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Irrigation and Debridement Before a 2-Stage Revision Total Knee Arthroplasty Does Not Increase Risk of Failure

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A B S T R A C T

Background: Studies have suggested that the success of 2-stage revision total knee arthroplasty (rTKA) may be compromised by a prior failed irrigation and debridement (I&D). The purpose of this study was to use 2 large state inpatient databases to compare the 2-stage rTKA failure rates for those patients with and without a prior I&D.
Methods: This retrospective, longitudinal study used inpatient discharge data from the State Inpatient Database of 2 states (California and New York) from 2005 to 2011. A combination of *International Classification of Diseases, Ninth Revision*, diagnosis and procedure codes was used to identify rTKA patients and compare failure rates for rTKA patients with and without prior I&D. The primary outcome was failure of the staged revision, which was defined as subsequent surgery due to infection within 4 years of the 2-stage rTKA.
Results: Of the 750 patients who underwent 2-stage rTKA, 57 had undergone a prior I&D. In all, 126 patients failed rTKA. After 4 years, the estimated failure rate was 8.7% (95% confidence interval [CI], 1.9%-16.9%) in the group with prior I&D and 17.5% (95% CI, 14.7%-20.4%) in the group without prior I&D. After adjusting for sex, race, insurance, median household income, and comorbidities, the hazard ratio for the group with a failed I&D was 0.49 ($P = .122$; 95% CI, 0.20-1.20), which indicated a lower risk of failure compared to the group without prior I&D.
Conclusion: These findings indicate that the failure rate of 2-stage rTKA is not increased by prior failed I&D.

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Prosthetic joint infection (PJI) after total knee arthroplasty (TKA) is a leading cause of implant failure requiring revision surgery [1]. The incidence of PJI after primary TKA ranges from 0.4% to 4% [2,3] and increases after revision TKA (rTKA) [4]. Infected prosthetic joints are often unresponsive to antibiotic therapy due to poor vascular supply and biofilm formation on the implant surface [5]. Various surgical treatment options include irrigation and debridement (I&D) with or without polyethylene exchange [6,7], single-stage revision arthroplasty [7], 2-stage revision arthroplasty with antibiotic laden spacer placement [8], resection arthroplasty [9], arthrodesis [10], and amputation [11].

Irrigation and debridement with polyethylene exchange has been considered a viable option for early postoperative or late hematogenous infections [12,13]. It entails arthrotomy, synovectomy, irrigation, debridement of all infected soft tissues, and implantation of a new polyethylene liner while retaining the fixed components. The procedure is less invasive than single-stage revision arthroplasty and requires far less time than the cumbersome process of a 2-stage revision. However, previous studies have reported that I&D is associated with variable success rates ranging from 38% to 48% [6,14,15]. Patients who experience failure of I&D typically undergo multiple additional surgeries to achieve infection clearance.

The 2-stage rTKA with antibiotic laden spacer placement has become the criterion standard for management of PJI [16-18]. Reported success rates for this procedure vary from 65% to 93.5% when defined as 5-year survivorship free of implant removal for reinfection [19,20]. The first stage of this procedure, known as resection arthroplasty, generally involves the removal of all infected tissue, hardware, and foreign material followed by the insertion of a static or articulating antibiotic-impregnated spacer. The patient is then typically given a 6-week course of antibiotics to treat underlying osteomyelitis. A new prosthesis is implanted during the second stage only after laboratory tests and cultures confirm the absence of infection [8,19,21,22].

Despite the high failure rates reported with I&D, it remains an appealing treatment option for PJI due to the lower cost and risk relative to 2-stage rTKA. However, some studies have suggested that the success of the 2-stage procedure may be compromised by prior failure of I&D [7,23]. The purpose of this study was to use a large

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database to compare the 2-stage rTKA failure rates for those patients with and without a prior I&D.

Materials and Methods

This is a retrospective, longitudinal study using inpatient discharge data from the State Inpatient Database (SID) of 2 states (California and New York) from 2005 to 2011. The SID, which contains all nonfederal inpatient records for each participating state, is part of the Healthcare Cost and Utilization Project under the Agency for Healthcare Research and Quality. Data from New York and California were selected due to their large populations and the availability of unique identifiers to track patient visits over time. These SIDs include demographic, insurance, and hospital and comorbidity variables as well as diagnosis and procedure codes from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (*ICD-9-CM*).

The study population included patients of age 18 years and older who underwent 2-stage rTKA from 2007 to 2009. These patients were identified using the relevant *ICD-9-CM* diagnosis and procedure codes (infection and inflammatory reaction due to internal joint prosthesis [DXn: 996.66] and removal of spacer [PRn: 84:57] along with one of the following: rTKA all components [PRn: 00.80], rTKA femur component [PRn: 00.81], rTKA tibia component [PRn: 00.82], or rTKA not otherwise specific [PRn: 81.55]). The main exposure was I&D (infection [DXn: 996.66] and replacement of tibial liner [PRn: 00.84]). A 2-year look-back period was used to detect those who had I&D before 2-stage rTKA, and the outcomes of both groups (ie, with and without prior I&D) were compared.

