Randomized Trial of Hibiclens vs Benzoyl Peroxide Soap for Surgical Preparation

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Study Protocol and SAP

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Study Protocol

Adult male patients planning to undergo shoulder arthroplasty were assessed for eligibility by a research coordinator at their pre-operative appointment in the clinic. The study was confined to male patients because of their higher risk of Cutibacterium periprosthetic infections. Exclusion criteria were as follows: (1) self-reported skin sensitivity, (2) reported sensitivity or allergy to either chlorhexidine or benzoyl peroxide, (3) use of antibiotics within three months of surgical date, (4) use of medication for acne within three months of surgical date, and (5) lack of fluency in the English language. Patient age, sex, American Society of Anesthesiologist (ASA) classification, body mass index (BMI), and history of previous surgery on ipsilateral shoulder were recorded.

The patients were randomized by a research coordinator using simple randomization implemented through REDCap. The first group received a bottle of 4% chlorhexidine gluconate solution (CHG group). The second group received a bar of 10% benzoyl peroxide soap (BPO group). Both the chlorhexidine solution and benzoyl peroxide soap were stocked in the clinic so that all patients in each group received the same preparation. Both groups were instructed to apply the wash or soap to the surgical shoulder the night prior and the morning of surgery and to scrub for at least 60 seconds with the wash. The treating surgeon and all care providers were blinded to treatment group throughout the patient's care.

In the operating room, the unprepared, unshaved skin surface was sampled with a swab (Eswab™, #480C, Copan Diagnostics, Inc., Murrieta, CA) in the area of the planned incision. Four passes with the swab were taken by a surgical assistant wearing sterile gloves, turning the swab 90 degrees for each pass. The skin was then prepared with dual application of 2% CHG in 70% isopropyl alcohol and administration of intravenous antibiotics. Immediately after skin incision, swabs of the dermal wound edge were obtained in a similar fashion to the skin surface.

All specimens were processed by the laboratory in a Class 2 laminar flow biological safety cabinet. Specimens were inoculated onto the following microbiological media: blood agar (trypticase soy agar with 5% sheep blood), chocolate agar, Brucella agar (with blood, hemin, and vitamin K), and brainheart infusion broth. All media, with the exception of the Brucella agar, were incubated at 37 °C with 5% CO2 for 21 days. Brucella agar plates were incubated anaerobically at 37 °C for 21 days. Plates were sealed in a manner that allows sterile aeration without desiccation. Media were examined daily for growth visually but were only opened if growth was noted.

The cultures results were reported in a semiquantitative manner as the Specimen Cutibacterium Value (SpCuV) across a range of 0 (no growth) to 4 (4+ positive growth on agar plates).

SAP

An a priori sample size calculation was performed using previous data regarding growth of Cutibacterium from the skin of shoulder arthroplasty patients. Based on pilot data combined with previous published data, we estimated the incidence of positive Cutibacterium cultures on the skin surface of male patients to be 77%. We determined the sample size of 50 was necessary to detect a reduction of 50% between the two groups with 1:1 allocation ratio, a power of 0.80, and an alpha of 0.05. Given that the intervention and outcome were only separated by 1 day, we anticipated a 0% dropout rate. Baseline demographics were compared between groups using a t test for continuous variables and a chi-square test for categorical variables. The two groups were compared with regards to the percent positivity of the skin surface and incised dermal edge as well as the bacterial load at each site using a chi-square test.