Economic Analysis

Economic Analysis of Kiva VCF Treatment System Compared to Balloon Kyphoplasty Using Randomized Kiva Safety and Effectiveness Trial (KAST) Data

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Background: Vertebral compression fractures (VCFs) are the most common osteoporotic fractures and cause persistent pain, kyphotic deformity, weight loss, depression, reduced quality of life, and even death. Current surgical approaches for the treatment of VCF include vertebroplasty (VP) and balloon kyphoplasty (BK). The Kiva® VCF Treatment System (Kiva System) is a next-generation alternative surgical intervention in which a percutaneously introduced nitinol Osteo Coil guidewire is advanced through a deployment cannula and subsequently a PEEK Implant is implanted incrementally and fully coiled in the vertebral body. The Kiva System's effectiveness for the treatment of VCF has been evaluated in a large randomized controlled trial, the Kiva Safety and Effectiveness Trial (KAST). The Kiva System was non-inferior to BK with respect to pain reduction (70.8% vs. 71.8% in Visual Analogue Scale) and physical function restoration (38.1 % vs. 42.2% reduction in Oswestry Disability Index) while using less bone cement. The economic impact of the Kiva system has yet to be analyzed.

Objective: To analyze hospital resource use and costs of the Kiva System over 2 years for the treatment of VCF compared to BK.

Setting: A representative US hospital.

Study Design: Economic analysis of the KAST randomized trial, focusing on hospital resource use and costs.

Methods: The analysis was conducted from a hospital perspective and utilized clinical data from KAST as well as unit-cost data from the published literature. The cost of initial VCF surgery, reoperation cost, device market cost, and other medical costs were compared between the Kiva System and BK. The relative risk reduction rate in adjacent-level fracture with Kiva [31.6% (95% CI: -22.5%, 61.9%)] demonstrated in KAST was used in this analysis.

Results: With 304 vertebral augmentation procedures performed in a representative U.S. hospital over 2 years, the Kiva System will produce a direct medical cost savings of $1,118 per patient and $280,876 per hospital. This cost saving with the Kiva System was attributable to 19 reduced adjacent-level fractures with the Kiva System.

Limitations: This study does not compare the Kiva System with VP or any other non-surgical procedures for the treatment of VCF.

Conclusion: This first-ever economic analysis of the KAST data showed that the Kiva System for vertebral augmentation is hospital resource and cost saving over BK in a hospital setting over 2 years. These savings are attributable to reduced risk of developing adjacent-level fractures with the Kiva System compared to BK.

Key words: Vertebral compression fracture, vertebral augmentation, osteoporosis, adjacent-level fractures, kyphoplasty, balloon kyphoplasty, Kiva System

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Vertebral compression fractures (VCFs) are the most common osteoporotic fractures with an annual incidence of over 1.4 million (1,2). Manifestations of VCFs include severe chronic back pain, disability, kyphosis, increased risk of future vertebral fractures, and in some circumstances, death (3). In an age-adjusted longitudinal cohort study, the relative risk of death was 8.6% (95% CI: 4.45, 16.74) following a vertebral fracture (4). Clinical trial data shows that the relative risk of developing a new vertebral fracture within a year of the index fracture is 9.3% (95% CI, 1.2, 71.6; $P = .03$) (3). The estimates of direct medical costs attributed to osteoporosis in the United States are between $13.7 to 20.3 billion with osteoporotic VCFs accounting for ~$1.1 billion annually (5). As the population ages, prevalence and related costs associated with VCF treatment are projected to increase 50% by the year 2025 (6).

Vertebroplasty (VP) and balloon kyphoplasty (BK) are 2 minimally invasive surgical procedures currently used for the treatment of VCF (7). A meta-analysis of Level-I and Level-II prospective multiple-arm studies (total number of patients = 1,624) indicated that BK and VP result in better patient outcomes than non-surgical management of osteoporotic VCF (8). While most studies have shown VP and BK to be safe, effective, and cost efficient, they do have some limitations, suggesting that there is a need for a new VCF treatment system that will effectively increase vertebral height, control cement delivery, and conserve the native cancellous bone structure, among others (9,10). The Kiva® VCF Treatment System (Kiva System, Benvenue Medical, Inc., Santa Clara, CA) is an emerging technology specifically designed to meet these needs. Unlike traditional bilateral BK, the Kiva System utilizes a unilateral transpedicular approach which allows the surgeon to correct the kyphosis, which is key to preventing adjacent-level fractures.

