Full length article

Inpatient orthopaedic hardware removal in children: A cross-Sectional study

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ABSTRACT

Introduction: Few data describe the specific reasons for inpatient hardware removal in the pediatric population. This study was designed to understand the conditions necessitating inpatient removal following fracture surgery. Cost data was analyzed to understand the financial implications of these procedures.

Methods: The Kids' Inpatient Database (KID) was evaluated for the year 2012. Patients undergoing open reduction internal fixation following upper and lower extremity fractures as well as those undergoing hardware removal due to hardware complications were identified using ICD-9 CM diagnosis and procedure codes. Univariable and multivariable logistic regression were used to determine predictors of surgical removal due to complications, controlling for patient demographics and comorbidities.

Results: The most common indication for removal was infection (1141 patients; 32%), followed by mechanical dysfunction (923; 25.4%), and pain (472; 13%). Logistic regression analysis showed that femur fractures (OR = 8.27, 95% CI: 7.63–8.96) and tibia/fibula fractures (OR = 1.24, 95% CI: 1.17–1.35) were independent predictors of infection-related hardware removal ($P < 0.001$). Patients who underwent removal due to infection were more likely to have asthma (OR = 1.87, 95% CI: 1.62–2.07), smoke tobacco (OR = 1.12, 95% CI: 1.05–1.23), and suffer from developmental delays (OR = 1.32, 95% CI: 1.19–1.54) ($P < 0.001$). Average hospital charges and costs were \$36,349 and \$11,792 respectively.

Conclusion: While most commonly performed as an outpatient procedure, inpatient hardware removal occurs with relative frequency and is most often performed for infection, mechanical failure, or pain. Risk factors for infection-related removal were identified and provide a basis for further investigation.

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1. Introduction

Operatively treated fractures in pediatric patients most commonly occur in the extremities. Following initial fixation, hardware removal is one of the most common procedures performed by pediatric orthopedic surgeons. However, there exists a paucity of literature examining the indications for hardware removal after open reduction internal fixation (ORIF). In addition, few explicit guidelines address the specific indications for hardware removal following ORIF. Pediatric orthopedic surgeons nonetheless remove hardware for a variety of reasons in children including pain, infection, and surgeon and patient preference.¹

Fracture fixation in the pediatric population often involves implantation of hardware either with closed reduction and percutaneous pinning (CRPP) or ORIF. While percutaneous pins can be routinely removed in the outpatient setting, no official guidelines or recommendations have been published regarding removal of internal hardware after successful fracture healing.² The decision to remove hardware in the pediatric patient is varied and may be related to fear of affecting future growth, surgeon preference to not leave hardware in young patients, or patient/family preference. Despite the lack of evidence-based guidelines, common pediatric orthopedic practice is to remove hardware in children after fracture healing or upon patient/family request.^{3–5} Reported indications for hardware removal include pain, soft tissue irritation, and infection.^{6,7} While a majority of these procedures are done in the outpatient setting, little is known about the factors associated with inpatient hardware removal. Furthermore, given the high prevalence of infection in ORIF patients, risk factors and

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conditions associated with infection-related removal should be further investigated.

We sought to query the 2012 Healthcare Cost and Utilization Project (HCUP) Kid's Inpatient Database (KID) in order to describe the type and frequency of diagnoses associated with hardware removal, risk factors for hardware removal, and hospital charges and costs associated with these procedures. We hypothesized that inpatient hardware removal would be a relatively common procedure most frequently performed due to symptomatic hardware and infection. Additionally, we hypothesized that certain patient characteristics and fracture types and locations would be associated with higher rates of removal.

2. Methods

2.1. Data collection

The Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID) was utilized to examine the incidence of fracture management and hardware removal in the United States in the year 2012. The HCUP-KID is the largest publically available all-payer pediatric inpatient database that is compiled based on 2 to 3 million hospital stays. The database is a result of the data collected in the 46 states that have partnered with the Agency for Healthcare Research and Quality (AHRQ) and maintain statewide data collection efforts. The database approximates a 20-percent stratified sample of all pediatric discharges at all of the

hospitals in participating states. The large sample size generates data that is generalizable to the national pediatric population. Data collected from KID include demographic information, including patient age, gender, median income and ZIP code, primary and secondary diagnoses, procedures, payment information, and patient length of stay. KID also collects information on factors including hospital size, teaching status, type of hospital and hospital location.