The primary outcome was failure of the staged revision, and this was defined as subsequent surgery due to infection within 4 years of the 2-stage revision TKA. Study patient records from the 2-stage revision discharge date until the end of the study period were reviewed. Search parameters were set according to the relevant *ICD-9-CM* codes (described in the Appendix). The minimum follow-up period was 2 years, and the maximum was 4 years (SID data used till 2011). The time to failure was calculated as the number of days between the discharge date of the index procedure and the date of readmission for failure.

Patient characteristics, including age, sex, race/ethnicity, insurance status, median household income in the patient's zip code of residence, and count of Agency for Healthcare Research and Quality comorbidities, were compared between both groups [24]. These characteristics were adjusted for as potential confounders in the multivariable models. The source for these variables was each patient's discharge record after hospitalization for the 2-stage revision TKA.

Statistical Analysis

Descriptive statistics of the overall study population were produced for each covariate. Differences between the 2 groups were tested using Fisher exact test for categorical variables and thr Student *t* test for continuous variables. It is important to note that the Healthcare Cost and Utilization Project data use agreement states that table cells with values less than or equal to 10 are not to be published. However, there were less than 11 failures in the I&D group. To address this while simultaneously accounting for potential bias due to the small sample size, bootstrapping was performed to show the frequency of failure outcomes. Bootstrapping is a process whereby the sample data are repeatedly resampled with replacement. In this study, 500 iterations were used. The point estimate is the mean of the means from each of the 500 resamples, and the 95% confidence interval is formulated from range of resample means at the 2.5th and 97.5th percentile. The Kaplan-Meier method was used to compare the cumulative incidence of failure stratified by I&D. An unadjusted and multivariable-adjusted Cox proportional hazards model was used to model failure outcomes. This enabled estimation of the risk of failure among patients in the group with prior I&D compared to those in the group without prior I&D. The risk measure is presented as the hazard ratio. All analyses were conducted using the SAS system for UNIX, version 9.3.

Results

There were 750 patients who had undergone 2-stage revision TKA in the study population. Among these, 57 (7.6%) had undergone I&D within 2 years before revision, and 693 (92.4%) had not (Table 1). Patients from California comprised 63% of the study cohort, and all others were from New York. A higher percentage of the I&D group was older than 65 years, male, white, enrolled in Medicare, and had 4 or more comorbidities. However, none of these differences was statistically significant. Patients who had I&D before 2-stage rTKA were, on average, approximately 2 years older than those who did not ($P = .177$), and they were more likely to live in an area above the median household income ($P = .094$).

Of the 750 total patients in the study, 126 (16.8%) required a revision procedure. Less than 10 of these occurred in the group of patients, which had I&D before rTKA. Bootstrap analysis showed that the estimated number of failures by year 2 was higher in the group without prior I&D (Table 2). After 4 years, the estimated failure was still 8.7% (95% confidence interval [CI], 1.9%-16.9%) in the I&D group and 17.5% (95% CI, 14.7%-20.4%) in the group without prior I&D. The mean time to failure did not achieve statistical significance ($P = .131$). The latest observed failure in the I&D group was 212 days after surgery.

Kaplan-Meier survival analysis revealed that the cumulative incidence of failure was similar between both groups during the initial 9 months of the study. After this period, the I&D group had no further failures, whereas the group without prior I&D continued to experience failures (Figure).

The unadjusted Cox model showed that risk of failure was lower in the I&D group, although this did not achieve statistical significance ($P = .142$; hazard ratio, 0.51; 95% CI, 0.21-1.25). After adjusting for sex, race, insurance, median household income, and comorbidities, the hazard ratio for the I&D group was 0.49 ($P = .122$; 95% CI, 0.20-1.20),

Table 1
Characteristics of Patients Undergoing 2-Stage Knee Revision in New York and California, 2007-2009.

	Total		I&D		No I&D		
	n	%	n	%	n	%	*P*
Total	750	100%	57	100%	693	100%	
State							.023
California	474	63%	44	77%	430	62%	
New York	276	37%	13	23%	263	38%	
Age category							.211
<65	311	41%	19	29%	292	42%	
≥65	439	59%	38	71%	41	58%	
Female	392	52%	24	42%	368	53%	.129
Race							.062
White	530	71%	49	86%	481	69%	
Black	66	9%	*	*	*	*	
Hispanic	103	14%	*	*	*	*	
Other	51	7%	*	*	*	*	
Payer							.674
Medicare	450	60%	36	63%	414	60%	
Other	300	40%	21	37%	279	40%	
Zip code level median household income							.094
Below median	395	53%	37	65%	358	52%	
Above median	355	47%	20	35%	335	48%	
Comorbidities							.461
0-1	218	29%	16	28%	202	29%	
2-3	328	44%	21	37%	307	44%	
≥4	204	27%	20	35%	184	27%	
Continuous variables	Mean	SD	Mean	SD	Mean	SD	*P*
Age, y	66.0	11.1	68.1	10.4	66.0	11.1	.177
Length of stay, d	6.9	10.2	6.2	6.8	7.1	10.3	.519

** Cells with frequency <11 are suppressed as a safeguard to protect patient confidentiality.