The Kiva System uses a flexible implant made from PEEK-OPTIMA® is inserted percutaneously over a removable, fully coiled, Nitinol Osteo guidewire in the vertebral body. Retaining the coiled configuration of the guidewire, the Kiva System Implant serves to restore the vertebral height, correct the kyphotic angle, and prevent cement leakage. The Kiva System is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6 to L5 and is intended to be used in combination with the Benvenue's Vertebral Augmentation Cement Kit (11).

The effectiveness of the Kiva System compared to BK for the treatment of patients with osteoporotic VCFs has been evaluated in a prospective, multi-center, randomized, non-inferiority controlled clinical trial, the Kiva® Safety and Effectiveness Trial (KAST) (12). Three hundred patients were enrolled at 21 medical centers. This large trial reported that the Kiva System was non-inferior to BK with respect to pain reduction (70.8% vs. 71.8% in Visual Analogue Scale [VAS]), physical function restoration (38.1 % vs. 42.2% reduction in Oswestry Disability Index), and no device-related serious adverse events (SAE) were observed (12).

Additional analysis of the KAST per-protocol (PP) population, constituting patients with 12-month data and no major protocol deviations, showed that 13.8% (16/116) of the Kiva System group and 20.2% (23/114) of the BK group experienced a new adjacent-level fracture (12). This analysis is consistent with a recent Otten et al study (13) comparing Kiva System to BK among 26 matched pairs. The incidence of adjacent-level and subsequent fractures was lower in the Kiva System group compare to BK (11.5% vs. 53.8%, respectively) (13). Korovesis et al (14) compared the Kiva System with BK in a randomized trial of 168 individuals eligible for surgery and reported that the patients treated with the Kiva System experienced significant reduction in the Gardner angle ($P = 0.002$) and lower rates of cement leakage (0.03%, $P \leq 0.05$). New fractures were observed in 10 (12.2%) patients in Kiva System group and in 11 (13%) patients in BK group ($\chi2 = 0.014$, $P > 0.2$) (14). Another retrospective study comparing the efficacy and safety of the Kiva System with PMMA versus BK reported significant improvement in postoperative VAS score (preoperative: 7.2 ± 3; postoperative: 3 ± 2) and SF-36 role physical score (preoperative: 38 ± 17; postoperative: 77 ± 18) with use of the Kiva System (15). In addition, lower rates of extracanal calcium phosphate and PMMA leakage were reported in the Kiva System group (15%), as compared to the BK group (18%) (15). No new fractures were observed in both Kiva System and BK groups, possibly due to the inclusion of a relatively young population with traumatic, non-osteoporotic fractures in the BK control group.

The objective of our analysis was to assess the economic impact of the Kiva System on hospital resource use and direct costs of VCF treatment compared to BK over a 2-year time period from the hospital perspective. Hospital resources associated with VCF surgical treatment included device utilization, reoperation to manage adjacent-level fractures and other medical costs related to management of complications, follow-up visits, and rehabilitation.

