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CLINICAL RESEARCH

Patient and Procedure-specific Risk Factors for Deep Infection After Primary Shoulder Arthroplasty

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Abstract

Background Deep infection after shoulder arthroplasty is a diagnostic and therapeutic challenge. The current literature on this topic is from single institutions or Medicare samples, lacking generalizability to the larger shoulder arthroplasty population.

Questions/purposes We sought to identify (1) patient-specific risk factors for deep infection, and (2) the pathogen profile after primary shoulder arthroplasty in a large integrated healthcare system.

Methods A retrospective cohort study was conducted. Of 4528 patients identified, 320 had died and 302 were lost to followup. The remaining 3906 patients had a mean followup of 2.7 years (1 day-7 years). The study endpoint was the diagnosis of deep infection, which was defined as revision surgery for infection supported clinically by more than one of the following criteria: purulent drainage from the deep incision, fever, localized pain or tenderness, a positive deep culture, and/or a diagnosis of deep infection made by the operating surgeon based on intraoperative findings. Risk factors evaluated included age, sex, race, BMI, diabetes status, American Society for Anesthesiologists (ASA) score, traumatic versus elective procedure, and type of surgical implant. For patients with deep infections, we reviewed the surgical notes and microbiology records for the pathogen profile. Multivariable Cox regression models were used to evaluate the association of risk factors and deep infection. Adjusted hazard ratios and 95% CI are presented.

Results With every 1-year increase in age, a 5% (95% CI, 2%–8%) lower risk of infection was observed. Male patients had a risk of infection of 2.59 times (95% CI, 1.27–5.31) greater than female patients. Patients undergoing primary reverse total shoulder arthroplasty had a 6.11 times (95% CI, 2.65–14.07) greater risk of infection compared with patients having primary unconstrained total shoulder arthroplasty. Patients having traumatic arthroplasties were

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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2.98 times (95% CI, 1.15–7.74) more likely to have an infection develop than patients having elective arthroplasties. BMI, race, ASA score, and diabetes status were not associated with infection risk (all $p > 0.05$). *Propionibacterium acnes* was the most commonly cultured organism, accounting for 31% of isolates.

Conclusions Younger, male patients are at greater risk for deep infection after primary shoulder arthroplasty. Reverse total shoulder arthroplasty and traumatic shoulder arthroplasties also carry a greater risk for infection. *Propionibacterium acnes* was the most prevalent pathogen causing infection in our primary shoulder arthroplasty population.

Level of Evidence Level II, prognostic study. See the Instructions for Authors for a complete description of levels of evidence.

Introduction

Shoulder arthroplasty is a commonly performed procedure for various degenerative and traumatic conditions affecting the glenohumeral joint. In recent years, the total number of shoulder arthroplasties performed in the United States has exponentially increased [6]. Infection is one of the most common reasons for revision surgery after shoulder arthroplasty. Although the overall risk of deep infection after primary shoulder arthroplasty is low, the consequences can be devastating for the patient and costly for the healthcare system [2, 5, 10, 15–19].

Few studies address the patient-specific risk factors associated with deep infection after primary shoulder arthroplasty [11, 14, 17]. These studies were conducted at high-volume single academic centers, which may not be generalizable to other practice settings. Additionally, another study was conducted using a Medicare cohort, which excludes younger patients and provides limited clinical information [11]. It is important to have a better understanding of the patient-specific risk factors that are related to deep infections requiring hospital readmission for repeat shoulder surgery. This information will help orthopaedic surgeons identify patients at greater risk, counsel them appropriately, and allow for use of potential preventive measures.

Previous studies have reported Gram-positive aerobic bacteria as the most common offending organism [16, 17]. However, there is increasing concern that anaerobic bacteria, *Propionibacterium acnes* in particular, may be more prevalent [16, 18]. Identification of changing contemporary infectious origins may assist in improved prophylaxis measures.

The purposes of our study are to (1) evaluate the patient-specific risk factors associated with deep infection after primary shoulder arthroplasty in a large integrated healthcare system; and to (2) describe contemporary pathogen prevalence in this population.