2.2. Data management

Orthopaedic hardware removal and co-morbidities were identified and classified by International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9 CM) diagnosis codes and Current Procedural Terminology (CPT) codes. All discharges in patients aged 0–17 years old were included. National estimates of incidence and standard errors were calculated using HCUP national discharge weights. To calculate rates and estimates, we used a method described by Rasouli et. al.⁸ Population data was downloaded from the census.gov website. Variables queried included: demographics, diagnostic code associated with removal, causative organism in cases involving infection, average length of stay and average hospital charges and costs. Data was stratified by both age and limb affected. Demographic variables collected were patient age and sex, census division and insurance status (Table 1). Procedural data queried included diagnostic code associated with removal specific to orthopedic procedures, site of removal, and

Table 1
Demographic and Descriptive Variables of Study Population.

		Total number of orthopedic hardware removal from the upper and lower extremities	
All discharges		3621	100.00%
Age group	<1	7	0.19%
	1–4	259	7.16%
	5–9	750	20.71%
	10–14	1506	41.57%
	15–17	1100	30.36%
Sex	Male	2114	58.38%
	Female	1506	41.59%
	Missing	1	0%
Payer	Medicare	20	0.54%
	Medicaid	1382	38.17%
	Private insurance	1868	51.57%
	Uninsured	99	2.74%
	Other	238	6.57%
	Missing	15	0%
Owner (Hospital)	Government	356	9.83%
	Private, not-for-profit	2980	82.28%
	Private, for-profit	286	7.90%
Location/teaching status	Rural	70	1.95%
	Urban nonteaching	398	10.98%
	Urban teaching	3153	87.08%
Bedsize	Small	784	21.65%
	Medium	607	16.75%
	Large	2231	61.60%
Region	Northeast	539	14.89%
	Midwest	942	26.01%
	South	1168	32.25%
	West	972	26.85%
Children's hospital	Not a children's hospital	820	22.65%
	Children's hospital	2801	77.35%
Free-standing children's hospital	Not a free-standing children's hospital	2078	57.39%
	Free-standing children's hospital	1543	42.61%

causative organism in cases involving infection. To ensure that infection was related to the orthopedic hardware, we also queried ICD-9 codes 996.6x (infection and inflammatory reaction due to internal prosthetic device, internal orthopedic device, implant, and graft), which encompasses orthopedic hardware. We excluded the cases where an organism was missing or not specified. Additionally, we queried the number of ORIF procedures associated with ICD-9 diagnostic codes for open fractures. Outcomes queried were length of stay and total hospital charges. Procedures were stratified based on age, gender, body part affected, indication for removal (pain, infection, dysfunction, malunion). The data is reported as the frequency of specific diagnoses as well as their corresponding national estimates. When data points had significant missing values, they were excluded from the diagnosis. Additionally, for those patients who were admitted, we excluded patients who had other significant diagnoses listed as the primary reason for admission.

2.3. Statistical analysis

Means and standard deviations were calculated for continuous variables. Percentages were computed for categorical variables. Associations of various patient characteristics with the frequency of hardware removal were tested using Chi-square or Fisher's exact tests as appropriate. Student's *t*-test was used for continuous variables. Chi-square test was used to compare the frequency of hardware removal indications between age groups and by site of hardware removal. Univariate analysis was used to determine the association between total charges of admission and site of hardware removal. Logistic regression by using weighted data was used to identify significant associations between patient or hospital factors and the occurrence of hardware removal. Census data was used to calculate rates per 100,000 population. This analysis represents a cross sectional view of an entire year [2012] of procedures in the database and represents the most recent year in which complete data are available. National estimates and 95% confidence intervals (CIs) were calculated by using discharge-level statistical weights provided by KID for this purpose. All statistical analyses were performed utilizing SAS statistical software v.9.4 (SAS Institute, Inc. Cary, NC). Statistical significance was set at $P < 0.05$.

