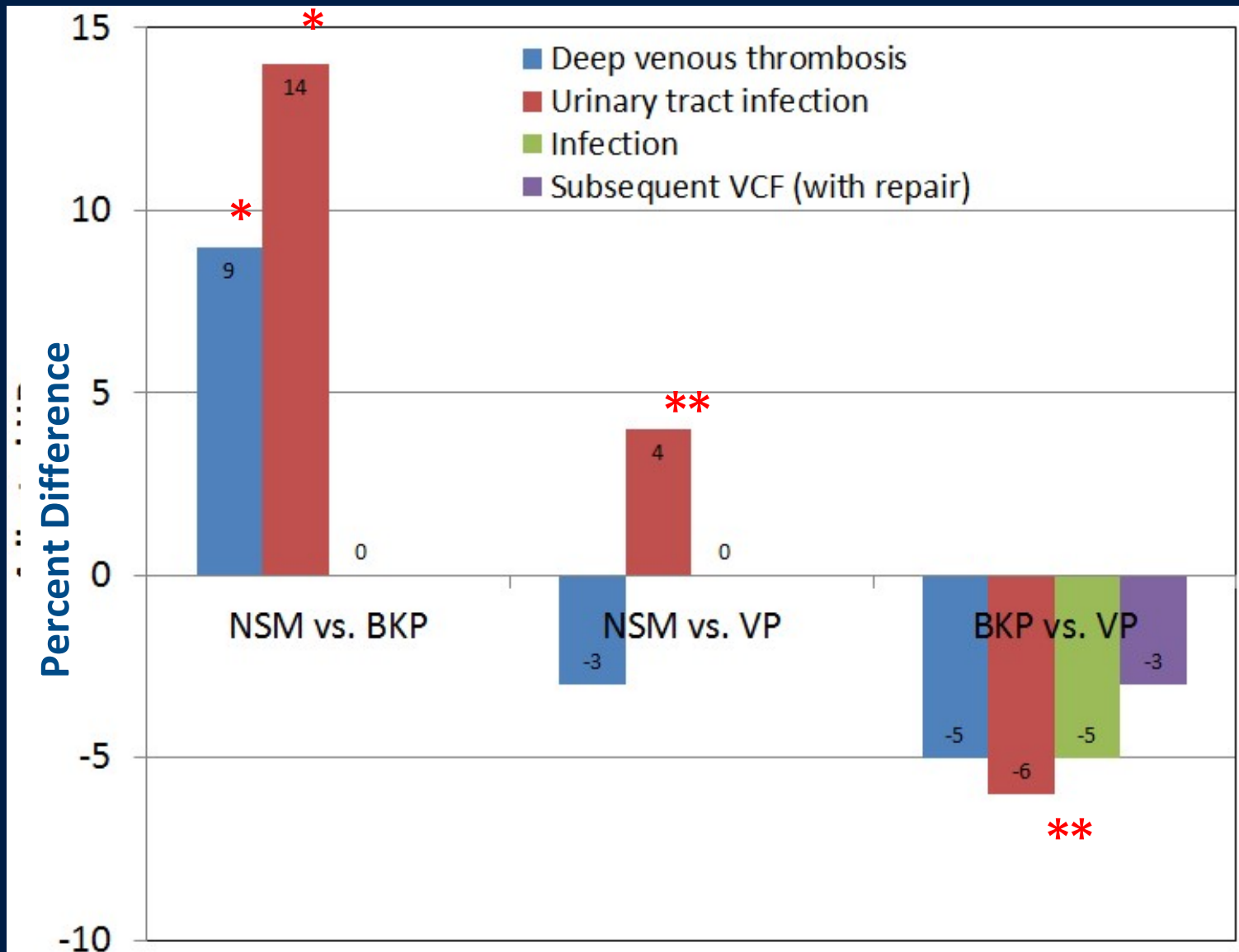
* $p < 0.001$
** $p < 0.01$

RELATIVE MORBIDITY (OVCF) PROPENSITY MATCHED AND ADJUSTED FOR COMORBIDITIES



*p<0.001
+p<0.05

RELATIVE MORBIDITY (OVCF) PROPENSITY MATCHED AND ADJUSTED FOR COMORBIDITIES



*p<0.001

**p<0.01

DISCUSSION

EDIDIN A, ET AL. (SPINE 2015)

- Improved outcomes for operative cohort over NSM
 - Generally consistent for subgroup analyses
- Relied on morbidities to provide some insight into potential causes of death for VCF patients

LIMITATIONS

EDIDIN A, ET AL. (SPINE 2015)

- Cause of death not available in database
- May be confounded by other variables not considered in the analysis
- Unclear whether confounded by other unmeasured selection bias
 - Use of instrumental variables analysis can help address this
- Cannot demonstrate causality of treatment received with mortality outcomes
- Unclear if results also apply to those <65 y.o.

STRENGTHS

EDIDIN A, ET AL. (SPINE 2015)

- Large population-based study
- Consistency and duration of follow-up
- Ability to evaluate patient subgroups
- Propensity score matching to account for potential treatment selection bias

DISCUSSION

CHEN A, ET AL. (J BONE JOINT SURG AM. 2013)

1729

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Impact of Nonoperative Treatment, Vertebroplasty, and Kyphoplasty on Survival and Morbidity After Vertebral Compression Fracture in the Medicare Population

Andrew T. Chen, MPH, David B. Cohen, MD, MPH, and Richard L. Skolasky, ScD

Investigation performed at the Bloomberg School of Public Health and the Department of Orthopaedic Surgery, The Johns Hopkins University, Baltimore, Maryland

- 2006 Medicare (MEDPAR) data
- Hospitalized patients
- 68,752 VCF patients (33.2% BKP, 11.2% VP)

RESULTS HIGHLIGHT

CHEN A, ET AL. (J BONE JOINT SURG AM. 2013)

TABLE II Survival Rates by Treatment Type (Overall and Stratified by Age)

| Type of Treatment | Survival Rate (%) | |
|----------------------------------|-------------------|-------------|
| | One Year | Three Years |
| Nonoperative (n = 38,249) | | |
| Overall | 73.1 | 42.3 |
| 65 to 75 years | 78.1 | 56.5 |
| 76 to 85 years | 75.5 | 44.8 |
| ≥86 years | 68.1 | 32.1 |
| Vertebroplasty (n = 7686) | | |
| Overall | 78.8 | 49.7 |
| 65 to 75 years | 80.6 | 61.3 |
| 76 to 85 years | 80.0 | 50.7 |
| ≥86 years | 76.3 | 40.2 |
| Kyphoplasty (n = 22,817) | | |
| Overall | 85.2 | 59.9 |
| 65 to 75 years | 87.7 | 69.1 |
| 76 to 85 years | 86.3 | 61.8 |
| ≥86 years | 80.4 | 47.6 |

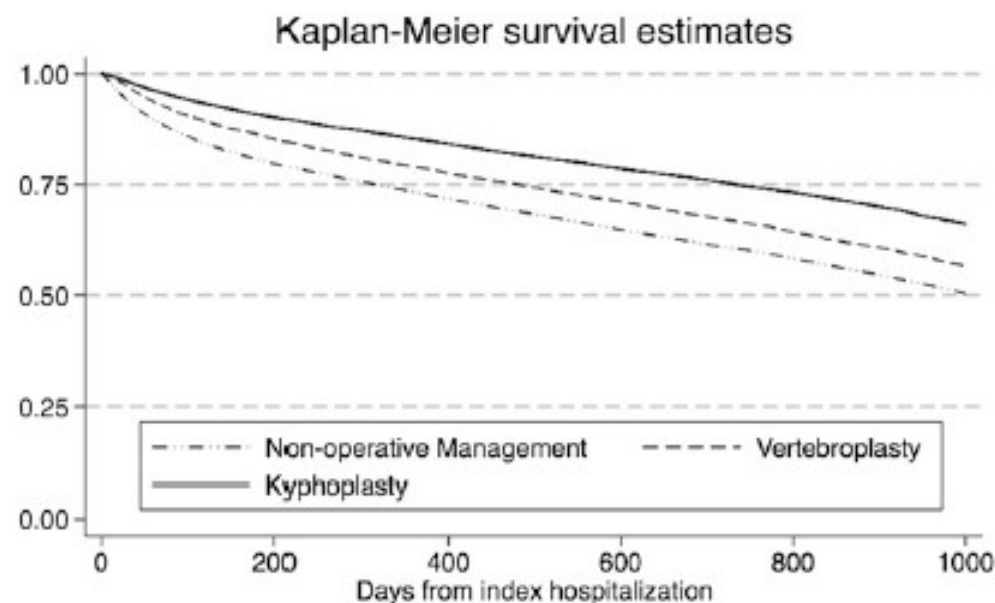


Fig. 1
Kaplan-Meier survival curves for the nonoperative, vertebroplasty, and kyphoplasty groups.