Patients and Methods

Study Design, Data Collection, and Study Sample

A retrospective cohort study using prospectively collected data from a shoulder arthroplasty registry was conducted. The registry was established in 2005 in a large healthcare system that has more than nine million members throughout the United States. The data collection procedures, quality control, and participation of the registry have been described [13]. In brief, this registry collects patient, surgical, implant, surgeon, and hospital data for all patients undergoing shoulder arthroplasties using operative paper forms and administrative databases including electronic medical records. The registry monitors postoperative complications such as infections, thromboembolic events, revisions, and reoperations of the patients. In 2010, there was 100% capture of procedures by the registry of cases performed at our institutions.

All primary total shoulder arthroplasties, reverse total shoulder arthroplasties, and hemiarthroplasties performed between January 1, 2005, and December 31, 2011, in the two largest geographic regions (Southern California and Northern California) that participate in the registry were identified. Procedures performed for cancer (n = 1) or infection (n = 13) at the time of the primary procedure were not included in the sample. Of the total 4528 patients included, 320 died (two had infections before death, 7.0%), and 302 (6.7%) were lost to followup. The patients who were lost to followup had a mean followup of 348 days (SD, 260 days). The final sample included procedures from 32 medical centers and 257 surgeons. A total of 4528 primary shoulder arthroplasties were included in the analysis and the patients had a mean followup of 2.7 years (range, 1 day–7 years). Of these, 2229 (49.2%) were total shoulder arthroplasties, 1753 (39%) were hemiarthroplasties, and 546 (12%) were reverse total shoulder arthroplasties. A total of 3683 (81%) were elective procedures, and the remainder were performed for trauma. The mean age of the cohort was 69.7 years (SD, 10.3 years; range, 25–101 years) and the majority were females (n = 2538 [56%]) and white (n = 3716 [82%]) (Table 1).

Outcome of Interest

Deep infection after primary shoulder arthroplasty was the endpoint of this study. Infections were identified using a

Table 1. Overall sample description by infection status

Variable	Total sample		No infection		Infection		p value
	Number	Percent	Number	Percent	Number	Percent	
All patients	4528	100.0	4483	99.0	45	1.0	
Age (years)							
< 45	240	5.3	239	99.6	1	0.4	0.088
45–64	71	1.6	70	98.6	1	1.4	
65–84	1276	28.2	1256	98.4	20	1.6	
85+	2941	65.0	2918	99.2	23	0.8	
Mean (range)	69.7	69.4–70.0	69.7	69.4–70.0	65.3	61.8–68.8	0.005
95% CI	25–101		25–101		27–86		
Gender							
Female	2538	56.1	2523	99.4	15	0.6	0.002
Male	1990	44.0	1960	98.5	30	1.5	
Race							
White	3716	82.1	3676	98.9	40	1.1	0.828
Hispanic	425	9.4	423	99.5	2	0.5	
Black	216	4.8	214	99.1	2	0.9	
Asian	101	2.2	100	99.0	1.	1.0	
Other/multi	47	1.0	47	100.0	None	None	
Unknown	23	0.5	23	100.0	None	None	
BMI (kg/m^2)							
< 30	2561	56.6	2536	99.00	25	1.0	0.102
30–34	1047	23.1	1032	98.6	15	1.4	
> 35	863	19.1	859	99.5	4	0.5	
Unknown	57	1.3	56	98.3	1	1.8	
ASA class							
I and II	2239	49.5	2212	98.8	27	1.2	0.061
> III	1881	41.5	1869	99.4	12	0.6	
Unknown	408	9.0	402	98.5	6	1.5	
Diabetes							
Yes	1186	26.2	1173	98.9	13	1.1	0.679
No	3342	73.8	3310	99.0	32	1.0	
Indication and procedure							
Elective/hemiarthro- plasty	955	21.1	950	99.5	5	0.5	0.007
Elective/reverse total shoulder arthroplasty	509	11.2	497	97.6	12	2.4	
Elective/total shoulder arthroplasty	2219	49.0	2203	99.3	16	0.7	
Trauma/hemi- arthroplasty	798	17.6	786	98.5	12	1.5	
Trauma/reverse total shoulder arthroplasty	37	0.8	37	100.0	None	None	
Trauma/total shoulder arthroplasty	10	0.2	10	100.0	None	None	

