

Factors Associated With Nonunion and Infection Following Ankle Arthrodesis Using a Large Claims Database: Who Has Elevated Risk?

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Abstract

Background: Complications such as nonunion and infection following ankle arthrodesis can lead to increased patient morbidity and financial burden from repeat operations. Improved knowledge of risk factors can improve patient selection and inform post-ankle arthrodesis surveillance protocols.

Methods: This is a large retrospective, database study with structured query of a national insurance claims database (PearlDiver Technologies) for patients treated with ankle arthrodesis from 2015 to 2019 as identified by *International Classification of Diseases, Tenth Revision (ICD-10)*, codes. Patients with any operation 1 year prior to or following ankle arthrodesis were excluded from analysis to prevent attributing complications to another operation. Likelihoods of nonunion and infection within 1 year and 3 years following ankle arthrodesis were analyzed using Kaplan-Meier estimations. Patient characteristics associated with the identified complications following ankle arthrodesis were analyzed using multivariable logistic regression analyses.

Results: Our query yielded 2463 patients in the 5-year period who underwent ankle arthrodesis. Nonunion occurred in 11% (95% CI 10-12) of patients within 1 year of ankle arthrodesis and 16% (95% CI 14-17) of patients within 3 years. Infection occurred in 3.9% (95% CI 3.1-4.7) of patients within 1 year of ankle arthrodesis and in 6.2% (95% CI 5.1-7.2) of patients within 3 years. Obese patients increased odds of nonunion on multivariable analysis (OR 1.6, 95% CI 1.3-2.0; $P < .001$). On multivariable analysis, diabetes (OR 1.7, 95% CI 1.2-2.6; $P = .010$) and each 1-unit increase in Elixhauser Comorbidity Index scores (OR 1.1, 95% CI 1.1-1.2; $P < .001$) contributed to increased odds of infection after ankle arthrodesis.

Conclusion: Nonunion and infection following ankle arthrodesis have a 3-year probability of 16% and 6%, respectively. More than one-quarter of patients with nonunion following ankle arthrodesis experience a delay in diagnosis beyond 1 year. The risk of post-ankle arthrodesis nonunion is highest in patients with obesity; the risk of post-ankle arthrodesis infection is highest in patients with diabetes or an elevated Elixhauser Comorbidity Index score.

Level of Evidence: Level III, prognostic study.

Keywords: outcome studies, arthritis, diabetes

Introduction

Ankle arthrodesis is an operative technique used to treat a variety of pathologic conditions of the ankle, most commonly used in managing end-stage osteoarthritis with good success in reducing pain and improving function.^{7,13} However, the operation is not without potential complications, with incidence ranging from 1% to 26%.^{14,21,29,30} Postoperative complications such as nonunion and infection

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require reoperation or a revision arthrodesis. The increased healing time of these complications leads to increased patient morbidity and financial consequences for the patient and health care system.^{12,17}

High-quality risk stratification may help surgeons minimize post-ankle arthrodesis complications and unnecessary reoperations by informing appropriate selection of patients where operation will likely be successful vs patients who are likely to have a complication and should avoid surgery. In addition, risk stratification can also help identify patients who may benefit from increased postoperative surveillance.

Because of the relatively low complication probability associated with ankle arthrodesis, large-database studies provide greater statistical power to identify risk factors and demonstrate intervention efficacies.^{1,3} Previous studies identified factors associated with nonunion following ankle arthrodesis such as male gender, smoking, and operative site infection prior to arthrodesis. However, the majority were small retrospective studies ($n < 200$) with limited power to identify associations.^{2,9,25,34}

Factors associated with post-ankle arthrodesis operative site infections have not been well studied. Rather than focusing specifically on infections following ankle arthrodesis, many studies have analyzed infections following any orthopaedic ankle operation.^{20,22,23,31,35} Associated factors included obesity, diabetes, alcohol use, and open fractures.^{20,22,23,31,35} Therefore, using a large administrative claims database, we analyzed the likelihood of nonunion and infection within 1 and 3 years of ankle arthrodesis. Additionally, we evaluated how obesity, diabetes, or increased comorbidity burden correlate with nonunion and infection after ankle arthrodesis.