RESULTS HIGHLIGHT

CHEN A, ET AL. (J BONE JOINT SURG AM. 2013)

TABLE III Summary of Hazard Ratios (Cox Regression Analysis)

| Comparison Groups | Hazard Ratio (95% Confidence Interval) | | P Value |
|--|--|---------------------|---------|
| | Unadjusted | Adjusted* | |
| Nonoperative treatment compared with percutaneous vertebroplasty | 0.81 (0.78 to 0.84) | 0.85 (0.81 to 0.88) | <0.001 |
| Nonoperative treatment compared with balloon kyphoplasty | 0.58 (0.57 to 0.60) | 0.68 (0.66 to 0.70) | <0.001 |
| Percutaneous vertebroplasty compared with balloon kyphoplasty | 0.72 (0.69 to 0.75) | 0.80 (0.77 to 0.84) | <0.001 |

*Adjusted for age, sex, race, comorbidities, and length of hospital stay.

RESULTS HIGHLIGHT

CHEN A, ET AL. (J BONE JOINT SURG AM. 2013)

TABLE IV Parameters of Interest by Treatment Type

| Parameter | Nonoperative Treatment (N = 38,249) | Vertebroplasty (N = 7686) | Kyphoplasty (N = 22,817) | All (N = 68,752) | P Value |
|---------------------------|--|------------------------------|-----------------------------|------------------|---------|
| In-hospital | | | | | |
| Length of stay* (d) | 7.38 ± 12.81 | 5.73 ± 4.78 | 3.74 ± 4.19 | 5.98 ± 10.12 | <0.001 |
| Total charges* (US\$) | 21,394 ± 34,129 | 29,199 ± 28,355 | 33,426 ± 24,313 | 26,260 ± 31,068 | <0.001 |
| Complications (%) | | | | | |
| Pulmonary embolism | 0.30 | 0.42 | 0.23 | 0.29 | 0.006 |
| Deep-vein thrombosis | 2.49 | 3.29 | 2.74 | 2.66 | <0.001 |
| Pneumonia | 3.87 | 3.70 | 1.73 | 3.14 | <0.001 |
| Infection (postoperative) | 0.11 | 0.15 | 0.06 | 0.10 | 0.103 |

Post-discharge

| | | | | | |
|---|-------|-------|------|-------|--------|
| Readmission within 30 days (%) | 61.9 | 52.4 | 35.2 | 52.0 | <0.001 |
| Complications at 6 months (%) | | | | | |
| Pulmonary embolism | 1.42 | 1.87 | 1.27 | 1.42 | 0.001 |
| Deep-vein thrombosis | 5.52 | 6.61 | 5.32 | 5.58 | <0.001 |
| Pneumonia | 12.95 | 11.09 | 8.05 | 11.11 | <0.001 |
| Infection | 0.79 | 0.73 | 0.66 | 0.74 | 0.167 |
| Neurologic compromise | 0.07 | 0.12 | 0.11 | 0.09 | 0.131 |
| Bedsore | 4.41 | 3.02 | 2.39 | 3.58 | <0.001 |
| Additional vertebral augmentation procedure within 6 months after discharge | NA† | 7.89 | 9.41 | 9.03 | <0.001 |

*The values are given as the mean and the standard deviation. †NA = not applicable.

within 6 months after discharge

*The values are given as the mean and the standard deviation. †NA = not applicable.

LIMITATIONS

CHEN A, ET AL. (J BONE JOINT SURG AM. 2013)

- Retrospective database analysis and may be prone to selection bias
- May be confounded by other variables not considered in the analysis
- Unclear whether confounded by other unmeasured selection bias
- Considered limited comorbidities (Charlson score)
- Outcomes from inpatient data
- Cannot demonstrate causality of treatment received with mortality outcomes

CHEN STUDY COMMENTARY

e146(1)

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COMMENTARY & PERSPECTIVE

Time to Reconsider

Commentary on an article by Andrew T. Chen, MPH, et al: "Impact of Nonoperative Treatment, Vertebroplasty, and Kyphoplasty on Survival and Morbidity After Vertebral Compression Fracture in the Medicare Population"

John Glaser, MD

In their report titled "Impact of Nonoperative Treatment, Vertebroplasty, and Kyphoplasty on Survival and Morbidity After Vertebral Compression Fracture in the Medicare Population," Chen et al. present important information that may cause us to reconsider how we manage individuals who have an osteoporotic compression fracture that is severe enough to necessitate hospital admission. The authors analyzed the records for a very large group of inpatients with osteoporotic compression fractures with use of the 2006 Medicare Provider Analysis and Review File database.

For the sake of full disclosure, although I have no financial relationship related to these procedures, I do receive research funding from a company (SI-BONE, San Jose, California) that was started by the individual who was instrumental in bringing the kyphoplasty procedure to market.

The current study compared various outcomes at various time points for patients who underwent kyphoplasty or vertebroplasty with those for patients who were managed nonoperatively. The outcomes included mortality, destination following discharge from the hospital, hospital readmission, and a number of complications for which information could be gathered. Hospital charges, but not payments, were also evaluated. The general take-home points were that patients who were managed with kyphoplasty generally fared better than those who were managed with vertebroplasty and that patients who were managed with vertebroplasty generally fared better than those who were managed without either procedure. There were often large differences between the kyphoplasty group and the nonoperative treatment group. For example, the patients in the kyphoplasty group stayed in the hospital roughly half as long as those in the nonoperative treatment group and went to a skilled nursing facility at a rate less than half that of the patients in the nonoperative treatment group. Mortality, although high for all groups, was significantly lower at all time points in the kyphoplasty group.

These findings are somewhat different from those of other well-known studies of vertebroplasty and kyphoplasty. Comparing some of those studies with this one seems worthwhile. Possibly the two most referenced studies were published in 2009 in the *New England Journal of Medicine*^{1,2}. Both were prospective, multicenter, randomized trials comparing vertebroplasty with sham treatment, primarily in outpatients. Those trials involved far smaller groups of patients, and recruitment took place over the course of years. The duration of follow-up was far shorter, with one study analyzing primary outcomes at one month¹ and the other study analyzing primary outcomes at three months². Although one study demonstrated a trend toward reduced pain associated with vertebroplasty, neither study showed significant differences in outcome between vertebroplasty and a sham procedure. Mortality was quite low in both studies. In one study, the mortality rate at three months was two of thirty-eight in the vertebroplasty group and one of forty in the placebo group. The other study did not specifically discuss mortality, but sixty-four of sixty-eight patients in the vertebroplasty group and sixty-one of sixty-three patients in the placebo group were evaluated. I believe that it is reasonable to assume that the mortality rate in that study was 0% or close to it. The current study evaluated mortality during hospitalization, at one year, and at three years. Mortality was quite low during hospitalization, but at one year the survival rate had decreased to 73% in the nonoperative treatment group, 79% in the vertebroplasty group, and 85% in the kyphoplasty group. Although the time frame for reporting mortality differed considerably between the studies, it is reasonable to conclude that the groups in the current study and those in the other two studies were different, which explains the difference in outcomes.

