Research Article

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Complications and its impact in patients with closed and open tibial shaft fractures requiring open reduction and internal fixation

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Aim: To evaluate the rates of infection and nonunion and determine the impact of infections on healthcare resource use and costs following open and closed fractures of the tibial shaft requiring open reduction internal fixation. **Methods:** Healthcare use and costs were compared between patients with and without infections following pen reduction internal fixation using MarketScan® databases. **Results:** For commercial patients, the rates of infection and nonunion ranged from 1.82 to 7.44% and 0.48 to 8.75%, respectively, over the 2-year period. Patients with infection had significantly higher rates of hospital readmissions, emergency room visits and healthcare costs compared with patients without infection. **Conclusion:** This real-world study showed an increasing rate of infection up to 2 years and infection significantly increased healthcare resource use and costs.

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Keywords: costs • healthcare resource use • infection • nonunion • open reduction internal fixation • tibial shaft fractures

Fractures of the tibia and fibula bones are a common orthopedic injury, with an incidence of 492,000 per year, and result in approximately 77,000 hospitalizations and 825,000 physician visits annually in the USA [1]. In the elderly, this is even more daunting, with almost 70% of Medicare patients being hospitalized following fractures and 38% receiving follow-up home healthcare [1].

Surgical treatment of tibia shaft fractures with open reduction and internal fixation (ORIF) is often indicated for open fractures, unstable or segmental fractures, when accompanied by fibula fracture or significant soft tissue injury. Potential complications following ORIF include post-surgical infection, malunion, nonunion, knee pain, malrotation, compartment syndrome and nerve injury [2–5]. As far back as 1987, Moore *et al.* [6] reported a 19% overall complication rate over a median 3.7 years, while other older studies report infection-specific rates ranging from 2 to 11% [7], far higher than the 1 to 3% infection rate reported for all orthopedic surgical procedures [8]. In a study conducted within Johns Hopkins Health System, inpatient length-of-stay was double (10.56 vs 5.64 days), and 30-day readmission rates sixfold higher (52 vs 8%) for patients with post-ORIF infections compared with patients who do not develop these infections [9]. Another complication of ORIF, delayed union or nonunion, occurs in up to 8% of closed and 3–17% of open fractures [10]. Studies utilizing large claims databases also report a 12–14% nonunion rate after tibial shaft fractures [1,11].

One of the challenges in the management of tibial shaft fractures includes the lack of recent reliable, and nationally-representative, complication rates of infection and nonunion post-ORIF. Available studies addressing complication rates are based on center-specific, single-setting populations limited by small sample sizes [2,8,12]. Moreover, risk factors associated with complications like infection and nonunion after ORIF are not well-defined,

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and limited data are available on the rate of infection or nonunion with respect to time after the ORIF. Clinicians must better understand the risk and the temporal relationship of the complication, whether the rates increase, decrease, or remain the same, to better optimize a patient-specific post-operative care plan that will result in improved complication-free outcomes.

Thus, given that currently there is lack of information on nonunion and infection rates in the same population in a large-scale, nationally representative claims database at different follow-up periods. And only few studies address the resource utilization or economic impact of ORIF complications [13]. This study utilizes large, geographically representative administrative claims databases in the USA to ascertain the complication rate at different time points post-ORIF, identify associated risk factors in a real-world population, and estimate the economic burden of infection.

Objectives

The primary objective was to estimate the real-world short-term and mid-term rates of infection and nonunion in patients with open and closed tibial shaft fractures after ORIF. Secondary objectives were to:

- Estimate potential healthcare resource use and economic impact of post-ORIF infection;
- Identify patient-specific factors associated with increased post-surgical complication risk.

Methods

Study design & setting

This retrospective, observational cohort study was conducted using a US-based administrative claims data (January 2007–June 2017) from the nationally representative IBM MarketScan® Research Databases including the Commercial, Medicare Supplemental and Medicaid databases. These databases include administrative medical (inpatient, outpatient, emergency room) and pharmacy claims from employer-sponsored plans for approximately 40 million enrollees per year with commercial insurance (i.e., working-age adults, spouses and dependents), 8 million enrollees per year with Medicaid coverage (Medicaid provides health coverage to low-income adults, children, pregnant women, elderly adults and people with disabilities) and 3–4 million enrollees per year with Medicare Supplemental coverage (Medicare provide health insurance for people who are 65 years and older and certain younger people with disabilities or End-Stage Renal Disease). MarketScan databases comply with the Health Information Portability and Accountability Act of 1996 (HIPAA). This study utilized de-identified patient records and did not include any primary data collection; hence Institutional Review Board approval was not needed.

Participants

Adult patients ($\geq$18 years of age), with open or closed tibial shaft fractures requiring ORIF surgery during an out- or inpatient admission were identified through a comprehensive list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and ICD-10-CM codes (Supplementary Material 1). Index date was defined as the date of the ORIF procedure, or the date of admission for the ORIF procedure in cases of inpatient admissions. All patients were required to have continuous enrollment for at least 180 days prior to index date (pre-index period) to reduce potential bias of prior fractures and a minimum of 30 days of follow-up. Patients were followed for a maximum of 2 years.

