

HK80: How Soon After Treatment of Patients With Periprosthetic Joint Infection Can Success Be Declared?

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Response/Recommendation:

Failure after surgical management of patients with periprosthetic joint infection can occur anytime. For assessing the success of surgical treatment, we recommend a minimum follow-up period of five years. For the purpose of comparative efficacy trials or evaluation of novel technologies for regulatory approval, we recommend a minimum of one-year follow-up.

Delegate Vote:

Level of Evidence: Moderate

Rationale:

The definition of success after treatment of prosthetic joint infection (PJI) depends on multiple factors and is irrespective of treatment strategy (one-stage exchange, two-stage exchange, or debridement, antibiotics and implant retention [DAIR]). Success has been defined in several forms (Musculoskeletal Infection Society Outcome Reporting Tool [MSIS-ORT], Delphi-based consensus definition, microbiological success, implant success, and surgical success) including the combination of normal laboratory and clinical evidence of infection control following treatment, and/or the absence of septic revision surgery (with or without implant revision/removal), or infection-related death or unplanned outcome.[1–3] It has been shown that success rates vary dramatically depending on the definition used to evaluate outcome.[2] Although external validations and agreements on what tool is best to report success after treatment of PJI are still necessary, an issue that has been barely considered in the definition of success is time. Diaz-Ledezma *et al* reported that 71% of the participants in a consensus meeting agreed that 2 years was an acceptable time period after definitive surgery for PJI when considering short-term results.[1] In this study, follow-up durations of 2, 5, and 10 years were classified as short, mid, and long-term, respectively. Tan *et al* reported that

getting a lengthy follow-up in this patient population is very difficult, with 355/570 patients having two-year follow-up, 166/570 reaching five-year follow-up, and only 27/570 patients having ten year follow-up.[2] In this sense, the follow-up time required to define success remains unknown.

Therefore, to answer the posed question, we performed a systematic review of the literature on the treatment outcomes of DAIR, one-stage, and two-stage exchange treatment strategies with specific focus on time to failure. Following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, we conducted a systematic search of the online bibliographic databases MEDLINE, Embase and PubMed from inception through November 2024 to identify studies reporting on survival analysis (Kaplan-Meier, cumulative incidence, Cox-regression or similar analyses) with ≥ 2 years of follow-up after treatment of acute and/or chronic PJI. Exclusion criteria consisted of studies reporting outcomes without time-to-event analyses, editorials, commentaries, case reports, reviews, technique articles without patient data and articles not written in English language. Two of the authors independently screened the title and abstract of an initial number of 7746 articles to apply the selection criteria. Disagreements were solved by consensus after reading the full-text. We reviewed the full-text of 93 articles and finally included 57 articles for analysis.

There were 12 articles reporting on septic events that continued to appear after the first 2 years of follow-up for all types of PJI treatment strategies.[4–15] In two different studies, Xu *et al* showed no substantial improvement in the success rates of PJI treated in a 20-year period,[15] highlighting that given the difficulty with obtaining proper follow-up, a one-year follow-up was sufficient for an accurate reporting of treatment failure.[14] In the latter study, although Kaplan-Meier curves had an abrupt drop in the initial months and plateaued after 1.09 years (irrespective of treatment type), failures continued to appear even after 5 years after treatment, especially following DAIR-surgery.[14] In a retrospective cohort study of 108 polymicrobial PJIs, Tan *et al* reported infection-free survival rates of 52.2% (95% confidence interval [CI] 42.1-62.3) at the 2-year follow-up, 49.3% (95%CI 39-59.6) at the 5-year follow-up, and 46.8% (95%CI 35.9-57.7) at the 10-year follow-up.[12] Similarly, Cochran *et al* described a retrospective cohort of 16,622 total knee arthroplasty-patients, reporting that patients undergoing DAIR had higher risk of failure when compared to one- and two-stage strategies ($p < 0.001$), with failure rates of 28.2% at 1 year, 34% at 2

years, 41.7% at 5 years, and 43.2% at 6 years after treatment.[4] On the other hand, the risks of reinfection were 24.6% and 19% at 1 year and 38.3% and 29.1% at 6 years for one- and two-stage revisions, respectively.[4] In other words, survival rates continued to decrease in all treatment types during the first five/six postoperative years. In all these studies, risk factors for failure included polymicrobial infections, gram-negative bacteria, Streptococcal and Enterococcal infections, and non-biofilm-active antibiotic treatment, all of them irrelevant to time to failure.[6–9,11,12]

