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Articulating spacers in elderly patients affected by periprosthetic knee infection: clinical findings and outcome

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Abstract. – OBJECTIVE: Although the two-stage technique is a validated strategy in periprosthetic joint infections, there is a lack of data on the patients' clinical outcomes after the spacer placement. This study aims at evaluating the quality of life, joint function, and pain in patients over 70 years affected by periprosthetic joint infection treated with a two-stage exchange using metal on polyethylene spacers.

PATIENTS AND METHODS: We conducted a follow-up study to evaluate the quality of life and functionality of consecutive patients over 70 years treated for PJI at our institution using a validated assessment set including the Western Ontario and Mac Master University (WOMAC) score, Knee Society Score (KSS), numerical rating scale (NRS). Knee Range of Movement (ROM) before and after the surgery was also analyzed.

RESULTS: Forty-five patients with a mean age of 76 ± 5.3 years were included. Coagulase-negative staphylococci were the most isolated microorganisms. In the preoperative study group, the WOMAC score was 48.4 ± 18.9, and the KSS objective and functional score were 37.6 ± 17.3 and 27.6 ± 22.3, respectively. NRS was 7.3 ± 1.8. After three months of follow-up, we found better results than preoperative clinical evaluation. We retrieved similar results comparing our post-operative PROMS (WOMAC and KSS scores) with published thresholds for treatment success two months after primary total knee arthroplasty. The infection eradication rate was 87%.

CONCLUSIONS: The two-stage technique confirmed its efficacy in the treatment of PJI. Patients over 70 years who had undergone the first stage of the two-stage technique for PJI showed a good quality of life and knee function.

Key Words:
PJI, TKA, Two-stage technique, Periprosthetic knee infection.

Introduction

Periprosthetic joint infection (PJI) is a severe complication of total knee arthroplasty (TKA) in about 1-2% of all TKA[1-5]. PJI leads to severe pain, particularly during the night, with a reduction of articular knee function and disability, with a decreased quality of life in affected patients[6], and sometimes systemic complications[7]. The treatment depends on the type of infection (acute *vs.* chronic), the causative microorganism, and the host bone and soft tissues[8]. The two-stage technique represents the gold standard approach with an infection eradication rate that ranges between 83 and 91[9,10]; it consists of debridement of all infected tissues, prosthetic removal, and spacer implantation with subsequent revision, once the septic process is eradicated[11]. The cement spacers aim at maintaining the joint space in distraction while providing local release of antibiotics and could be classified as static and articulating[12]. It is reported that there is no significant difference in terms of infection eradication rate between the two kinds of spacers. Non-articulating spacers are strongly recommended in patients with massive bone loss and lack of integrity of soft tissues or ligamentous restraint[13-15]. Articulating spacers provide a better function for patients in between the stages of total knee arthroplasty (TKA) and more straightforward reimplantation surgery than non-articulating spacers. Various kinds of articulating spacers have been introduced, i.e., metal-on-polyethylene, cement-on-cement, or cement-on-polyethylene spacers. Hofmann et al[16] first described an articulating spacer made by cleaning and autoclaving the original femoral component, which was then re-implanted with a new tibial polyethylene. Further studies[17-20] have described the use of cruciate retaining femoral

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component and ultra-congruent polyethylene insert as a mobile spacer, and both were cemented using antibiotic bone cement. A recent systematic review[21] has reported that the intraoperative autoclaving and re-use of a removed infected prosthesis is an effective procedure in managing knee PJI with a cumulative re-infection rate of 13.7%. Although different studies[22-26] have described the outcome in terms of infection, eradication rate and the functional knee outcome after the second stage revision, to the best of our knowledge no studies have focused on quality of life and joint function in patients with the spacer in place. This is particularly important in elderly patients where the two-stage technique may negatively impact joint function, quality of life, and overall morbidity and mortality. Therefore, this study aims at evaluating the quality of life, joint function, and pain in patients over 70 years.