ASA = American Society of Anesthesiology, CI = confidence intervals, BMI = body mass index.

comprehensive electronic screening algorithm of electronic medical records and administrative claims of the institution using International Classification of Disease, 9th Revision, Clinical Modification codes. After initial electronic review, all procedures flagged by the electronic screening are adjudicated by a trained clinical content expert using modified National Healthcare Safety Network (NHSN)/CDC guidelines [7]. Deep infection was defined as revision surgery for infection supported clinically by more than one of the following criteria: purulent drainage from the deep incision, fever, localized pain or tenderness, a positive deep culture, and/or a diagnosis of deep infection by the operating surgeon based on intraoperative findings. To capture patients with an indolent infection not diagnosed in the early postoperative time, we continuously monitor patients (for an indefinite time), unlike the NHSN/CDC

surveillance parameter of 1 year or the updated 2013 guideline of 90 days [3]. Our study period was from 2005 to 2011 and we monitored all deep infections during that time.

During the study period, 45 (1.0%) patients had a diagnosis of deep infection at a median of 212 days (interquartile range, 67–538 days; mean time, 446 days; range, 12–2227 days). Of these 45 patients, 30 (67%) had infections within the first year postoperatively and the remaining patients had infections occur after 1 year.

Exposures of Interest

Patient and procedure characteristics were explored as possible risk factors for deep postoperative infection. The patient characteristics investigated included age, gender, race, BMI, general health status at the time of surgery as measured by the American Society of Anesthesiology (ASA) score, and diabetes status. The procedure-related variables included the type of procedure performed (total shoulder arthroplasty, reverse total shoulder arthroplasty, and hemiarthroplasty) and whether the procedure was traumatic or elective.

Pathogen Profile

For the patients identified as having an infection, we also determined the prevalence of the cultured organisms. We extracted these data from microbiology reports and surgical notes and they are reported as absolute numbers and percentages of positive cultures. Aerobic cultures from all study centers were kept at one central microbiology laboratory for 2 weeks.

Statistical Analysis

Means, 95% CIs, and ranges were used to describe continuous variables, and Student's t-tests were used to compare different groups with respect to age. Frequencies and proportions were used to describe categorical variables and chi-square and Fisher's exact test were used to compare these variables between groups. Cox proportional hazards regression models were used to evaluate the association of the independent variables and the outcome of deep infection. If variables were significant in the bivariate ($p < 0.20$) models, they subsequently were included in a multivariable model. Proportional hazards assumptions were met, collinearity was evaluated using tolerance values (all < 0.10), and outliers were manually investigated. Patients were censored from the analysis if they had an event of deep infection, died, or left the healthcare plan during the study period. Patients with missing data were excluded from the final model. To determine the effect of missing data in the final estimates, sensitivity analysis was conducted (models evaluated all case information without variable missing data). Hazard ratios, 95% CIs, and Wald chi-square p values are presented. All analyses were two-tailed with an alpha of 0.05 used as the statistical significance threshold; all analyses were performed using SAS for Windows 9.2 (SAS, Cary, NC, USA).

Results

After adjusting for variables, we identified younger age, male sex, reverse shoulder arthroplasty, and a traumatic indication for arthroplasty to be associated with an increased risk of deep infection (Table 2). For each year increase in age, the risk of infection is 5% less (95% CI, 2%–8%, $p < 0.001$). In males, the risk of infection is 2.59 times (95% CI, 1.27–5.31; $p = 0.009$) greater than in females. With reverse total shoulder arthroplasty, the risk of infection was 6.11 times (95% CI, 2.65–14.07; $p < 0.001$) greater than for total shoulder arthroplasty. For traumatic indications, the risk of infection is 2.98 times (95% CI, 1.15–7.74; $p = 0.025$) greater than for elective procedures. BMI, race, diabetic status, and general health status (ASA score) were not found to be associated with an increased risk of deep infection in this study cohort.