Methods

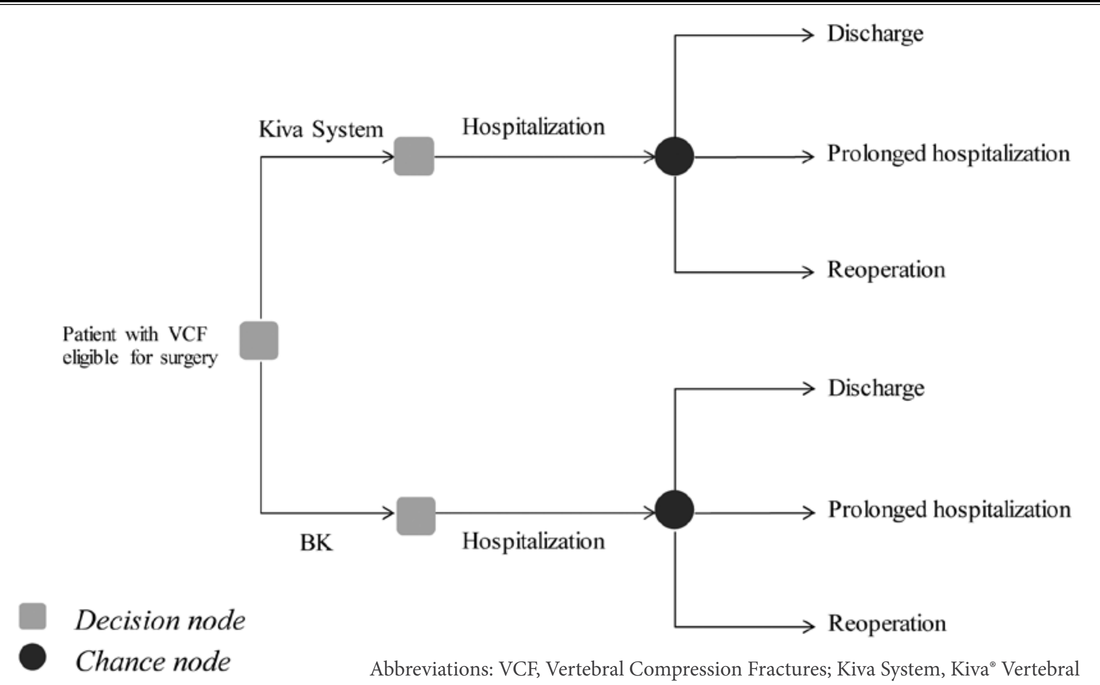
The international health economic guidelines (16) and CHEERS checklist (17) were used to design the study and analysis was performed in MS Excel and Visual Basic. The clinical endpoint data were obtained from KAST (details of KAST's design, conduct, and analytic methods are detailed elsewhere) (12) and unit-cost estimates were obtained from published peer-reviewed literature and publicly available fee schedules.

According to the American Association for Neurological Surgeons (AANS), an estimated 750,000 osteoporotic VCFs occur each year in the US alone (18). Of these, 165,000 individuals with one or more VCFs are considered eligible for vertebral augmentation (19). For our analysis, the target cohort size of a representative US hospital was derived from the KAST patient population which included 300 patients in year 1 and 309 patients in year 2 [accounting for an annual population growth rate factor of 2.86% (20)], totaling to 609 cumulative cohort size. The device utilization rate of the Kiva System was set to 50%, i.e., 150 of 300 patients in year 1 and 154 of 309 patients in year 2 will receive VCF treatment with the Kiva System, resulting in 304 total number of patients.

Fig. 1 shows the decision-analytic flowchart for patients undergoing VCF surgery with the Kiva System and BK. In both scenarios, patients will stay in the hospital immediately after the surgery. However, subsequent outcomes such as discharge, reoperation, and prolonged hospital stay probabilities will differ in both groups.

The reduction rate of adjacent-level vertebral fractures is a significant clinical outcome that can potentially reduce the overall VCF treatment cost. The KAST study demonstrated that the relative risk reduction in adjacent-level fractures with the Kiva System was 31.6% (95% CI: -22.5%, 61.9%) compared to BK. The absolute risk reduction rate was 6.4% (95% CI: -3.38%, 16.01%) (12).

The direct cost of VCF surgery with BK was based on 2 year cost data reported in Ong et al's paper (21). The average adjusted direct costs for BK patients within the first and second year were reported to be $27,150 (95% CI, $26,394 – 27,927) and $41,339 (95% CI, $40,154, – 42,560) respectively, in 2011 US dollars (USD). These costs were inflated to 2014 USD ($29,394 and $44,756 for year 1 and 2, respectively) for our analysis. The device cost for both the Kiva System and



Abbreviations: VCF, Vertebral Compression Fractures; Kiva System, Kiva® Vertebral Augmentation System; BK, Balloon Kyphoplasty

Fig. 1. *Decision-analytic flow chart.*

BK were set at the published price of $4,319 in 2014 USD to reflect competitive pricing (22). The cost of reoperation with BK was based on Fritzell et al data that reported the cost as $17,510 in 2014 USD over 2 years (23). Other medical costs were calculated by subtracting the BK device cost and reoperation costs from the direct cost. It was assumed that other medical costs would not differ between the Kiva System and BK.