A prospective, industry-sponsored, multicenter study in which kyphoplasty was compared with nonoperative (but not placebo) treatment was published in 2009 in *The Lancet*³. In the analysis of primary outcome measures in that study, kyphoplasty showed significant superiority at one month but with diminution of the difference by one year. The survival rate at one year was 94% in the kyphoplasty group and 95% in the nonoperative treatment group. Once again, the large difference in survival rates suggests that the groups were different.

This difference is important because, as stated earlier, I think that reconsideration is indicated. In 2010, the American Academy of Orthopaedic Surgeons (AAOS) released a clinical practice guideline for the treatment of symptomatic osteoporotic

“... the use of **cement augmentation should be considered reasonable** and indicated care, at least for patients who are hospitalized for osteoporotic compression fractures.”

“As noted in the **AAOS clinical practice guideline**, there was **weak evidence for the use of kyphoplasty** in the appropriate patient. I was generally of the opinion that there was probably no true, clinically relevant difference between the two procedures. **The current study has pushed me to reconsider this opinion.**”

CHEN STUDY COMMENTARY

e146(1)

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COMMENTARY & PERSPECTIVE

Time to Reconsider

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“... we are looking at a **retrospective, nonrandomized, noncontrolled study** ... we have **moderately strong evidence that the patients who underwent kyphoplasty generally did better, in almost every outcome measured.** To me, this is a moderately strong argument in favor of kyphoplasty over vertebroplasty and is a **very strong argument for the consideration of the use of kyphoplasty** for the patient who has been hospitalized because of symptomatic osteoporotic compression fracture(s).”

DISCUSSION-GERMAN CLAIMS DATA ANALYSIS

LANGE A , ET AL. (SPINE 2014)

Spine

SPINE Volume 39, Number 4, pp 318-326
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HEALTH SERVICES RESEARCH

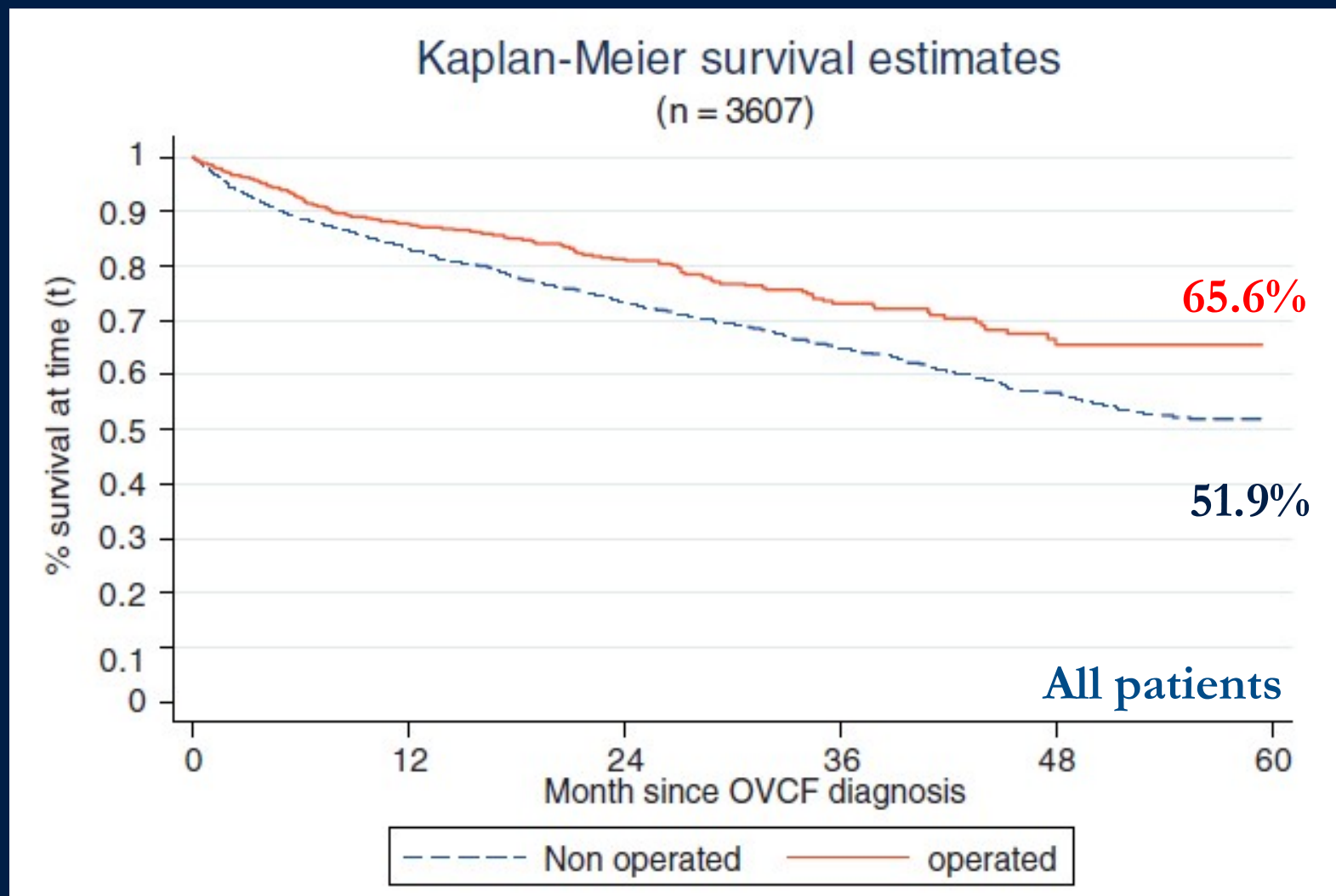
Survival and Cost Comparison of Kyphoplasty and Percutaneous Vertebroplasty Using German Claims Data

Ansgar Lange, Dipl Oec,* Christian Kasperk, MD,† Luisa Alvares, MSc,‡ Sven Sauermann, MD,§ and Sebastian Braun, PhD¶

- 2006-2010 period
- Incident OVCF patients \geq 60 y.o.
- 441 BKP, 157 VP, 3009 non-operated

GERMAN CLAIMS DATA ANALYSIS

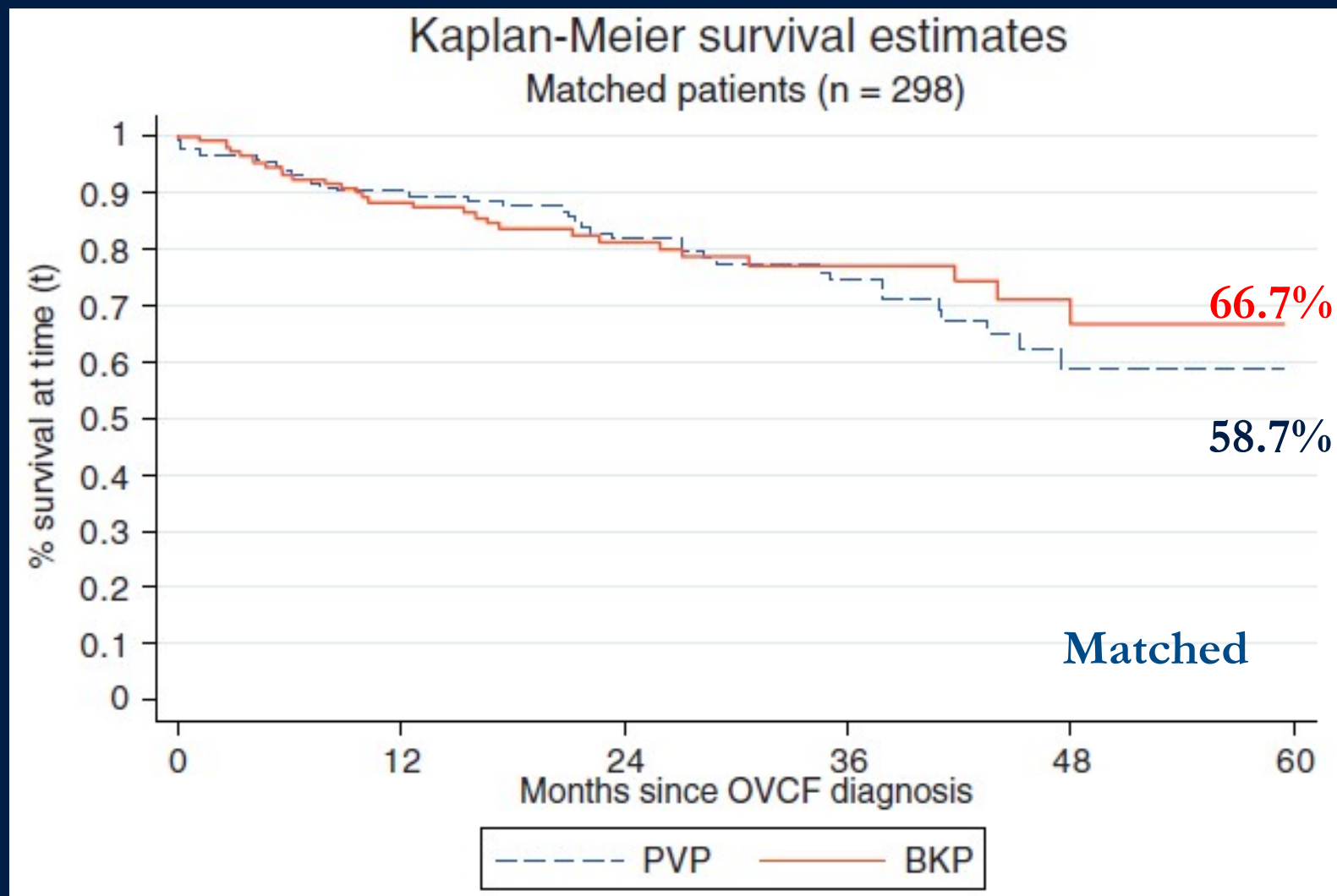
LANGE A , ET AL. (SPINE 2014)