Methods

Study Design and Setting

This institutional review board–approved, retrospective, large database study included patient data extracted from PearlDiver Patient Record Database (PearlDiver Technologies, Inc, Colorado Springs, CO), for patients treated with ankle arthrodesis from 2015 through 2020. The PearlDiver database is a commercially available database composed of patient demographics, procedural volumes, and specific diagnoses representing the use and reimbursement of hospital costs billed as fee-for-service. The PearlDiver national administrative claims database contains 91 million individual patient records to include populations from all payer types such as commercial (Humana and United Healthcare), Medicare, Medicaid, Government, and cash. Patient data can be queried by patient billing codes including *International Classification of Diseases (ICD)*, *Current Procedural Terminology*, and *Diagnosis-Related*

Group codes. Queried data are deidentified and Health Insurance Portability and Accountability Act compliant. Using a national administrative claims database such as the PearlDiver database enables this study to investigate a procedure with relatively low probability of complications, cover a broad age range, add geographic diversity, and include substantial follow-up data for >30 days after discharge.³³

Patient Selection

To include patients with at least 1 year of continuous enrollment in the database, the analysis included only patients treated from 2015 through 2019. All patient records in this 5-year period were queried from the PearlDiver database using all *International Classification of Diseases, Tenth Revision (ICD-10)* codes for ankle arthrodesis: ICD-10-P-0SGF04Z, ICD-10-P-0SGF07Z, ICD-10-P-0SGF0JZ, ICD-10-P-0SGF0KZ, ICD-10-P-0SGF0ZZ, ICD-10-P-0SGG04Z, ICD-10-P-0SGG0JZ, ICD-10-P-0SGG0KZ, ICD-10-P-0SGG0ZZ, and ICD-10-P-0SGG07Z.

To prevent attributing either nonunion or infection complications to a different operation, we excluded patients with any other operation 1 year prior to or following ankle arthrodesis. We identified operative infection using *ICD-10* diagnostic codes: ICD-10-D-T8141XA, ICD-10-D-T8141XD, ICD-10-D-T8141XS, ICD-10-D-T8142XA, ICD-10-D-T8142XD, ICD-10-D-T8142XS, ICD-10-D-T8143XA, ICD-10-D-T8143XD, ICD-10-D-T8143XS, ICD-10-D-T8149XA, ICD-10-D-T8149XD, ICD-10-D-T8149XS, ICD-10-D-T84629A, ICD-10-D-T84629D, and ICD-10-D-T84629S. Nonunion was coded as ICD-10-D-M960.

Patient Data and Outcomes

Patient data included age at time of operation, sex, obesity, smoking record, diabetes, and the Elixhauser Comorbidity Index score.⁶ The Elixhauser Comorbidity Index is a validated index of comorbidity burden used to predict in-hospital mortality, similar to the Charlson Comorbidity Index. The Elixhauser Comorbidity Index is composed of 31 comorbidities, compared with 17 in the Charlson Comorbidity Index, and covers both acute and chronic conditions.^{6,32} The Charlson Comorbidity Index continues to be commonly used; however, the Elixhauser Comorbidity Index was used in the present study as it has yielded increased discrimination and has been shown to outperform the Charlson Comorbidity Index in predicting inpatient mortality in orthopaedic operations.^{16,32} Smoking record was evaluated by any documented claim of tobacco use in the database. Because of the nature of the database, this includes both patients who currently smoke or were a

smoker at a time during which the database was established.

The primary outcome of interest was the likelihood of nonunion and infection within 1 and 3 years following ankle arthrodesis using Kaplan-Meier estimations. The secondary outcome of interest was the association between identified patient characteristics and nonunion or infection following ankle arthrodesis as determined by multivariable logistic regression analyses.