We hypothesized that the reduction in number of adjacent-level fractures with the Kiva System would potentially eliminate the need for reoperation(s), allowing hospital resources such as physician's time, OR availability, and personnel to be allocated in performing other procedures. For the purpose of this analysis, it was assumed that 50% of the OR time saved would be spent performing other procedures, such as revascularization with atherectomy or transluminal stent placement, arthroplasty, laminotomy, laminectomy, and sacroiliac joint stabilization. These procedures were identified based on a prior hospital reimbursement analysis (24) and were adjusted for procedure time based on physician times reported by Centers for Medicare and Medicaid Services (CMS) (25). The costs of these substitute procedures were based on the 2014 Ambulatory Payment Classification (APC) payment rates (26) and were weighted by procedure distribution and frequency, which was extracted from the estimates reported by the State of California Office of Statewide Health Planning and Development (26). Table 1 shows the clinical and economic input parameters that were included in the base case analysis to compare the hospital resource use and cost between the Kiva System and BK.

Table 1. *Input parameters.*

Parameter	Value
Target population	
VCF patients eligible for VA surgery, nationwide per year (19)	165,000
Number of surgeries in the hospital, per year	300
Device utilization (27)	
Base year market share	50.0%
Clinical outcomes	
Relative reduction in adjacent-level fractures by Kiva System* (12)	-31.6%
Direct costs, per patient	
Direct cost, BK** (21,28,29)	
1 year	$29,394
2 years	$44,756
Device costs (30)	
Kiva System	$4,319
BK	$4,319
Reoperation cost (23)	
1 year	$11,500
2 years	$17,510
Cost savings with more efficient resource use of OR time and personnel (Efficiency costs)	
Include	
Surgeon (or hospital) opportunity cost (24-26)	$9,499
Proportion of substitutable procedures	50%
Year of APC rates	2014
Time horizon, years	**2**

Abbreviations: VCF, Vertebral Compression Fracture; VA, Vertebral Augmentation; Kiva System, Kiva® Vertebral Augmentation System; BK, Balloon Kyphoplasty; OR, Operating Room; APC, Ambulatory Payment Classification
*Absolute risk reduction = 6.4%
** Included device cost, reoperation cost, and other medical costs
All costs reported in 2014 USD

Sensitivity Analysis

One-way sensitivity analysis was performed to determine which factors had the greatest impact on the difference in VCF surgery costs between the Kiva System and BK. The 95% confidence intervals provided in the KAST and other published literature were utilized to set the range for input parameters. A default value of ± 25% was used when the direct value was not available.

Results

Considering a 50% device utilization rate for the Kiva System in a representative hospital, 304 (of 609 total) vertebral augmentation procedures will be performed using the Kiva System during a 2 year time period. With a relative rate reduction of 31.6% in adjacent-level fractures, use of the Kiva System in place of BK led to 10 fewer adjacent-level fractures over one year and 19 less adjacent-level fractures over 2 years (Table 2). The total cost savings with the Kiva System compared to BK is $1,118 per patient and $280,876 per hospital over 2 years. The difference in total medical costs is attributable to the reduction in adjacent-level fracture risk with the Kiva System.

The findings from this economic analysis suggest that with the reduction of 19 adjacent-level vertebral augmentation procedures, hospital resources (physician's time and OR time) can be utilized towards 7 additional procedures, with adjustment for procedure time. Considering the average cost of $9,499 per procedure, the Kiva System offers additional efficiency cost savings (i.e., generate additional hospital revenue) of $227 per patient and $69,179 per hospital over 2 years (Table 3).