2.4. IRB approval

Prior to analysis, the Institutional Review Board concluded that the study did not require review. All research protocols adhered to the HCUP user agreement.

3. Results

There were an estimated 19,759 ORIF procedures and 3621 removals in pediatric patients in 2012. The rate of ORIF of the upper and lower extremities was 26.8 per 100,000 population. Removal rate was 4.9 per 100,000. Of the fractures that underwent ORIF, 5078 were classified as open (6.9 per 100,000). The highest rate of hardware removal was in the 10–14 age group (20.6%). Males accounted for 58.4% of hardware removal patients compared to 41.6% for females ($P < 0.01$). The highest rate of removal was observed in femur fractures (48%), followed by tarsal/metatarsal (19%) and tibia/fibula (18%). There was no statistically significant difference in the frequency of hardware removal in different body parts based on sex. The most common indication for hardware removal was infection (1141 patients; 32%), followed by mechanical dysfunction (923; 25.4%), other and non-specified causes (844; 23%), and pain (472; 13%) (Table 2).

Table 2

Causes of Hardware Removal.

Cause of Removal	Cases	Percent
Infection	1141	32.00%
Mechanical	923	25.40%
Pain	472	13.00%
Nonunion	188	5.20%
Malunion	40	1.10%
Other/Not Specified	844	23%
Total	3621	100%

Admissions involving hardware removals accounted for an estimated 10,500 hospital days, with a mean length of stay of 2.9 days. Average hospital charges and costs were \$36,349 and \$11,792 respectively, with \$131.3 million and \$42.9 million in total charges and costs nationally. In patients where hardware was removed due to infection, mean length of stay was significantly longer at 7 days ($P < 0.01$). Mean charges and costs were also significantly higher at \$69,343 and \$22,506 respectively. For all other removals excluding infection, charges and costs were \$21,040 and \$6984 respectively (Fig. 1).

The hardware removal procedures associated with the greatest mean costs were metatarsal/tarsal (\$13,547), tibia/fibula (\$12,336) and femur (\$11,929). The lowest cost hardware removals were performed in the humerus (\$10,482) and radius/ulna (\$9919). These differences were not statistically significant. There was no statistically significant difference in length of stay and costs between hospital types, gender, and age.

Methicillin-sensitive *Staphylococcus aureus* (MSSA) was the most frequently isolated organism, followed by methicillin-resistant *S. aureus* (MRSA), other gram negatives, other staphylococcal species, and pseudomonas (Table 3).

Logistic regression analysis showed that femur fractures ($OR = 8.27$, 95% CI: 7.63–8.96, $P < 0.001$) and tibia/fibula fractures ($OR = 1.24$, 95% CI: 1.17–1.35, $P < 0.001$) were independent predictors of infection-related hardware removal. Patients who underwent hardware removal due to infection were more likely to have asthma ($OR = 1.87$, 95% CI: 1.62–2.07, $P < 0.001$), smoke tobacco ($OR = 1.12$, 95% CI: 1.05–1.23, $P < 0.001$), and suffer from developmental delays ($OR = 1.32$, 95% CI: 1.19–1.54, $P < 0.001$).

Age (0–1, and 15–17) ($OR = 1.27$, 95% CI: 1.09–1.56 and $OR = 1.2$, 95% CI: 1.14–1.31, respectively ($P < 0.001$)) were independent predictors of hardware removal due to pain. Patients with tarsal/metatarsal fractures ($OR = 2.59$, 95% CI: 2.17–3.31), tibial/fibula fractures ($OR = 1.82$, 95% CI: 1.63–2.14), and femur fractures ($OR = 1.39$, 95% CI: 1.17–1.78) were more likely to undergo hardware removal due to pain ($P < 0.001$).

4. Discussion

Fractures in skeletally immature patients often heal with non-operative management, however, certain injuries necessitate operative intervention for multiple reasons including patient age, degree of displacement, open injury, and neurovascular or associated injuries. Utilizing orthopedic hardware in pediatric patients can lead to secondary procedures in order to remove the hardware. The indications for hardware removal in pediatric patients are varied and there are few evidence-based guidelines to inform clinical decision-making.

