Rate of and Risk Factors for Reoperations After Open Reduction and Internal Fixation of Midshaft Clavicle Fractures

A Population-Based Study in Ontario, Canada

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Background: Reoperation rates following open reduction and internal fixation (ORIF) of midshaft clavicle fractures have been described, but reported rates of nonunion, malunion, infection, and implant removal have varied. We sought to establish baseline rates of, and risk factors for, reoperations following clavicle ORIF in a large population cohort.

Methods: Administrative databases were used to identify patients sixteen to sixty years of age who had undergone an ORIF of a closed, midshaft clavicle fracture from April 2002 to April 2010. The primary outcome was a reoperation within two years (isolated implant removal, irrigation and debridement [deep infection], pseudarthrosis reconstruction [nonunion], or clavicle osteotomy [malunion]). The secondary outcome was rare perioperative complications, including pneumothorax, subclavian vasculature injury, and brachial plexus injury. A multivariable logistic regression analysis was performed to determine the influence of patient and provider factors on these outcomes.

Results: We identified 1350 patients who underwent midshaft clavicle ORIF (median age, thirty-two years [interquartile range, twenty-one to forty-four years]; 81.3% male). One in four patients (24.6%) underwent at least one clavicle reoperation. The most common procedure was isolated implant removal (18.8%), and females were at highest risk (odds ratio [OR], 1.7; p = 0.002). The median time to implant removal was twelve months. A reoperation secondary to nonunion, deep infection, and malunion occurred in 2.6%, 2.6%, and 1.1% of the patients after a median of six, five, and fourteen months, respectively. Risk factors for clavicle nonunion included female sex (OR, 2.2; p = 0.04) and a high comorbidity score (OR, 2.8; p = 0.009). For surgeons, fewer years in practice was associated with a small risk of the patient developing an infection (OR, 1.1; p < 0.001). Sixteen pneumothoraces (1.2%) were identified; however, brachial plexus and subclavian vessel injuries were each found in five or fewer patients.

Conclusions: Following clavicle ORIF, one in four patients underwent a reoperation. The most common procedure was implant removal, and although the rates of reoperations secondary to nonunion, malunion, and infection were low they were higher than previously reported. Pneumothoraces and neurovascular injuries were infrequent and should continue to be considered rare complications of clavicle ORIF.

Level of Evidence: Prognostic Level IV. See Instructions for Authors for a complete description of levels of evidence.

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Historically, nonunion and symptomatic malunion following the nonoperative treatment of displaced, midshaft clavicle fractures was considered an infrequent event[1,2]. This has been refuted in more recent clinical studies[3-5]. In 2007, a randomized controlled trial comparing nonoperative with operative management of displaced, midshaft clavicle fractures demonstrated that patients who underwent open reduction and internal fixation (ORIF) had significantly lower nonunion rates and better functional outcome scores at the one-year follow-up evaluation[6]. Since 2007, six randomized controlled trials have compared operative with nonoperative management[6-11]. A recent meta-analysis of these trials, which included a total of only 212 surgically treated patients, showed the overall complication and nonunion rates to be 29% and 1.4%, respectively[12]. Moreover, postoperative infections were rarely reported, and there were no reports of clavicle malunion after ORIF[12].

Clavicle ORIF techniques include both plate osteosynthesis and intramedullary fixation[13]. In a meta-analysis of four trials comparing these techniques, ORIF with a plate was associated with a higher prevalence of symptoms (plate prominence, skin irritation, and persistent pain), but there was no difference in functional outcome scores or nonunion, malunion, infection, implant failure, and reoperation rates[14].

Rare complications have been reported, although primarily in case reports, in patients with midshaft clavicle fracture; these complications have included injury to the brachial plexus[15-17] or subclavian vasculature[18,19], and pneumothorax[20-26]. There are also reports of subclavian vessel injury following ORIF of a midshaft clavicle fracture[27,28], and cadaveric studies have been performed to investigate safe drilling depths, drilling angles, screw lengths, and ipsilateral arm positions during surgery[29-31].