Patients and Methods

This is part of an observational cohort study including consecutive patients with PJI undergoing two-stage exchange, referred to the Orthopaedic Unit of Federico II University of Naples between January 2019 and May 2021. The research was conducted in accordance with the Declaration of Helsinki and national and institutional standards, and patients gave their informed consent prior to be included in this observational study. The diagnosis of chronic infection (> 90 days after the index procedure) was made according to the 2018 ICM criteria[27,28]. The inclusion criteria were: age >70 years, and delayed PJI diagnosed based on above criteria. Patients with acute (< 90 days after the index procedure) and late hematogenous (symptoms of less than three weeks duration) infections, were excluded. Patients who presented any local conditions that contraindicated the use of mobile spacers were also excluded. All the included patients underwent knee prosthetic removal, accurate debridement and implantation of a metal on poly spacer (cruciate retaining femoral component and ultra-congruent polyethylene insert) both cemented using antibiotic bone cement. The Italian PJI guidelines recommend a two-phase antibiotic treatment protocol of 2 weeks of intravenous therapy followed by oral targeted therapy for 6 weeks, when feasible, based on microbiologic test results[29,30]. Hence, antibiotic therapy began with parenteral antibiotics for 2 weeks after implant removal. When available, the synovial fluid cultures determined the selection of drugs administered before the infected implants were explanted. When synovial fluid culture results were negative, empiric antibiotic therapy was used, which comprised drugs that were active against gram-positive methicillin-resistant bacteria, until the microbiologic results from cultures of the periprosthetic tissues or implant sonication became available. The subsequent 6-week course of antibiotic therapy included oral drugs, when possible, which were selected based on the microbiologic evaluations. When all preoperative and intraoperative culture results were negative, combination regimens that contained a drug active against methicillin-resistant staphylococci (for example, cotrimoxazole or minocycline) were considered for the first-line therapy after the parenteral antibiotic therapy. After completing a course of antibiotics, the patients underwent reimplantation, while continuing antibiotic therapy. Reimplantation was scheduled for patients whose C reactive protein (CRP) levels and ESR remained normal and who did not have any local symptoms preoperatively.

Data Collection

Demographic data and the Charlson's comorbidity index adjusted by age (CCI) were recorded for all patients. Prior to surgery, before reimplantation and at last-follow up, the Knee Range of Movement (ROM), the knee pain using a numerical rating scale (NRS) and the Knee Society Score (KSS) divided in two parts (objective one and functional one), the Italian version of the Western Ontario and Mac Master University (WOMAC) Questionnaire[31,32], for valuation of the quality of life were evaluated. After all surgical procedures and antibiotic treatment were completed, clinical findings, CRP and ERS were assessed during a 96-week period. A cure was defined as the disappearance of all clinical and radiological evidence of PJI coupled with CRP and ERS normalization during a 96-week period after the discontinuation of antibiotic treatment.

Statistical Analysis

Quantitative data were expressed as mean ± standard deviation (SD) and compared using a two-sample *t*-test. The Chi-squared test was used to compare qualitative variables. $p < 0.05$ was considered significant. SPSS Statistical software 21.0.0.1 (IBM Corp., Armonk, NY, USA) was used for the database construction and the statistical analysis.

Table I. Comparison of the NRS scale, WOMAC, and KSS scores before spacer implantation and before the second surgical stage.

Variables	Preoperative study group	Postoperative study group	*p*-value
WOMAC Total	48.4 ± 18.9	20.4 ± 18.2	< 0.001
KSS Objective Score	37.6 ± 17.3	66.3 ± 16.9	< 0.001
KSS Function Score	27.6 ± 22.3	50.9 ± 24.5	< 0.001
NRS	7.3 ± 1.8	3.0 ± 3.2	< 0.001

WOMAC = Western Ontario and Mac Master University; KSS = Knee Society Score; NRS: Numerical Rating scale.

Results

Forty-five consecutive patients with painful TKA were included. The mean age was 76 ± 5.3 years, 25 (52%) patients were females. Comorbidities related to an increased risk of infection were reported in 15 (33%) cases. Diabetes mellitus without compliances was reported in 8 of 15 cases with delayed infection; diabetes mellitus with organ damaged was reported in 2 cases; history of cancer was reported in 3 cases; chronic hepatitis in 3 cases; history of myocardial infarction in 5; chronic renal failure needing dialysis in 1; anamnesis of cerebrovascular disease in 2 cases. Higher CCI was significantly correlated to the probability of developing infection. The mean Body Mass Index (BMI) was. 28.7 ± 3.9. Obesity defined as a body mass index above 30 was reported in 15 (33%) cases. Microbiological investigations were positive in 29 (64%) patients. Coagulase-negative staphylococci were isolated in 12 (27%) patients (5 were methicillin-resistant). *Staphylococcus aureus* was isolated in 7 (16%) patients (3 were methicillin-resistant). Gram-negative bacteria were isolated in 3 (7%) patients. *Streptococcus* spp. and *Enterococcus faecalis* were retrieved in four and two patients, respectively. The NRS scale, WOMAC, and KSS scores were significantly different (all $p < 0.001$) before spacer implantation and before the second surgical stage (Table I). Table II reports the comparison of post-operative PROMS (WOMAC and KSS scores) with published thresholds for treatment success two months after total knee arthroplasty (TKA), as described by Giesinger et al[32].

