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Irrigation and Debridement Prior to a Two-Stage Revision Total Knee Arthroplasty Does Not Increase Risk of Failure

Olubusola Brimmo, MD^a, Deepak Ramanathan, MBBS^a, Nicholas K Schiltz, PhD^b, Aiswarya Lekshmi Pillai Chandran Pillai, MBBS, MS^b, Alison K Klika, MS^a, and Wael K Barsoum, MD^a

Olubusola Brimmo: lordburray@hotmail.com; Deepak Ramanathan: dr.dpk@yahoo.com; Nicholas K Schiltz: nicholas.schiltz@case.edu; Aiswarya Lekshmi Pillai Chandran Pillai: aiswaryaa83@gmail.com; Alison K Klika: klikaa@ccf.org; Wael K Barsoum: barsouw@ccf.org

^aCleveland Clinic, Department of Orthopaedic Surgery, Cleveland, OH

^bCase Western Reserve University, Department of Epidemiology & Biostatistics, Cleveland, OH

Abstract

Background—Studies have suggested that the success of two-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 two large state inpatient databases to compare the two-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 (SID) of two states (California and New York) from 2005 to 2011. A combination of ICD-9 diagnosis and procedure codes were 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 four years of the two-stage rTKA.

Results—Of the 750 patients who underwent two-stage rTKA, fifty-seven had undergone a prior I&D. In all, 126 patients failed rTKA. After four years, the estimated failure rate was 8.7% (95% 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 gender, race, insurance, median household income, and comorbidities, the hazard ratio for the group with a failed I&D was 0.49 (p=0.122; 95% CI 0.20 – 1.20) which indicated a lower risk of failure compared to the group without prior I&D.

Conclusions—These findings indicate that the failure rate of two-stage rTKA is not increased by prior failed I&D.

Keywords

Irrigation and debridement; Prosthetic joint infection; Revision total knee arthroplasty; State inpatient database

Corresponding Author: Alison K Klika, Cleveland Clinic, Department of Orthopaedic Surgery – A41, 9500 Euclid Ave., Cleveland, OH, USA - 44195, 001-216-444-4954, klikaa@ccf.org.

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Introduction

Prosthetic joint infection (PJI) following total knee arthroplasty (TKA) is a leading cause of implant failure requiring revision surgery.[1] The incidence of PJI following 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] two-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] 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 two-stage revision. However, previous studies have reported that I&D is associated with variable success rates ranging from 38% to 48%.[6,14,34] Patients who experience failure of I&D typically undergo multiple additional surgeries to achieve infection clearance.

The two-stage rTKA with antibiotic laden spacer placement has become the gold standard for management of PJI.[15–17] Reported success rates for this procedure vary from 65% to 93.5% when defined as 5-year survivorship free of implant removal for reinfection.[19,29] 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 six-week course of antibiotics to treat underlying osteomyelitis. A new prosthesis is implanted during the second stage only after lab tests and cultures confirm the absence of infection. [8,18–20]

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 two-stage rTKA. However, some studies have suggested that the success of the two-stage procedure may be compromised by prior failure of I&D.[7,33] The purpose of this study was to use a large database to compare the two-stage rTKA failure rates for those patients with and without a prior I&D.

Material and Methods

This is a retrospective, longitudinal study using inpatient discharge data from the State Inpatient Database (SID) of two states (California and New York) from 2005 to 2011. The SID, which contains all non-federal inpatient records for each participating state, is part of the Healthcare Cost and Utilization Project (HCUP) under the Agency for Healthcare Research and Quality (AHRQ). 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, hospital and comorbidity variables, as

well as diagnosis and procedure codes from the 9th Revision of the International Classification of Diseases, Clinical Modification (ICD-9-CM).

The study population included patients of age 18 years and older who underwent two-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: (1) 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 two year look-back period was used to detect those who had I&D prior to two-stage rTKA and the outcomes of both groups (i.e., 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 four years of the two-stage revision TKA. Study patient records from the two-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 two years and the maximum was four years (SID data utilized 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, gender, race/ethnicity, insurance status, median household income in the patient's zip code of residence and count of AHRQ comorbidities were compared between both groups.[21] 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 two-stage revision TKA.

