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Complications - Infection

Single vs Repeat Surgical Skin Preparations for Reducing Surgical Site Infection After Total Joint Arthroplasty: A Prospective, Randomized, Double-Blinded Study

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ABSTRACT

Background: Preventing surgical site infection (SSI) after total joint arthroplasty (TJA) is a high priority and is partly linked to the efficacy of surgical site preparation solutions (SPSs) in reducing the number of pathogens on the skin before incision. The aim of this study is to investigate the effectiveness of SRS reapplication after draping to reduce the incidence of SSI after TJA.
Methods: Six hundred patients undergoing primary TJA between 2010 and 2011 at a single institution were recruited and randomly assigned to one of 2 groups. The patients in the intervention group (n = 300) received SPS that included alcohol and povidone-iodine before draping and an additional SPS by iodine povacrylex and isopropyl alcohol before application of the final adhesive drape, whereas the patients in the control group (n = 300) received a single SPS with alcohol and povidone-iodine before draping. Randomization was performed by an opaque envelope, and the rates of SSI and blistering were compared between groups.
Results: Five seventy-seven patients completed the study and were included in the final analysis. There was a significant reduction in the incidence of superficial SSI for the intervention group (1.8%, 5 of 283) compared to the control group (6.5%, 19 of 294, $P = .02$). There were 2 (0.7%, 2 of 294) deep incisional SSIs in the control group, and 2 (0.7%, 2 of 283) organ-space SSIs in the intervention group ($P = 1.00$). In addition, skin blistering was lower in the intervention group (3.5%, 10 of 283) vs the control group (6.5%, 19 of 294), but this difference also did not reach statistical significance ($P = .13$).
Conclusion: Reapplication of an SPS after draping and before the application of iodophor-impregnated incisive draping resulted in a significant reduction in the rate of SSI in patients undergoing elective TJA.

It is estimated that more than 500,000 surgical site infections (SSIs) occur each year in the United States, at a rate of 2.8 per 100 operations [1]. SSI after total joint arthroplasty (TJA) can lead to prolonged hospitalization, increased morbidity and mortality, and higher costs [2,3]. Therefore, SSIs after TJA can be a devastating complication with an immense psychological and economic burden for the patient and the health care system [4,5].

Although the etiology of SSI is multifactorial, the ability to prevent bacterial proliferation at the incision site is an important factor for preventing wound-related complications [6]. Skin preparation in the operating room before surgery is routinely implemented worldwide in daily clinical practice [7]. Povidone-iodine [8] or chlorhexidine [9] have generally been used for skin antisepsis, with the recommendation of using these antimicrobial solutions with alcohol [10]. In orthopedic surgery, studies in patients undergoing shoulder [11] or foot and ankle surgery [12] have demonstrated that chlorhexidine with alcohol was effective in reducing bacterial counts at the site of surgery compared to other surgical preparation solutions. The rationale behind skin preparation is the attempt to reduce the number of resident bacteria at the site of incision, recognizing that true sterilization of the surgical site is impractical [13]. Therefore, the prevention of SSI is dependent on

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a balance between the bioburden of infective agents at the incision site and the immune threshold of the host to handle the given bioburden. Thus, it is reasonable to assume that effective reduction of bioburden may result in a lower incidence of SSI.

Numerous strategies are available to reduce bioburden which relate to the operating room environment, such as decreasing operating room traffic; wearing clean scrub attire and wearing sterile gowns and gloves; and preoperative patient optimization, such as skin cleansing before surgery by applying a skin preparation solution [14-17]. Traditionally, patients receive a skin preparation solution, draping of the surgical site occurs, and the surgery proceeds. However, contamination of the surgical site may arise during draping, after the initial surgical preparation solution has been applied and dried. No study to date has evaluated the utility of applying a second surgical site preparation solution after draping for reducing SSI.

Thus, the hypothesis of this study was that repeating skin antisepsis after the standard draping process and before the application of iodophor-impregnated incise drapes can reduce the rate of SSI.

Materials and Methods

A prospective, randomized, single-blinded clinical trial was conducted between March 2010 and November 2011 at a single institution. Institutional review board approval was obtained, and every patient was consented to participate in the study. The trial was registered on ClinicalTrials.gov (NCT01097135). A total of 899 patients undergoing primary TJA were assessed for eligibility. Subjects aged between 18 and 80 years who underwent primary, unilateral TJA and were willing to provide written informed consent were included in this study. Excluded patients were those who were allergic to iodine or iodophors, patients undergoing revision TJA, TJA for trauma-related reasons, bilateral TJA, or unicompartmental TJA. Based on the exclusion criteria, 299 patients were excluded for the following reasons: 33 patients did not meet the inclusion criteria, 250 declined to participate, and 16 for other reasons.

