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ORIGINAL ARTICLE

Implant Removal and Spacer Placement for Infected Shoulder Arthroplasty: Risk Factors for Repeat Procedures, Spacer Retention, and Mortality

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Abstract *Background:* Current studies reporting on patients following prosthesis removal and spacer placement for periprosthetic joint infection (PJI) of the shoulder have largely been descriptive and insufficiently powered to determine risk factors for outcomes other than reimplantation. *Purpose:* The objective of the present study is to provide a national perspective on the 1-year outcomes following prosthesis removal and spacer placement and risk factors for outcomes other than reimplantation for treatment of PJI following shoulder arthroplasty. *Methods:* A national database was queried for Medicare patients who underwent prosthesis removal and spacer placement for PJI between 2005 and 2012. These patients were then evaluated for 5 major study endpoints including: (1) replantation of a shoulder prosthesis within 1 year postoperatively, (2) a repeat irrigation and debridement with second antibiotic spacer placement procedure within 1 year postoperatively, (3) in-hospital death within 1 year postoperatively, (4) a shoulder Girdlestone-type procedure within 1 year postoperatively, and (5) the remaining patients, who were considered to have a retained spacer. Patients with a study endpoint within 1 year postoperatively were included in the study: (1) mortality, (2) repeat debridement, (3) resection arthroplasty, and (4) reimplantation. While it is possible that some patients were not captured due to errors in coding, it is unlikely that patients were lost to follow-up due to change in location of services, given that the database captures all episodes of care that are coded throughout the USA. Independent risk factors were evaluated using logistic regression analysis. *Results:* Nine hundred seventy-five patients who underwent prosthesis removal and spacer placement were included. Within 1 year postoperatively, 21 patients died (2.2%), 70 patients had a repeat debridement procedure (7.2%), 55 patients had a resection arthroplasty procedure (5.6%), 349 patients retained their spacers (35.8%), and the remaining 480 patients had a shoulder arthroplasty reimplanted (49.2%). Numerous independent risk factors exist for all outcomes studied. *Conclusion:* The fate of antibiotic spacers placed for PJI of the shoulder at 1 year is variable, with numerous independent risk factors for outcomes other than reimplantation. Patients with PJI following total shoulder arthroplasty should be counseled on the risk factors that influence the outcomes of staged revision for shoulder PJI.

Keyword shoulder arthroplasty · infection · revision · complications · spacer

Level of Evidence: Therapeutic Study: Level IV

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Introduction

Periprosthetic joint infection (PJI) is a devastating complication following shoulder arthroplasty (SA) and continues to pose significant challenges for the orthopedic community [1, 4, 7]. PJI has been reported to complicate approximately 0 to 3.9% of primary total shoulder arthroplasty (TSA) and 2 to 18% of reverse TSA [1, 2, 10, 13, 14, 16]. Similar to total hip and knee arthroplasty, 2-stage exchange arthroplasty has emerged as a common treatment strategy for deep infection following SA. Stage 1 of the 2-stage exchange process involves implant removal, irrigation and debridement, and placement of an antibiotic spacer. While there remains no "gold-standard" for the treatment of PJI of the shoulder, a recent systematic review demonstrated that the number of studies reporting on 2-stage exchange arthroplasty for established PJI of the shoulder is approximately double that of any other treatment modality [7].

In the limited available reports on staged revision for PJI after SA, success rates are variable, ranging from 60 to 100% rate of infection eradication [4, 5, 7, 15, 17]. While the majority of those studies focus on the clinical outcomes following successful reimplantation, there remains a substantial number of patients within the original cohorts who undergo repeat stage 1 irrigation and debridement and placement of a second antibiotic spacer or resection arthroplasty following the index procedure [12]. In addition, there is also a subset of patients who do not undergo a second-stage reimplantation procedure, with the spacer serving as the definitive treatment [12]. Thus, the fate of spacers implanted in the treatment of PJI for the shoulder is variable, and current studies reporting on patients in the interstage period have largely been descriptive and insufficiently powered to determine risk factors for subsequent procedures, mortality, reimplantation, resection arthroplasty, and no reimplantation [9, 12, 13, 17, 18].

While the incidence of PJI following TSA is low, the prevalence of this complication is expected to increase alongside the increasing number of TSA being performed annually, and data regarding the outcomes of antibiotic spacer placement is important in managing both patient and surgeon expectations [6, 11]. The aim of the present study was to use a national database to provide a national perspective on the natural history of resection arthroplasty and antibiotic spacer implantation in patients being treated for PJI of the shoulder.