Forty-five patients had deep infections. There were a total of 43 positive cultures in 37 patients; of which five patients had polymicrobial infections. An additional 8 patients had culture negative results. Our investigation revealed the most common organism to be *Propionibacterium acnes* with 14 (27.5%) cultures. There were seven (13.7%) cultures of coagulase-negative staphylococcus infections, four (7.8%) caused by methicillin-resistant *Staphylococcus aureus*, and three (5.9%) caused by methicillin-sensitive *S aureus*. We found three (5.9%) cultures of *Finegoldia magna*, three (5.9%) cultures of *Enterobacter*, and eight (15.7%) infections with negative cultures with the diagnosis made clinically and intraoperatively. Five (11%) patients had polymicrobial infection (more than one infectious organism isolated). Several other organisms accounted for one or two positive cultures each (Table 3).

Discussion

Infectious complications after primary shoulder arthroplasty can lead to devastating consequences. Because the cause of infection can be multifactorial, it is important to analyze these data in a broad population setting. Unlike previous

Table 2. Patient and procedure risk factors for infection

Risk factor	Univariate hazard ratio (95% CI)	p value	Adjusted hazard ratio (95% CI)	p value
Age, per 1-year increments	0.97 (0.94–0.97)	0.006*	0.95 (0.92–0.98)	< 0.001
Males versus females	2.56 (1.38–4.75)	0.003*	2.59 (1.27–5.31)	0.009
ASA class ≥ III versus I and II	0.56 (0.28–1.11)	0.094*	0.71 (0.34–1.45)	0.344
Procedure		0.003*		< 0.001
Hemiarthroplasty versus total shoulder arthroplasty	1.26 (0.64–2.49)	0.508	0.63 (0.24–1.63)	0.338
Reverse total shoulder arthroplasty versus total shoulder arthroplasty	3.54 (1.67–7.50)	0.001	6.11 (2.65–14.07)	< 0.001
Traumatic versus elective procedure	1.62 (0.83–3.12)	0.156	2.98 (1.15–7.74)	0.025
BMI (kg/m^2)		0.095*		0.000
30–34 versus < 30	1.54 (0.81–2.92)	0.187	1.88 (0.95–3.73)	0.081
≥ 35 versus < 30	0.48 (0.17–1.37)	0.168	0.63 (0.21–1.91)	0.416
Race				
Nonwhite versus white	0.59 (0.23–1.49)	0.261	–	–
Diabetes				
(Yes versus no)	1.11 (0.58–2.12)	0.747	–	–

* Included in multivariable analysis ($p < 0.20$); ASA = American Society of Anesthesiologists.

Table 3. Deep surgical site infection organisms

Isolate	Total number of cultures (N = 51; 100%)
Propionibacterium acnes	14 (27.5)
Coagulase-negative *Staphylococcus aureus*	7 (13.7)
Methicillin-resistant *Staphylococcus aureus*	4 (7.8)
Methicillin-sensitive *Staphylococcus aureus*	3 (5.9)
Enterobacter cloacae	3 (5.9)
Finegoldia magna	3 (5.9)
Corynebacterium	3 (5.9)
Bacillus species	2 (3.9)
Enterococcus	1 (2.0)
Diphtheroids	1 (2.0)
Proteus mirabilis	1 (2.0)
Pseudomonas aeruginosa	1 (2.0)
Cultures negative*	8 (15.7)

*2 had (+) gram stain

studies that were performed in single high-volume institutions by a few high-volume surgeons [2, 6, 8], the surgeons and medical centers participating in this study are from various settings (ie, urban, rural) and have different surgical volumes. Therefore, our findings may have more generalizable findings compared with previous studies. In our study, which used the registry of a large healthcare system, we aimed to identify patient-specific risk factors associated with deep postoperative infection after primary shoulder arthroplasty. We also aimed to characterize the organism profile in this patient population.

