Are Prophylactic Postoperative Antibiotics Necessary for Immediate Breast Reconstruction? Results of a Prospective Randomized Clinical Trial

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BACKGROUND: Closed-suction drains, implants, and acellular dermal matrix (ADM) are routinely used in tissue expander-based immediate breast reconstruction (TE-IBR). Each of these factors is thought to increase the potential for surgical site infection (SSI). Although CDC guidelines recommend only 24 hours of antibiotic prophylaxis after TE-IBR, current clinical practices vary significantly. This study evaluated the difference in SSI between 2 different prophylactic antibiotic durations.

STUDY DESIGN: A noninferiority randomized controlled trial was designed in which TE-IBR patients received antibiotics either 24 hours postoperatively or until drain removal. The primary outcome was SSI, as defined by CDC criteria. Operative and postoperative protocols were standardized. Secondary endpoints included clinical outcomes up to 1 year and all implant loss, or reoperation.

RESULTS: There were 112 TE-IBR patients (180 breasts) using ADM who were randomized into 2 study arms, with 62 patients in the 24-hour group and 50 in the extended group. Surgical site infection was diagnosed in 12 patients in the 24-hour group and 11 in the extended group (19.4% vs 22.0%, $p = 0.82$). The extended group had 7 patients who required IV antibiotics and an overall implant loss in 7 patients (14.0%). The 24-hour group had 4 patients who required IV antibiotics, with 3 requiring removal (4.8%). Patients with diabetes, postoperative seroma, or wound dehiscence were all more likely to develop SSI ($p < 0.02$).

CONCLUSIONS: In a randomized controlled noninferiority trial, 24 hours of antibiotics is equivalent to extended oral antibiotics for SSI in TE-IBR patients. Additional multicenter trials will further assess this important aspect of TE-IBR postoperative care. (J Am Coll Surg 2016;222:1116–1124.

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Abbreviations and Acronyms

ADM = acellular dermal matrix
IBR = immediate breast reconstruction
SSI = surgical site infection
TE-IBR = tissue expander-based immediate breast reconstruction

More than 102,000 breast reconstructions were performed in 2014, more than 70% of which used tissue expanders and implants.[1] Postoperative management of these patients is a challenge. Overall complication rates of breast reconstruction using tissue expanders have been reported to exceed 52%.[2] Infection rates are reported to be as high as 31% in those patients who, in addition, had acellular dermal matrix (ADM) used during their reconstruction.[3,4] This is significantly greater than the potential mastectomy infection rates of 18%,[5] and well above the accepted rates of 1% to 3% for clean, elective operations.[6] Despite these reports of increased infection risks, ADM is now heavily used in tissue expander-based immediate breast reconstruction (TE-IBR) because of its advantages of inferolateral pole coverage, increased intraoperative expansion, and some assertions of improved overall cosmesis.[7,8] Infections after breast reconstruction can have dire consequences for already vulnerable cancer patients, and may delay the start of adjuvant chemotherapy and radiation.[9] It is therefore interesting to optimize aspects of postoperative care to reduce these risks.

Postoperative antibiotics are commonly administered to breast reconstruction patients due to the highly perceived infection risk that implants, surgical drains, and ADM present.[3,10-12] The optimal duration of antibiotic prophylaxis is unclear, and is generally based on the surgeon's experience and previous training. Defensive medicine likely plays a role in decision-making.[13] A survey of American Society of Plastic Surgeons members found that 72% of respondents reported giving prolonged antibiotics up to the time of drain removal.[14] Previous studies found that closed suction drains are often colonized with bacteria, providing a basis for the theory that they may serve as a potential conduit for surgical site infection (SSI).[15] However, more recent work suggested that this fear is unfounded.[16]

The addition of postoperative antibiotics to "cover the drains" is not supported by current literature or evidence-based recommendations. The CDC advocates for only 24 hours of perioperative antibiotics in clean elective surgery.[17] Although the clinical infection rate within breast reconstruction patients continues to be higher than in other elective operations, the American Society of Plastic Surgeons task force and Cochrane database reviews have been ambivalent on the use of postoperative antibiotics.[18,19] The risks of prolonged antibiotic therapy include increased cost, systemic side effects, bacterial resistance, *Clostridium difficile*, and other super-infections.[20] Consensus laments the lack of high quality randomized controlled trials examining this issue.

Here we present the findings of a randomized controlled trial comparing 24-hour antibiotic prophylaxis with an extended regimen until drain removal. We hypothesized that there would be no difference in SSI between these groups.

METHODS

Trial design

A single center, nonblinded, nonplacebo, randomized controlled trial was conducted at a large academic medical center in the northeastern United States. It was designed as a noninferiority trial with 2 parallel groups and a 1:1 allocation ratio with biostatistical support.

Participants

In an Institutional Research Board (IRB)-approved and clinicaltrials.gov registered study, all patients aged 18 or older, presenting to our institution, for TE-IBR were eligible for participation. Exclusion criteria included delayed, revision, or autologous flap breast reconstruction, refusal or inability to consent, significant allergies to penicillin and clindamycin, serious existing systemic infection, or other surgical complications and contraindications as determined by the attending plastic surgeon (ie significant mastectomy skin flap ischemia, bleeding/hematoma, and use of a different ADM not in the protocol). Data collection forms were approved as part of the IRB application.

Interventions

All patients who consented for this study underwent TE-IBR and were then randomized to 1 of 2 study arms at 24 hours postoperatively. Participants either immediately discontinued antibiotics at 24 hours or continued antibiotics until all drains were removed. All patients received preoperative cefazolin 1 or 2 g (BMI > 30 kg/m^2) or clindamycin 600 mg or 900 mg (BMI > 30 kg/m^2) if allergic to penicillin. Repeat intraoperative dosing was provided between 4 and 6 hours after the initial dose if the overall operative time warranted. All patients received intravenous antibiotics for a total of 24 hours. Patients who continued oral antibiotics were placed on cephalexin 500 mg qid or clindamycin 300 mg tid. These antibiotic