Is a Low-Cost Drill Cover System Non-Inferior to Conventional Surgical Drills for Skeletal Traction Pin Placement?

SUMMARY

The Drill Cover system was developed as a low-cost alternative to conventional surgical drills with specific applicability to low- and middle-income countries. However, the system may also be useful for the sterile placement of traction pins in the emergency department of high-income country hospitals. In September 2019, a US-based Level-1 trauma center began using the Drill Cover system to apply skeletal traction pins in patients with femoral shaft fractures. With these data, we performed a retrospective interrupted time series study to determine if the Drill Cover system was non-inferior to conventional surgical drills in terms of infections at the traction pin site. The study included 205 adult patients with femoral shaft fractures initially placed in skeletal traction using a conventional surgical drill (n=150, pre-intervention group) or the Drill Cover system (n=55, post-intervention group). The primary outcome was an infection at the site of skeletal traction pin placement that required surgery or antibiotics was compared between groups using a non-inferiority test with a one-sided alpha of 0.05 and a non-inferiority margin of 3%. No infections at the site of skeletal traction pin placement were found in either the pre-intervention or the post-intervention group (difference 0%, 95% CI: 0.0 to 1.4%, non-inferiority p-value<0.01). The results suggest that the Drill Cover system was non-inferior to conventional surgical drills regarding infections at the site of skeletal traction pins. The Drill Cover system may be a safe alternative to the more expensive surgical drills for skeletal traction pin placement in the emergency room environment.

INTRODUCTION

Frugal innovations are effective, well-performing products, designed with economic and resource constraints in mind [1-3]. These innovations often originate in low-income countries and are engineered to perform under austere conditions [4]. However, many of these devices may also benefit high-income country healthcare systems striving for value-based care [5-7].

The Drill Cover system (Arbutus Medical Inc., Vancouver, Canada) is one potential example of a frugal innovation. At less than one-tenth the cost of conventional surgical drills [6], this system was designed to be a low-cost alternative. It consists of a reusable medical-grade fabric cover that enwraps a regular hardware drill with a chuck adapter to create a sterile device with similar microbiological and mechanical performance metrics to conventional surgical drills [6,8]. In low-income countries, the price tag of at least USD 30,000 for a conventional drill is often cost prohibitive [6]. However, the Drill Cover system allows hardware drills to be safely used for fracture surgery. In high-income countries, the implementation of this device could reduce the upfront cost of procuring drills' or increase the supply of available drills [6]. Specifically, the Drill Cover system may be well-suited for skeletal traction pin placement - a procedure often performed outside of the operating room. The hardware drills could be kept in emergency rooms with multiple covers available for easy access and use.

The Drill Cover system has been approved by regulatory bodies in the US and Canada, and used in clinical practice in low-income countries and military settings. Post-market surveillance is currently available through the company but no formal evaluations on the safety of the drill for treating fractures has been performed. This study aimed to determine if the Drill Cover system

was a safe alternative to conventional surgical drills for applying skeletal traction pins in patients with femoral shaft fractures. We hypothesized that the Drill Cover system was non-inferior to conventional surgical drills on infection at the site of traction pin insertion .

PATIENTS AND METHODS

Study Design

A Level I trauma center in the United States began using the Drill Cover system for skeletal traction pin placement in September 2019, creating the ideal setting for a quasi-experimental study. As such, we conducted an interrupted time series analysis to compare infection outcomes from patients treated with conventional surgical drills (pre-intervention group) to patients treated with the Drill Cover system (post-intervention group). The Institutional Review Board at the [redacted] approved the study with a waiver of consent as the research was deemed no more than minimal risk (HP-00091633).