Adjusted hazard ratio (operated vs. non-operated): 0.57 (p<0.001)

GERMAN CLAIMS DATA ANALYSIS

LANGE A , ET AL. (SPINE 2014)



PSM-matched cohorts: BKP vs. VP; $p=0.68$

LIMITATIONS

LANGE A , ET AL. (SPINE 2014)

- Retrospective database analysis and may be prone to selection bias
- May be confounded by other variables not considered in the analysis
- Unclear whether confounded by other unmeasured selection bias
- Considered limited comorbidities (Charlson score)
- Cannot demonstrate causality of treatment received with mortality outcomes

DISCUSSION

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

Original Investigation | LESS IS MORE

Major Medical Outcomes With Spinal Augmentation vs Conservative Therapy

Brandon J. McCullough, MD, PhD; Bryan A. Comstock, MS; Richard A. Deyo, MD, MPH; William Kreuter, MPA; Jeffrey G. Jarvik, MD, MPH

IMPORTANCE The symptomatic benefits of spinal augmentation (vertebroplasty or kyphoplasty) for the treatment of osteoporotic vertebral compression fractures are controversial. Recent population-based studies using medical billing claims have reported significant reductions in mortality with spinal augmentation compared with conservative therapy, but in nonrandomized settings such as these, there is the potential for selection bias to influence results.

OBJECTIVE To compare major medical outcomes following treatment of osteoporotic vertebral fractures with spinal augmentation or conservative therapy. Additionally, we evaluate the role of selection bias using preprocedure outcomes and propensity score analysis.

DESIGN, SETTING, AND PARTICIPANTS Retrospective cohort analysis of Medicare claims 2002-2006 period. We compared 30-day and 1-year outcomes in patients with newly diagnosed vertebral fractures treated with spinal augmentation (n = 10 541) or conservative therapy (control group, n = 115 851). Outcomes were compared using traditional multivariate analyses adjusted for patient demographics and comorbid conditions. We also used propensity score matching to select 9017 pairs from the initial groups to compare the same outcomes.

EXPOSURES Spinal augmentation (vertebroplasty or kyphoplasty) or conservative therapy.

MAIN OUTCOMES AND MEASURES Mortality, major complications, and health care utilization.

RESULTS Using traditional covariate adjustments, mortality was significantly lower in the augmented group than among controls (5.2% vs 6.7% at 1 year; hazard ratio, 0.83; 95% CI, 0.75-0.92). However, patients in the augmented group who had not yet undergone augmentation (preprocedure subgroup) had lower rates of medical complications 30 days post fracture than did controls (6.5% vs 9.5%; odds ratio, 0.66; 95% CI, 0.57-0.78), suggesting that the augmented group was less medically ill. After propensity score matching to better account for selection bias, 1-year mortality was not significantly different between the groups. Furthermore, 1-year major medical complications were also similar between groups, and the augmented group had higher rates of health care utilization, including hospital and intensive care unit admissions and discharges to skilled nursing facilities.

CONCLUSIONS AND RELEVANCE After accounting for selection bias, spinal augmentation did not improve mortality or major medical outcomes and was associated with greater health care utilization than conservative therapy. Our results also highlight how analyses of claims-based data that do not adequately account for unrecognized confounding can arrive at misleading conclusions.

JAMA Intern Med. doi:10.1001/jamainternmed.2013.8725
Published online July 8, 2013.

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Source: University of Portland (McCullough); Kaiser Permanente Center for Health Research, Portland, Oregon (Deyo); Department of Health Services, University of Washington, Seattle (Kreuter, Jarvik); Department of Neurological Surgery, University of Washington, Seattle (Jarvik); Department of Pharmacy, University of Washington, Seattle (Jarvik).

E1

METHODOLOGY HIGHLIGHTS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

- Used 20% sample of Medicare data (2002-2006)
- N=115,851 controls, N=10,541 augmented
- Baseline comorbidities using modified Quan comorbidity index and individual conditions
 - chronic pulmonary disease, heart disease, osteoporosis, diabetes mellitus, obesity, tobacco use disorder
- Excluded patients with cancer

METHODOLOGY HIGHLIGHTS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

- Attempted to examine unmeasured selection bias for a “preprocedure” subgroup
 - Compared complications for augmented patients who had not undergone VP/BKP within 30 days of index VCF
 - N=3,023 out of 10,541 augmented patients (29.0%)
- Propensity score matching performed to account for selection bias

RESULTS HIGHLIGHTS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

Table 2. Mortality, Major Medical Complications, and Resource Utilization

| Characteristic | Patients, No. (%) | | HR or OR (95% CI) | P Value |
|--|--------------------------|--------------------------------------|-------------------|---------|
| | Control (n = 115 851) | Augmented (n = 10 541) | | |
| Death | | | | |
| 30 d | 1754 (1.5) | 39 (0.4) | 0.29 (0.20-0.41) | <.001 |
| 1 y | 7768 (6.7) | 546 (5.2) | 0.83 (0.75-0.92) | <.001 |
| Major medical complication | | | | |
| 30 d | 12 057 (10.4) | 975 (9.3) | 0.85 (0.79-0.92) | <.001 |
| 1 y | 33 497 (28.9) | 3051 (28.9) | 1.00 (0.95-1.04) | .90 |
| Health care utilization, 1 y | | | | |
| Hospitalization ^a | 55 164 (47.6) | 6324 (60.0) | 1.37 (1.30-1.44) | <.001 |
| ICU admission | 13 247 (11.4) | 1470 (13.9) | 1.14 (1.06-1.21) | <.001 |
| SNF discharge | 19 819 (17.1) | 2284 (21.7) | 1.16 (1.10-1.23) | <.001 |
| Wrist fracture | 2387 (2.1) | 194 (1.8) | 0.90 (0.76-1.07) | .23 |
| Hip fracture | 7664 (6.6) | 677 (6.4) | 0.96 (0.87-1.05) | .37 |
| Preprocedure major medical complications | 12 057 (10.4) | 199 (6.6) (n = 3023) ^b | 0.66 (0.57-0.78) | <.001 |

MCCULLOUGH STUDY COMMENTARY

Opinion

Invited Commentary

Vertebral Augmentation vs Nonsurgical Therapy Improved Symptoms, Improved Survival, or Neither?

