Major Medical Outcomes With Spinal Augmentation vs Conservative Therapy

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**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 for the 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 9,017 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 the 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.


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Vertebral augmentation, have until recently received widespread acceptance as effective, minimally invasive treatments for rapid symptomatic relief following osteoporotic vertebral compression fractures. These procedures involve percutaneous injection of bone cement into the collapsed vertebral body.

Numerous observational studies, nonrandomized trials, and randomized clinical trials (RCTs) have supported the use of spinal augmentation for the treatment of vertebral compression fractures.\(^1\)\(^-\)\(^3\) The 2 largest RCTs comparing vertebroplasty and kyphoplasty with conservative, nonsurgical therapies found significant reductions in pain, analgesic usage, and disability with spinal augmentation at 1 month and 1 year.\(^2\)\(^,\)\(^3\) However, results from 2 double-blinded RCTs failed to demonstrate improvements in pain or disability with vertebroplasty.\(^4\)\(^-\)\(^6\) These results suggest that the benefits of spinal augmentation might largely reflect a placebo effect.

The importance of effectively treating osteoporotic compression fractures, however, goes beyond the acute symptoms. Mortality rates are doubled following a fracture, perhaps owing to the acute symptoms superimposed on significant underlying comorbid conditions.\(^7\)\(^-\)\(^12\) Early intervention with spinal augmentation, therefore, has the potential to lessen the risk of death by ameliorating the acute symptoms. Several recent, population-based studies have suggested that spinal augmentation is associated with marked reductions in mortality,\(^13\)\(^-\)\(^15\) supporting this hypothesis. However, a small, retrospective cohort study found similar mortality following vertebral augmentation compared with historical controls.\(^16\)

To clarify these conflicting results, we studied the Medicare population to compare mortality, rates of major medical complications, and several measures of health care utilization among patients with osteoporotic vertebral fractures who were treated with either spinal augmentation or conservative therapy. We also investigated the potential role of selection bias by examining pre-procedure outcomes in the augmented group compared with controls and by using propensity score analysis.

Methods
The institutional review board of the University of Washington approved this project.

Data Source
We used a 20% random sample of the Centers for Medicare and Medicaid Services (CMS) outpatient (physician/supplier; Part B) billing claims and a corresponding sample of the inpatient Medicare Provider Analysis and Review (MedPAR; Part A) claims from 2002 through 2006. The Medicare enrollment file (denominator) was used to determine dates of death. Unique patient identifiers allow linkage of patients among databases and provide the ability to follow them over time.

We excluded beneficiaries receiving Social Security Disability income, those with end-stage renal disease, and those enrolled in a health maintenance organization. These special groups are often excluded from this type of analysis because they may be receiving additional medical coverage from an outpatient provider that is not included in the Medicare database.\(^17\)\(^-\)\(^19\) Patients younger than 66 years were also excluded to allow 1 full year of Medicare eligibility prior to the index event.

Patients and Index Fracture
We identified patients using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes (methods in the Supplement) for thoracic or lumbar vertebral fractures and “pathologic fracture of vertebrae,” which includes osteoporotic fractures. To limit our sample to newly diagnosed, osteoporotic vertebral fractures, we excluded patients with other diagnoses that could result in fracture (eMethods in the Supplement). In total, we identified 127 238 beneficiaries.

Treatments
We defined treatment groups based on the presence (augmented group) or absence (control group) of Current Procedural Terminology (CPT) and ICD-9-CM procedural codes for vertebroplasty or kyphoplasty in the year following the index fracture. We excluded patients who underwent spinal augmentation 6 months or more after their fracture (n = 846), allowing at least 6 months of postprocedure follow-up. Additionally, we excluded patients in the control group with a procedural code for “unlisted procedure, spine” (n = 2814) because this code may include spinal augmentation. After these exclusions, 115 851 patients were in the control group and 10 541 patients were in the augmented group.

Demographics and Measures of Comorbidity
We collected available demographics for all patients. We categorized race as white or nonwhite. Race was not specified in 0.2% of patients in the control and augmented groups. We determined rural-urban commuting areas (RUCA)\(^20\) from patient zip codes. A zip code was not available for less than 0.5% of patients in both groups. We used state subsidization of Medicare premiums and deductibles (buy-in status) as a measure of socioeconomic status.