In light of recent clinical evidence, it is likely that rates of clavicle ORIF will increase. Thus, it is important for clinicians and administrators to have accurate data regarding reoperations following ORIF of a midshaft clavicle fracture in the general population. We attempted to establish reoperation rates and associated risk factors in a large population cohort of patients who had undergone ORIF for an isolated, closed midshaft clavicle fracture.

Materials and Methods

Study Design

This was a retrospective cohort study.

Cohort Development

Administrative databases in the public health system of Ontario, Canada, were accessed and analyzed through the Institute for Clinical Evaluative Sciences (ICES; www.ices.on.ca), an independent nonprofit health-services organization.

Patients were initially included if they had an Ontario Health Insurance Plan (OHIP) physician fee code for ORIF of a clavicle fracture from April 2002 to April 2010 (see Appendix). OHIP provides universal health coverage to Ontario residents for >95% of physician services in Ontario[32]. Coverage also extends to Ontario residents undergoing procedures in other Canadian provinces. Importantly, OHIP fee codes were found to have a high level of accuracy (>96%) on chart review, but this has not been directly assessed for clavicle fractures[32].

TABLE I Exclusion Criteria

	Cohort Size	No. Excluded
Pre-exclusion	2933	
Age <16 or >60 yr		360
Not Ontario resident		3
Prior clavicle ORIF		85
Prior/concomitant glenohumeral, acromioclavicular, or sternoclavicular dislocation		284
Medial or lateral-third clavicle fracture		312
Polytrauma		248
Concurrent procedure		
Bone-grafting		95
Clavicle osteotomy		54
Clavicle nonunion reconstruction		86
Irrigation and debridement		43
Incomplete demographic data		13
Post-exclusion	1350	

Hospital admission records (Discharge Abstract Database [DAD] or Same Day Surgery [SDS]) were accessed to determine fracture location (medial, middle, or lateral third of the clavicle). Patients with International Classification of Diseases, Tenth Revision (ICD-10) diagnostic codes for medial or lateral-third clavicle fracture were excluded (see Appendix).

The exclusion criteria (Table I) were based on ICD-10 and/or OHIP fee codes and are listed in detail in the Appendix. Briefly, polytrauma cases (Injury Severity Score [ISS] of ≥15 and/or concomitant fracture anywhere in the body) and patients with a prior or concomitant glenohumeral, acromioclavicular, or sternoclavicular joint dislocation were excluded. Patients who underwent a concurrent clavicle procedure during the index surgery (nonunion reconstruction, osteotomy, or bone-grafting) were also excluded, as were patients with a prior clavicle fracture. Lastly, open clavicle fractures (concurrent clavicle ORIF and irrigation and debridement) were excluded; however, the annual volume of these cases was compared with similar data for the study cohort (see Appendix).

Main Outcome

The main outcome of this study was a reoperation (implant removal, irrigation and debridement [deep infection], pseudarthrosis reconstruction [nonunion], or clavicle osteotomy [malunion] and a composite reoperation rate [rate of reoperations for any cause]). We sought to identify all reoperations performed during the two years following the index event (see Appendix).

Database limitations precluded a determination of laterality for the index event or potential outcomes. Ipsilateral clavicle procedures in the follow-up period were assumed on the basis of exclusion of prior clavicle surgery since July 1, 1991 (a minimum look-back window of more than ten years).

Secondary Outcome

The secondary outcome was a rare perioperative complication during the index hospital admission, including pneumothorax (with or without insertion of a chest tube), subclavian vessel injury, and brachial plexus injury (see Appendix).