A total of 600 patients were then consented and randomized for the clinical trial by a research coordinator. Three hundred patients were assigned to each arm of the study. Of these patients, 23 subjects did not qualify for the analysis; 15 subjects canceled surgery, 7 withdrew consent after consenting initially, and 1 died during their postoperative stay in the hospital because of cardiac arrest. Of the 577 who qualified for the analysis, 283 were in the intervention group and 294 were in the control group (Fig. 1). The patients in the 2 groups were similar with respect to demographic characteristics and type of surgery (Table 1).

Randomization and Masking

Enrolled patients were stratified into 4 groups according to the location of surgery (knee vs hip) and treatment group (intervention

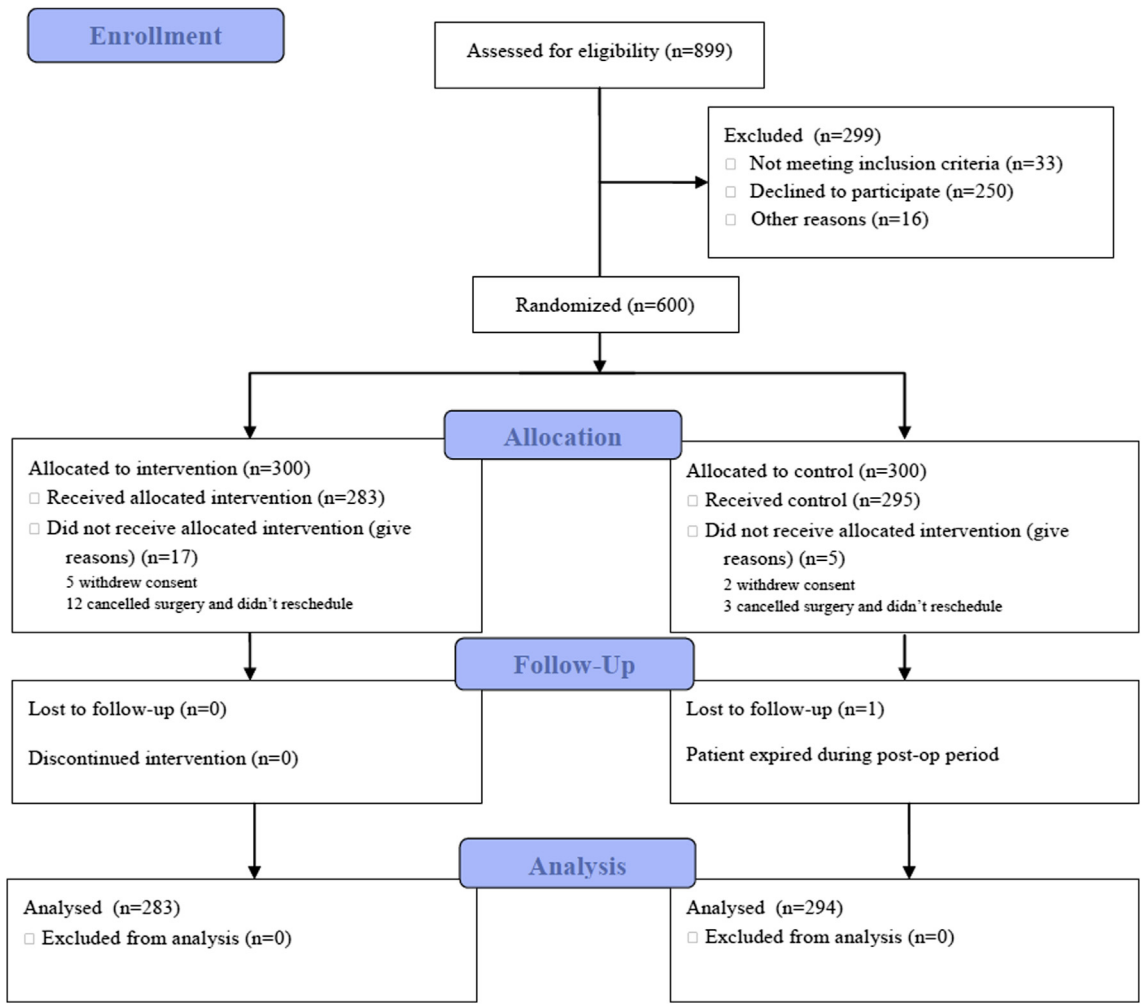

Fig. 1. CONSORT study flow diagram.