We accounted for baseline patient comorbid conditions using the modified Quan comorbidity index and individual conditions included in the index.\(^21\)\(^,\)\(^22\) We also recorded the number of hospitalizations in the prior year as an additional measure of overall disease burden.\(^17\)

Complications
We evaluated mortality and the occurrence of a major medical complication within 1 year from the time of the index vertebral fracture. Major medical complications included diagnosis codes for cardiorespiratory arrest, acute myocardial infarction, respiratory failure, pulmonary embolism, pneumonia, and stroke as well as relevant procedural codes (eMethods in the Supplement). We chose these complications because they have a major effect on health and are more consistently coded than minor complications.\(^17\)\(^-\)\(^23\)

Health Care Utilization
We recorded general hospital admissions, intensive care unit (ICU) admissions, and discharges to a skilled nursing facility (SNF) during the year following vertebral fracture. We did not
include hospital admissions during which spinal augmentation was performed.

**Statistical Analysis**

We initially compared 30-day and 1-year mortality and rates of major medical complications between augmented and control groups using a multivariate Cox proportional hazards model and Kaplan-Meier survival curves. We compared hospitalizations, ICU admissions, and discharges to SNFs within 1 year from the index fracture between groups using multivariate logistic regression. Time points were prespecified. We adjusted all regression models for year, patient demographics and comorbid conditions, fracture level, hospital admission at the time of fracture, and the use and timing of advanced imaging following fracture.

To examine the potential for unmeasured selection bias between augmented and control groups, we compared rates of major medical complications within 30 days of the index fracture between patients in the augmented group who had not yet undergone spinal augmentation (preprocedure subgroup) and the control group using multivariate logistic regression.

In addition to standard covariate adjustment, we used propensity score matching methods to better account for selection bias inherent in observational studies in which patients are selected for a given treatment in a nonrandom manner and compared with untreated patients. We matched augmented patients with control patients 1-to-1 using the `psmatch2` function with the adjustment variables already noted. This technique identified 9085 pairs of adequately matched augmented and control patients. Sixty-eight pairs were excluded because the control patient died before the augmented patient underwent the procedure, and therefore, differences in survival could not be due to spinal augmentation. Propensity scores were equal between treatment groups after matching (mean, 0.18 for both) (t test \( P = .99 \)). We then repeated the outcome analyses using matched-sample tests and compared results to the standard covariate analysis.

All analyses were performed using Stata 12 statistical software (StataCorp).

**Results**

**Traditional Multivariate Analysis**

Differences in baseline characteristics between the augmented and control groups were small (Table 1). In part owing to the absence of a distinct CPT code for kyphoplasty...
until 2005, most of the patients in the augmented group in our sample (71.0%) were coded as having only vertebroplasties.

**Mortality**

Thirty-day mortality following the index vertebral fracture was markedly lower in the augmented group than among controls (0.4% vs 1.5%), with an odds ratio (OR) of 0.29 (95% CI, 0.20-0.41) (**Table 2**). At 1 year, mortality remained significantly lower in the augmented group than among controls, but the relative difference was attenuated (5.2% vs 6.7%), with a hazard ratio (HR) of 0.83 (95% CI, 0.75-0.92). **Figure 1** displays 1-year Kaplan-Meier curves for survival.

**Major Medical Complications**

The augmented group also had significantly fewer major medical complications than controls during the 30 days following the index fracture (9.3% vs 10.4%) with an OR of 0.85 (95% CI, 0.79-0.92) (**Table 2**). At 1 year, however, rates of complications were equal between groups (28.9% for both) (HR, 1.00; 95% CI, 0.95-1.04). **Figure 1B** displays 1-year Kaplan-Meier curves for time without a major medical complication.

In the augmented group, the first major medical complication occurred after the spinal augmentation in 79.9%, with the greatest peak immediately after the procedure (**Figure 2**). The risk of death was significantly higher among patients who experienced a major medical complication (OR, 5.59; 95% CI, 5.13-6.09).

**Health Care Utilization**

We also tracked additional measures of health care utilization during the year following the index vertebral fracture. Compared with controls, the augmented group had significantly higher rates of hospitalizations (excluding those for the spinal augmentation), ICU admissions, and discharges...
to SNFs (Table 2). In the augmented group, the first of these events occurred after the procedure in a majority of the patients: 4,472 of the hospitalizations (70.7%), 1,278 of the ICU admissions (86.9%), and 1,746 of the SNF discharges (76.4%). Rates of wrist and hip fractures during the year following the index vertebral fracture were similar between groups, suggesting roughly similar severity of osteoporosis.