Patients were excluded if they met any of the following:

1. Any fractures, surgical interventions for fractures, hospitalizations, or emergency room visits during the pre-index period up to 30 days prior to the index date (i.e., Day -180 to Day -30). In some instances, the fracture may be treated with a 1–2 week delay hence Day -30 to Day 0 buffer for diagnosis of fracture was allowed;
2. Any ORIF procedures for tibia during the pre-index period; and,
3. Any infections, osteomyelitis or nonunion diagnosis in the 180-day pre-index period and up to 2 days post the index date or from date of discharge, whichever was greater (Figure 1).

Study cariables

Patient characteristics assessed at index date included age, gender, region, health insurance plan type and place of service. Patient history was identified using ICD-9-CM or ICD-10-CM codes, and comorbidities included in the Charlson Comorbidity Index (CCI) were identified during the pre-index period and a composite CCI score

Figure 1. Process of sample attrition.
ORIF: Open reduction and internal fixation.

was calculated for each patient. Patients were identified as having an 'open' fracture if they had the corresponding diagnosis at any point during the 30 days pre- and post- index. This was true even in cases where the first diagnosis was that of 'closed' fracture.

The primary outcome measure was rate of infection or nonunion. Infection and nonunion were each categorized as a binary variable ('Yes'/'No'), based on the presence of diagnostic or procedural codes (Supplementary Material 1), identified at least 2 days post-index date or from date of discharge, whichever was greater. The date of first-diagnosed infection or nonunion was recorded to identify the short-term (at 30, 60, 90, 180 days) and mid-term (at 365 days, 18 and 24 months) rates. Other clinical measures identified during the pre-index period included obesity, alcohol abuse, drug use disorder, smoking, diabetes and rheumatoid arthritis, and were based on ICD-9 and ICD-10 codes (Supplementary Material 2) were included for risk factors assessments.

Resource use during follow-up was recorded as all-cause hospitalizations and emergency room visits. Total estimated health care costs included all-cause hospitalizations, emergency room visits, outpatient visits and prescriptions during the follow-up period. All costs were inflated to the year 2017.

Data analysis & statistical methods

Demographic and comorbidity data were summarized using descriptive statistics for each insured group (commercial, Medicare and Medicaid). Infection and nonunion rates were calculated, separately and as a composite, for each follow-up period, and included only those patients that had the corresponding minimum follow-up duration. The proportion of patients with any hospitalizations and emergency room visits were compared between groups with and without infections, across all payer type databases. Similarly, total health care costs were estimated by summing the total net payments made by payers and compared between patients with and without infection. Chi-square tests were used to compare the proportions while the Wilcoxon rank sum tests were used to compare cost data. Logistic regressions were used to examine associations between infection, and separately, nonunion and various independent risk factor variables; models were run for 1-year follow-up period. Independent variables evaluated in the logistic regressions included gender, age groups, region, obesity, smoking status, drug and alcohol use, diabetes, CCI score, place of service and fracture type.

Results

The study included 19,383 commercially insured, 2654 Medicare and 2299 Medicaid patients (Figure 1). There was a greater proportion of women in the Medicare (67%) and Medicaid groups (57%) compared with the commercially insured group (47%; Table 1). The majority (64%) of commercially insured patients were under PPO (Preferred Provider Organization) plans. The Medicare population, overall, had the highest mean comorbidity score based on the Charlson Comorbidity Index (1.03 [SD: 1.46], followed by the Medicaid population (0.83 [1.43], and commercial (0.29 [0.78]).

Across all payer groups, there was a greater proportion of closed tibial shaft fractures compared with open (commercial: 91.9 vs 8.1%; Medicare: 91.9 vs 8.1%; Medicaid: 91.6 vs 8.4%).

Table 2 shows the rates of infection and nonunion, by payer and time of follow-up, in which rates for both outcomes increased over study follow-up. Within the first 30 days after index, almost 3% of patients developed infection, with the lowest infection rate (1.8%) observed in patients under commercial insurance, followed by 2.7% in Medicaid, and 2.9% under Medicare. At day 180, infection rates rose almost threefold, to 4.8% (commercially insured), 9.3% (Medicare) and 7.3% (Medicaid), whereas at 365 days, these rates rose to 6.2, 10.1 and 9.2%, respectively.

Nonunion rates were lower than infection rates across payer types within the first 30 days post-index (range 0.3–0.5). At day 180, the rates of nonunion exceeded infection rates specifically in the commercial insurance population (6%), 4.5% under Medicare and 4.7% under Medicaid. At the 365-day time point, these rates were as high as 8.2% for commercially insured patients, 5.8% for the Medicare population and 7% for the Medicaid patients.

By study end (24 months), the rate of infection was 7.4% in 8159 commercially insured patients, 12.3% in 1274 Medicare patients and 11.3% in 1002 Medicaid patients. Nonunion rates were 8.8% in commercially insured, 6.0% in Medicare and 8.0% in Medicaid.

