RESEARCH ARTICLE

Unplanned Operations and Adverse Events after Surgery for Diaphyseal Fracture of the Clavicle

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Abstract

Background: We used a database of patients treated at three hospitals to study the primary null hypothesis that there are no factors associated with unplanned reoperations or adverse events after surgical repair for diaphyseal clavicle fracture. Additionally we addressed the following secondary study questions: 1. What is the prevalence of unplanned reoperations or adverse events after surgical repair for diaphyseal clavicle fracture? 2. Is early implant loosening or breakage after surgical repair for diaphyseal clavicle fracture related to fixation type? 3. Is the type of fixation associated with the prevalence of brachial plexus palsy after surgical repair of a diaphyseal clavicle fracture?

Methods: We retrospectively analyzed 249 adult patients who had surgery for a diaphyseal clavicle fracture to determine factors associated with unplanned reoperations or adverse events. Thirty-two patients (13%) had at least one unplanned reoperation or adverse event. Four of 249 patients (1.6%) developed early implant loosening or breakage. Patients that had local implant irritation, planned implant removal, or sensory symptoms thought to be due to nerve irritation were not included in the reported unplanned reoperations or adverse event rate.

Results: Only female sex was associated with unplanned reoperations or adverse events after surgery for diaphyseal clavicle fracture. No other patient, technical, or injury related factors tested in this study were associated with unplanned reoperations or adverse events.

Conclusion: Patients that have surgery for diaphyseal clavicle fracture have an approximately 13% risk of an unplanned second surgery or an adverse event. Women can be counseled that they are three times as likely as men to have an unplanned reoperations or adverse event.

Level of evidence: III

Keywords: Adverse events, Brachial plexus palsy, Clavicle fracture, Diaphyseal fracture, Retrospective study, Surgery

Introduction

Surgery is now offered or recommended for displaced diaphyseal fractures of the clavicle (1-3). Several recent prospective studies confirm nonunion rates of 15%-20% with nonoperative treatment of displaced diaphyseal fracture, but the differences in patient-reported outcomes are more varied (4-9). The systematic review of Lenza et al. found that, while nonunion and malunion were less common after surgery, upper arm function or pain was not improved one to two years post surgery for displaced diaphyseal

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fractures of the clavicle (10). Aesthetic results were not addressed. One advantage of nonoperative treatment is the avoidance of operative risks including implant prominence sufficient to request a second unplanned surgery for implant removal, numbness or pain below the incision site from injury to the supraclavicular nerves, wound separation, infection, and an occasional brachial plexus or subclavian vein injury (1, 2).

We used a database of patients treated at three hospitals to study the primary null hypothesis that there are no factors associated with unplanned reoperations or adverse events after surgical repair of a diaphyseal fracture of the clavicle. Additionally we addressed the following secondary study questions: (1) What is the prevalence of unplanned reoperations or adverse events after surgical repair of a diaphyseal fracture of the clavicle? (2) Is early implant loosening or breakage after surgical repair of a diaphyseal fracture of the clavicle related to fixation type? (3) Is the type of fixation associated with the prevalence of brachial plexus palsy after surgical repair of a diaphyseal fracture of the clavicle?

Materials and Methods

This retrospective study was approved by our Institutional Review Board. Using a multi-institutional database that combines billing information with the electronic medial record, we identified 528 adult patients who had open reduction and internal fixation of a clavicle fracture between January 2002 and March 2015 at three area hospitals. Two hospitals are level 1 trauma centers and one hospital is a community hospital. Current Procedural Terminology (CPT) procedure code for operative treatment of clavicle fractures (CPT code: 23515) were used to identify patients. Medical record data, International Classification of Diseases, ninth Revision code (ICD-9), demographic information (such as, sex, date of birth, and race), surgery, and radiology reports of patients with this CPT code were retrieved. For patients who had more than one clavicle fracture surgery, we tracked the first surgery as the index procedure.

We excluded (1) patients with lateral clavicle fracture (n=123) or no clavicle fracture (n=2, presumed miscoding); (2) patients with recorded follow-up<10 weeks (n=95) (3) patients who underwent primary surgery for a clavicle malunion or nonunion (n=56); (4) patients with prior surgery elsewhere (n=2) and (5) patients who had a pathological clavicle fracture (n=1). Fracture healing is well established at about three months. If patients were evaluated approximately three months or greater after injury (>10 weeks), we were confident that fracture healing was assured. No attempt was made to contact patients that had a follow-up of <10 weeks.

The final cohort included 249 patients who had surgery for a displaced diaphyseal clavicle fracture. The final evaluation documented in the record was an average of eight months after surgery (range 10 weeks to 60 months). Plate fixation was used in 157 fractures and an intramedullary rod was used in 92 fractures.