Methods

The PearlDiver Patient Records Database (www.pearldiverinc.com, Fort Wayne, IN, USA), a for-fee insurance-based patient records database, was used for the present study. The database consists of several separate private insurers and a Medicare database with procedural volumes and patient demographics for patients with International Classification of Diseases, 9th Revision (ICD-9), diagnoses and procedures, or Current Procedural Terminology (CPT) codes. The data obtained is anonymous, and thus the authors' Institutional Review Board deemed this study exempt. The data for the present study was derived from the Medicare database within PearlDiver, which contains over 100 million individual patients' records from 2005 to 2012. The Medicare data contained within the database is the complete 100% Medicare Standard Analytical File, indexed and reorganized to allow for patient tracking over time, among other advantages. One notable advantage for the present study is that the database is able to capture any coded treatment across the USA, eliminating any loss of follow-up from patients who may have gone elsewhere to receive further surgery following the index prosthesis explantation and spacer placement.

The goal study population was patients who underwent stage 1 SA, defined as removal of a shoulder prosthesis and placement of an antibiotic cement spacer for a diagnosis of infection. The database was first queried for all patients who fit this criteria using ICD-9 procedure code 80.01 (arthrotomy for removal of prosthesis without replacement, shoulder), coupled with ICD-9 procedure code 84.56 (insertion of cement spacer) during the same procedure. Only patients who had an associated infection ICD-9 diagnostic code, including codes for periprosthetic infection, septic shoulder, or postoperative infection, were then included in the study cohort. First, the trend in the incidence of removal of a shoulder prosthesis and placement of an antibiotic cement spacer for a diagnosis of infection stage 1 TSA was evaluated from 2006 to 2012, as at least 1 of the ICD-9 codes was not introduced until late 2005; thus, the incidence in this year was not reflective of an entire year's worth of patients. Next, patients without a study endpoint within 1 year postoperatively, or without at least 1 year of follow-up in the database were then excluded.

Five major study endpoints were evaluated: (1) replantation of a shoulder prosthesis within 1 year postoperatively, (2) a repeat irrigation and debridement with a second antibiotic spacer placement procedure within 1 year postoperatively, (3) in-hospital death within 1 year postoperatively, (4) a shoulder Girdlestone-type procedure within 1 year postoperatively, and (5) the remaining patients, who were considered to have a retained spacer. Replantation was defined as a subsequent SA procedure following the stage 1 procedure index prosthesis removal and antibiotic spacer placement procedure, including a hemiarthroplasty, anatomic TSA, or reverse TSA. A repeat stage 1 irrigation and debridement procedure with placement of a second antibiotic spacer was characterized by a removal and replantation of a cement spacer (ICD-9 procedure codes 84.57 and 84.56 in the same operation) following the index prosthesis removal and antibiotic spacer placement procedure. A Girdlestone-type procedure was identified as removal of a cement spacer without replacement of a second spacer, or without placement of a shoulder prosthesis using ICD-9 procedure code 84.57 (removal of cement spacer) without an associated spacer insertion code (ICD-9 84.56), or CPT 23195 without an associated arthroplasty or spacer code. All remaining patients who were not coded as dead during the minimum 1 year of follow-up were considered to have retained cement spacers.

A logistic regression analysis was then performed to evaluate independent risk factors for each of 3 study endpoints: (1) death within 1 year postoperatively, (2) repeat irrigation and debridement procedure with placement of a second antibiotic spacer within 1 year postoperatively, and (3) no replantation (spacer retention) within 1 year postoperatively. The same risk factor variables were entered into the regression model for each endpoint of interest: gender, age (as a categorical variable), obesity, morbid obesity, tobacco use, alcohol abuse, inflammatory arthritis, depression, hypercoagulable state, diabetes mellitus, hyperlipidemia, hypertension, peripheral vascular disease, congestive heart failure, coronary artery disease, chronic kidney disease, need for hemodialysis, lung disease, and liver disease. For all significant variables, odds ratio (OR) and 95% confidence interval (CI) were calculated. For all regression analyses, $p < 0.05$ was considered statistically significant. SPSS version 23 for Macintosh (IBM, Armonk, NY, USA) was used for all statistical calculations.