Patients with a diagnosed infection post-ORIF had significantly higher ($p < 0.0001$ for all) rates of hospital readmissions as well as emergency room visits across every time period during study follow-up, compared with patients with no diagnosed infection (Figure 2). At the 90-day time point, 55% of patient (commercially insured) with diagnosed infection had readmissions compared with only 4% of those without the infection diagnosis. At 365 days, 60% of patients with infection were rehospitalized compared with those without infection (9%). Within the Medicare population, 26% of patients with an infection diagnosis were re-hospitalized within 3 months compared with 6% of those without infections; and 44% in the Medicaid subsample with infection compared with 8% without infection.

The total healthcare cost to the payer incurred was significantly higher for the group developing infections during follow-up (Table 3). At day 30, the average healthcare expenditure for commercially insured patients with infection was US$25,942 (SD: 38,278) which is 11-times greater than the group without infections (US$2360 [SD:8053]; $p < 0.0001$). At the end of day 365, the average cost incurred by patients with infections rose to as much as US$67,494 (SD: 94,657), more than five-times higher than the group without infections (US$13,434 [SD: 27,436]; $p < 0.0001$). At 1 year follow-up, younger commercially insured patients were less likely to develop infections, compared with those aged 46–64 years (vs 18–24 years, odds ratio (OR): 0.63; 95% CI: 0.48–0.83; vs 25–45 years, OR: 0.74; 95% CI: 0.63–0.88). Patients with open fractures were 69% more likely to develop infections compared with closed fractures (OR: 1.69; 95% CI: 1.35–2.12). Similarly, patients with open fractures were significantly more likely to develop nonunions compared with those with closed fractures (OR: 1.67; 95% CI: 1.36–2.04) Commercially insured patients diagnosed with diabetes in the pre-index period had a 45% increased

Table 1. Demographic and clinical characteristic distribution.

Demographic	Database					
	Commercial		Medicare		Medicaid	
	n	%	n	%	n	%
n	19,383	100.00%	2654	100.00%	2299	100.00%
Gender						
Female	9070	46.79%	1768	66.62%	1299	56.50%
Male	10,313	53.21%	886	33.38%	1000	43.50%
Age						
18–24	2294	11.84%	–	–	289	12.57%
25–45	6642	34.27%	–	–	710	30.88%
46–64	10,447	53.90%	–	–	919	39.97%
65–74	–	–	1435	54.07%	215	9.35%
75+			1219	45.93%	166	7.22%
Payer						
Data n/a	685	3.53%	78	2.94%	30	1.30%
CDHP	1017	5.25%	19	0.72%	–	–
Comprehensive	578	2.98%	1134	42.73%	1461	63.55%
EPO	281	1.45%	12	0.45%	–	–
HDHP	676	3.49%	3	0.11%	–	–
HMO	2177	11.23%	237	8.93%	655	28.49%
POS	1434	7.40%	101	3.81%	–	–
POS with capitation	103	0.53%	6	0.23%	147	6.39%
PPO	12,432	64.14%	1064	40.09%	6	0.26%
Type of fracture						
Closed	17,820	91.94%	2439	91.90%	2106	91.61%
Open	1563	8.06%	215	8.10%	193	8.39%
Year of ORIF						
2007	1824	9.41%	156	6.79%	212	7.99%
2008	1949	10.06%	170	7.39%	223	8.40%
2009	1967	10.15%	190	8.26%	259	9.76%
2010	2085	10.76%	197	8.57%	276	10.40%
2011	2498	12.89%	162	7.05%	379	14.28%
2012	2427	12.52%	213	9.26%	295	11.12%
2013	1928	9.95%	293	12.74%	311	11.72%
2014	1937	9.99%	312	13.57%	291	10.96%
2015	1151	5.94%	376	16.35%	174	6.56%
2016	1141	5.89%	230	10.00%	174	6.56%
2017	476	2.46%	n/a	n/a	60	2.26%
Place of service						
Emergency care	6515	33.61%	866	32.63%	1119	48.67%
Inpatient	8627	44.51%	1215	45.78%	435	18.92%
Other	3669	18.93%	389	14.66%	724	31.49%
Outpatient	572	2.95%	184	6.93%	21	0.91%
Region						
Data NA	2526	13.03%	216	8.14%	382	16.62%
North Central	4182	21.58%	819	30.86%	–	–
Northeast	2501	12.90%	390	14.69%	–	–
South	6927	35.74%	764	28.79%	–	–
Unknown	207	1.07%	26	0.98%	–	–
West	3040	15.68%	439	16.54%	–	–

CCI: Charlson comorbidity index; CDHP: Consumer directed health plan; EPO: Exclusive provider organization; HDHP: High deductible health plan; HMO: Health maintenance organization; n/a: Not applicable; ORIF: Open reduction and internal fixation; POS: Point-of-service; PPO: Preferred provider prganization.

Table 1. Demographic and clinical characteristic distribution (cont.).