Covariates

Available patient and provider factors were considered. Patient factors included age, sex, income quintile, comorbidity score, and urban or rural residence. All demographic variables were obtained from the Registered Persons Database (RPD) of Ontario citizens with valid OHIP coverage. Age was evaluated as a continuous variable. Income quintile, a surrogate for socioeconomic status, was estimated via an established technique with use of Statistics Canada census data[33]. The Collapsed Aggregate Diagnosis Group (CADG) was used as a measure of comorbidity[34]. We chose this measure over other measures of comorbidity as the CADG score includes all possible diagnoses (acute, including injury, and chronic)[34]. Moreover, it has been validated and previously used in young healthy populations[35-38]. With this scoring system, patients are assigned to any number of twelve different disease categories with use of ICD-9 and ICD-10 codes derived from hospital admissions and emergency department visits in Canada during the three years preceding their respective index event[39]. Patients were further categorized on the basis of their overall CADG score (zero to four versus five or more categories, with a maximum of twelve categories), as has been previously done (see Appendix)[40].

Provider factors related to the surgeon and hospital were tied to each index event. Index surgeon-related factors included the physician's subspecialty, year of orthopaedic subspecialty certification in Canada, and volume of ORIF procedures performed for clavicle fracture in the calendar year preceding the index event as well as the calendar year of the surgery. Index hospitals were categorized as either "academic" or "non-academic" on the basis of their membership in the Council of Academic Hospitals of Ontario (www.caho-hospitals.com).

Two measures of the time from injury to surgery were estimated. The first was calculated as the number of days from the consultation with the orthopaedic surgeon to the index surgery. The second was calculated as the number of days from presentation to the emergency department to the index surgery. The National Ambulatory Care Reporting System (NACRS), which collects data from emergency departments in Ontario hospitals[41], was used to identify the latter (see Appendix).

Reporting

Privacy protection rules instituted by the Ministry of Health and ICES preclude reporting of results based on five or fewer patients.

Statistical Analysis

Demographic data were summarized, and a comparison between included and excluded patients was performed (t test [continuous variables] or Fisher exact test [categorical variables]). A multivariable logistic regression model was used to determine the influence of each covariate on the main and secondary outcomes. A second multivariable logistic regression model was utilized to examine available estimates of time from injury to surgery. We also determined the median time (with interquartile range [IQR]) to each main and secondary outcome.

Two post-hoc analyses were performed. First, a Pearson correlation was performed after we determined that there was a relationship between age and comorbidity. Second, a generalized estimating equation model of linear regression clustering by surgeon (with provider covariates removed) was calculated to determine the effect that the index surgeon had on relationships between the index event and reoperation outcomes.

All statistical analyses were performed with use of version 9.1 for UNIX (SAS Institute, Cary, North Carolina), and alpha was set at 0.05.

Source of Funding

This study was funded by a resident research grant from the Orthopaedic Trauma Association (OTA).

Results

We identified 1350 eligible patients with ORIF of a closed, isolated midshaft clavicle fracture (Table I). The median patient age was thirty-two years (IQR, twenty-one to forty-four years), and 81.3% were male (Table II). Included (n = 1350) and excluded (n = 1583) patients differed with respect to age (an exclusion criteria), sex, income quintile, and comorbidity (see Appendix).

TABLE II Cohort Demographics

Demographic Variable	
No. of patients	1350
Age *(yr)*	
Mean and stand. dev.	33 ± 12.7
Median	32
IQR	21-44
Sex *(no. [%])*	
Male	1097 (81.3%)
Female	253 (18.7%)
Income quintile *(no. [%])*	
1	257 (19.0%)
2	234 (17.3%)
3	247 (18.3%)
4	286 (21.2%)
5	326 (24.1%)
CADG score *(no. [%])*	
0-4	863 (63.9%)
≥5	487 (36.1%)
Residence *(no. [%])*	
Rural	219 (16.2%)
Urban	1131 (83.8%)

The index procedure volume increased considerably from sixty cases in 2003 to 276 cases in 2009 (see Appendix). In comparison, the number of isolated open clavicle fractures was unchanged at four to seven per year. Almost all (99.2%) of the index procedures were performed by orthopaedic surgeons, with the remainder done by general surgeons, and most (62.3%) took place in non-academic hospitals.