Statistical Analysis

All statistical analyses and data visualizations were performed using R, version 4.0.5 (R Foundation, Vienna, Austria). All Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist elements were addressed.³⁸

Inferential statistics were compared using χ^2 test and Welch unpaired *t* test where appropriate. The Kaplan-Meier method was used to assess survivorship free from nonunion and infection after ankle arthrodesis. Multivariable logistic regression analyses were performed using patient age, sex, obesity, diabetes, smoking record, and Elixhauser Comorbidity Index score as covariates for each of the identified complications following ankle arthrodesis. Variables significant in univariable and multivariable analysis were reported. A *P* value less than .05 was considered statistically significant.

Results

Our query yielded 3058 patients treated with an ankle arthrodesis. Of those, 14% (430/3058) were excluded for not having at least 1 year of continuous enrollment in the database. Of the remaining 2628 patients, 6.3% (165/2628) were excluded for having an operation within 1 year prior to or following ankle arthrodesis. The remaining cohort numbered 2463 patients (Figure 1),³⁸ with almost equal distribution between males and females (47.9% and 52.1%, respectively) in the 5-year period. Nonunion occurred in 14% (346/2463) of patients following ankle arthrodesis. Infection occurred in 5% (115/2463) of patients following ankle arthrodesis (Table 1).

Likelihood of Nonunion and Infection

Nonunion occurred in 11% (95% CI 10-12) of patients within 1 year of ankle arthrodesis and in 16% (95% CI 14-17) of patients within 3 years using Kaplan-Meier estimations (Figure 2A). Infection occurred in 3.9% (95% CI 3.1-4.7) of patients within 1 year of ankle arthrodesis and in 6.2% (95% CI 5.1-7.2) of patients within 3 years using Kaplan-Meier estimations (Figure 2B).

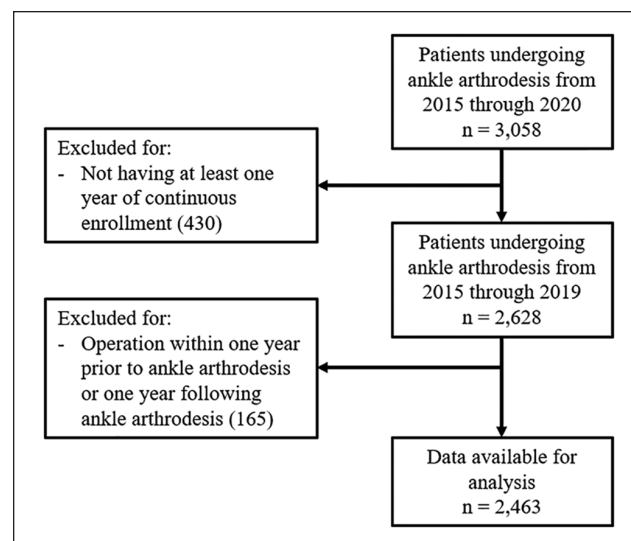


Figure 1. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) flowchart of cohort selection.

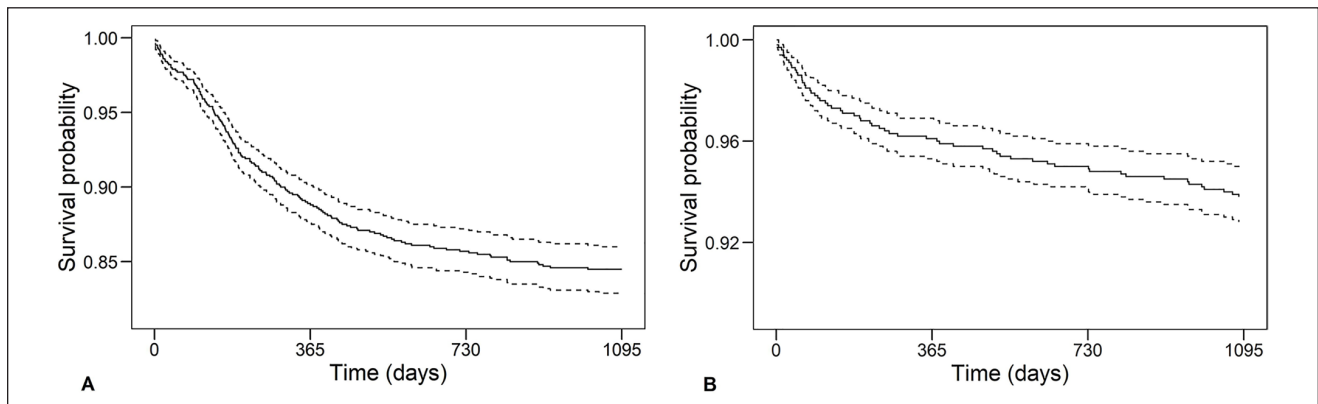
Effects of Obesity and Diabetes on Nonunion and Infection

