

Research Article

High Value Tibial Nail Utilization Improves Cost Without Compromising Outcomes: Experience at a Level II Trauma Center

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Keywords: cost containment, generic implants, high value implants, tibial nail

<https://doi.org/10.60118/001c.28237>

Journal of Orthopaedic Experience & Innovation

Vol. 2, Issue 2, 2021

Introduction

In today's opportunistic healthcare climate, value based care has moved to the forefront of cost containment. With respect to orthopaedic trauma, it has become increasingly important to factor cost into the treatment of an often underinsured patient population. As patents expire on many commonly used trauma implants, high value alternatives represent an excellent opportunity for trauma surgeons to provide value-based care so long as it does not compromise outcomes. The objective of this study was to appraise the

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clinical and economic impact of the use of high quality, low-cost tibial nails in the treatment of tibial shaft fractures.

Methods

Two hundred patients treated with high value tibial nail implants were compared to two hundred patients treated with conventional implants at a busy community level II trauma center between January 2011 and December 2019. Operative records were reviewed to identify intraoperative complications, operative time, and estimated blood loss. Cases of infection, malunion, nonunion, or need for repeat surgery were recorded. Hospital financial records were analyzed to determine implant cost.

Results

There was no appreciable difference in age, sex, diabetes, smoking, or American Society of Anesthesiologist (ASA) physical status score between the high value and conventional groups. A significant difference in operative time was observed. No differences were observed in intraoperative or postoperative complications. There was no significant difference found in return to the operating room or interlocking screw removal. Analysis found an average of \$735 per case in implant savings. This represented a 38% reduction in implant cost with an overall realization of \$147,000 in savings across the study period.

Conclusion

The use of high value tibial nails at our institution resulted in significantly reduced implant expenditures with equivalent radiographic and clinical outcomes. Based on this data, the use of high value tibial nail implants has potential to markedly reduce operative costs without compromising patient care as long as quality products are utilized.

INTRODUCTION

In the current healthcare and political climate, value based care has moved to the forefront of cost containment discussions. Within healthcare, Michael Porter, PhD, of Harvard Business School discussed the term “high value” as an equation of quality/cost (Porter 2010). Within orthopaedics, trauma surgery has a potential to provide high value healthcare to a population who is often under- or uninsured through appropriate implant choice and utilization.

The orthopaedic trauma implant market in 2018 was \$3.8 billion with a forecasted capitalized annual growth of 3.5% to reach \$4.5 billion by 2025 (“U.S. Market for Orthopedic Trauma Devices.” 2019). There is substantial room for cost savings within this environment. Previously, there has been documented cost savings in forms such as matrix pricing, sole-source contracting, and single or dual vendor negotiation (Althausen, Lapham, and Mead 2016). Several recent publications have demonstrated cost effectiveness with the use of high value implants in orthopaedic trauma (McPhillamy et al. 2016; Althausen et al. 2014; Lybrand and Althausen 2018; Gurnea et al. 2021). As availability of high value implants increases, it is important that the clinical efficacy of these devices is evaluated and compared to conventional implants to ensure that improved cost does not come with compromised patient care. The purpose of our study is to evaluate cost containment and clinical outcomes resulting from high value tibial nail utilization at our trauma center.

METHODS

After approval by the institutional review board, four trauma trained orthopaedic surgeons at our facility began to utilize high value intramedullary nail implants (Orthopedic Implant Company, Reno, NV) in 2016. Prior to utilization, these implants had been biomechanically tested to ensure equivalence to major conventional implants. A review of our trauma database from January 1, 2011 to December 31, 2019 was performed. All patients treated with tibial shaft fractures with high value intramedullary nail were included and a consecutive group of an equal number of patients who were treated with conventional implants was identified. Patients under the age of 18 and those with pathologic fractures were excluded. In addition, polytrauma patients who underwent multiple procedures during a single anesthetic were removed as operative time for the tibial nailing alone could not be extracted. All patients were treated with a reamed intramedullary nail with interlocking screws. Preoperative, intraoperative, and postoperative protocols were similar in both high value and conventional implant groups. Implant selection was based on surgeon discretion.

Retrospective chart review of all identified patients in the high value and conventional implant group was completed to obtain demographics such as age, sex, smoking history, and presence of diabetes. Operative records were reviewed to determine operative time, approach, and intraoperative complications. Hospital and clinic data was analyzed to determine any postoperative complications such as malunion, nonunion, infection, and symptomatic hardware. Clinic charts were reviewed by authors blinded to implant type to minimize bias. Pricing was obtained from the

Table 1. Patient Demographics for Tibia Fractures

	Conventional (n=200)	High Value (n=200)	P-value
Mean (SD) Age, y	45.0 (17.1)	47.1 (17.7)	0.59
Sex, % male	66.3%	65.0%	0.07
Mean (SD) ASA Score	2.26 (0.96)	2.28 (0.83)	0.80
Smoking Status, %	27.5%	30.7%	0.95
Diabetic, %	10.1%	10.0%	0.99

hospital materials manager based on standard constructs to determine implant costs.