Preprocedure Major Medical Complications
Seventy-one percent of patients in the augmented group underwent spinal augmentation during the first 30 days after the index vertebral fracture. Therefore, the remaining 3,023 patients (29.0%) who had not yet undergone augmentation at 30 days (preprocedure subgroup) offered a unique internal control of overall health between treatment groups. Any differences in 30-day outcomes could not be due to a procedure that had not yet occurred.

Patients in this preprocedure subgroup experienced significantly lower rates of major medical complications during the first 30 days than controls (6.6% vs 10.4%), with an OR of 0.66 (95% CI, 0.57-0.78) (Table 2).

Mortality cannot be compared in this manner because any patient who died prior to spinal augmentation would automatically be included in the control group (having had no procedure).

Propensity Score Matched Analysis
We performed propensity score matching to better control for unmeasured factors between groups. Baseline characteristics of the matched-sample groups were similar to those in the traditional analysis but better matched between groups (Table 3).

Matched-Sample Mortality
Thirty-day mortality was significantly lower in the augmented group than among controls in the propensity matched-sample comparison (0.3% vs 0.6%), with an OR of 0.61 (95% CI, 0.39-0.95) (Table 4), but this difference was attenuated compared with that in the traditional multivariate analysis. At 1 year, the difference was no longer statistically significant (5.2% vs 5.6%), with an HR of 0.92 (95% CI, 0.81-1.04). Figure 3A displays 1-year Kaplan-Meier curves for survival for the propensity score matched sample.

Matched-Sample Major Medical Complications
Thirty-day rates of major medical complications were borderline lower in the augmented group than among controls (9.5% vs 10.5%), with an OR of 0.90 (95% CI, 0.81-0.99) (Table 4). At 1 year, the risk of a major medical complication was equivalent between groups (HR, 1.00; 95% CI, 0.94-1.06), as in the traditional multivariate analysis. Figure 3B displays 1-year Kaplan-Meier curves for time without a major medical complication in the propensity score matched sample.

In the augmented group, the initial major medical complication occurred after spinal augmentation was performed in 2,123 patients (78.9%). The risk of death remained significantly higher in patients who experienced a major medical complication than among those who had not (OR, 6.05; 95% CI, 5.19-7.04).

Matched-Sample Health Care Utilization
As in the complete sample, the augmented group was more likely than controls to require hospitalization, ICU admission, or discharge to a SNF (Table 4). Rates of wrist and hip fractures during the year following fracture diagnosis were similar between groups.

Matched-Sample Preprocedure Complications
The augmented group in the propensity score matched sample included 2,773 patients (31.0%) who had not yet undergone spinal augmentation at 30 days (preprocedure subgroup). As in the traditional analysis, major medical complications were significantly less likely in the preprocedure subgroup than among controls (OR, 0.66; 95% CI, 0.54-0.80) (Table 4), suggesting that residual unmeasured confounders are resulting in healthier patients in the augmented group.
Discussion

The results from this study suggest that treatment of osteoporotic vertebral fractures with spinal augmentation does not improve long-term mortality or major medical complications and increases several measures of health care utilization compared with conservative therapy. Our analysis also illustrates how selection bias hidden within billing claims data can significantly alter the results of population-based outcomes research.

Two recent studies using billing claims data reported markedly better survival following spinal augmentation compared with conservative therapy.13,15 Edidin et al13 reported that spinal augmentation was associated with a 37% lower adjusted risk of death at 4 years using Medicare claims from the 2005-2008 period, and Zampini et al15 showed a 48% lower adjusted risk of inpatient mortality in patients treated with kyphoplasty using the 2005 National Inpatient Sample.

Our initial analysis paralleled these studies. Using standard covariate adjustments, we observed significantly lower mortality in the augmented group compared with controls. However, patients in the augmented group who had not yet undergone augmentation (preprocedure subgroup) had better 30-day outcomes than controls. Since a procedure that has not yet been performed cannot improve outcomes, we concluded that this difference was due to selection bias: providers performing spinal augmentation were excluding patients at higher risk for complications. We would also expect that the ability of the provider to predict a complication would be best in the short term, explaining the markedly lower risk of death at 30 days in the augmented group than among controls.