The odds of nonunion were similar among diabetic and non-diabetic patients: (14.2% [179/1261] vs 13.9% [167/1202]; *P* = .89). Elixhauser Comorbidity Index scores were similar between patients with and without nonunion following ankle arthrodesis (7.7 ± 4.4 vs 7.5 ± 4.4 , respectively; *P* = .76). The odds of nonunion were different in obese patients compared with nonobese patients (17.1% [252/1476] vs 9.5% [94/987]; *P* < .001) and among patients with a smoking record compared to patients without (18.0% [106/589] vs 12.8% [240/1874]; *P* = .002). Multivariable analysis demonstrated that obesity (OR 1.6, 95% CI 1.3-2.0; *P* < .001) remained a significant characteristic that contributed to increased odds of nonunion following ankle arthrodesis.

Infection was not associated with different odds among patients with a smoking record and patients without (5.3% [31/589] vs 4.5% [84/1874]; *P* = .50). The odds of infection following ankle arthrodesis were different among diabetic and nondiabetic patients (6.8% [86/1256] vs 2.4% [29/1207]; *P* < .001) and among obese and nonobese patients (5.5% [81/1476] vs 3.4% [34/987]; *P* = .024). Elixhauser Comorbidity Index scores diverged between patients with and without infection following ankle arthrodesis (9.6 ± 4.8 vs 7.1 ± 4.3 , respectively; *P* < .001). On multivariable analysis, diabetes (OR 1.7, 95% CI 1.2-2.6; *P* = .010) and each 1-unit increase in Elixhauser Comorbidity Index scores (OR 1.1, 95% CI 1.1-1.2; *P* < .001) contributed to increased odds of infection following ankle arthrodesis.

Table 1. Demographics of Overall Cohort and Cohorts With Infection or Nonunion After Ankle Arthrodesis.

Demographics	Overall (n = 2463)	Nonunion (n = 346)	P Value	Infection (n = 115)	P Value
Female, n (%)	1283 (52)	184 (53)	.74	60 (52)	.99
Age, y, n (%)			<.001		.20
≤19	15 (1)	0 (0)		0 (0)	
20-24	1 (19 (1)	0 (0)		0 (0)	
25-29	2 (44 (2)	0 (0)		0 (0)	
30-34	3 (72 (3)	6 (2)		0 (0)	
35-39	3 (80 (3)	10 (3)		3 (3)	
40-44	6 (145 (6)	26 (8)		10 (9)	
45-49	7 (165 (7)	33 (10)		11 (10)	
50-54	250 (10)	46 (13)		18 (16)	
55-59	353 (14)	56 (16)		16 (14)	
60-64	394 (16)	63 (18)		21 (18)	
65-69	324 (13)	49 (14)		15 (13)	
70-74	276 (11)	33 (10)		11 (10)	
75-79	263 (11)	24 (7)		10 (9)	
80-84	63 (3)	0 (0)		0 (0)	
Region, n (%)			.13		.036
Northeast	409 (17)	57 (16)		14 (12)	
Midwest	709 (29)	117 (34)		46 (40)	
South	922 (37)	109 (32)		33 (29)	
West	423 (17)	62 (18)		22 (19)	
Insurance, n (%)			.17		.49
Commercial	1507 (61)	223 (64)		69 (60)	
Medicaid	209 (8)	27 (8)		13 (11)	
Medicare	718 (29)	96 (28)		33 (29)	
Other	29 (1)	0 (0)		0 (0)	

**Figure 2.** Kaplan-Meier analysis of survivorship free from (A) nonunion and (B) infection within 3 years of ankle arthrodesis.