We reviewed the medical records of all patients for unplanned reoperations or adverse events including infection, numbness surrounding incision, brachial plexus dysfunction, nonunion, scar revision, early implant loosening or breakage, refracture after plate removal, hematoma, and adhesive capsulitis. Subsequent surgeries related to any unplanned reoperations or adverse event were recorded, excluding those related solely to implant irritation or aesthetics.

Table 1. Type of adverse events — **n=249**

Total number of adverse events	34	
Adverse event	**n**	**% of total n**
Infection	10	4%
Numbness surrounding incision	5	2%
Brachial plexus dysfunction	5	2%
Nonunion	4	2%
Early implant loosening or breakage	4	2%
Scar revision	3	1%
Refracture after plate removal	1	0.4%
Hematoma for which surgical evacuation	1	0.4%
Shoulder stiffness	1	0.4%

Thirty-two of 249 patients (13%) had at least one unplanned reoperation or adverse event [Table 1]. Two patients had two unplanned reoperations or adverse events. Fifteen of 32 patients (47%) had an unplanned reoperation. Thirteen patients had a single subsequent surgery, one patient had two subsequent surgeries, and one patient had four subsequent surgeries for an infected nonunion. Subsequent surgeries were for infection (n=4; 2%), implant loosening or breakage (n=4; 2%), scar revision (n=2; 1%), hematoma (n=1; <1%), nonunion (n=1; <1%), fracture after implant removal 20 months after surgery treated with a second surgery for plate and screw fixation (n=1; <1%), or nerve injury exploration and nerve transfer (n=1; <1%). The patient with two subsequent surgeries had an irrigation and debridement procedure and a secondary vacuum dressing after infection.

Sixty-one patients (24%) had removal of their implant not related to an adverse event, solely for aesthetics or implant irritation.

We retrieved the following explanatory variables from the record: age, Charlson index, experience surgeon after graduation, sex, smoking, alcohol dependence, diagnosed obesity, open fracture, injury side, comminuted fracture (minor to severe comminution), fixation type (plate or intramedullary rod) and number of incisions.

Statistical analysis

Normality of our continuous data was tested using the Shapiro-Wilk test. The difference in explanatory variables among unplanned reoperations or adverse events was assessed using a Fisher's exact test for dichotomous and categorical variables and an unpaired t-test for continuous variables. Variables were presented with

frequencies and percentages for categorical variables and as mean with SD for continuous variables. A two-sided *P value < 0.05* was considered to indicate statistical significance. No multivariable analysis was performed, as only one factor in bivariate analysis was significant.

Results

In bivariate analysis, only female sex was associated with unplanned reoperations or adverse events after surgery of diaphyseal clavicle fracture [Table 2]. No other patient, technical, or injury related factors

Table 2. Bivariate analyses: factors associated with unplannend reoperations or adverse events after operative treatment of midshaft clavicle fractures

Parameter	Yes (32, 13%)	No (217, 87%)	n=249
	Mean (SD)	Mean (SD)	*P* value
Age. y	37 (13)	35 (14)	0.51
Charlson index	0.31 (1.6)	0.23 (0.7)	0.62
Experience surgeon. y	8.5 (7.2)	9.8 (8.6)	0.42
	Number (%)	Number (%)	*P value*
Sex			0.011
Men	17 (53)	164 (76)	
Women	15 (47)	53 (24)	
Smoking			0.58
Yes	5 (16)	27 (12)	
No	27 (84)	190 (8)	
Alcohol dependance			0.24
Yes	1 (3)	1 (0)	
No	31 (97)	216 (100)	
Diagnosed obesity			0.17
Yes	2 (6)	4 (2)	
No	32 (94)	213 (98)	
Open fracture			1.0
Yes	0 (0)	1.0 (0)	
No	32 (100)	216 (100)	
Injury Side			0.34
Left	18 (56)	100 (46)	
Right	14 (44)	117 (54)	
Athlete			0.20
Yes	5 (16)	58 (27)	
No	27 (84)	159 (73)	
Comminuted fracture			1.0
Yes	28 (88)	185 (85)	
No	4 (13)	32 (15)	
Fixation type			0.12
Plate	16 (50)	141 (65)	
Intramedullary rod	16 (50)	76 (35)	
Number of incisions			0.13
One	28 (88)	205 (94)	
Two	4 (13)	12 (6)	

SD = standard deviation

tested in this study were associated with unplanned reoperations or adverse events.

Thirty-two patients (13%) had at least one unplanned reoperation or adverse event. Four of 249 patients (1.6%) developed early implant loosening or breakage [Table 1].

In two of 249 patients the plate broke within three months after surgery. In two patients the intramedullary rod loosened in the medial fragment. Patients that had local implant irritation, planned implant removal, or sensory symptoms thought to be due to nerve irritation were not included in the reported adverse event rate.