To better control for selection bias, we performed propensity score matching and repeated the analyses. Comparing matched samples, improvements in 30-day outcomes in the augmented group were attenuated compared with the traditional analysis, and the mortality advantage at 1 year was lost. Hospitalizations, ICU admissions, and SNF discharges remained significantly higher in the augmented group. The risk of a major medical complication at 30 days remained lower in the preprocedure subgroup, suggesting residual selection bias.

This study has several strengths. The large sample size provides adequate power to detect small differences in relatively rare events such as death and major medical complications. We also used data from routine clinical practice rather than

Table 3. Baseline Characteristics of Patients and Procedures for Matched Samples

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n = 9017)</th>
<th>Augmented (n = 9017)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>80.3 (7.0)</td>
<td>80.0 (6.7)</td>
<td>.01</td>
</tr>
<tr>
<td>Female sex</td>
<td>7120 (79.0)</td>
<td>7077 (78.5)</td>
<td>.43</td>
</tr>
<tr>
<td>White race</td>
<td>8776 (97.3)</td>
<td>8765 (97.2)</td>
<td>.62</td>
</tr>
<tr>
<td>State buy-in</td>
<td>914 (10.1)</td>
<td>902 (10.0)</td>
<td>.77</td>
</tr>
<tr>
<td>Quan comorbidity score</td>
<td></td>
<td></td>
<td>.83</td>
</tr>
<tr>
<td>0</td>
<td>2195 (24.3)</td>
<td>2194 (24.3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2134 (23.7)</td>
<td>2138 (23.7)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1660 (18.4)</td>
<td>1628 (18.1)</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>3028 (33.6)</td>
<td>3057 (33.9)</td>
<td></td>
</tr>
<tr>
<td>Prior inpatient admissions</td>
<td></td>
<td></td>
<td>.06</td>
</tr>
<tr>
<td>0</td>
<td>5921 (65.7)</td>
<td>5707 (63.3)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1388 (15.4)</td>
<td>1562 (17.3)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>852 (9.5)</td>
<td>860 (9.5)</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>856 (9.5)</td>
<td>888 (9.9)</td>
<td></td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>2937 (32.6)</td>
<td>3005 (33.3)</td>
<td>.28</td>
</tr>
<tr>
<td>Admitted at diagnosis</td>
<td>2496 (27.7)</td>
<td>2536 (28.1)</td>
<td>.51</td>
</tr>
<tr>
<td>Fracture level</td>
<td></td>
<td></td>
<td>.05</td>
</tr>
<tr>
<td>Thoracic</td>
<td>1611 (17.9)</td>
<td>1754 (19.5)</td>
<td></td>
</tr>
<tr>
<td>Lumbar</td>
<td>2832 (31.4)</td>
<td>2786 (30.9)</td>
<td></td>
</tr>
<tr>
<td>Both</td>
<td>208 (2.3)</td>
<td>211 (2.3)</td>
<td></td>
</tr>
<tr>
<td>Unspecified</td>
<td>4366 (48.4)</td>
<td>4266 (47.3)</td>
<td></td>
</tr>
<tr>
<td>Advanced imaging</td>
<td>9017 (100)</td>
<td>9017 (100)</td>
<td>NA</td>
</tr>
<tr>
<td>Procedure type</td>
<td></td>
<td></td>
<td>NA</td>
</tr>
<tr>
<td>Vertebroplasty</td>
<td>NA</td>
<td>6404 (71.0)</td>
<td>NA</td>
</tr>
<tr>
<td>Kyphoplasty</td>
<td>NA</td>
<td>2393 (26.5)</td>
<td>NA</td>
</tr>
<tr>
<td>Both</td>
<td>NA</td>
<td>220 (2.4)</td>
<td>NA</td>
</tr>
<tr>
<td>Multiple levels at once</td>
<td>NA</td>
<td>1562 (17.8)</td>
<td>NA</td>
</tr>
<tr>
<td>Inpatient</td>
<td>NA</td>
<td>4944 (56.2)</td>
<td>NA</td>
</tr>
</tbody>
</table>

Abbreviation: NA, not applicable.
from selected populations in clinical trials or academic medical centers. However, there are also limitations. Medicare data cannot be used to evaluate symptomatic outcomes such as pain and disability. Diagnoses and procedures may have been mis-coded even though they were used for billing and subject to audit. We tracked major complications, which are more reliably coded than minor complications, to mitigate this shortcoming. Additionally, there is no ICD code specific to osteoporotic vertebral fractures; we were forced to exclude patients with other comorbid conditions that may have resulted in the fracture.