Reoperations

We identified 332 patients (24.6%) who underwent one or more additional clavicle operations within two years after the index clavicle ORIF.

Implant Removal

There were 254 (18.8%) isolated implant removals. A significantly greater proportion of females than males underwent implant removal (Table III), and implant removal was more common in females (odds ratio [OR], 1.7; 95 % confidence interval [CI], 1.2, 2.4) (p = 0.002). It was also more common in patients who underwent clavicle ORIF in non-academic hospitals than in those treated in academic hospitals (Table III). The median time to isolated implant removal was twelve months (IQR, 5.8 to 16.1 months).

Deep Infection

There were thirty-five procedures (2.6%) to manage deep infection; the odds of such procedures being performed were

TABLE III Demographic Factors Significantly Associated with Reoperation

Demographic Variable	Proportion of Patients with Reoperation	
	Implant Removal	Nonunion Reconstruction
Sex		
Female	26.1%	5.5%
Male	17.1%	1.9%
Difference	p = 0.001	p = 0.001
Hospital type*		
Non-academic	20.6%	
Academic	15.7%	
Difference	p = 0.01	
CADG score		
0-4		1.3%
≥5		4.9%
Difference		p < 0.001

*Hospital type was based on where the index procedure was performed (academic versus non-academic).

highest among orthopaedic surgeons who had more recently attained subspecialty certification (OR, 1.1; 95% CI, 1.0, 1.2) (p < 0.001), with a 10% increase in odds for each year of certification after 1969. The median time to an infection-related procedure was five months (IQR, 2.3 to 8.0 months).

Nonunion

There were thirty-five reconstructions (2.6%) for clavicle pseudarthrosis. Patients who underwent nonunion reconstruction were significantly older than those who did not (median age, forty-one years [IQR, thirty-two to forty-nine years] versus thirty-two years [IQR, twenty-one to forty-three years]) (p = 0.002). Sex and comorbidity score also differed significantly between patients who underwent reconstruction and those who did not (Table III). Female sex (OR, 2.2; 95% CI, 1.0, 4.5) (p = 0.04) and a high comorbidity score (OR, 2.8; 95% CI, 1.3, 6.3) (p = 0.009) increased the odds of undergoing a nonunion reconstruction, while clavicle ORIF performed in an academic hospital decreased the odds (OR, 0.4; 95% CI, 0.2, 1.0) (p = 0.04). A post-hoc Pearson correlation showed a significant positive relationship between patient age and CADG score (r = 0.4, p < 0.0001) and explains the finding that age differed significantly between those who underwent reconstruction and those who did not (Table III) on analysis with the t test but not in a regression model that assumed independence between variables. Subsequent sensitivity analysis (sequential removal of interacting demographic variables) confirmed that only sex and CADG were risk factors for nonunion reconstruction. The median time to nonunion reconstruction was six months (IQR, 2.9 to 11.3 months).

Malunion

There were fifteen clavicle osteotomies (1.1%) for malunion and no identified risk factors for the procedure. The median time to osteotomy for malunion was fourteen months (IQR, 7.8 to 15.7 months).

Of note, a post-hoc generalized estimating equation model revealed that the index surgeon did not influence relationships between the index event and reoperation outcomes.

Rare Perioperative Events

Pneumothorax

Sixteen patients (1.2%) were diagnosed with a pneumothorax during the index hospital admission, and eight underwent tube thoracostomy (chest tube). The odds of pneumothorax were significantly increased by older age (OR, 1.09; 95% CI, 1.03, 1.15) (p = 0.003), with each year over sixteen years associated with a 9% increase in the odds, and by clavicle ORIF performed in an academic hospital (OR, 14.7; 95% CI, 3.2, 68.1) (p = 0.0006).