Data was then analyzed using Microsoft Excel v16.32 for Mac. Descriptive statistics were used to describe data. Two sample T-tests were applied to detect differences of means for continuous variables and chi-square tests were performed to test the differences of proportions of categorical variables between conventional and high value groups. Level of significance was set as p-value <0.05.

RESULTS

Retrospective review of our institutional database identified 200 patients treated with high value implants for tibia shaft fractures which were compared to a consecutive series of 200 patients treated with conventional implants for similar injuries. [Table 1](#) demonstrates patient demographics. Mean (SD) age was 47.5 (17.7) in the conventional group and 45 (17.1) in the high value group (p=0.59). The conventional group was 66.3% male while high value group was 65% male (p=0.07). Mean (SD) ASA score was 2.26 (0.96) in the conventional group and 2.28 (0.83) in the high value group (p=0.80). Smoking in the conventional and high value groups were 27.5% and 30.7% respectively (p=0.95). Prevalence of diabetes was 10.1% and 10.0% in the conventional and high value groups respectively (p=0.99). No significant differences were found in any recorded patient demographic.

There was no significant difference in mechanism of injury ([Table 2](#)). There was no significant difference in estimated blood loss (p=0.65). There were no intraoperative complications in either group. There was a significant difference in mean operative time with 76.6 minutes in the conventional group and 56.2 minutes in the high value group (p<0.01) ([Table 3](#)). Mean healing time for the conventional group was 137 days and 116 days for the high value group (p<0.01). Chart review did not show a statistically significant difference in postoperative complications including infection (p=0.74) or nonunion (p=0.65). There was no hardware failure in either group. There was no significant difference in all cause return to the operating room (p=0.13) or symptomatic hardware requiring screw removal (p=0.20) ([Table 4](#)).

Cost analysis showed a mean implant cost of \$1,935 for the conventional group and \$1,200 for the high value group. This represents an average implant cost savings of \$735 (38%) with the use of high value implants (p<0.01)

([Table 5](#)). Total savings across our study group was approximately \$147,000.

DISCUSSION

National healthcare spending continues to rise at a concerning rate. In 2017, national healthcare spending topped \$3.5 trillion, roughly \$10,739 per person in the United States (Centers for Medicare & Medicaid Services, n.d.). The orthopedic trauma implant market is only a small fraction of that at an estimated \$3.8 billion in 2018 ("U.S. Market for Orthopedic Trauma Devices." 2019). Nevertheless, healthcare professionals have a responsibility to help curtail healthcare spending and contain costs. However, care must be taken to ensure that cost containment does not come at the expense of patient safety and outcomes. High value orthopedic implant options have only become available in recent years as patents expire on proven conventional implants. When compared to articles demonstrating the clinical equivalence of high value medications, there is a relative dearth of data regarding high value orthopaedic implants.

Only four articles comparing clinical equivalence and cost containment in orthopaedic implants were identified. The first published article in 1995 by Waddell *et al* evaluated high value total hip arthroplasty in Canada. The use of high value implants resulted in no increased complication rates and no decrease in hip scores when compared to the conventional branded equivalents (Waddell and Morton 1995). The remainder of published articles come from our facility. Althausen *et al* examined the impact of high value 7.3-mm cannulated screws on cost and outcomes in femoral neck fractures and percutaneous sacroiliac fixation. This article demonstrated a 70% reduction in implant costs without a change in clinical outcome (Althausen *et al*. 2014). Papers by McPhillamy *et al* and Gurnea *et al* similarly evaluated high value locking plate fixation and external fixator utilization demonstrating a 56% and 58% reduction in implant costs respectively without a difference in clinical outcomes (McPhillamy *et al*. 2016; Gurnea *et al*. 2021). Our study adds to the existing data, now demonstrating similar results with intramedullary nail fixation of tibia shaft fractures with a robust 38% implant cost reduction without diminishing clinical outcomes.

Despite growing literature to support the use of high value implants, barriers still exist to its widespread adoption. In an OTA survey conducted by Walker *et al*, concern regarding the track record of high value implants was a

Table 2. Mechanism of Injury

	Conventional (n=200)	High Value (n=200)	P-value
Fall	36.2%	19.6%	0.07
Motor vehicle accident	8.51%	17.4%	0.20
Other	55.3%	63.0%	0.45

Table 3. Intraoperative Data

	Conventional (n=200)	High Value (n=200)	P-value
Mean (SD) Operative Time (minutes)	76.6 (45.4)	56.2 (35.2)	<0.01
Mean (SD) Estimated blood loss (mL)	10.1 (13.8)	15.4 (11.2)	0.65
Intraoperative Complications	0	0	N/A

Table 4. Postoperative Data

	Conventional (n=200)	High Value (n=200)	P-value
Infection	2.0% (4)	2.5% (5)	0.74
Nonunion	4.5% (9)	5.5% (11)	0.65
Hardware Failure	0.00%	0.00%	N/A
Healing time, days	137	116	<0.01
All cause return to OR	37	26	0.13
Screw Removal	20	13	0.20

Table 5. Cost Data

	Conventional (n=200)	High Value (n=200)	P-value
Mean implant cost per case	\$1,935	\$1,200	<0.01
Mean savings per case	-	\$735	-
Total Study Savings	-	\$147,000	-

common reason for why respondents had not begun utilizing them (Walker and Althausen 2016). Despite 96% of respondents prescribing high value medications regularly, only 25% of responding surgeons utilized high value implants for their patients. This is despite 75% having an awareness of high value implants availability. Among other reasons for lack of use were satisfaction with current implants and a lack of financial incentive to change.