Demographic	Database					
	Commercial		Medicare		Medicaid	
	n	%	n	%	n	%
CCI score						
0	15,974	82.41%	1359	51.21%	1393	60.59%
1	2118	10.93%	581	21.89%	424	18.44%
2–3	1074	5.54%	534	20.12%	357	15.53%
4–5	143	0.74%	129	4.86%	75	3.26%
5+	74	0.38%	51	1.92%	50	2.17%
Smoking event in baseline period of 180 days	128	0.66%	24	1.04%	19	0.72%
Obesity event in baseline period of 180 days	612	3.16%	124	5.39%	58	2.19%
Rheumatoid arthritis event in baseline period of 180 days	154	0.79%	28	1.22%	60	2.26%
Alcohol abuse	282	1.45%	101	4.39%	16	0.60%
Drug abuse	115	0.59%	95	4.13%	4	0.15%
Diabetes event in baseline period of 180 days	1586	8.18%	376	16.35%	599	22.57%
CCI 01 Myocardial infarction	58	0.30%	17	0.74%	23	0.87%
CCI 02 Congestive heart failure	146	0.75%	87	3.78%	150	5.65%
CCI 03 Periphral vascular disease	185	0.95%	108	4.70%	185	6.97%
CCI 04 Cerebrovascular disease	179	0.92%	92	4.00%	195	7.35%
CCI 05 Dementia	8	0.04%	49	2.13%	59	2.22%
CCI 06 Chronic pulmonary disease	908	4.68%	320	13.92%	289	10.89%
CCI 07 Connective tissue disease-rheumatic disease	192	0.99%	31	1.35%	83	3.13%
CCI 08 Peptic ulcer disease	30	0.15%	12	0.52%	14	0.53%
CCI 09 Mild Liver Disease	230	1.19%	58	2.52%	28	1.06%
CCI 10 Diabetes without complications	1536	7.92%	367	15.96%	577	21.74%
CCI 11 Diabetes with complications	328	1.69%	95	4.13%	175	6.59%
CCI 12 Paraplegia and hemiplegia	64	0.33%	71	3.09%	12	0.45%
CCI 13 Renal disease	203	1.05%	99	4.31%	176	6.63%
CCI 14 Cancer	432	2.23%	55	2.39%	210	7.91%
CCI 15 Moderate or severe liver disease	15	0.08%	4	0.17%	4	0.15%
CCI 16 Metastatic carcinoma	36	0.19%	10	0.43%	27	1.02%
CCI 17 AIDS/HIV	24	0.12%	29	1.26%	4	0.15%

CCI: Charlson comorbidity index; CDHP: Consumer directed health plan; EPO: Exclusive provider organization; HDHP: High deductible health plan; HMO: Health maintenance organization; n/a: Not applicable; ORIF: Open reduction and internal fixation; POS: Point-of-service; PPO: Preferred provider prganization.

likelihood of nonunion (OR: 1.45; 95% CI: 1.08–2.96), whereas Medicare patients with diabetes had an 85% increased likelihood of nonunion (OR: 1.85; 95% CI: 1.03–3.33; Supplementary Material 2)

Discussion

Tibial shaft fractures, apart from directly adding to the healthcare burden, can be complicated by nonunion and infections. These complications significantly increase the rates of emergency room visits and readmissions with significantly increased total healthcare costs. Small, single setting, studies allow hypothesis generation related to nonunion and infection risk factors, while large real-world data (data relating to patient health status and/or the delivery of healthcare routinely collected from a variety of sources, for example, registries, collections of electronic health records and administrative healthcare claims databases) [14] studies expand our understanding of risks post-ORIF and test the hypothesis. To our knowledge this study is the first to assess nonunion and infection rates

Table 2. Infection and nonunion rates.

	Database								
	Commercial			Medicare			Mediciad		
	Patients (n)	Patients with enrollment (n)	Rate	Patients (n)	Patients with enrollment (n)	Rate	Patients (n)	Patients with enrollment (n)	Rate
Infection									
30-day follow-up	352	19,383	1.82%	78	2654	2.94%	62	2299	2.70%
60-day follow-up	589	18,770	3.14%	143	2557	5.59%	102	2219	4.60%
90-day follow-up	697	18,101	3.85%	188	2482	7.57%	114	2140	5.33%
180-day follow-up	773	15,969	4.84%	208	2245	9.27%	140	1908	7.34%
12-month follow-up	783	12,589	6.22%	187	1858	10.06%	139	1515	9.17%
18-month follow-up	704	10,094	6.97%	176	1530	11.50%	123	1212	10.15%
24-month follow-up	607	8159	7.44%	157	1274	12.32%	113	1002	11.28%
Nonunion									
30-day follow-up	94	19,383	0.48%	10	2654	0.38%	NR	2299	NR
60-day follow-up	195	18,770	1.04%	19	2557	0.74%	20	2219	0.90%
90-day follow-up	362	18,101	2.00%	43	2482	1.73%	31	2140	1.45%
180-day follow-up	955	15,969	5.98%	101	2245	4.50%	89	1908	4.66%
12-month follow-up	1027	12,589	8.16%	108	1858	5.81%	106	1515	7.00%
18-month follow-up	867	10,094	8.59%	92	1530	6.01%	93	1212	7.67%
24-month follow-up	714	8159	8.75%	76	1274	5.97%	80	1002	7.98%
Infection or nonunion									
30-day follow-up	437	19,383	2.25%	88	2654	3.32%	67	2299	2.91%
60-day follow-up	763	18,770	4.06%	159	2557	6.22%	118	2219	5.32%
90-day follow-up	1024	18,101	5.66%	220	2482	8.86%	139	2140	6.50%
180-day follow-up	1613	15,969	10.10%	286	2245	12.74%	207	1908	10.85%
12-month follow-up	1643	12,589	13.05%	271	1858	14.59%	215	1515	14.19%
18-month follow-up	1421	10,094	14.08%	243	1530	15.88%	187	1212	15.43%
24-month follow-up	1190	8159	14.59%	211	1274	16.56%	169	1002	16.87%