Results

One thousand four hundred nine patients met all inclusion criteria. From 2006 to 2012, the incidence of irrigation and debridement with placement of an antibiotic spacer increased each year, from 148 procedures to 273 procedures, representing an 85% increase over the study period. Of these patients, 975 patients had a study endpoint within 1 year, or had a minimum of 1-year follow-up within the database and formed the final study cohort. Within 1 year postoperatively, 21 patients died (2.2%), 70 patients had a repeat irrigation and debridement procedure with placement of a second antibiotic spacer (7.2%), 55 patients underwent resection arthroplasty (5.6%), 349 patients retained their spacers (35.8%), and the remaining 480 patients had an SA reimplanted (49.2%) (Fig. 1).

Independent risk factors for death within 1 year following irrigation and debridement with placement of an antibiotic spacer included age 80 to 84 years old (OR 11.76, $p < 0.0001$) and age over 85 years (OR 9.45, $p = 0.007$), alcohol use (OR 4.77, $p = 0.005$), coronary artery disease (CAD) (OR 2.36, $p = 0.02$), and hemodialysis (OR 13.79, $p < 0.0001$) (Table 1).

Independent risk factors for no reimplantation within 1 year include female gender (OR 1.42, $p = 0.0002$), age 75 to 79 years (OR 1.33, $p = 0.049$), age 80 to 84 years (OR 2.22, $p < 0.0001$) and age over 85 years (OR 4.85, $p = 0.007$), tobacco use (OR 1.29, $p = 0.036$), alcohol use (OR 1.56, $p = 0.014$), and inflammatory arthritis (OR 1.33, $p = 0.016$) (Table 1).

Independent risk factors for a repeat irrigation and debridement procedure with placement of a second antibiotic spacer include age of 65 to 70 years (OR 1.92, $p = 0.004$) and age less than 65 years (OR 2.09, $p = 0.007$), morbid obesity (OR 2.84, $p < 0.0001$), diabetes mellitus (OR 1.44, $p = 0.042$), and CAD (OR 1.57, $p = 0.011$) (Table 1).

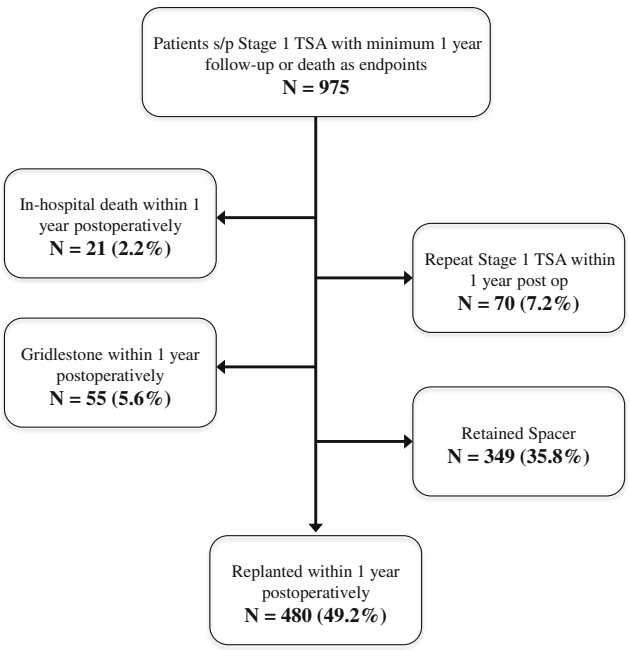

Fig. 1. Flow chart depicting the outcomes of the final cohort at minimum 1-year follow-up or death as endpoints.

Discussion

In the past decade, the number of SA procedures in the USA has increased dramatically and is expected to continue to increase, with annual procedure volume growth rates of 9.4% for TSA and 5.6% for hemiarthroplasty shoulder procedures [6, 11]. While SA has been shown to produce excellent clinical outcomes and long-term survival rates, complications occur, and PJI is responsible for a substantial number of failures [1]. Several treatment strategies exist, but the majority of the modern literature has focused on 2-stage exchange arthroplasty [7]. Existing studies describing 2-stage exchange arthroplasty for PJI of the shoulder are limited to small, retrospective, institutional case series that largely focus on outcomes after successful reimplantation [12, 13, 18]. Furthermore, as opposed to lower-extremity arthroplasty, permanent spacer implantation following explantation for the treatment of PJI after SA has been demonstrated to provide satisfactory relief of pain and preserved function and may obviate the need for a second-stage procedure [12]. Thus, the fate of spacers implanted in the treatment of PJI for the shoulder is highly variable, with limited literature available regarding the risk factors and likelihood for future procedures, including reimplantation [9, 12, 13, 18].