Our results further challenge the value of spinal augmentation for the treatment of osteoporotic vertebral compression fractures. Spinal augmentation is intended to limit acute pain and disability and, by extension, to improve medical outcomes. However, 2 double-blinded RCTs failed to demonstrate benefits in pain or disability with vertebroplasty, and the results of this study suggest that long-term mortality and major medical complications are not improved and health care utilization is increased with spinal augmentation compared with conservative therapy. Furthermore, our analysis highlights how unmeasured selection bias in billing claims data can lead to overestimation of the benefits of a procedure. This has implications for patients diagnosed with an osteoporotic vertebral fracture and also for outcomes research in general that uses medical billing claims.

Table 4. Mortality, Major Medical Complications, and Resource Utilization in Propensity Score Matched Groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n = 9017)</th>
<th>Augmented (n = 9017)</th>
<th>HR or OR (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 d</td>
<td>51 (0.6)</td>
<td>31 (0.3)</td>
<td>0.61 (0.39-0.95)</td>
<td>.03</td>
</tr>
<tr>
<td>1 y</td>
<td>505 (5.6)</td>
<td>469 (5.2)</td>
<td>0.92 (0.81-1.04)</td>
<td>.18</td>
</tr>
<tr>
<td>Major medical complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30 d</td>
<td>947 (10.5)</td>
<td>860 (9.5)</td>
<td>0.90 (0.81-0.99)</td>
<td>.03</td>
</tr>
<tr>
<td>1 y</td>
<td>2709 (30.0)</td>
<td>2691 (29.8)</td>
<td>1.00 (0.94-1.06)</td>
<td>.96</td>
</tr>
<tr>
<td>Health care utilization, 1 y</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalization*</td>
<td>5023 (55.7)</td>
<td>5585 (61.9)</td>
<td>1.31 (1.23-1.39)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>ICU admission</td>
<td>1187 (13.2)</td>
<td>1300 (14.4)</td>
<td>1.11 (1.02-1.21)</td>
<td>.02</td>
</tr>
<tr>
<td>SNF discharge</td>
<td>1901 (21.1)</td>
<td>2051 (22.8)</td>
<td>1.10 (1.03-1.19)</td>
<td>.006</td>
</tr>
<tr>
<td>Wrist fracture</td>
<td>191 (2.1)</td>
<td>169 (1.9)</td>
<td>0.88 (0.72-1.09)</td>
<td>.24</td>
</tr>
<tr>
<td>Hip fracture</td>
<td>601 (6.7)</td>
<td>582 (6.5)</td>
<td>0.97 (0.86-1.09)</td>
<td>.57</td>
</tr>
<tr>
<td>Preprocedure major medical complications</td>
<td>264 (9.5) (n = 2773)</td>
<td>180 (6.5) (n = 2773)*</td>
<td>0.66 (0.54-0.80)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: CI, confidence interval; HR, hazard ratio; ICU, intensive care unit; OR, odds ratio; SNF, skilled nursing facility.

*Hospitalizations after vertebral fracture diagnosis and excluding hospitalization at the time of spinal augmentation procedure.

Preprocedure subgroup includes patients from the augmented group who had not yet undergone spinal augmentation at 30 days.

Figure 3. Major Medical Outcomes Following Vertebral Compression Fracture in the Propensity Score Matched Analysis

A, Survival. B, Time without a major medical complication. Hazard ratios (HRs) were calculated with a matched-sample Cox proportional hazards model.

ARTICLE INFORMATION

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Conflict of Interest Disclosures: Dr Deyo receives honoraria as a board member of the nonprofit Informed Medical Decisions Foundation. In the recent past, he has received honoraria as member of an Advisory Committee for the nonprofit Robert Wood Johnson Foundation. He receives honoraria from UpToDate for authoring topics on low back pain. His research receives support from grants from the National Institutes of Health and the Agency for Healthcare Research and Quality. His position at Oregon Health and Science University is supported in part by an endowment from Kaiser Permanente. Dr Jarvik serves on the Comparative Effectiveness Research Advisory Board for General Electric Healthcare. He is a consultant for HealthHelp (a radiology benefits management company). He is also a cofounder, stockholder, and co-patient holder for PhysioSonics (a high-intensity focused-ultrasound diagnostics company).

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REFERENCES