Statistical Analysis

Descriptive statistics of the overall study population were produced for each covariate. Differences between the two groups were tested using Fishers exact test for categorical variables and student's t-test for continuous variables. It is important to note that the HCUP data use agreement states that table cells with values less than or equal to ten are not to be published. However, there were fewer than eleven failures in the I&D group. In order 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 multi-variable 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 two-stage revision TKA in the study population. Among these, 57 (7.6%) had undergone I&D within two years prior to 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 over the age of 65 years, male, white, enrolled in Medicare and had four or more comorbidities. However, none of these differences was statistically significant. Patients who had I&D prior to two-stage rTKA were, on average, approximately two years older than those who did not ($p=0.177$) and they were more likely to live in an area above the median household income ($p=0.094$).

Of the 750 total patients in the study, 126 (16.8%) required a revision procedure. Less than ten of these occurred in the group of patients which had I&D prior to rTKA. Bootstrap analysis showed that the estimated number of failures by year two was higher in the group without prior I&D (Table 2). After four years, the estimated failure was still 8.7% (95% 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 ($p=0.131$). 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 nine 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 1).

The unadjusted Cox model showed that risk of failure was lower in the I&D group; although this did not achieve statistical significance ($p=0.142$; hazard ratio: 0.51; 95% CI: 0.21 – 1.25). After adjusting for gender, race, insurance, median household income, and comorbidities, the hazard ratio for the I&D group was 0.49 ($p=0.122$; 95% CI 0.20 – 1.20) which indicated a lower risk of failure compared to the group without prior I&D (Table 3). Gender was the only variable which was statistically significant, with females less likely to fail the rTKA ($p<0.001$).

Discussion

This study identified failure rates of two-stage revision knee arthroplasty with and without prior I&D. Kaplan-Meier analysis, defining survivorship as being infection-free following either treatment pathway, showed an estimated overall survival rate of 91% at four years for those who underwent preliminary I&D. By comparison, the survival rate was estimated as 84.8% at four years in the group without prior I&D. The risk of failure was lower in the I&D group although the unadjusted Cox model did not demonstrate this to be of statistical significance.

A post-hoc power analysis revealed that this study was powered to detect a medium effect size of approximately $d=0.39$, given the sample size and using $\alpha=0.05$ and $(1-\beta)=0.80$. Given that the failure rate in the group without prior I&D was 17.5%, any significant difference would be detected if the failure rate in the I&D group was less than 4.7% or

greater than 34.1%. The actual difference in proportions between both groups was much smaller than this.

Despite these study limitations, the findings add to the discussion of whether a failed I&D increases the failure rate of a subsequent two-stage revision TKA. The data demonstrate that the estimated number of failures was lower at two and four years in the I&D group (9%) compared to the group without prior I&D (14.4% at two years and 17.5% at four years). This indicates that a failed I&D did not increase the risk of failure rate in patients who underwent a subsequent two-stage revision TKA. The failure rate in this study is similar to that of previous studies which report rates ranging between 9 and 33%.[15,18–20,23,28,29,31,32] Kubista et al [28] reported a 15.8% infection rate and subsequent failure in 368 patients treated with two-stage revision TKA. Similarly to this study, they noted that prior I&D did not increase the risk of re-infection and failure in their cohort.

These findings contrast with the high failure rate of 34% noted by Sherrell et al [33] in 83 knees that underwent a two-stage revision TKA after a failed I&D. The results of this study also contrast with results from Gardner et al [7] who reported a failure rate of 42% in 19 patients treated with revision TKA after a failed I&D. The difference in failure rates may possibly be explained by the larger sample size of the cohort in this study.

Sabry et al [29] reported a mean time to failure of 429 days following 105 cases of failed two-stage rTKA. Schwarzkopf et al [30] reported a similar mean time to failure of 438 days following 12 cases of two-stage revision TKA. However, neither of these studies reported the number of failed two-stage revision TKA cases which underwent a prior I&D. The mean failure time in this study was less in the I&D group (136 days) compared with the group without prior I&D (365 days), indicating that the I&D group is more likely to fail earlier.