Douglas C. Bauer, MD

Vertebral fractures are the most common clinical manifestation of osteoporosis. In the United States alone, approximately 550 000 individual experience a vertebral fracture each year, resulting in significant pain and short-term disability.¹ The morbidity caused by symptomatic vertebral fractures is re-

phoplasty treatment improved pain and function scores at 6 and 12 months of follow-up, but by 24 months the differences were attenuated and mostly nonsignificant.⁵ To date, no sham-controlled trials of kyphoplasty have been reported, leading to speculation that some or all of the subjective improvement

“An important limitation of these data, acknowledged by the authors, is the **lack of separate analyses for vertebroplasty and kyphoplasty procedures**. Nonetheless, these results strongly suggest that previously reported differences in mortality among those who do and do not receive vertebral augmentation reflect baseline differences and **not a beneficial effect of augmentation itself.**”

MCCULLOUGH STUDY COMMENTARY

Opinion

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phoplasty treatment improved pain and function scores at 6 and 12 months of follow-up, but by 24 months the differences were attenuated and mostly nonsignificant.⁵ To date, no sham-controlled trials of kyphoplasty have been reported, leading to speculation that some or all of the subjective improvement

“The highest-quality evidence (ie, randomized and adequately blinded trials) **do not provide a compelling rationale for augmentation procedures** and suggest that there are little or no differences in long-term pain and function compared with conservative management. The utility of augmentation to alleviate short-term pain and disability remains unclear. Furthermore, **the study by McCullough et al⁸ convincingly demonstrates that vertebral augmentation is unlikely to reduce mortality after vertebral fracture.**”

LIMITATIONS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

- Claimed residual selection bias for augmented patients
 - Vast majority of augmented patients (71%) was excluded from preprocedure subgroup analysis, i.e., subgroup contains “healthiest” of augmented patients
 - Majority of augmented patients may have needed emergent care

LIMITATIONS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

Did not stratify augmented patients by BKP and VP

Table 1. Baseline Characteristics of Patients and Procedures

| Characteristic | Patients, No. (%) | | P Value |
|---|-----------------------|------------------------|---------|
| | Control (n = 115 851) | Augmented (n = 10 541) | |
| Age, mean (SD), y | 80.2 (7.2) | 80.0 (6.7) | .006 |
| Female sex | 89 815 (77.5) | 8244 (78.2) | .11 |
| White race | 109 240 (94.3) | 10 206 (96.8) | <.001 |
| State buy-in | 16 985 (14.7) | 1069 (10.1) | <.001 |
| Quan comorbidity score ^{21,22} | | | |
| 0 | 29 267 (25.3) | 2570 (24.4) | .004 |
| 1 | 27 900 (24.1) | 2518 (23.9) | |
| 2 | 21 356 (18.4) | 1905 (18.1) | |
| ≥3 | 37 328 (32.2) | 3548 (33.7) | |
| Prior inpatient admissions | 76 555 (66.1) | 6731 (63.8) | |

| Procedure type | Control (n = 115 851) | Augmented (n = 10 541) | P Value |
|-------------------------|-----------------------|------------------------|---------|
| Vertebroplasty | NA | 7488 (71.0) | NA |
| Kyphoplasty | NA | 2797 (26.5) | NA |
| Admitted at diagnosis | 26 720 (23.1) | 2894 (27.5) | <.001 |
| Fracture level | | | |
| Thoracic | 21 504 (18.6) | 2058 (19.5) | <.001 |
| Lumbar | 31 453 (27.1) | 3243 (30.8) | |
| Both | 1909 (1.6) | 237 (2.2) | |
| Unspecified | 60 985 (52.6) | 5003 (47.5) | |
| Advanced imaging | 46 512 (40.1) | 9116 (86.5) | <.001 |
| Procedure type | | | |
| Vertebroplasty | NA | 7488 (71.0) | NA |
| Kyphoplasty | NA | 2797 (26.5) | NA |
| Both | NA | 256 (2.4) | NA |
| Multiple levels at once | NA | 1776 (17.3) | NA |
| Inpatient | NA | 5740 (54.5) | NA |

LIMITATIONS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

- Considered limited comorbidities
 - Only baseline comorbidities
 - Did not consider cancer, hip fracture, wrist fracture, pneumonia, stroke, etc.
- Used subset of Medicare data (20%) vs. 100% dataset in present study (~10k vs. ~200k augmented patients)
 - Also earlier years of dataset (2002-2006 vs. 2005-2009)
- Healthcare utilization did not consider financial expenses and other components of utilization (office visits, rehabilitation facilities, home health agency)

LIMITATIONS

MCCULLOUGH B, ET AL. (JAMA INTERN MED. 2013)

Interpretation of 1 year health care utilization and major medical complications may be flawed; includes those occurring prior to augmentation

Table 2. Mortality, Major Medical Complications, and Resource Utilization

| Characteristic | Patients, No. (%) | | HR or OR (95% CI) | P Value |
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Post-augmentation:

23.1%

42.4%

8.7%

16.6%

GUIDELINES

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

NICE APPRAISAL GUIDELINES 2013


NICE National Institute for Health and Care Excellence

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures

Issued: April 2013

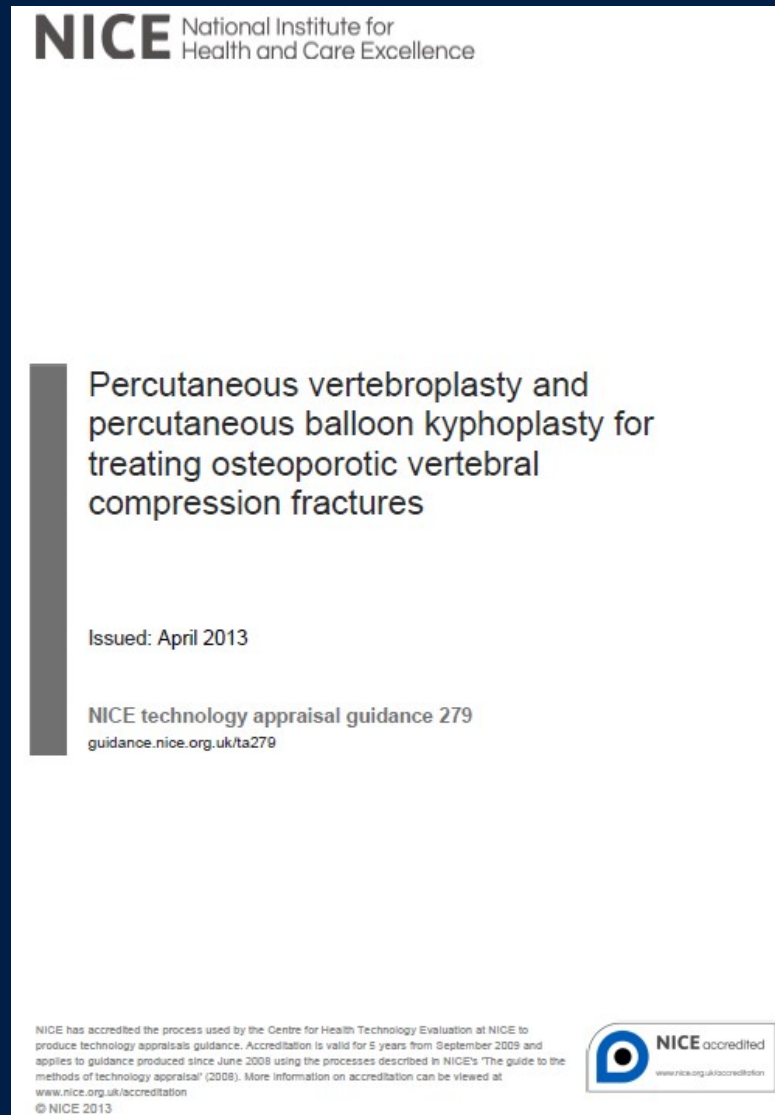
NICE technology appraisal guidance 279
guidance.nice.org.uk/ta279

NICE has accredited the process used by the Centre for Health Technology Evaluation at NICE to produce technology appraisals guidance. Accreditation is valid for 5 years from September 2009 and applies to guidance produced since June 2008 using the processes described in NICE's 'The guide to the methods of technology appraisal' (2008). More information on accreditation can be viewed at www.nice.org.uk/accreditation
© NICE 2013