Brachial plexus dysfunction occurred in five of 249 (2%) patients, two of 157 (1.2%) after plate fixation and three of 92 (3.3%) after fixation with an intramedullary pin (*P=0.36*). All brachial plexus dysfunction resolved completely within six months.

Discussion

A better understanding of the unplanned reoperations or adverse events of surgery for a displaced diaphyseal clavicle fracture can help inform patients and surgeons deciding between operative and nonoperative treatment (1-3). Prior studies identified adverse events after surgery in as many as 64% of patients (11). It's not clear whether certain patient, injury, or treatment factors are associated with unplanned reoperations or adverse events. We studied the primary null hypothesis that there are no factors associated with unplanned reoperations or adverse events after surgical repair of a diaphyseal fracture of the clavicle. Additionally we addressed the following secondary study questions: (1) What is the prevalence of unplanned reoperations or adverse events after surgical repair of a diaphyseal fracture of the clavicle? (2) Is early implant loosening or breakage after surgical repair of a diaphyseal fracture of the clavicle related to fixation type? (3) Is the type of fixation associated with the prevalence of brachial plexus palsy after surgical repair of a diaphyseal fracture of the clavicle? Our rate of unplanned reoperations or adverse events after surgery of a displaced diaphyseal fracture of the clavicle was 13%. Female gender was the only factor associated with unplanned reoperations or adverse events.

This study should be interpreted in light of several limitations. First, we used ICD-9 and CPT codes to identify the initial diagnoses and procedures rather than review of the medical records. There might be a small amount of miscoding as is typical for studies based on databases. Second, we included patients treated in three centers that might not be representative of the average centers. Third, the follow-up in our study was relatively short-to fracture healing only. Fourth, we did not include removal of plate for irritation or aesthetics because we studied reoperation. We cannot study implant irritation because this may or may not be reported in the medical record. The same goes for sensory problems. Lastly, the study design is retrospective, and therefore more susceptible to data loss (such as repeat surgeries in other hospitals), bias, and confounding than a prospective study. It is possible that the unplanned reoperations or adverse events are underrepresented, for example if patients had follow-up treatment in another hospital. Despite these limitations, it is likely that we have captured the majority of the important adverse events. The strength of this study is the large consecutive series of operative treated displaced diaphyseal fractures of the clavicle.

Our finding that women were more likely to experience an unplanned reoperation or adverse event after surgery for a displaced diaphyseal fracture of the clavicle is consistent with Leroux et al. who found that women had a 1.7 times higher rate of implant removal than men (12). Although in this study they also included implant removal for cosmetics or irritation. We speculate that plates may be more prominent in women or that women may be more likely to prefer implant removal.

Our rate of unplanned reoperations or adverse events after surgery of a displaced diaphyseal fracture of the clavicle (13%) is relatively low compared to rates in prior studies (14%-64%) (1, 5, 10, 11, 13). An explanation might be the varied definitions of adverse event. For instance, we did not include local implant irritation, planned implant removal, or sensory symptoms thought to be due to nerve irritation as an adverse event.

Four of 249 patients (1.6%) had early implant loosening or breakage. This rate is lower compared to prior studies (range: 3.4-14.6%) (1, 13). The two plate problems observed in our study were due to inadequate sized plates (third tubular plate and reconstruction plate). When an adequate sized plate is used, implant loosening and breakage are uncommon. The two intramedullary rod issues were due to propagation or underappreciated fracture lines in the medial fragment leading to inadequate or lost fixation. Our nonunion rate (2%), infection rate (4%), and refracture rate (0.4%), are consistent with prior studies (1, 2, 5, 10, 11, 13, 14).

In our study 2% of patients (5 of 249 patients) developed symptoms related to brachial plexus dysfunction. Brachial plexus palsy was diagnosed in four patients and in one patient brachial plexus irritation was described. Three of the brachial plexus palsies were previously described in a case report (15). In the Canadian Orthopaedic Trauma Society (COTS) study eight of 62 (13%) patients developed transient brachial plexus symptoms (but no motor palsies) after surgery (16). Bostman et al. found that two of 103 (2%) patients in their cohort developed brachial plexus irritation symptoms, but no palsies (1). Brachial plexus dysfunction might occur due to traction on the plexus during surgery. In our study, the type of fixation did not influence postoperative development of brachial plexus palsy.

In conclusion, patients considering surgery for a diaphyseal fracture of the clavicle trade improved alignment and a decreased risk of nonunion (from 10 to 15% with nonoperative treatment to 2% with

operative treatment), for an approximately 13% risk of an unplanned operation or an adverse event. Women are about three times as likely to have an unplanned reoperation or adverse event. Technical factors (such as suboptimal plate size, or unrecognized and extended medial fractures with intramedullary devices) and brachial plexus dysfunction (likely related in part to traction) might be responsive to planning and awareness.

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