Our study found that pediatric hardware removal after fracture surgery accounted for 3621 cases in 2012. For comparison, there were 4315 cases involving ORIF of the radius and ulna during this same time period. Infection was the most common indication for removal, followed by mechanical dysfunction, and pain. Retained hardware has repeatedly been shown to serve as a possible nidus

Fig. 1. Costs and Charges Associated with Inpatient Hardware Removal by body part and cause.

Table 3

Frequency of Organisms Associated with Hardware Infections.

	Cases	Percent
MSSA	371	32.50%
MRSA	176	15.40%
Other Gram Negative	128	11.20%
Other Staph	118	10.30%
Pseudomonas	96	8.40%
Strep D	59	5.20%
Other Anaerobe	55	4.80%
E. Coli	46	4.00%
Proteus mirabilis	24	2.10%
Other Strep	23	2.00%
Klebsiella	22	1.90%
Strep A	9	0.80%
Strep B	5	0.40%
Haemophilus Influenzae	3	0.30%
Strep G	3	0.30%
Pneumococcus	3	0.30%
Total cases with listed organism	1141	100%
Not Specified *	262	23%

for infection.^{9–14} This study found that methicillin-sensitive *S. aureus* was the most common infecting organism (32.5%), followed by MRSA (15.4%), and other gram negatives (11.2%). This is important to consider when prescribing antibiotics for patients with infected hardware prior to speciation. Berkes et al. reviewed 123 hardware infections within 6 weeks of treatment via open reduction and internal fixation in pediatric patients.¹⁵ In this study 40 patients were infected with MRSA, 33 with MSSA, 9 with *Pseudomonas*, and 28 with more than one pathogen. Overall 87 (71%) of patients went on to union with retention of hardware and suppressive antibiotics. Ultimately, 56 retained their hardware with 5 undergoing removal for pain and 26 for recurrence of infection after union.¹⁵ No specific organism was associated with a statistically significant increased rate for non-union, however *Pseudomonas* approached significance with only 44% of patients with this organism going on to union as opposed to 78.8% with MSSA, and 65.0% with MRSA.¹⁵ Rasouli et al. used the National Inpatient Sample (NIS) and found that the highest rates of hardware removal in adult patients after ORIF occurred following infection in tibial (3.65%), tarsal (5.56%), and carpal (3.37%) fractures, most likely related to injury mechanism and relative amounts of soft tissue coverage.⁸

Symptomatic hardware was found to be a major indication for hardware removal following fracture fixation in the current study. We observed a 25.4% rate of mechanical dysfunction and a 13% rate of pain as indications for patients who underwent hardware

removal. In a study observing flexible titanium nail removal in femurs and forearms of children, the main reasons for removal included nail protrusion or discomfort. The authors recommended preventative measures to reduce complications with possible future procedures.¹⁶ Vopat et al. found that in 58 pediatric patients with forearm fractures treated with plates, 18% elected for removal of their implant secondary to irritation.¹⁷ Fractures anywhere in the body are subject to the risks of symptomatic hardware. Williams et al. observed that patients with retained foot and ankle hardware reported more pain associated with resumption of weight bearing activities, with patients reporting significantly less pain following elective removal.¹⁸ This is consistent with other studies in the literature in with our findings. Schmittenebecher reviewed the indications for implant removal in children and found that subcutaneous pins led to hardware removal due to skin irritation and increased risk of infection in distal radius fractures.^{19,20} For those procedures where the primary indication for removal was pain, we could not identify a reason for admission. This emphasizes the need for further investigation in order to reduce unnecessary admissions and costs.