NOTE: Guidelines were generated prior to the Chen 2013 , McCullough 2013, Lange 2014 and Edidin 2015 studies

NICE APPRAISAL GUIDELINES 2013



“Percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people:

- who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and
- in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging”

NOTE: Guidelines were generated prior to the Chen 2013 , McCullough 2013, Lange 2014 and Edidin 2015 studies

NICE APPRAISAL GUIDELINES 2013


NICE National Institute for Health and Care Excellence

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures

Issued: April 2013

NICE technology appraisal guidance 279
guidance.nice.org.uk/ta279

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“The Assessment Group stated that, apart from the possibility of uncontrolled confounding, **these studies raise the possibility that improvement in biomechanical factors after treatment improves survival.**”

NOTE: Guidelines were generated prior to the Chen 2013 , McCullough 2013, Lange 2014 and Edidin 2015 studies

NICE APPRAISAL GUIDELINES 2013


NICE National Institute for Health and Care Excellence

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures

Issued: April 2013

NICE technology appraisal guidance 279
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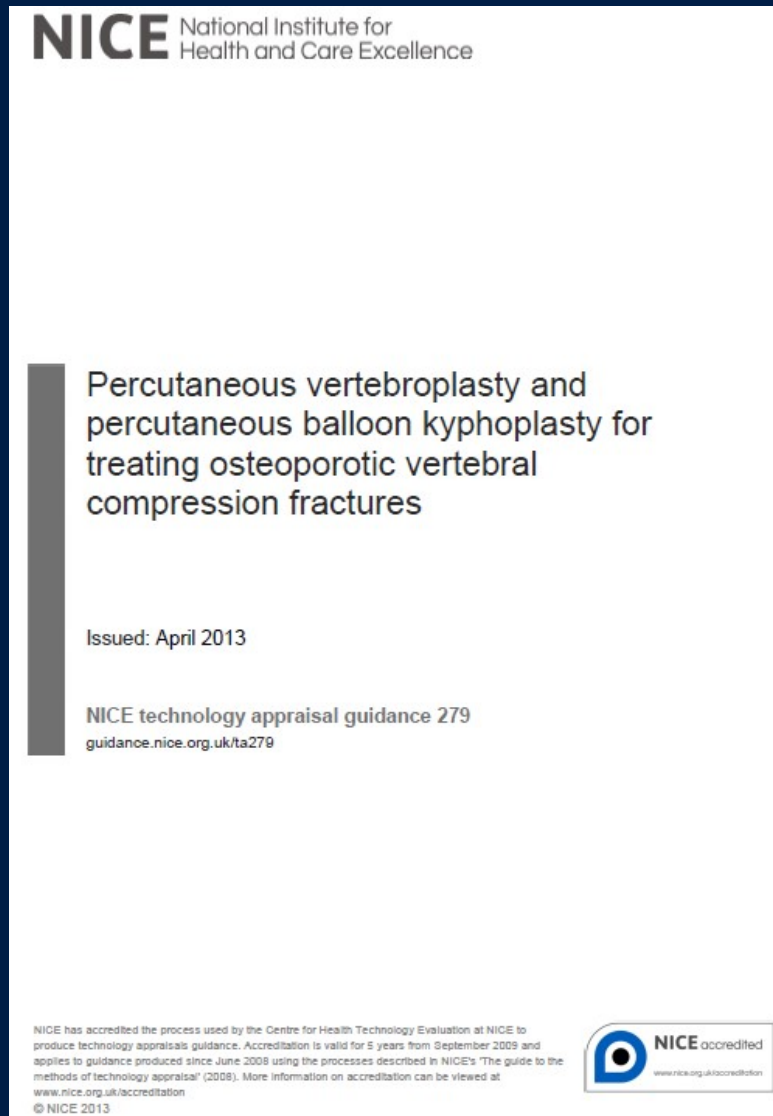
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“... reducing pain may confer a mortality benefit ... concluded that it was **reasonable to assume that both vertebroplasty and kyphoplasty prolong life compared with optimal pain management**, but that the precise mechanism or magnitude of such a benefit in clinical practice in the NHS was uncertain.”

NOTE: Guidelines were generated prior to the Chen 2013 , McCullough 2013, Lange 2014 and Edidin 2015 studies

NICE APPRAISAL GUIDELINES 2013



“The Committee also noted that, based on both sets of observational data, **patients who had kyphoplasty lived longer than patients who had vertebroplasty ...**”

“On balance, the Committee concluded that, given the degree of uncertainty, it was plausible that kyphoplasty may be associated with a greater mortality benefit than vertebroplasty, but the Committee would also consider the **possibility that kyphoplasty and vertebroplasty had the same degree of mortality benefit.**”

NOTE: Guidelines were generated prior to the Chen 2013 , McCullough 2013, Lange 2014 and Edidin 2015 studies

CONCLUSIONS

Majority of studies show that BKP/VP patients have lower mortality risk (up to 43% lower at up to 5 years³) than patients treated with non-surgical management.

Several recent large studies followed for at least 12 months after vertebral compression fracture (VCF) have concluded that mortality rates following VCFs are significantly higher for patients treated conservatively versus VP or BKP, while other studies have concluded no difference.

For more information, visit www.medtronic.com/bkpmortality

Kyphon Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion.

The complication rate with Kyphon Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

1. Edidin AA, Ong KL, Lau E, Kurtz SM. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. *J Bone Miner Res*. 2011 Jul;26(7):1617-26. doi: 10.1002/jbmr.353. PubMed PMID: 21308780. <http://www.ncbi.nlm.nih.gov/pubmed/21308780>
2. Chen AT, Cohen DB, Skolasky RL. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the medicare population. *J Bone Joint Surg Am*. 2013 Oct 2;95(19):1729-36. doi: 10.2106/JBJS.K.01649. PubMed PMID: 24088964. <http://www.ncbi.nlm.nih.gov/pubmed/24088964>
3. Lange A, Kasperk C, Alvares L, Sauermann S, Braun S. Survival and cost comparison of kyphoplasty and percutaneous vertebroplasty using German claims data. *Spine (Phila Pa 1976)*. 2014 Feb 15;39(4): 318-26. doi: 10.1097/BRS.000000000000135. PubMed PMID: 24299715. <http://www.ncbi.nlm.nih.gov/pubmed/24299715>
4. Edidin AA, Ong KL, Lau E, Kurtz SM. Morbidity and Mortality after Vertebral Fractures: Comparison of Vertebral Augmentation and Non-Operative Management in the Medicare Population. *Spine (Phila Pa 1976)*. 2015 Aug 1;40(15):1228-41. doi: 10.1097. PubMed PMID: 26020845. <http://www.ncbi.nlm.nih.gov/pubmed/26020845>
5. McCullough BJ, Comstock BA, Deyo RA, Kreuter W, Jarvik JG. Major medical outcomes with spinal augmentation vs conservative therapy. *JAMA Intern Med*. 2013 Sep 9;173(16):1514-21. doi: 10.1001/jamainternmed.2013.8725. PubMed PMID: 23836009; PubMed Central PMCID: PMC4023124. <http://www.ncbi.nlm.nih.gov/pubmed/23836009>

■ CASE STUDY

- Courtesy of:
- Douglas P. Beall, MD
- Chief of Radiology Services
- Clinical Radiology of Oklahoma



Medtronic
Further, Together



If noted, the relationships with Medtronic are as follows:

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- (b) Consulting Fee/Honoraria
- (c) Ownership Interest
- (d) Royalties
- (e) Intellectual Property Rights

Douglas P. Beall, MD

(a) + (b)

This therapy is not for everyone.

Please consult your physician. A prescription is required.