Seven studies focused specifically on the mid- to long-term survival rates after one-stage exchange.[16–22] In a study of 87 chronic PJIs treated with one-stage exchange with antibiotic-impregnated allograft, Dersch and Winkler reported an infection-free survival of 93.9% (95%CI 88.8–99.1) at 1 year, 89.9% (95%CI 83.2–96.6) at 2 years and 81.5% (95%CI 72.1–90.9) at 5 years.[16] In a similar study of 84 cases who underwent single-stage revision total knee arthroplasty, the Kaplan-Meier infection-free survival was 97.6% at one year (95%CI 90.8–99.4), 91.1% at five years (95%CI 81.8–95.6), and 88.3% at 12 years (95%CI 76.6–94.3).[20] Likewise, Slullitel *et al* analyzed 88 one-stage hip revisions and reported a cumulative incidence of septic failure of 8% (95%CI 3.5–15) at one year, 13.8% (95%CI 7.6–22) at two years, and 19.7% (95%CI 12–28.6) at five and ten years of follow-up.[22] Only Ohlmeier *et al* showed that survival rates stayed stable after the first two postoperative years in 101 patients with infected rotating-hinge knee prostheses, with a survival rate of 90% (95%CI 83–97) both at 2 and 6 years. Overall, these studies showed that survival curves had most infection relapses occurring within the first five postoperative years, with some additional septic failures occurring between the sixth and tenth year of follow-up.[16–22]

Twenty-seven articles analyzed the survival rates after two-stage revision surgery.[2,23–48] In two different studies analyzing the long-term results of two-stage revisions, Petis *et al* reported a cumulative incidence reinfection of 10% at 1 year, 14% at 5 years, and 15% at 10 and 15 years in chronic hip PJIs; and a cumulative incidence of reinfection of 4% at 1 year, 14% at 5 years, 16% at 10 years, and 17% at 15 years in chronic knee PJIs.[37,38] Correspondingly, in a retrospective cohort of 96 chronic hip PJIs, Slullitel *et al* reported a cumulative incidence of 14% (95%CI 8–22) at one year, 18% (95%CI 11–27) at two years, 22% (95%CI 14–31) at five years, and 23% (95%CI 15–33) at ten years, highlighting that if there were no recurrent infections within the first five years after a reimplantation, the chances of having a reinfection thereafter were remote.[44] In another

study of 97 joints treated with two-stage exchange, Garvin *et al* reported that seven out of twelve failures occurred at a late follow-up (>5 years after reimplantation), with an estimated 10-year cumulative incidence of reinfection of 14% (95%CI, 7-23).[27] Thus, the authors highlighted that late PJI may recur more than 5 years after reimplantation and therefore patients should be counseled about the importance of ongoing follow-up.[27] In general, all of the included studies on two-stage exchanges showed survival curves with relapses occurring mostly within the first five postoperative years.[2,23–48]

Eleven articles focused primarily on the survival rates of irrigation and debridement procedures for acute PJIs.[49–59] In two similar studies, Grammatopoulos *et al* performed a survival analysis of periprosthetic hip infections treated with DAIR, showing five- and ten-year implant survivals of 85% (95%CI 78-92) and 77% (95%CI 68-86), and 89% (95%CI 82-96) and 78% (95%CI 88-98), respectively.[52,53] In a registry study of 5406 acute PJIs, it was shown that the cumulative incidences of developing an infection-related event were 48% (95%CI 42-54) at 8 years after a DAIR following a total knee arthroplasty, and 42% (95%CI 37-46) at 4 years following a total hip replacement.[50] Additionally, Weston *et al* analyzed the results of DAIR with chronic antibiotic suppression for infected knee arthroplasties, and reported a cumulative incidence of recurrent infection (with death as a competing risk) of 13% at 90 days, 18% at one year, and 34% at five years.[59] Although some have reported that most septic failures after DAIR occur within the first two years of follow-up,[54,57,58] it seems clear in the literature that DAIR procedures require a longer-term follow-up in order to fully discard an eventual relapse.[49,51,55] This concept is especially applicable for those requiring chronic suppressive antibiotic therapy, in which failure events continue to appear after the fifth year of follow-up.[60]

In conclusion, it seems that a 2-year follow-up is not enough to declare success after treatment of PJI. In fact, one- and two-stage revision surgeries may require at least five years of follow-up, while those undergoing DAIR and in need of chronic suppressive antibiotics might even need longer-term follow-ups. However, for the purpose of comparative efficacy trials or evaluation of novel technologies, especially those requiring regulatory approval, a one-year outcome may be adequate to assess the efficacy and safety of a given technology in the setting of a randomized controlled trial, noting that a thorough power analysis is essential, as multiple failures can occur beyond the one-year mark, reflecting the potential fragility of results.

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