in the same population in a large-scale, nationally-representative claims database. This is also the first study to measure these outcomes at different follow-up periods and assess the risk within each timeframe thus, can assist in developing the surgical and post-surgical treatment plan. The study further validates the need to address this patient population to help control costs and improve outcomes.

Recent studies reported post-surgical infection-specific rates of 2–3% at 30 days [9] and about 8% at 7 years [8]. Shepard *et al.* conducted a retrospective analysis at four Johns Hopkins Health System acute care hospitals and found the surgical site infection rate was 2.76 per 100 surgical procedures; the length-of-stay for patients with infection was almost twice that for patients without infection (10.56 vs 5.64 days in hospital, respectively) with statistically higher 30-day readmission rate (51.94 vs 8.19%, $p < 0.001$, respectively) [9]. Our nationwide claims-based study showed similar results, with an average 3% infection rate in the 30-day post-ORIF; 30-day readmission rates were 55% for patients with infection and 3% for those without infections. Another center-specific retrospective study of patients treated at a Level 1 trauma center reported a 7-year infection rate of 7.8% (20 out of 256 cases) [8], very similar to our 2-year infection rate of 7.4%, although their 4-week infection rate of 4.7% was higher than our 3% 30-day rate.

Antonova and colleagues [1] conducted a retrospective US managed care claims study of 853 patients with tibial shaft fractures, and reported an overall nonunion rate of 12% over the 2-year follow-up, with a higher rate observed among patients with open fractures (23%) compared with closed (10%). For a similar follow-up duration, we observed a 9% rate of nonunion among patients with both closed and open tibial shaft fractures.

Our study found an 11-fold difference between the mean 30-day total healthcare costs for tibial shaft fractures post-ORIF for those experiencing an infection (US$25,942) compared with those without infection (US$2360); there was a fivefold difference at 1 year. In contrast, the Johns Hopkins Health System study [9] of multiple inpatient surgical procedures (not including tibial shaft fracture [TSF]), reported average post-surgery hospital