Discussion

Using the largest available administrative claims database made up of all claims fee-for-service data, we sought to evaluate the likelihood of and characteristics independently associated with nonunion and infection following ankle arthrodesis. We report that nonunion occurred in 11% of

patients within 1 year of ankle arthrodesis and in 16% of patients within 3 years using Kaplan-Meier estimations. We found that infection occurred in 3.9% of patients within 1 year of ankle arthrodesis and in 6.2% of patients within 3 years using Kaplan-Meier estimations. The risk of nonunion was highest in patients with obesity. Patients with

diabetes or an elevated Elixhauser Comorbidity Index score had the highest odds of infection post ankle arthrodesis. Recognition of these conditions may establish appropriate expectations of ankle arthrodesis outcomes and increase patient and clinician understanding of ankle arthrodesis risks.

Our results demonstrate that about 1 in 6 patients have nonunion within 3 years of ankle arthrodesis where more than one-quarter of those patients experience a delay in diagnosis beyond 1 year. Among patients identified in the PearlDiver database who were treated with ankle arthrodesis from 2015 through 2019, the likelihood of nonunion occurring within 3 years of index operation was 16%. This probability aligns with the range of 3% to 23% in previous studies investigating nonunion following ankle arthrodesis.^{5,8,11,25,36} The majority of nonunion complications in our cohort were diagnosed within 1 year, with an additional 4.4% of patients diagnosed with nonunion in the following 2 years. There are several possible explanations for this delayed diagnosis of nonunion. Conclusive objective data confirming nonunion may be lacking or difficult to obtain, or physicians may have difficulty accepting diagnosis of nonunion and instead recommend the patient to continue to wait and see whether union is delayed. Alternatively, patients may be disinclined to seek additional care after having found the recovery from the index surgery difficult. Regardless, our results demonstrate a more accurate nonunion rate that covers a large population across multiple regions and institutions. These findings suggest that a routine computed tomographic scan might be a reasonable tool in postoperative follow-up given this relatively high rate of nonunion at 3 years.

Infection had a lower likelihood of 6.2% within 3 years of ankle arthrodesis; 3.0% of those patients were diagnosed with an infection within 6 months. These probabilities support reported infection probabilities following all orthopaedic ankle operations with a range of 1% to 6%.^{44,46} Many basic guidelines have been published in an attempt to minimize causes of operative site infections, yet the risk of infection is not negligible. Although the reported incidences are relatively low, patients and clinicians must be aware of these risks to remain vigilant in minimizing infections. It may also inform better patient selection, akin to the body mass index restrictions now common in selecting hip and knee replacement candidates.

Our analysis identified obesity as the only independently associated risk factor for nonunion following ankle arthrodesis. Other studies have identified male gender, smoking, and surgical site infection prior to arthrodesis as factors associated with postoperative nonunion.^{2,9,25,34} A large national database study revealed obesity as univariately associated with significantly higher probabilities of major, minor, medical, infectious, and systemic complications, as well as revision procedures following total ankle arthroplasty and ankle

arthrodesis.⁴¹ Our study adds to the literature by demonstrating the multivariable association of obesity with nonunion following ankle arthrodesis. As the prevalence of obesity continues to increase throughout the United States, with projections reaching nearly 50% of adults by 2030,³⁹ it is essential for clinicians and patients to understand this considerable risk characteristic and increase commitment to reducing the impacts and prevalence of obesity.

We found no multivariable association between nonunion and diabetes. This adds to the growing knowledge that well-controlled diabetes may not necessarily inhibit healing. However, uncontrolled diabetes or diabetes involving vascular disease or neuropathy has been shown in many studies to reduce successful wound healing and bone growth.⁴²⁻⁴⁴ Perhaps more importantly, the mechanical consequences of post-ankle arthrodesis healing under an obese frame could be just as, or more, important than compromised biology of tissue regeneration in diabetics. Further investigation with more granular variables characterizing obesity may help differentiate why increased body mass index impacts nonunion. Further study may also reveal whether this complication arises from factors such as the increased difficulty of the operation or the lack of scientific guidance in treatment,^{28,40} contributions from the increased periarticular soft tissue envelope size,⁴⁵ higher proinflammatory state following the procedure,¹⁸ or potential differences in postoperative management.