The results of the one-way sensitivity analysis are shown in Table 4. Of the 9 parameters that were varied, the difference in costs per patient was most sensitive to variance of the reduction in the rate of adjacent-level fractures (ranging from -$2,185 to $795), followed by the cost of the device (ranging from -$2,197 to -$38). Per hospital costs were most sensitive to the number of surgeries performed in the hospital during the first year

Table 2. *Base-case results.*

	Kiva System	BK	Difference
Epidemiology			
Patients eligible for VCF treatment	609	609	0
Patients treated	304	304	0
Adjacent-level fractures			
Number of patients	42	61	-19
Direct costs			
Cumulative per patient initial surgery costs			
Device cost	$4,319	$4,319	$0
Direct medical costs	$39,320	$40,437	-$1,118
Total	$43,638	$44,756	-$1,118
Overall for patients treated over time horizon*			
Device cost	$1,314,065	$1,314,065	$0
Direct medical costs	$9,653,484	$9,934,360	-$280,876
Total	$10,967,549	$11,248,425	-$280,876

Abbreviations: Kiva System, Kiva® Vertebral Augmentation System; BK, Balloon Kyphoplasty
*Time horizon set to 2 years
All costs reported in 2014 USD

Table 3. *Base-case results with efficiency costs related to operating room use and time.*

	Kiva System	BK	Difference
Epidemiology			
Patients eligible for VCF treatment	609	609	0
Patients treated	304	304	0
Adjacent-level fractures			
Number of patients	42	61	-19
Costs			
Cumulative per patient surgery costs			
Device cost	$4,319	$4,319	$0
Direct medical costs	$39,320	$40,437	-$1,118
Efficiency costs	$0	$227	-$227
Total	$43,638	$44,983	-$1,345
Overall costs for patients treated over time horizon*			
Device cost	$1,314,065	$1,314,065	$0
Direct medical costs	$9,653,484	$9,934,360	-$280,876
Efficiency costs	$0	$69,179	-$69,179
Total	$10,967,549	$11,317,604	-$350,055

Abbreviations: Kiva System, Kiva® Vertebral Augmentation System; BK, Balloon Kyphoplasty
*Time horizon set to 2 years
All costs reported in 2014 USD

(ranging from $1,320,117 to -$132,012), followed by the risk reduction in adjacent-level fractures (ranging from -$549,160 to $199,897). Fig. 2 shows the tornado diagram comparing the relative importance of variables included in this economic evaluation.

Discussion

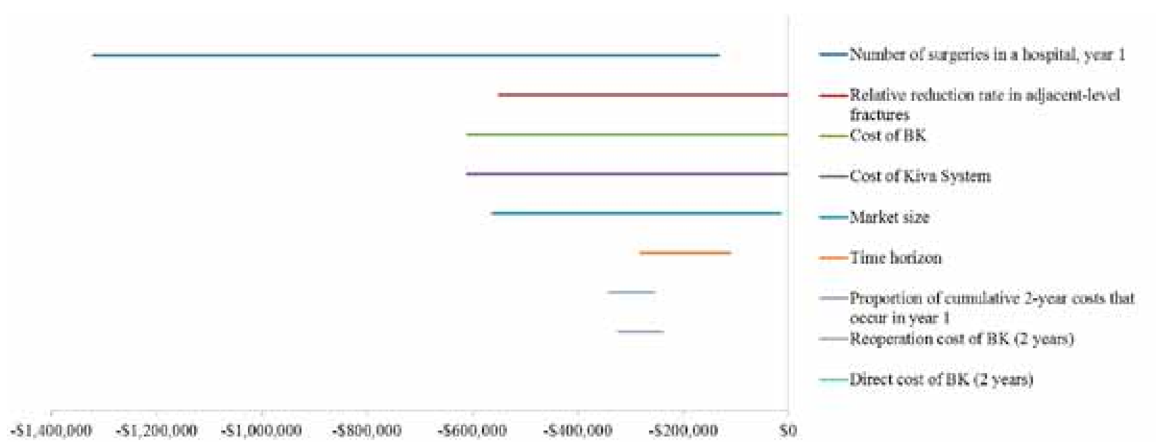
This is the first economic analysis of the Kiva System to assess the hospital resource use and direct costs associated with VCF surgery compared to BK in a hospital setting. The Kiva System saves $1,118 per patient and $280,876 per hospital in direct costs over a 2 year time period. The results of this analysis were based on the findings from a Level-I randomized controlled trial (12) and demonstrate that VCF treatment with the Kiva System offers substantial cost savings as compared to BK.