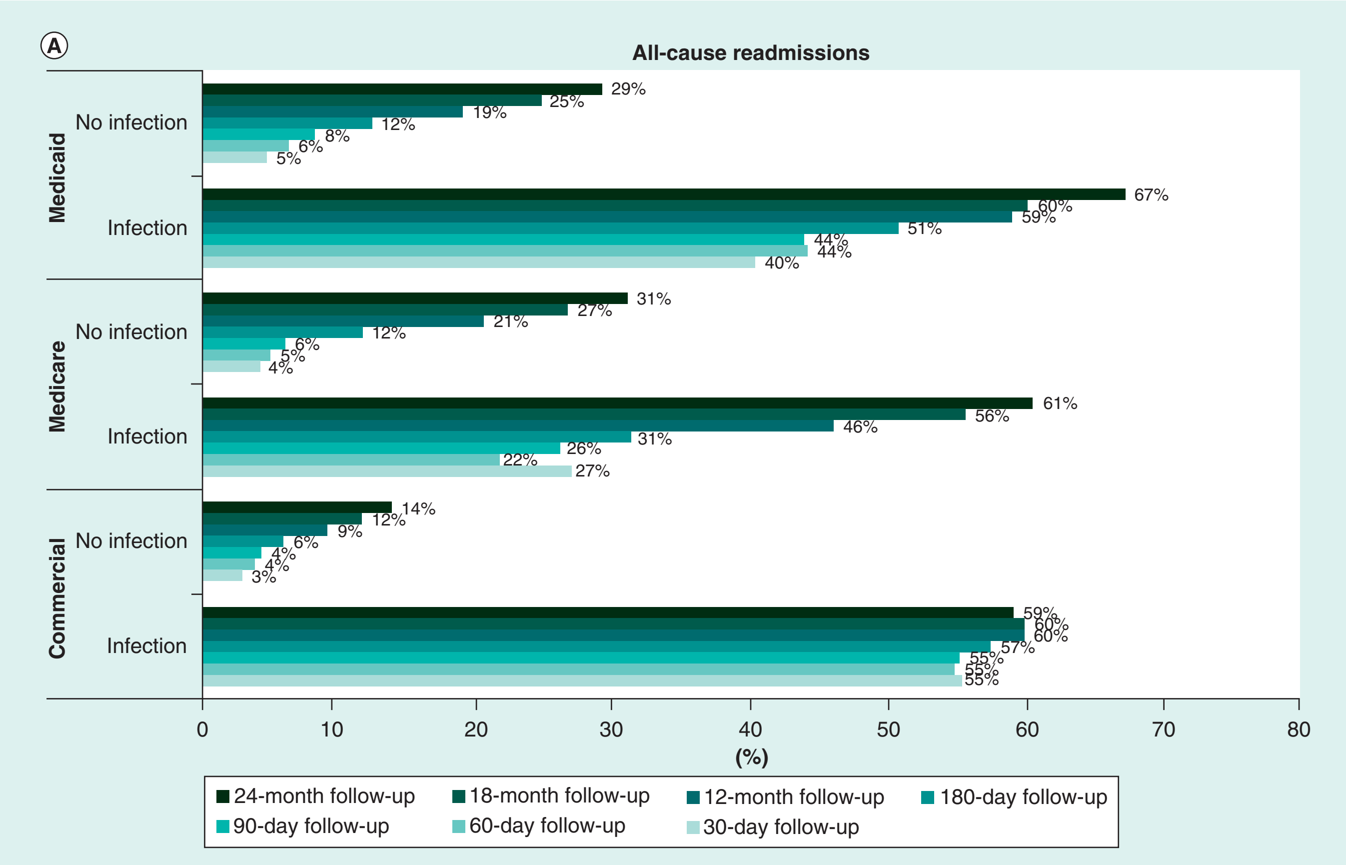

Figure 2. Hospital readmissions and emergency room visits rates across every time period during study follow-up, compared with patients with no diagnosed infection. Percentage of patients with resource use were compared between those with infections and no infections. All comparisons were made using Chi-square tests and all results were statistically significant at $p < 0.0001$.

charges (as opposed to costs) to be 1.8-fold higher for those experiencing infection compared with those who do not (US$79,134/10.56 day median length of stay [LOS] vs US$44,727/5.64 day median LOS), and the average duration of follow-up is unclear. In another cost analysis of nonunion after TSF, Antonova *et al.* [1] found median 2-year total healthcare costs to be more than twice as high compared with those without nonunion (median US$25,556 vs US$11,686).

Despite study design differences, mainly in case-finding criteria, these closely aligned results offer good external validity to our infection, nonunion and readmission rates. For example, Lin *et al.* [8] limited study inclusion to patients who had treatment for an infection within 6 months post-surgery, while our study assessed infection rates up to 24 months. Other study design factors provide a rationale for differences in costs between our research and others. Shepard *et al.* [9] evaluated multiple inpatient surgical procedures, not including TSF, in a single center analysis involving multiple surgical procedure hospital charges over a maximum period of 4 years. Antonova *et al.* [1] specifically assessed nonunion rates and costs, in an analysis based on treatment approaches from 2006 to 2008, while our cost analysis was specific to surgical infections. Further, our findings are consistent with other literature suggesting greater hospitalization and higher healthcare costs in individuals experiencing surgical complications, including infection [15,16]. This research also provides insight into patient characteristics that may be associated with more intense healthcare utilization immediately post-surgery. Within the acute timeframe, it was observed that males and the elderly patient population were more likely to develop infections and therefore probably require more individualized postoperative/postprocedure care. This care should extend beyond acute management as similar result trends are observed even at a longer follow-up duration (results not reported). Patients with open fractures also need alternative therapy management because their risk of developing infection and nonunion is consistently much higher, across all time frames.