Study Participants

The study included adult patients with femoral shaft fractures that had documented skeletal traction. Following skeletal traction, all patients either underwent subsequent intramedullary nailing or had an external fixator placed then underwent intramedullary nailing at a second surgery. Per institution protocol femoral shaft fractures routinely received placement of a traction pin in the emergency department prior to surgery. The pre-intervention group included patients who received skeletal traction using conventional surgical drills between January 2018 and August 2019. The post-intervention group included patients who received skeletal traction using the Drill Cover system between October 2019 and June 2020. September 2019 was a washout

period, and we excluded patients who received skeletal traction in that month. Patients were also excluded if their chart did not have at least 30 days of follow-up information.

Interventions

The traction pins in this system are placed by resident orthopaedic surgeons in the emergency department with local antiseptic skin prep and draping. Historically, the pins were inserted using the same drill that is used in the operating room. These drills are expensive to purchase and must be maintained. Additionally, two were lost in the preceeding year motivating a change in practice. The Drill Cover was introduced and the procedure for inserting all traction pins was modified to use this system instead of the sterile operating room drills.

The technical aspects of the Drill Cover system have been previously reported [8]. In brief, the system uses a fitted sterilizable medical-grade fabric cover to wrap an off-the-shelf hardware drill sealed with a surgical chuck adaptor (**Figure 1, Figure 2**). The system has been approved for human use by the US Food and Drug Administration, Health Canada, and is in the process of securing a CE mark. The study location adopted the Drill Cover system to apply skeletal traction pins in femoral shaft fracture patients for two reasons. First, the cost of the Drill Cover system is an order of magnitude lower than conventional surgical drills, up to 94% less [6]. Skeletal traction pins were predominately applied while the patient was in the trauma resuscitation unit, which did not previously have a dedicated supply of surgical drills.

Outcome

The primary outcome was infection at the site of skeletal traction pin placement. This outcome variable was chosen because iatrogenic infection was the primary concern of this new technology as it no longer used a sterile drill. Although the procedure still used the same sterile pin place into the femur. We defined infection at the pin site based on Center for Disease Control and Prevention criteria and recorded any instances of either surgery or antibiotic treated infection at the pin site placement [9]. Due to concern that infection at the site of the skeletal traction pin would be a rare event [10], several sources of data were carefully reviewed for possible infection information. Specifically, we monitored daily orthopaedic progress notes, consultations with infectious disease specialists, and discharge summaries. Additionally, we reviewed all documentation from orthopaedic post-operative visits and any emergency department encounters for at least 30 days after skeletal traction. To ensure that one group was not at a higher risk for infection, we collected data on known risk factors for infection, including age, body mass index, smoking status, diabetes status, and open fractures.

Sample Size Calculation

Assuming a 1% pre-intervention infection rate, we estimated that 274 patients provided 80% power to conclude non-inferiority with a non-inferiority margin of 3% and a one-sided alpha of 0.05. Hospital admissions were substantially lower during the post-intervention period than anticipated, likely attributable to the COVID-19 pandemic. While the overall sample size did not reach our initial target, the study maintained over 80% for the primary comparison due to the negligible event rate.

Statistical Analysis

Continuous variables (age, body mass index) were compared between groups using t-tests. Categorical variables (sex, race, ethnicity, mechanism of injury, smoking status, percentage of diabetic patients, and percentage of open fractures) were compared between groups using chi-square analysis. To compare infection rates, we used a non-inferiority test with a one-sided alpha of 0.05 and a non-inferiority margin of 3%. For all statistical tests, $p < 0.05$ was considered statistically significant. All analyses were performed using R Version 4.0.0 (Vienna, Austria).

RESULTS

Of the 357 patients who met the inclusion criteria, we excluded 94 patients lacking documentation of skeletal traction, 41 patients without 30 days of follow-up information available, and 17 patients under 18 years of age. Among the 205 patients included in the final analysis, 150 patients were in the pre-intervention group, and 55 patients were in the post-intervention group.

The mean age of the sample was 36 years (SD: 18), and 34% were female. The majority of the fractures were due to high energy mechanisms (85%), and 19% had an open fracture. Nearly one-third reported regular tobacco use, and 7% were diabetic. There was no evidence of an imbalance in infection risk factors between the groups (**Table 1**).