Diabetes and elevated Elixhauser Comorbidity Index score were independently associated with increased risk of post-ankle arthrodesis infection in our analysis. Uncontrolled diabetes has been clearly established as an independent risk for surgical site infections following ankle surgery.^{19,43,44} Other studies have used hemoglobin A1c, neuropathy, and peripheral artery disease as surrogate markers of uncontrolled diabetes.⁴²⁻⁴⁴ However, data on these factors were not readily available or associated with the index operation time through the PearlDiver database. To express uncontrolled diabetes, we used the increased comorbidity burden as identified by Elixhauser Comorbidity Index score.^{26,47} Our findings demonstrated that each 1-unit increase in Elixhauser Comorbidity Index score was associated with a 10% increase in odds of infection following ankle arthrodesis. Currently, the predictive capabilities of the Elixhauser Comorbidity Index on postoperative complications following orthopaedic surgery have been poorly demonstrated and validated.^{10,16} However, the Elixhauser Comorbidity Index has been shown to help predict in-hospital mortality, hospital length of stay, adverse hospital events, and hospital discharges.^{16,32} Further investigation is needed to evaluate and compare both indexes in predicting orthopaedic postoperative complications. However, based on our results, increased use of the Elixhauser Comorbidity Index in orthopaedic foot and ankle surgery may have the potential to advance orthopaedic outcomes research.

We note several limitations. Limited granularity of patient data impeded our ability to fully elucidate the underlying cause of associations as well as prevented review of individual charts, which would have given our study insight into the surgical techniques and postoperative protocols used. The use of patient billing codes minimizes the ability of the present study to capture the clinical context and differentiate the severity of complications. For instance, infections identified by the included *ICD-10* codes may include minor wound complications requiring oral antibiotics or infections requiring secondary debridement procedures; both types of infections are of clinical interest but are largely disparate problems. However, our exclusion criteria helped refine our results by directly attributing all complications to the index procedure.

As a retrospective study, this analysis is susceptible to selection bias introduced by public and selected commercial health plan data in the PearlDiver national administrative claims database. However, our cohort's large sample size and geographic diversity may limit the impact of any selection bias.^{1,24,27} Use of this database is also limited by the quality, accuracy, and overall availability of data entered into the database.¹⁵ In particular, administrative databases may underreport chronic medical conditions considered less acute in the perioperative orthopaedic surgery setting.¹⁶ There may be misclassification bias of the collected factors (eg, smoking record, obesity) because we relied on administrative data and electronic health records. However, misclassification errors have been shown to distribute equally in large studies.³⁷ Additionally, the percentage of patients with a smoking record analyzed (24%) corresponds to the known current tobacco use in the United States (21%).⁴ Although this study used a large database to increase power of associations, exclusively used claim data may limit the external validity of the reported results. Even with these limitations, our study with a large population that covers multiple regions and institutions provides insight into patient characteristics that complicate orthopaedic patient care as their prevalence increases.

Conclusions

Among this population derived from a large all-claims database using *ICD-10* coding, ankle arthrodesis carries a 16% risk of nonunion and a 6% risk of infection within 3 years. More than one-quarter of patients with nonunion following ankle arthrodesis experience a delay in diagnosis beyond 1 year. The risk of post-ankle arthrodesis nonunion is highest in patients with obesity. Although diabetes and its associated "poor biology" is often viewed as the culprit in an obese diabetic patient who fails to heal, our research suggests that we should pay more attention to the mechanical and biologic consequences of obesity. The risk of post-ankle arthrodesis infection is highest in patients with diabetes or an elevated

Elixhauser Comorbidity Index score. Both patients and clinicians should be aware of these factors prior to ankle arthrodesis to set appropriate expectations of risks and outcomes.

Ethical Approval

Ethical approval of this study was waived by the Oregon Health and Science University research integrity office institutional review board because it is "research not involving human subjects."

Declaration of Conflicting Interests

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