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Characterizing infections in prosthetic breast reconstruction: A validity assessment of national health databases☆

Merisa L. Piper [a,1], Lauren O. Roussel [b,1], Peter F. Koltz [b], Frederick Wang [a], Kyra Singh [b], Robin Chin [a], Hani Sbitany [a,*], Howard N. Langstein [b]

[a] *Division of Plastic and Reconstructive Surgery, Department of Surgery, University of California, San Francisco, San Francisco, CA, USA*
[b] *Division of Plastic and Reconstructive Surgery, Department of Surgery, University of Rochester Medical Center, Rochester, NY, USA*

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Summary *Introduction:* Current guidelines in the United States require reporting only the 30-day postoperative outcomes to standardized databases, including the National Surgical Quality Improvement Program (NSQIP). Thus, many breast implant-related complications go unreported in standard databases. We sought to characterize late periprosthetic infections following implant-based breast reconstruction.
Methods: We conducted a retrospective analysis of all women who underwent expander/implant reconstruction from 2005 to 2014 at two institutions. All periprosthetic infections were identified and divided into early and late cohorts ($\leq$30 days or $>$30 days). Infection was defined as any episode where antibiotics were initiated or a prosthetic device was explanted because of clinical evidence of the infection.
Results: In the 1820 patients (2980 breasts) identified, 421 periprosthetic infections occurred (14%). Of these, 173 (41%) were early and 248 (59%) were late (mean time to infection = 66.4 ± 101.9 days). Patients with late infections were more likely to be current smokers or have diabetes than patients with early infections ($p < 0.034$ for both). Infections caused by gram-negative bacteria and antimicrobial-resistant strains of *Staphylococcus* were more common in the early infection group ($p < 0.001$ for both). Implant loss due to infection was more common in the late infection group ($p = 0.037$).

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* Corresponding author. 505 Parnassus Avenue, Suite M-593, San Francisco, CA 94143, USA. Fax: +1 415 353 4320.
E-mail address: hani.sbitany@ucsf.edu (H. Sbitany).

[1] Co-first authors.

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Discussion: Late periprosthetic infections following implant-based breast reconstruction are underestimated in national outcome databases and have unique risk factors and microbiology compared to early infections. A system-level change in reevaluating and redefining a timeline for tracking and treating implant infections is necessary, given the substantial morbidity associated with, and frequency of, late periprosthetic infections.

Introduction

Breast cancer is the second most commonly diagnosed cancer among American women, which has currently affected more than 2.3 million Americans.[1] Over 40% of patients with breast cancer undergo mastectomy for multifocal disease, tumor size, and patient preference.[2] Women are diagnosed and treated at younger ages, thus accounting for the increase in the number of women who opt for reconstruction following mastectomy by using either autologous tissue or prostheses.[3] The most common technique for post-mastectomy reconstruction is tissue expansion and implant placement, which is often chosen for its shorter recovery time and no requirement of donor tissue.[4–6]

This technique can be complicated by periprosthetic infections, which affect 1–35% of reconstruction patients.[7] Periprosthetic breast infections are significantly associated with patient-related morbidity and additional health care costs. They often require treatment with multiple antibiotics, result in additional interventions and surgeries, and take an emotional toll on the patient.[8] Many studies either do not explicitly define "infection" or only report on infections that led to hospital readmission and/or implant loss. These subjective definitions of infection and lack of a universal grading scale for breast implant surgical infection make it likely that the true number of periprosthetic infections is not appreciated.

Numerous studies have identified risk factors for the development of periprosthetic infections, including chemotherapy,[9,10] radiation therapy,[11,12] history of smoking,[9,13] higher body mass index (BMI),[14,15] larger breast size,[15,16] immediate reconstruction,[14,17] and history of lymph node dissection.[11] However, most of these studies followed patients postoperatively for a limited time of 6.5 weeks to 31 months. In the augmentation mammoplasty population, one study found that late periprosthetic infections (defined as infections that occur more than 20 days after surgery) occurred more frequently and were more severe than early infections.[18] The mean time to infection was 82 days after surgery, and the causative organism varied depending on the time of infection. However, patients who undergo augmentation mammoplasty do not possess the increased risk profile and the resultant possible significant morbidity associated with reconstruction patients, and thus their findings should be considered separately. Often, the reconstruction population must deal with variable mastectomy flap perfusion, radiation therapy, and the use of acellular dermal matrix (ADM).

Current surgical outcome tracking databases in the United States including the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) and Tracking Operations and Outcomes in Plastic Surgery (TOPS) focus on 30-day surgeon-reported outcomes. It is our impression that these capture only a fraction of total complications, particularly infection. Furthermore, there is a paucity of data on late implant infections, which are defined as infections that occur >30 days postoperatively. Few studies have evaluated how patient demographics, risk factors, and infectious organisms vary between early and late periprosthetic infections in women who underwent implant-based breast reconstruction. Therefore, in this study, we sought to identify and characterize periprosthetic infections that occur >30 days after surgery in women who underwent implant-based breast reconstruction.

Methods

Patient selection

We conducted a 10-year, IRB-approved, retrospective review of prospectively collected data on all women who underwent immediate or delayed tissue expander or implant-based breast reconstruction after mastectomy at two institutions, namely University of Rochester and University of California, San Francisco. The strengthening the reporting of observational studies in epidemiology guidelines were followed. Patients who underwent autologous and implant reconstruction were also included. Patients who had a seroma but no overlying cellulitis and culture-negative aspirate were excluded from data analysis. Patients who had erythema related to a noninfectious process (i.e., untreated radiation-related erythema) were also excluded from data analysis.

Infection

"Infection" was defined as any episode where antibiotic treatment was initiated in addition to the prophylactic postoperative regimen, or a prosthetic device was explanted due to any clinical signs of infection, which is consistent with prior literature on this topic.[15,16] We defined early and late infections as those that occur ≤30 days and >30 days postoperatively, respectively. The time to infection was reset at the time of implant exchange. We chose >30 days as the cutoff time point for late infections because surgical outcomes after 30 days are not currently captured by

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