For further information, please call Medtronic Office of Medical Affairs at 1.800.876.3133

DR. DOUGLAS P. BEALL - MUSCULOSKELETAL RADIOLOGIST

BALLOON KYPHOPLASTY

Case Study: Primary Osteoporosis

- 88 y.o. female
- Primary osteoporosis
- No history of previous VCF's, currently treated with calcium, vitamin D and Alendronate (4 years)
- No known injury; 16 week duration of symptoms
- Progressive pain requiring hospitalization
- T11, T12 and L1 fractures as determined by MR imaging

*Courtesy of Dr. Douglas P. Beall Musculoskeletal Radiologist
Clinical Radiology of Oklahoma*



88 YO FEMALE W/ T11, T12 AND L1 VCF'S & SEVERE PAIN IMPLICATIONS OF VCF'S & IMPACT ON PATIENTS

- VCF's predict risk of add'l VCF's (1)
 - 1 Fx – 5x increased risk
 - 2 Fx's – 12x increased risk
 - 3 Fx's – 75x increased risk
- Risk of Mortality for a VCF – RR = 8.6x age matched controls (2)
- NSM have sig ↑ risks of pneumonia, DVT, myocardial infarction/cardiac complications, & UTI (3)
- LOS in Hosp: NSM – 7.38 days; KP 3.74 days (4)
- Readmission Rate : NSM 61.9%; KP 35.2% (4)
- KP assoc w/ > likelihood of a routine D/C 59.9% comp to NSM – 24.3%(4)

1 Lindsay R, et al. JAMA. 2001 Jan 17;285(3):320-3.

2. Cauley JA, et al. Osteoporos Int. 2000;11(7):556-61.

3. Edidin AA, et al. Spine. 2015 Aug 1;40(15):1228-1241. doi: 10.1097.

4. Chen A, et al. . J Bone Joint Surg Am. 2013;95:1729-36

Majority of studies show that BKP/VP patients have lower mortality risk (up to 43% lower at up to 5 years follow up⁴) than patients treated with non-surgical management



4 studies¹⁻⁴



1,038,956 patients
(Edidin et al, 2015⁴)



Up to **5 years** of
MEDPAR data

KEY FINDING

Up to 43% lower mortality risk for BKP/VP patients vs. NSM patients, up to 5 years



1 study⁵



126,392 patients
(McCullough et al, 2013⁵)



1 year of
MEDPAR data

KEY FINDING

No difference in mortality risk between surgical and non-surgical patients

Several recent large clinical studies that followed patients for at least 12 months after vertebral compression fracture (VCF) have concluded that mortality rates following VCFs are significantly higher for patients treated conservatively versus VP or BKP, while other studies have concluded no difference. For more information visit www.medtronic.com/bkpmortality.¹⁻⁵

IMPORTANT LIMITATIONS: Studies reviewed : are retrospective database analyses and are prone to selection bias; have variables that are not captured in the database that may explain mortality effects; have study designs that cannot demonstrate causality of treatment received with mortality outcomes; indicate to some extent that BKP (and VP) subjects have better “baseline” health, which may at least partially explain the mortality benefit.

1. Edidin AA, et al. *Spine*. 2015 Aug 1;40(15):1228-1241. doi: 10.1097. PubMed PMID: 26020845.
2. Edidin AA, et al. *J Bone Miner Res*. 2011 Jul;26(7):1617-1626. doi: 10.1002/JBMR.353. PubMed PMID: 21308780.
3. Chen AT, et al. *J Bone Joint Surg Am*. 2013 Oct 2;95(19):1729-1736. doi: 10.2106/JBJS.K.01649. PubMed PMID: 24088964.
4. Lange A, et al. *Spine*. 2014 Feb 15;39(4): 318-326. doi: 10.1097/BRS.00135. PubMed PMID: 24299715.
5. McCullough BJ, et al. *JAMA Intern Med*. 2013 Sep 9;173(16):1514-1521. doi: 10.1001/jamainternmed.2013.8725. PubMed PMID: 23836009; PubMed Central PMCID: PMC4023124.

TREATMENT CHOICES AND MORTALITY RISK

Patients treated with BKP/VP had :

SIGNIFICANTLY LOWER MORTALITY RISK THAN PATIENTS TREATED WITH NSM AT UP TO 5 YEARS OF FOLLOW UP *1,2,3,4

NO DIFFERENCE IN MORTALITY RISK AT 1 YEAR⁵

Eddidin et al. *
(JBMR 2011)¹
n=858,978

BKP: 44% lower mortality risk than NSM

(AHR =0.56, 95% CI 0.55–0.57)

VP: 24% lower mortality risk than NSM

(4 years) +

Chen et al. *
(JBJS 2013)²
n= 68,752

BKP: 32.3% lower mortality risk than NSM

(AHR =0.68, 95% CI 0.66–0.70)

VP: 15.5% lower mortality risk than NSM

(3 years) +

Lange et al. *
(SPINE 2014)³
n=3,607

BKP/VP : 43% lower mortality risk than NSM

(AHR = 0.57; 95% CI: 0.48–0.70)

(5 years) ++

Eddidin et al. *
(Spine 2015)⁴
n=1,038,956

NSM: 55% higher mortality risk than BKP

(AHR =1.55 95% CI: 1.53-1.56)

NSM: 25% higher mortality risk than VP

After propen-sity matching, the Kaplan-Meier risk of mortality at 4 years was still found to be greater for the nonoperated cohort.

(AHR 1.62; 95% CI: 1.60–1.64)
(4 years) +

McCullough et al.
(JAMA 2013)⁵
n=126,392

BKP/VP: Significantly lower mortality risk than NSM

(HR 0.83; 95%CI, 0.75-0.92)

After propensity score matching to better account for selection bias, 1-year mortality was not significantly different between the groups (5.2% vs 6.7%)

(HR 0.92; 95% CI, 0.81-1.04)
BKP/VP (n=10,540) / NSM (n=115,851)
(1 year) +

BKP/VP (n=182,946) / NSM (n=676,032)

BKP/VP (n=30,503) / NSM (n=38,249)

BKP/VP (n=598) / NSM (n=3,009)

* Adjusted mortality risk (p < 0.001) / AHR = adjusted hazard ratio

+ Retrospective database review of claims data that evaluated the mortality risk for patients with VCFs undergoing different treatment modalities

++ Observational study of claims data that examined the survival of patients treated with BKP/vertebroplasty (VP) vs NSM with a follow-up time of up to 5 years

Several recent large clinical studies followed for at least 12 months after VCF have concluded that mortality rates following VCFs are significantly higher for patients treated conservatively versus VP or BKP, while other studies have concluded no difference. For more information, visit