Brachial Plexus and Subclavian Vessel Injury

Fewer than five patients had either event; thus, we cannot report the exact number because of the privacy constraints previously described.

Time to Surgery

We found that 1202 (89.0%) of the 1350 cohort patients had had an orthopaedic consultation at a median of four days (IQR, one to ten days) prior to the index surgery date. We also found that 678 (50.2%) of the 1350 cohort patients had presented to the emergency department because of a clavicle fracture, at a median of eight days (IQR, three to fifteen days) prior to the index surgery date. The time from the emergency department visit to the clavicle ORIF was determined on an annual basis from 2002 to 2010, and there were no significant year-to-year variations in time (p = 0.36). Lastly, two separate regression models failed to identify time as a risk factor for any outcome.

Discussion

Among the 1350 patients with clavicle ORIF following an isolated, closed, midshaft clavicle fracture from 2002 to 2010, almost one in four (24.6%) underwent a subsequent clavicle operation within two years, a finding that uniquely reflects both academic and non-academic-based orthopaedic practices.

The most common reoperation procedure was isolated implant removal (18.8%). According to a recent systematic review, 0% to 53% of all clavicle ORIF plates are removed[42]. Interpretation of this finding, however, is difficult given that the involved studies had small sample sizes and the indications for implant removal are multifactorial, including personal and cultural preferences[6,12,43]. According to the highest-quality data available (COTS [Canadian Orthopaedic Trauma Society] trial; Level I), only 8% of patients who have clavicle ORIF undergo implant removal within one year[6]. Our finding that one in five patients (18.8%) underwent implant removal within two years is more than double that rate, and we believe that this has major clinical implications.

To our knowledge, no study has explored the patient and provider factors that influence the need for implant removal following clavicle ORIF. The odds of implant removal in females were 70% greater than that in males. There are likely a number of reasons to account for this finding; however, we hypothesize that skin irritation secondary to supportive undergarments that cross a clavicle plate placed in the anterosuperior position may partly account for this finding. We also found the rate of implant removal among patients who underwent clavicle ORIF in non-academic centers to be 5% greater than that among patients treated at academic hospitals. The reasons for this were not entirely clear.

A recent meta-analysis demonstrated that the rate of nonunion following ORIF of a displaced midshaft clavicle fracture (1.4%) was significantly lower than that following nonoperative management (14.5%) ($p = 0.001$)[12]. The rate of nonunion reconstruction was higher (2.6% versus 1.4%) in our cohort. This discrepancy may be explained by a number of factors unique to this study, including a larger cohort size, a longer duration of follow-up, and the broad inclusion of both generalized and specialized orthopaedic surgery practices. Looking more closely at academic and community-based practices reveals that the rates of nonunion reconstruction following primary clavicle ORIF were 1.8% and 3.1%, respectively, which closely approximate previously published rates reported from similar centers[12].

Risk factors for nonunion following clavicle ORIF are largely unknown. We found that female sex significantly increased the odds of nonunion reconstruction (OR, 2.2), but age did not. Patient comorbidity also increased the odds of nonunion development (OR, 2.8 for five or more CADG disease categories), but data privacy constraints precluded attempts to identify the specific comorbidities that increased risk.

A recent systematic review of complications identified an overall infection rate of <10% following clavicle ORIF but did not stratify the data according to infection severity or management[42]. We found that 2.6% of patients underwent a subsequent reoperation to manage a presumed deep infection within two years after the index surgery. The odds of a subsequent infection-related procedure were influenced by the year that the surgeon attained his or her subspecialty certification, with more recent certification increasing the odds (OR, 1.1). Initially, we were inclined to believe that certification year was a surrogate for surgeon experience; however, this fails to account for other factors, including fellowship (trauma and/or upper extremity), scope of practice, and patient volume. Moreover, we did not find that surgeon volume of clavicle ORIF procedures influenced the odds of subsequent infection-related procedures being performed, so our findings did not support our initial theory. Closer data examination showed that nine (26%) of thirty-five irrigation and debridement procedures were performed by a group of (four) surgeons who had attained specialization in 2004, and it is possible that this may have skewed the data, thereby identifying a "general relationship" that was actually attributable to a select few.