There were no infections at the site of skeletal traction pin placement in either the pre-intervention or post-intervention group (difference, 0%, 95% CI: -1.4% to 1.4%, non-inferiority p-value<0.01). One patient from the pre-intervention group and one from the

post-intervention group complained of severe or burning pain at the site of the skeletal traction pin, but neither had further evidence of infection.

DISCUSSION

The findings suggest that the Drill Cover system may be non-inferior to conventional surgical drills in preventing pin site infection in femoral shaft patients treated with skeletal traction. Emergency departments may consider implementing this lower cost strategy for routine skeletal traction pin insertion.

While the Drill Cover system is increasingly utilized in low- and middle-income countries [6], the results of the study support the potential value of the system for hospitals in high-income countries. Conventional surgical drills cost more than $30,000 USD and pose a considerable expense for the budgets of surgical departments [6]. Given the costs, a hospital's supply of surgical drills is typically restricted to the operating rooms. Demands for the drills in other areas, such as the emergency department, can present workflow challenges. A low-cost alternative with comparable performance to conventional surgical drills would allow for a decentralized supply of drills. Additionally, the Drill Cover system may extend the life of other surgical drills at the facility, thus reducing the frequency of replacement of more expensive, conventional surgical drills for use in the operating room [6].

The study had several limitations. The primary outcome of the study was known to be rare, and while we performed an extensive chart review [9], no events were detected. The infrequency of

the outcome is consistent with anectdotal evidence that traction pins rarely have infections and this result is not entirely unexpected. The reporting of skeletal traction was inconsistent within the patient charts so it is possible that we excluded some patients who actually had traction pins. However, we believe the skeletal traction application rate of 69% to have face validity for this study population as some femoral shaft fracture patients do not receive traction pins based on various factors such as being rushed urgently to the operating room for other injuries. Finally, the study only assessed the use of the Drill Cover system for the application of skeletal traction pins. Further research is required to determine if the findings generalize to other orthopaedic procedures that maybe performed outside traditional operating rooms, such as k-wire insertion in the emergency department or minor procedure rooms.

In summary, no femoral shaft patients treated with the Drill Cover system or a conventional surgical drill were found to have developed an infection at the site of the skeletal traction pin. This finding suggests the Drill Cover system likely has a non-inferior infection rate compared to the use of a sterile operating room drill for this task in the emergency department. Our findings suggest that infection does not appear to be a major concern associated with this use of this technology.

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Table 1. Patient characteristic (n=205)

	Pre-Intervention (n=150)	**Post-Intervention (n=55)**	**P-value**
Age, years, mean (SD)	36.1 (18.5)	36.8 (18.2)	0.81
Female, n (%)	54 (36.0%)	15 (27.3%)	0.32
Race, n (%)			0.06
African-American	74 (49.3%)	23 (41.8%)	
White	62 (41.3%)	22 (40.0%)	
Asian	4 (2.7%)	0 (0%)	
Other	10 (6.7%)	10 (18.2%)	
Hispanic or Latino, n (%)	10 (6.7%)	8 (14.5%)	0.15
BMI, mean (SD)	28.4 (8.25)	27.5 (6.74)	0.46
High energy mechanism, n (%)	126 (84.0%)	49 (89.1%)	0.49
Open fractures, n (%)	22 (14.7%)	16 (29.1%)	0.05
Bilateral fracture, n (%)	16 (10.7%)	2 (3.6%)	0.19
Diabetic, n (%)	13 (8.7%)	2 (3.6%)	0.33
Current tobacco use, n (%)	44 (29.3%)	19 (34.5%)	0.68

FIGURE LEGEND

Figure 1. The Drill Cover system includes a sterilizable fabric cover and chuck adaptor to encompass a hardware drill. The drill is not sterile but is placed inside the sterile bag. The pin is still sterile.

Figure 2. The study location implemented a dedicated supply of Drill Cover systems in the emergency department.