This retrospective observational study has limitations inherent to the SID database and administrative claims data, including the lack of granular clinical information such as operative details, infecting organism, antibiotic therapy and procedure complexity. Treatment protocols for two-stage revision TKA and I&D vary among institutions and patients. Also, the SID restricts publication of cell sizes less than or equal to ten and this was prohibitive in the present study. The follow-up period to detect failure was limited to a maximum of four years after the two-stage revision TKA. However, previous studies have either demonstrated a median time to failure between one and 3.6 years [19,27,28] or an average time to failure of 1.2 years.[29,30] It is possible that undetected failures of the two-stage revision TKA occurred beyond four years after surgery in some patients. Lastly, the study was too underpowered to detect a small effect size. Of note, this study included all cases in community hospitals from the first and fourth most populated states in the United States over a three-year time period. Therefore, finding a larger sample of two-stage revision total knee arthroplasties with sufficient follow-up data may be difficult at present.

The data presented in this study does not support previously reported findings that patients with a prior failed I&D demonstrated higher failure rates following two-stage revision TKA. It appears that a failed I&D does not increase the likelihood of failure, although a larger study with appropriate power is necessary to confirm this result.

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Appendix

ICD-9-CM Diagnosis and Procedure Codes Queried in the SID Database

Diagnosis code	Description	
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996.66	Infection and inflammatory reaction due to internal joint prosthesis	
<i>Procedure codes</i>	<i>Description</i>	
00.80	Revision TKA all components	
00.81	Revision TKA femoral component	
00.82	Revision TKA tibial component	
00.84	Replacement of tibial liner	
81.22	Arthrodesis of knee	
81.55	Revision of knee replacement, not otherwise specified	Removal of cement spacer
84.17	Amputation above knee	
84.56	Insertion of cement spacer	
84.57	Removal of cement spacer

Figure 1.
Cumulative Incidence of Failure of Two-Stage Revision TKA with and without prior I&D as estimated by Kaplan Meier Analysis

Table 1
 Characteristics of patients undergoing 2-stage knee revision in New York and California, 2007–2009

	Total		I&D		No I&D		p-value
	N	%	N	%	N	%	
Total	750	100%	57	100%	693	100%	
State							0.023
California	474	63%	44	77%	430	62%	
New York	276	37%	13	23%	263	38%	
Age category							0.211
Under age 65	311	41%	19	29%	292	42%	
65 and older	439	59%	38	71%	41	58%	
Female	392	52%	24	42%	368	53%	0.129
Race							0.062
White	530	71%	49	86%	481	69%	
Black	66	9%	**	**	**	**	
Hispanic	103	14%	**	**	**	**	
Other	51	7%	**	**	**	**	
Payer							0.674
Medicare	450	60%	36	63%	414	60%	
Other	300	40%	21	37%	279	40%	
Zip code level median household income							0.094
Below median	395	53%	37	65%	358	52%	
Above median	355	47%	20	35%	335	48%	
Comorbidities							0.461
0 – 1	218	29%	16	28%	202	29%	
2 – 3	328	44%	21	37%	307	44%	
4 or more	204	27%	20	35%	184	27%	

Continuous variables	mean	sd	mean	sd	p-value	
	66.0	11.1	68.1	10.4	66.0	0.177
Age, y						

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Continuous variables	mean	sd	mean	sd	mean	sd	p-value
Length of stay, d	6.9	10.2	6.2	6.8	7.1	10.3	0.519

Table 2

Bootstrap analysis of failure outcomes

Group	2-year failure	4-year failure	Failure time
	Percent (95%CI)	Percent (95%CI)	Days (95% CI)
I&D	8.7% (1.9% – 16.9%)	8.7% (1.9% – 16.9%)	136 (78 – 212)
No I&D	14.4% (11.8% – 17.2%)	17.5% (14.7% – 20.4%)	365 (294 – 440)

Table 3

Multivariable-adjusted model of failure

	HR (95% CI)	p-value
Unadjusted model: I&D vs Non I&D	0.51 (0.21 – 1.25)	.142
Multivariable adjusted model:		
I&D vs. Non I&D group	0.49 (0.20 – 1.20)	.122
Female vs. male	0.53 (0.37 – 0.77)	<.001
Non-white vs. white	1.04 (0.70 – 1.55)	.840
Medicare vs. other payer	0.96 (0.66 – 1.39)	.839
Median household income in zip code		
Below median vs. above	0.98 (0.68 – 1.41)	.893
Comorbidity score	1.03 (0.99 – 1.06)	.111

I&D = irrigation and debridement; HR=hazard ratio; CI=confidence interval