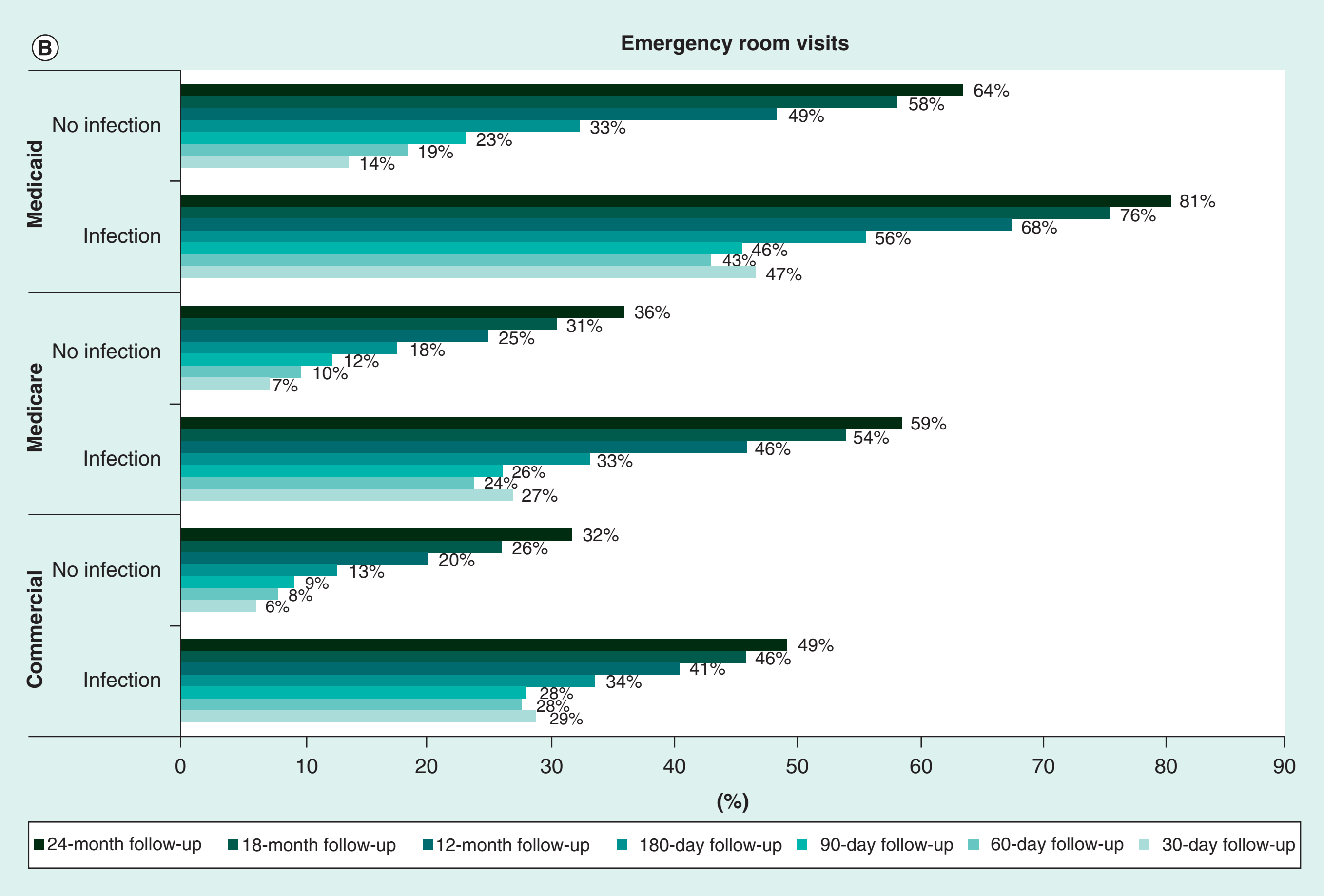

Figure 2. Hospital readmissions and emergency room visits rates across every time period during study follow-up, compared with patients with no diagnosed infection (cont.). Percentage of patients with resource use were compared between those with infections and no infections. All comparisons were made using Chi-square tests and all results were statistically significant at $p < 0.0001$.

The findings of our study should be considered notwithstanding a few limitations. The inclusion criteria and database used for analysis is limited to individuals with medical and prescription benefit coverage, thereby limiting generalizability to those without health insurance or coverage. The diagnosis codes for infection may lack specificity regarding the exact anatomy of the surgical site and there could be under-reporting or missed diagnoses, based on patient's choice (not to seek care) or access challenges. In this study, postoperative infection may not have been at the site of the ORIF, however the clinicians on the team reviewed and included codes to limit this potential bias. The presence of postoperative infection was identified based on ICD-9-CM, ICD-10-CM diagnosis and CPT codes, without the availability of laboratory confirmation. Results have been mixed regarding the accuracy of ICD-9-CM diagnosis codes for infection after various procedures [17]. However, administrative data using ICD-10-CM codes have shown reasonable test performance characteristics for identification of complex infections after surgery [18]. Future research using newer data with ICD-10 codes and laboratory confirmation is warranted to validate study findings [19]. Patients with adherence problems may be less likely to seek or comply with care, causing under-reporting of outcomes, and contribute to a selection bias among the sampled population. Additionally, the identification of patients and outcomes relied upon on clinician's use of diagnosis codes for billing purposes and therefore cannot completely exclude the likelihood of reporting errors or biases. This study is the first, to our knowledge, to investigate differences in rates of infection, nonunion and readmission, as well as healthcare costs by insurance type (commercial, Medicaid, Medicare); however, the association between fracture-related variables (e.g., compound, displaced, comminuted, among others) or patient characteristics (e.g., smoking, gender, age) on the outcome measures deserves further investigation. Productivity costs and indirect costs were not assessed; other studies have suggested that these costs may be substantial, with indirect costs exceeding direct medical healthcare

Table 3. Total healthcare expenditure.