In the present study, we report on 975 patients who underwent SA prosthesis removal and antibiotic cement spacer placement for infection. At 1 year following explant and spacer placement for PJI following TSA, only half of patients underwent reimplantation, one-third of patients retained their spacer, and just less than 10% required repeat explantation procedures. Death was uncommon in the first year following the first stage of treatment with spacer placement. Finally, we report numerous independent risk factors that exist associated with the need for repeat explantation, irrigation and debridement, and second spacer placement, no reimplantation, and death within 1 year following index stage 1 SA.

There are several limitations to the present study that must be considered, many of which are consistent with other studies using large, administrative databases [3, 19]. The power of our analysis relies on the quality of the data and the accuracy with which these procedures are coded within the database. Thus, miscoding and non-coding by physicians are potential sources of error. Age is reported by the insurers as a categorical variable and thus cannot be evaluated as a continuous variable. Furthermore, we are unable to determine perioperative lab values, the acuity of the infection, and the histopathological findings of cultures at the time of surgery. In addition, we are also unable to determine the combination and dosing of antibiotics within the antibiotic spacer placed during the stage-1 procedure. We are also not able to determine the type of infecting organism or its antibiotic sensitivities. Finally, we are unable to determine the functional outcomes associated with each endpoint in the present study. While this was not the goal of the study, limited literature is available on the functional outcomes following each of the endpoints examined in this study, and larger,

Table 1 Summary of significant risk factors for study endpoints within 1 year postoperatively

Risk factor	Odds ratio	95% confidence interval	*p*
Death within 1 year			
Age 80–84 years	11.76	[3.14–44.13]	< 0.0001
Age ≥ 85 years	9.45	[1.87–47.78]	0.007
Alcohol use	4.77	[1.62–14.04]	0.005
Coronary artery disease	2.36	[1.14–4.86]	0.02
Hemodialysis	13.79	[4.66–40.76]	< 0.0001
No replant			
Female gender	1.42	[1.18–1.72]	0.0002
Age 75–79 years	1.33	[1.00–1.77]	0.049
Age 80–84 years	2.22	[1.56–3.15]	< 0.0001
Age ≥ 85 years	4.85	[2.67–8.83]	< 0.0001
Tobacco use	1.29	[1.02–1.63]	0.036
Alcohol abuse	1.56	[1.10–2.21]	0.014
Inflammatory arthritis	1.33	[1.06–1.67]	0.016
Repeat stage 1 TSA			
Age < 65 years	2.09	[1.20–3.08]	0.007
Age 65–70 years	1.92	[1.27–3.45]	0.004
Morbid obesity	2.84	[1.83–4.41]	< 0.0001
Diabetes mellitus	1.44	[1.01–2.04]	0.042
Coronary artery disease	1.57	[1.11–2.22]	0.011

multicenter comparison studies are still needed to determine the optimal treatment strategy in regard to functional improvement following stage 1 arthroplasty of the shoulder [12].

Jawa et al. recently reported on the largest cohort of patients undergoing irrigation and debridement with placement of an antibiotic spacer for PJI using a prosthesis of antibiotic-loaded acrylic cement (PROSTALAC) spacer [12]. The authors evaluated 28 patients who were managed with the PROSTALAC spacer with an average follow-up of 27.6 months. Notably, 10 of the 28 patients had already undergone irrigation and debridement with retention of the prosthesis prior to placement of the PROSTALAC implant. The group reported that 5 patients (18%) had recurrent infections requiring debridement and revision spacer placement. Including these patients, 12 patients (43%) were satisfied with pain relief and function and did not undergo a reimplantation, and 16 patients (57%) had a successful second-stage procedure. Furthermore, the group reported no cases of resection arthroplasty or patient deaths at more than 2 years of follow-up. Jerosch and Schneppenheim reported on 10 patients who underwent explantation with antibiotic spacer placement and reported that 8 of these patients went on to successful reimplantation, with the remaining 2 patients refusing further surgery due to poor health status [13]. Finally, Strickland et al. retrospectively evaluated 17 patients who underwent explantation with antibiotic spacer placement followed by reimplantation [18]. While the authors reported no cases of revision spacer placement, resection arthroplasty, or patient deaths, the focus of this study was largely on the clinical outcomes following successful reimplantation and thus does not accurately reflect the overall success rate of 2-stage exchange arthroplasty for the treatment of PJI [18]. The rate of patients with retained spacers in the study by Jawa et al. (43%) was quite similar to the rate observed in our study (35.8%) [12].