There are many barriers to adoption of high value implants including surgeon and hospital conflicts of interest. Some orthopaedic surgeons are paid consultants or have royalty agreements with conventional branded companies. This financial relationship can introduce difficulty in eliciting change. Additionally, many hospitals receive educational and research grants from large implant companies or their parent companies. Fear may exist that implementation of a high value implant program could result in a loss of research funding. We propose that a portion of cost savings from use of high value implants could be reinvested toward service line improvements or research, thus freeing institutions from bias when making implant decisions. Ad-

ditionally, many high value implants, including the one utilized in this study, do not utilize company sales representatives and offer limited support in the operating room. This can be a factor in settings where these individuals are relied upon by the surgical staff to ensure smooth flow of cases in the operating room.

At our institution, several conditions exist that enable rapid acceptance of the high value implant model. Our orthopaedic surgeons have a management services agreement (MSA) with the hospital which includes value-based metrics for care. This incentivizes surgeons to maintain quality care while decreasing supply and implant costs, length of stay, and resource utilization. In addition, our trauma surgeons own stock in the high value company whose products were utilized in this study. They do, however, also own stock in the branded conventional implant companies utilized in the second group. There is no doubt that these conditions play a role in more rapid and fluid adoption of high value implants at our facility.

Our surgeons first began utilizing high value alternatives for fracture fixation in 2012. We have also employed other

cost savings strategies such as matrix pricing on hemiarthroplasty and nail constructs resulting in massive savings (Althausen, Lapham, and Mead 2016). Despite concern that high value implant use may negatively affect pricing on unique implants and instruments by conventional companies, the significant savings due to these programs has allowed the hospital to more effectively negotiate pricing on these products. Anecdotally, there has also been a perception of improved service from conventional company vendors as they work to preserve their market share.

As with similar generic products, high value orthopaedic implant credibility and viability of use rely on the research community to properly test these implants against their proven conventional counterparts to ensure there is no clinical inferiority. We continue to add to the growing number of peer reviewed articles comparing cost-effectiveness and clinical outcomes. Interventions with equivalent effectiveness at less than half the price are clearly beneficial. It magnifies the concept that surgeons can positively impact healthcare costs without compromising patient safety or outcome. As focus continues to shift on limiting healthcare resources, we must continue to find new ways to reduce costs. Cost savings programs such as high value implant utilization will continue to grow in importance as a way to preserve patient outcomes in an increasingly restrictive system.

Our study is not without limitations. As previously mentioned, financial conflicts do exist including ownership stakes in the high value implant company utilized in our study. This did play a role in adoption and ability to obtain these implants early. Additionally, our study focuses only on implant savings. We do not take into account the initial hospital cost to acquire these implants. We did find a significant difference in operative time which cannot entirely be explained by having all implants including nail and interlocking screws within the sterilized set. No portion of our analysis gave insight into the significant difference between implant groups. If this time difference were to hold true over a larger group, this could be another area of sav-

ings not accounted for in our analysis (Moody et al. 2020; Macario 2010).

As supported with prior literature, screw related complications were present in our study. We did not, however, show any statistically significant difference in conventional (20) versus high value (13) screw removal ($p=0.20$). The incidence of screw removal in our study is consistent with larger publications such as Hendrickx et al who demonstrated a 9% incidence for symptomatic hardware irritation (Hendrickx et al. 2020). Selection bias could have been present in our study as implant selection was at the discretion of individual surgeons. Our results, however, demonstrate no significant differences in the patient demographics across groups. Finally, our study outcomes only include complications and radiographic union. Future studies should include randomized, blinded trials and should outcome scores such as PROMIS to create more transparency and objectivity in outcomes.

CONCLUSION

The utilization of high value intramedullary tibial nail constructs has been a successful endeavor at our facility. Our institution was able to reduce implant costs by 38% and save a total of \$147,000 over our study period. There was no associated increase in complication rate or change in radiographic outcomes in study populations. Continued expansion of high value implant design and usage could markedly reduce implant costs in a similar manner to the generic pharmaceutical industry. Surgeons must be careful to select implants that are high quality and will not compromise patient care. The burden of cost containment will continue to fall on the shoulders of healthcare professionals. High value implant utilization such as the tibia nail utilized in this study is another tool to ensure we can provide effective high value care going forward.

Submitted: June 23, 2021 EDT, Accepted: September 15, 2021 EDT



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