A limitation of our study is the result of the low incidence of infections. This limits the study power and the statistical analyses that can be performed. The low number of events limits the risk factors that can be evaluated so that there are likely other infection risk factors not included in our analysis, such as associated dental-related issues, urinary tract infections, history of previous surgery, and other invasive procedures (eg, colonoscopy, prostate procedures) that may introduce bacterial loads into the bloodstream. Surgical-related factors such as implant type, operative time, antibiotic loaded cement, and type of scrub also may be related to infection risk. Additionally, surgeon and hospital-related factors such as volume and experience may be related to this risk. In our study, 6.7% of the patients were lost to followup after an average of 348 days. Given that the average time to infection was 212 days, we believe that this low attrition rate and long followup of patients who were lost to followup minimizes the bias that could be introduced by the attrition.

We identified younger age, male sex, reverse shoulder arthroplasty, and traumatic arthroplasty as risk factors for infection. Singh et al. [17] used data from one institution to report on patients who underwent total shoulder arthroplasties during a 33-year period and found older age was associated with a 3% lower risk of infection per year increase in age. In a similar study [16] focusing on patients who underwent hemiarthroplasties during the same 33-year period, an increased risk of infection in younger patients was not observed. In addition to younger patients, our study showed male patients had a 2.59 times greater risk of infection than female patients. Singh et al. [16] reported

males had a greater risk of infection (hazard ratio, 2.67) than females who underwent total shoulder arthroplasty. Sex, however, was not found to be a risk factor for infections in patients who underwent a hemiarthroplasty at the same institution. Although it is unclear why male patients are at greater risk than female patients, our study is consistent with studies that reported not only a greater risk in males [11, 14, 16], but that male patients without signs of infection have a much greater increased risk of having cultures positive for *P acnes* [14]. Patel et al. suggested that shoulder skin region has a greater bacterial load of *P acnes* compared with other body regions and this may be sex-related [12]. Studies have reported infection rates for shoulder arthroplasty of approximately 1%, with reverse total shoulder arthroplasty having the highest rate [1, 2, 16–18, 20]. We found that when evaluating patients who had total shoulder arthroplasties and reverse total shoulder arthroplasties separately, 0.7% of those having a total shoulder arthroplasty had an infection develop compared with 2.2% of patients having a reverse total shoulder arthroplasty. The overall incidence of infection in patients who had reverse total shoulder arthroplasties in our population was slightly less than the 3% to 4% reported previously [6, 20]. Finally, in a study of 1431 primary hemiarthroplasties, the risk of infection in patients who had the procedures for traumatic purposes was 3.18 times that for elective hemiarthroplasties [16]. It is possible that this increased risk in patients with trauma may be the result of the initial soft tissue injury occurring at the time of fracture leading to increased bleeding, the increased surgical time for prosthetic height adjustment and tuberosity reconstruction, or the hematoma formation before and after the injury [4]. However, although the evidence supporting greater infection risk in traumatic settings is indisputable, the exact mechanism is unclear.

Our study revealed *P acnes* to be the most common organism causing periprosthetic shoulder infection in this contemporary statewide multicenter patient sample. This may be the result of improved recognition and techniques to identify this organism and highlights a changing profile of infection etiology, which may justify consideration of a change in prophylactic measures such as preoperative skin preparation techniques specific to the shoulder and antibiotic coverage. Previous studies have shown the most common causative pathogens in shoulder arthroplasties to be Gram-positive aerobic bacteria [9, 16, 17, 19]. Singh et al. [16, 17] found, in their study spanning several decades, that *S aureus* was the most common offending organism in their single center study, with *P acnes* increasingly seen during the later period of their studies. They recommended future studies examining infectious organism prevalences in broader patient samples and larger centers and registries. Studies revealing a high rate of unexpected positive *P acnes* cultures in the setting of revision shoulder arthroplasty highlight the fact that the overall prevalence of this organism is underestimated [14, 20].

Younger, male patients and patients having reverse total shoulder arthroplasties or trauma-related procedures are greater risk for deep infection. *P acnes* is the most prevalent pathogen causing infection. Identifying these patient risk factors allows for an improved ability to develop predictive models and use preoperative measures to decrease the complication potential. We recommend more aggressive prophylaxis targeting pathogens such as *P acnes* in patients at greater risk.

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