Given the low incidence of infection following TSA procedures, data on the success of eradication of infection following explantation with spacer placement in PJI has been sparse, even when compiling data from multiple centers [10, 15]. While these studies have provided valuable information on the clinical and functional outcomes of patients undergoing this procedure, they have been inadequately powered to identify risk factors associated with each outcome [12, 13]. In the present study, the large cohort of patients allows us adequate power to identify independent risk factors for various outcomes studied at a minimum of 1 year post operatively. Similar to the results reported by Jawa et al. [12], we also found that less than half of patients undergoing explantation with spacer placement underwent reimplantation within 1 year, and more than one-third of patients retained their spacers at 1 year postoperatively. We found older age to be independently associated with increased odds of spacer retainment within 1 year. While there are no comparative studies available in the literature, prior studies have reported that patients who declined reimplantation were of advanced age or poor general health [13]. In addition, Jawa et al. reported on 12 patients who declined a second-stage procedure because they were satisfied with the pain relief and function that was provided by the spacer [12]. Other risk factors for a retained spacer at 1 year included tobacco use, alcohol abuse, and inflammatory arthritis. While it is not current practice to plan for spacer retention, permanent spacer placement for PJI of the shoulder must be considered as a potentially acceptable outcome, and data from the present study suggest that it might occur in more than a third of patients following explantation with spacer placement [12]. Thus, when discussing outcomes and treatment options with patients with PJI of the shoulder, it is important to understand and consider these risk factors and results in managing patient expectations.

Although there has been a recent focus on the morbidity and mortality associated with 2-stage exchange arthroplasty for PJI in the lower-extremity arthroplasty literature, there are few reports that describe the mortality rates between stages in staged revision for PJI of the shoulder [8]. While we report a 1-year mortality rate that is less than half of that seen in the lower-extremity arthroplasty literature, it provides a reminder of the serious risks associated with the procedure [8]. Risk factors for mortality within 1 year following explantation with spacer placement were similar to that of spacer retention and included older age and alcohol abuse, in addition to coronary artery disease and hemodialysis.

Finally, it is important for patients and surgeons alike to recognize that the use of an antibiotic spacer does not always successfully eradicate infection, and recurrence and unplanned procedures in the period between the index procedure and reimplantation do occur [9, 13, 18]. In the broader orthopedic literature, Gomez et al. recently investigated this period following 504 lower-extremity arthroplasty procedures and noted nearly a 12% rate of interim spacer exchanges for persistent infections [8]. There are few similar studies within the shoulder arthroplasty literature that report on failed irrigation and debridement with placement of an antibiotic spacer procedures requiring repeat irrigation and debridement and revision spacer implantation. Jawa et al. reported that 18% of patients from a cohort of 28

experienced recurrent infections requiring debridement and revision PROSTALAC placement [12]. We found that younger age, in addition to morbid obesity, diabetes, and coronary artery disease were all independently associated with a repeat stage-1 procedure within 1 year.

In conclusion, in this study of 975 Medicare patients who underwent irrigation and debridement with placement of an antibiotic spacer, only half of patients underwent reimplantation within 1 year postoperatively. One-third of patients retained their spacer, and just less than 10% required repeat irrigation and debridement procedure with placement of a second antibiotic spacer. Death is uncommon in the first year following irrigation and debridement with placement of an antibiotic spacer of the shoulder. Numerous independent risk factors exist for a repeat irrigation and debridement procedure with placement of a second antibiotic spacer, no reimplantation, or death within 1 year following explantation and antibiotic spacer placement for PJI associated with TSA.

Compliance with Ethical Standards

Conflict of Interest: J. M. Cancienne, MD, James C. Carr 2nd, MD, and B. C. Werner, MD, declare that they have no conflicts of interest. Stephen F. Brockmeier, MD, reports board or committee membership in American Orthopaedic Society for Sports Medicine, International Society of Arthroscopy, Knee Surgery, and Orthopaedic Sports Medicine, and MidAtlantic Shoulder and Elbow Society; editorial or governing board membership at Journal of Bone and Joint Surgery American, Orthopaedic Journal of Sports Medicine, Techniques in Shoulder and Elbow Surgery; research support and/or payment as presenter or speaker from Arthrex, Biomet, DePuy (A Johnson & Johnson Company), Tornier; publishing royalties or financial or material support from Springer; fees as a consultant to MicroAire Surgical Instruments LLC, Zimmer.

Human/Animal Rights: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

Informed Consent: Informed consent was waived from all patients for being included in this study.

Required Author Forms Disclosure forms provided by the authors are available with the online version of this article.

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