		ALL cost			SSI cost			Non-SSI cost		
		Commercial	Medicare	Medicaid	Commercial	Medicare	Medicaid	Commercial	Medicare	Medicaid
30-day follow-up	N	19,383	2654	2299	352	78	62	19,031	2576	2237
	Mean	2789	7928	2540	25,942	17,647	10,262	2360	7634	2326
	Median	729	2231	417	14,492	10,272	2002	710	2131	399
	StdDev	10,007	15,046	19,288	38,278	21,726	17,608	8054	14,703	19,292
60-day follow-up	N	18,770	2557	2219	589	143	102	18,181	2414	2117
	Mean	4670	12,492	4233	31,559	25,102	18,662	3799	11,745	3538
	Median	1537	3966	818	17,793	17,796	3590	1480	3674	770
	StdDev	14,520	20,280	23,918	46,520	26,165	59,184	11,113	19,632	20,541
90-day follow-up	N	18,101	2482	2140	697	188	114	17,404	2294	2026
	Mean	6291	16,064	5425	36,115	33,431	20,170	5097	14,641	4595
	Median	2448	6023	1237	21,498	24,126	6171	2344	5073	1171
	StdDev	17,460	26,782	19,096	50,825	36,371	56,497	13,293	25,326	13,933
180-day follow-up	N	15,969	2245	1908	773	208	140	15,196	2037	1768
	Mean	10,463	22,739	10,287	51,023	47,104	29,170	8400	20,251	8792
	Median	4424	10,923	2433	30,528	30,778	13,853	4189	9264	2138
	StdDev	25,943	36,321	27,820	67,920	54,962	58,899	19,621	32,864	23,063
12-month follow-up	N	12,589	1858	1515	783	187	139	11,806	1671	1376
	Mean	16,796	33,161	19,601	67,494	66,884	48,571	13,434	29,387	16,675
	Median	7165	17,548	5886	40,445	41,324	24,797	6605	15,299	4874
	StdDev	37,855	52,527	39,118	94,657	75,096	73,675	27,436	47,942	32,353
18-month follow-up	N	10,094	1530	1212	704	176	123	9390	1354	1089
	Mean	22,217	42,621	29,462	82,193	85,233	62,072	17,721	37,082	25,778
	Median	9568	24,435	10,125	46,304	56,712	33,139	8756	21,432	8670
	StdDev	47,605	60,957	52,735	125,433	84,796	83,762	31,116	54,792	46,636
24-month follow-up	N	8159	1274	1002	607	157	113	7552	1117	889
	Mean	26,455	50,263	43,055	82,306	96,344	91,852	21,966	43,786	36,853
	Median	12,139	30,377	13,396	50,706	63,307	58,260	10,885	25,955	11,224
	StdDev	48,698	65,411	79,302	102,387	108,054	113,101	38,077	53,923	71,653

All values in USD. All p-values comparing SSI to non-SSI were $p < 0.0001$.
SSI: Surgical site infections.

costs by a factor of two in patients with tibia fractures [20]. This finding may be exacerbated by the fact that many trauma patients are young otherwise productive adults that may see substantial drop in productivity as a result of trauma. Future studies should evaluate this as well as explore other patient-reported outcomes related to health-related quality of life. Despite these limitations, this study provides essential and needed perspective on post-surgical tibial shaft fracture complication rates and specific medical costs associated with infection over specific time periods and by type of insured population.

Conclusion

In this nationwide retrospective real-world analysis of patients with tibial shaft fractures undergoing ORIF, an increasing rate of infection up to 2 years was determined. These post-surgical complications are accompanied by added healthcare resource use and expenditure.

Supplementary data

To view the supplementary data that accompany this paper please visit the journal website at: www.futuremedicine.com/doi/suppl/10.2217/cer-2019-0108

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Ethical conduct of research

IBM MarketScan database is in compliance with the Health Information Portability and Accountability Act of 1996 (HIPAA). Only de-identified patient records from IBM MarketScan database were used in this study; hence Institutional Review Board approval was not required.

Summary points

- Potential complications following open reduction and internal fixation (ORIF) include post-surgical infection, malunion, nonunion, knee pain, malrotation, compartment syndrome and nerve injury.
- The objectives of this study were to estimate the real-world short-term and mid-term rates of infection and nonunion in patients with open and closed tibial shaft fractures after ORIF, as well as to estimate potential healthcare resource use and economic impact of post-ORIF infection.
- IBM MarketScan® Research Databases including the Commercial, Medicare Supplemental and Medicaid databases were used to identify patients with open and closed tibial shaft fractures requiring ORIF.
- Logistic regressions were used to examine associations between infection, and separately, nonunion and various independent risk factor variables; models were run for 1-year follow-up period.
- At the 365-day time point, the rates for infections were to 6.2% (commercially insured), 10.1% (Medicare) and 9.2% (Medicaid), nonunion rates were as high as 8.2% for commercially insured patients, 5.8% for the Medicare population and 7% for the Medicaid patients.
- This is the first study to investigate rates of infection, nonunion and healthcare resource use as well as costs by insurance type (commercial, Medicaid, Medicare) over different follow-up periods.
- This study found that the patients with tibial shaft fractures undergoing ORIF are under risk of developing infections and nonunion for up to 2 years.

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