Limitations to this analysis stem primarily from the variability in unit-cost estimates. The incidence of VCFs

Table 4. *One-way sensitivity analysis.*

Parameter	Base case	Range		ΔCosts per patient			ΔCosts per hospital		
		Lower	Upper	Left	Right	Difference	Left	Right	Difference
Number of surgeries in a hospital, year 1	300	141	1410	-$1,118	-$1,118	$0	-$132,012	-$1,320,117	$1,188,105
Relative reduction rate in adjacent-level fractures	-31.6%	-61.9%	22.5%	-$2,185	$795	$2,980	-$549,160	$199,897	$749,057
Cost of BK	$4,319	$3,239	$5,398	-$38	-$2,197	$2,159	$47,640	-$609,392	$657,032
Cost of Kiva System	$4,319	$3,239	$5,398	-$2,197	-$38	$2,159	-$609,392	$47,640	$657,032
Market size	50.0%	3%	100%	-$1,118	-$1,118	$0	-$14,044	-$561,752	$547,708
Time horizon	2	1	2	-$734	-$1,118	$384	-$110,096	-$280,876	$170,780
Proportion of cumulative 2 year costs that occur in year 1	65.7%	50%	100%	-$1,118	-$1,118	$0	-$253,846	-$340,058	$86,212
Reoperation cost of BK (2 years)	$17,510	$13,133	$21,888	-$838	-$1,397	$559	-$238,967	-$322,785	$83,817
Direct cost of BK (2 years)	$44,756	$43,473	$44,995	-$1,118	-$1,118	$0	-$280,876	-$280,876	$0

Abbreviations: BK, Balloon Kyphoplasty; Kiva System, Kiva® Vertebral Augmentation System
All costs reported in 2014 USD



Abbreviations: BK, Balloon Kyphoplasty; Kiva System, Kiva® Vertebral Augmentation System

Fig. 2. *One-way sensitivity analysis tornado diagram.*

has been reported to be highest among the Medicare population; however, the target population may vary among different hospital settings causing potential selection bias. The cost estimates used in this analysis from the Ong et al study (21) were based on 5% Medicare dataset (2005 – 2008) and derived cumulative costs from all resources (inpatient, outpatient, physician/carrier, skilled nursing facilities, home health agencies, hospice, and durable medical equipment claims files). While the utilization and costs of these hospital resources may vary for different hospital settings, this was the only available study that reported reoperation costs associated with BK. Hospital admissions due to device related side effects are uncommon. Peer-reviewed documentation of the rate of these admissions is limited thus they were omitted from our analysis. Reduction in the VCF related pain and adjacent-level fracture risk with the Kiva System can be expected to reduce or eliminate the need for concomitant pain medications, e.g., aspirin and narcotics. The costs associated with reduction in use of pain medications were not included in the final cost saving estimate.

VCF surgery and the management of surgery-related complications can cause significant societal burden to patients both from direct and indirect costs perceptive. The indirect cost includes post-surgery effects on work absenteeism. The Fritzell et al study (23) reported no difference between BK and standard medical treatment groups as virtually no study patients were working due to old age. Our aim was to assess economic impact of the Kiva System from the hospital perspective including direct costs only.

Mortality risk has been shown to increase by almost 9-fold following first VCF (4). The effect of the Kiva System on the survival rate of patients can provide additional insights on the societal implications of its use in hospital settings; however, these data are not yet available. Understanding of comorbidities is crucial as well, particularly among the Medicare population where the majority of older adults are commonly documented with at least one major comorbid condition. However, Edidin et al's subgroup analysis (31) confirmed that the mortality difference between BK and VP was not sensitive to the presence of comorbid conditions. In light of the imbalance in risk factors favoring the control group, there is an ongoing effort to further evaluate these trends.

Cost analyses showing the economic consequences of different available treatments are of high relevance in health care decision makers' ability to optimize allocation of limited resources. The additional clinical benefits demonstrated in the KAST, such as less total volume of cement delivered and lower rates of extravasation, may lead to additional cost savings. Future research on this topic is needed; cost-utility analysis of the Kiva System to quantify the impact on quality of life of patients with VCF will be useful.

Conclusion

This first-ever economic analysis of the KAST data showed that the Kiva System for vertebral augmentation is resource and cost saving over BK in a hospital setting over 2 years. These savings are attributable to reduced risk of developing adjacent-level fractures with the Kiva System compared to BK.

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