A favorable outcome was reported in 39 (87%) cases. Failure was reported in 6 patients in which infection was sustained by methicillin-resistant staphylococci (4 patients), gram-negative germs (1 patient) and *Enterococcus faecalis* (1 patient). All the patients with recurrence of infection were treated with suppressive antibiotic therapy (SAT).

The post-surgical degree of satisfaction measured from 0 (not satisfied) to 10 (completely satisfied) in 36 (80%) patients went from 8 to 10, in 7 (15%) patients was 7 and only in 2 (5%) patients was 5.

Discussion

The two-stage exchange procedure represents a reliable approach in delayed PJIs, infections caused by multidrug-resistant bacteria, and those showing a sinus tract[33-37]. Although the two-stage exchange technique is mainly standardized, several questions about how to increase its likelihood of success remain unanswered. To our knowledge, no previous studies have ever described how patients feel after a spacer implant and their quality of life following a PJI using valuation instruments at a follow-up period of 3 months. Marson et al[38] reported the Oxford Knee

Table II. WOMAC, and Knee Society scores in the study group (mean ± standard deviation) in comparison with published thresholds for treatment success (TTS) 2 months after total knee arthroplasty (TKA)[32].

Variables	Postoperative study group	TTS after TKA	Δ *vs.* postoperative study group
WOMAC Total	20.4 ± 18.2	24.1 ± 17.3	+ 4.1
KSS Objective Score	66.3 ± 16.9	68.7 ± 28.1	+ 2.4
KSS Function Score	50.9 ± 24.5	46.4 ± 22.7	- 4.9

WOMAC = Western Ontario and Mac Master University; KSS = Knee Society Score.

Score (OKS) and the degree of satisfaction of six patients with a median age of 75 years treated for PJI who underwent spacer replacement and retained the temporary implant. The median of OKS indicated the presence of moderate/severe symptoms, and the median of subjective satisfaction was 8. These results are worse than ours, probably for the longer follow-up (43 weeks). Further studies[32,39,40] have compared the patient's status before and after the two-stage technique. Mahmud et al[39] had reported the preoperative WOMAC and The Knee Society Clinical Rating scores before and after the two-stage approach. Their scores after the second stage, with the revision prosthesis, are in line with ours after spacer placement. Based on our discoveries, the main result of the present study is that patients who had undergone the first stage of the two-stage technique had similar or even better results concerning controls who had been treated with TKA for osteoarthritis[32,40]. Their KSS Function scores were higher than those previously reported in subjects two months after TKA. To our knowledge, no previous studies that used these have been published.

It is important to highlight that the rate of satisfied patients should not be surprising. Indeed, several factors, apart from knee functionality can influence the level of post-surgical satisfaction (i.e., patient expectation, pain relief, psychological benefit, and improvement in activities of daily life) although there is still the possibility of undergoing another surgery. Our values are very similar to those reported by Bourne et al[41], who analyzed the degree of satisfaction in patients after primary TKA. This enormous degree of happiness may depend on the selection made to include in the study only patients over 70, who generally do not have tremendous functional demand.

Furthermore, using prosthetic components as spacers means that patients very frail and low-demand patients or those with medical comorbidities precluding second-stage surgery may be satisfied with the spacer and be able to defer or avoid a second-stage operation. They have a high probability to avoid the second stage because of their excellent function, as demonstrated in revision hip arthroplasty[42,43].

The eradication rate is in line with the results reported in previous papers. Hsu et al[44], Haddad et al[45], and Lichstein et al[46] have reported an eradication rate after the two-stage technique of 87%, 93%, and 94%, respectively.

Limitations

This study presents different limitations. One is related to the minor number of patients enrolled in the study. The second limitation is correlated to the lack of stratification based on the patient's comorbidity, which could influence the clinical results. In contrast, this prospective study presents some points of strength.

1. It is a single-center study in which the same surgeon treats all the patients.
2. We adopted a strict treatment management protocol for all patients.

Conclusions

The strategy involving metal on polyethylene spacers, antibiotic therapy, and the subsequent re-implantation of the revision prosthesis is a reliable option for the management of periprosthetic knee infections. In elderly patients, mobile spacers guarantee better movement, better functional recovery, and an excellent quality of life.

Conflict of Interest

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

Informed Consent

The patients provided informed consent before they were included in the study.

Ethical Approval

The study was conducted in accordance with national and institutional standards and in accordance with the principles of the Declaration of Helsinki. The study was approved by the Department of Public Health, Orthopedic Unit, "Federico II" University, Naples, Italy.

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