A recent meta-analysis of Level-I surgical trials did not identify a single malunion following clavicle ORIF[12]. We found that 1.1% of patients treated with clavicle ORIF subsequently underwent a clavicle osteotomy; however, we could not determine the influence of implant selection, fracture reduction at surgery, or loss of reduction on our results. Although malunion following ORIF is plausible, we also cannot discount the possibility that some osteotomies were done to address a contralateral clavicle malunion following nonoperative management, or were misclassified nonunion reconstructions.

It has been speculated that pneumothorax complicates 3% of clavicle fractures—a statistic based on estimates from small studies and case reports[20-26,44]. We identified sixteen patients (1.2%) who developed a pneumothorax following clavicle ORIF. While the large sample size of our study increases the reliability of incidence estimates of rare complications, we cannot overlook limitations inherent to this study design. First, the data did not have the resolution to determine whether the pneumothorax was caused by the injury or the ORIF. Second, we only identified pneumothoraces that developed during the index hospital admission, and could not identify patients with a delayed pneumothorax[42]. Third, we attempted to exclude polytrauma cases, and thus our findings may represent a population that differs from those on which prior estimates were based.

This study provides the novel information that older patient age increased the odds of perioperative pneumothorax (OR, 1.09). One explanation for this relationship may be that older patients have reduced soft-tissue compliance and/or less ability to tolerate a pneumothorax acutely. Academic hospital status also increased pneumothorax risk (OR, 14.7). One rationale for this finding is that, despite our attempts to exclude patients with additional injury, patients with higher-energy injuries are more likely to be treated at academic hospitals in Ontario (all level-I trauma centers are academic hospitals). An additional explanation for this association may be iatrogenic injury secondary to the involvement of trainees in clavicle ORIF cases in academic hospitals.

There were several limitations of this study. An inherent problem of this type of study is that details pertaining to the injury or surgical technique were not available. Consequently, we could not determine the influence of the fixation device, plate type, plate orientation, degree of soft-tissue dissection and stripping, or initial fracture comminution and displacement on the reoperation risk. We also could not determine the indication for each reoperation. Reoperation codes used to identify procedures performed to manage deep infection or malunion are not specific, and we based our findings on the presumption that these procedures were performed to manage the aforementioned problems.

The focus of this study was reoperations following primary clavicle ORIF. Complications that were not managed with a reoperation were beyond the scope of this study.

In developing and analyzing this cohort, we limited our data collection to valid OHIP-covered patients within Ontario. It is possible that some patients chose to have a second operation related to the index clavicle ORIF in a jurisdiction outside Canada, but we suspect this to be a very rare occurrence as patients would be paying out of pocket.

Lastly, despite a look-back window of more than ten years, we cannot refute the unlikely possibility that a subsequent reoperation was performed to address a complication of a prior contralateral clavicle fracture, a limitation complicated by an inability to determine laterality.

In conclusion, one in four patients (24.6%) required a reoperation within two years after a clavicle ORIF to manage a closed, midshaft clavicle fracture. The most common reoperation was isolated implant removal (18.8%), which was more common in females. The rates of reoperations secondary to nonunion (2.6%), deep infection (2.6%), and malunion (1.1%) were low, albeit higher than the current literature suggests. Neurovascular injuries and pneumothoraces were infrequent and should be considered rare complications.

Appendix

eA A table showing codes and descriptions of inclusion and exclusion criteria, outcomes, and covariates; a table showing a comparison of demographics of included and excluded patients; and figures demonstrating the age distribution in the cohort as well as the annual volumes of ORIF procedures for closed and open clavicle fractures are available with the online version of this article as a data supplement at jbjs.org. ■

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