In addition to infection and symptomatic hardware, surgeons may recommend hardware removal to prevent future complications; this includes difficulty in removing implants later in life, *peri-implant* fracture due to stress shielding, metal allergy, and possible carcinogenesis due to corrosion of metallic hardware.^{1,3} Hardware removal is not without risk however and can result in potential postoperative complications such as re-fracture, infection, hematoma, wound dehiscence, blood loss, and prolonged operative time.³ In a survey of pediatric orthopedic surgeons, many physicians believed that implants should be retained because of the aforementioned complications and anesthesia concerns.⁶ Our study found that for patients included in this inpatient sample, the average hospital charge following hardware removal for any cause was \$36,349 and \$21,040 when infection-related causes were excluded. This is not an insignificant amount and may place financial strain on both patients and hospitals, especially if the removal is not done for symptomatic causes. We do caution, however, that this average hospital charge may be inflated because of the nature of the HCUP-KID sample, which represents admitted inpatients. Many elective hardware removals can be performed in an outpatient setting and is not captured by the dataset utilized in this study. What remains to be understood is why such a significant number of these procedures were performed inpatient. A dearth of evidence-based literature and practice guidelines leaves hardware removal versus retention following successful fracture healing a topic of debate. Complication rates for elective, non-symptomatic hardware removal, however, suggest that hardware removal should be performed only for clinical indications or valid reasons

such as infection, implant failure, or hardware-related pain.²¹ While we did identify reasons for a majority of the hardware removals (infection, dysfunction, pain), a large number of these admissions had unspecified indications. This could be for a variety of reasons, including pain control, but it merits further investigation and surgeons should be aware of the significant associated costs.

The strengths of our investigation include the large, national patient sample size that renders the results generalizable to the national pediatric population and the multivariable regression model we conducted to account for confounding factors that could influence our results. There are, however, several limitations of this investigation. First, like any large national claims-based database, the Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID) is at risk for coding misclassification. Second, we were not able to extract fracture characteristics at the time of removal, which limits our ability to fully understand how this may have influenced treatment complexity and infection risk. For example, the nature of the database did not allow us to elucidate whether or not the original fracture related procedure resulting in retained hardware was associated with an open or closed injury. However, we did find that 5071 of the ORIF cases in 2012 were due to open fractures. This would clearly influence risk of infection and subsequent need for hardware removal. Third, follow up data was not recorded such as functional outcome or failure of union/fixation to indicate if the correct management decisions were made. Fourth, this database only includes patients who were seen in the emergency department and/or required hospital admission, consequently, our database may underestimate the incidence of hardware removal given that many procedures can be done on a same-day basis without admission. Additionally, there are cases where certain data points are not specified, limiting our ability to fully understand the factors contributing to hardware removal. The reason for these omissions includes a lack of diagnostic specificity, and varying coding practices used by different hospitals. Despite its weaknesses the HCUP-KID database also has many strengths and is widely accepted and validated in the literature in the review of a number of conditions.^{22–34} The large sample size allows for a degree of error in missing values that does not significantly affect the results of the study. The database proves useful for examining trends in pediatric fracture management which can help surgeons when counseling patients as well as serve as a way to review one's own practices compared to national trends.

5. Conclusion

While routine hardware removal is commonly done as an outpatient procedure, the results of this study show that inpatient hardware removal due to complications occurs with relative frequency. The charges and costs associated with these admissions are significant. This study also showed that infection was a significant reason for hardware removal in a nationally representative sample of pediatric inpatients. We identified risk factors for infection-related removal, namely asthma, tobacco, and developmental delay. Additionally, femur and tibia/fibula fractures were found to be independent predictors of infection-related removal. These findings highlight the importance of identifying causes and risk factors for hardware failure in order to guide interventions to reduce the need for inpatient removal.

Compliance with ethical standards

The authors have no conflicts of interest to disclose. No funding was received for the research described in this paper. The HCUP database is completely de-identified and is not considered human

subjects research. All authors abided by the HCUP data use agreement.

Conflict of interest

The authors have none to declare.

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Appendix A. ICD-9 Codes Queried For Hardware Removal

78.60	Removal of implanted devices from bone, unspecified site
78.62	Removal of implanted devices from bone, humerus
78.63	Removal of implanted devices from bone, radius and ulna
78.64	Removal of implanted devices from bone, carpals and metacarpals
78.65	Removal of implanted devices from bone, femur
78.67	Removal of implanted devices from bone, tibia and fibula
78.68	Removal of implanted devices from bone, tarsals and metatarsals
78.69	Removal of implanted devices from bone, other bones
996.66	Infection and inflammatory reaction due to internal joint prosthesis
996.67	Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft

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