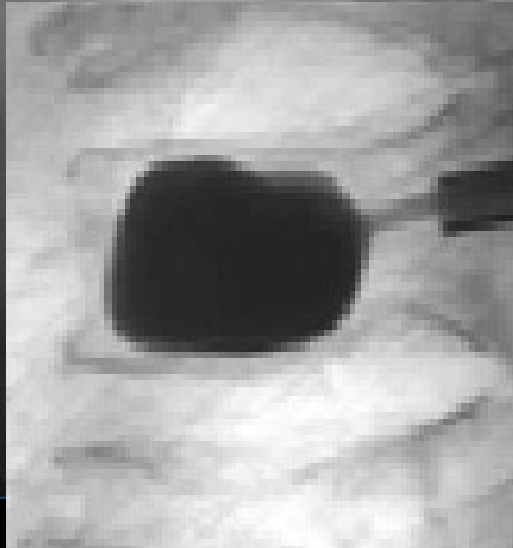
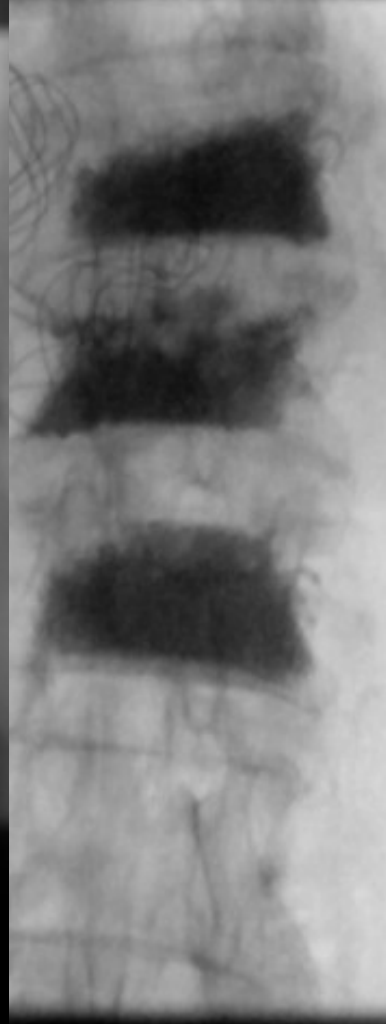
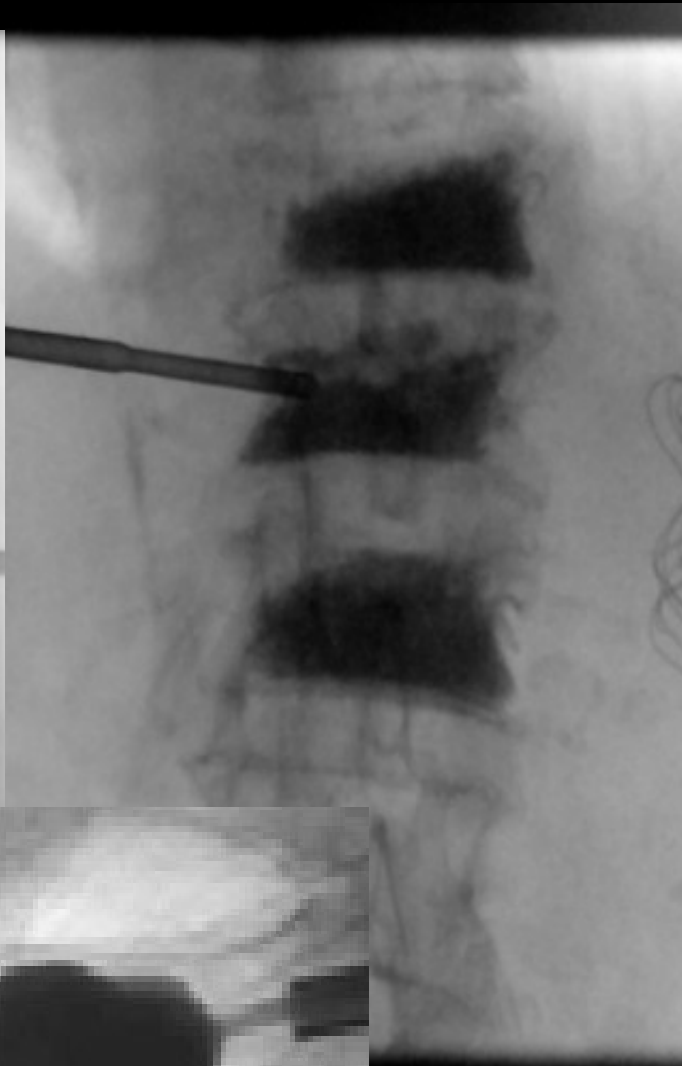
www.medtronic.com/bkpmortality

BALLOON KYPHOPLASTY PROCEDURE

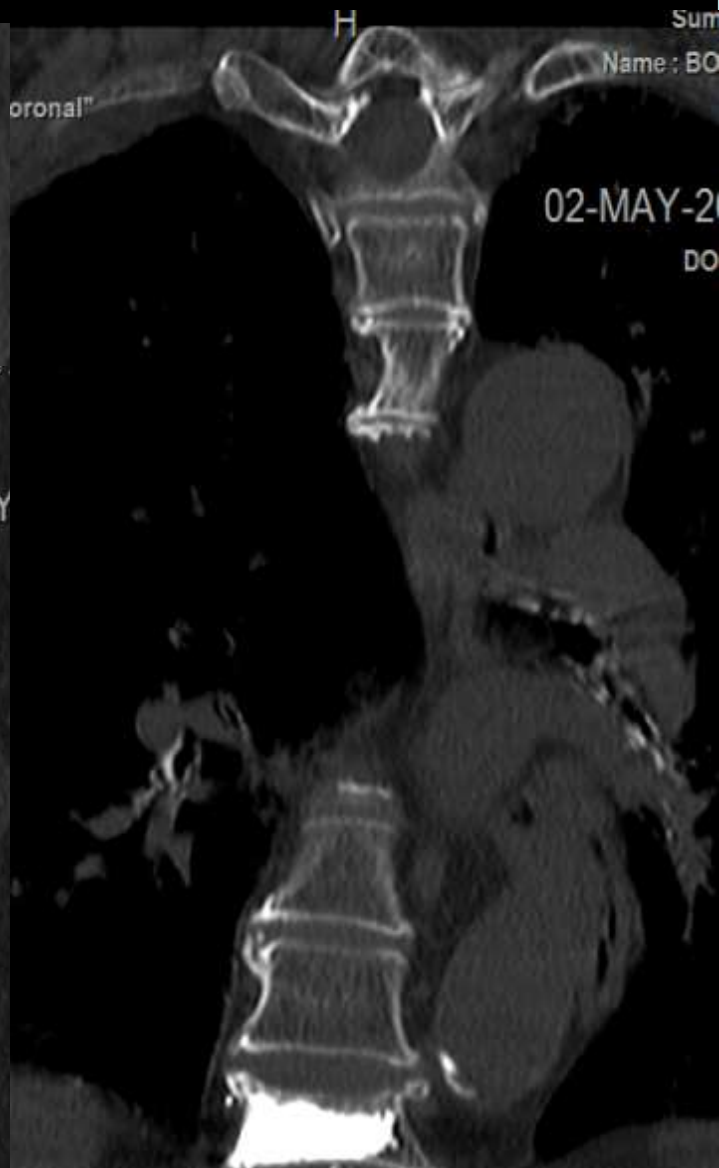
- BKP was performed at T11, T12 & L1
- All procedures were performed as an outpatient under conscious sedation
- Bilateral parapedicular approach
 - IBTs (KYPHON Express 15/2) were inflated with 2.5 cc of contrast each
 - Void filled with PMMA 10% HA bone cement (total cement fill = 5.1 cc for T11, 4.9cc for T12 and 6.0cc for L1)

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information





“The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.”



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BALLOON KYPHOPLASTY RESULTS

- Patient reported near complete pain relief the following day
- At 2 weeks post procedure she reported only minimal pain (0-1/10 on a VAS) and described her pain as the typical chronic low back pain she had before the recent injury
- Discontinued all pain medications and was back to normal activity by 2 weeks following the procedure

GAP OF DIAGNOSIS AND TREATMENT & AWARENESS OF OUTCOMES

- Only ~20% of VCF's undergo Vertebral Augmentation (1,2)
- Bracing is common but No Data exists comparing bracing to Vert Aug (2)
- Several RCTs and meta-analyses supports the benefits of BKP over NSM(3)
- ~80% of pts not tx for osteoporosis even after fragility fx (4, 5)
- Low complication rate with BKP (6,7,8)

1. Cox M, et al. J Am Coll Radiol. 2016 Jan;13(1):28-32.
2. Medtronic Data on File – D. Beall May 2016.
3. Papanastassiou ID, et al. Eur Spine J. 2012 Sep;21(9):1826-43.
4. Solomon DH, et al. Am J Med. 2003;398-400.
5. Dell RM, et al. J Bone Joint Surg Am. 2009;91(Suppl 6):79-86.
6. Boonen S, et al. J Bone Miner Res. 2011;26(7):1627-1637.
7. Wardlaw D, et al. Lancet. 2009;373(9668):1016-1024.
8. Van Meirhaeghe JV, et al. Spine. 2013;38(12):971–983.

BALLOON KYPHOPLASTY

INDICATION AND RISK STATEMENT

Kyphon Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer or benign lesion.

The Kyphon® Xpander™ and Kyphon® Express™ Inflatable Bone Tamps (IBT) are intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine (including use during a balloon kyphoplasty procedure with Kyphon® HV-R® Bone Cement), hand, tibia, radius, and calcaneus.

The complication rate with Kyphon Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and through rare, some of which may be fatal. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

THANK YOU!