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A Chlorhexidine Solution Reduces Aerobic Organism Growth in Operative Splash Basins in a Randomized Controlled Trial

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ABSTRACT

Background: Despite recommendations against the use of splash basins, due to the potential of bacterial contamination, our observation has been that they continue to be used in operating theaters. In hopes of decontaminating the splash basin, we sought to determine if the addition of chlorhexidine gluconate (CHG) would eliminate aerobic bacterial growth within the splash basin.
Methods: After Institutional Review Board approval, we began enrollment in a randomized controlled trial comparing 2 splash basin solutions. Splash basins (n = 111) were randomized to either the standard of care (control) solution of sterile water or the experimental solution containing 0.05% CHG. One 20 mL aliquot was taken from the basin at the end of the surgical case and delivered to an independent laboratory. Samples were plated on tryptic soy agar (medium) and incubated at 30°C-35°C to encourage growth. After 48-72 hours, the agar plates were examined for growth and a standard plate count of aerobic cultures was performed.
Results: The sterile water group was found to have bacterial growth in 9% of samples compared to no growth in the CHG group ($P = .045$). The organisms included *Micrococcus luteus*, *Staphylococcus hominis*, Gram-variable coccobacilli, and unidentifiable Gram-positive rods.
Conclusion: Given the safety and efficacy of a concentration of 0.05% CHG in reducing the bacterial contamination in the operative splash basin, it would seem that if the practice of using a splash basin in the operating theater is to be continued, the addition of an antiseptic solution such as that studied here should be considered.

The number of total joint arthroplasty procedures of both the hip and knee is growing substantially in the United States. Projections approach 2 million combined total hip arthroplasty (THA) and total knee arthroplasty (TKA) procedures by the year 2021 [1,2]. With the incidence of postarthroplasty infection ranging from 1% to 2% of primaries and 3%-5% of revisions, the number of cases of periprosthetic infection in the near future will be significant [1,3–7]. The associated economic burden is projected to exceed $1.62 billion [2]. With these numbers in mind it is our responsibility in the orthopedic community to do what we can to reduce the social and economic impact of this devastating complication.

While all surgical procedures carry the risk of bacterial contamination, those that implant prosthetic material are at a particularly high risk for future problems due to the development of biofilms and difficulty eradicating such infections. Inoculation of the implant at the time of surgery is a likely cause of infection [8]. Whyte et al [9] showed that the source of infection was the operating room (OR) personnel in 98% of cases while only 2% of the time it was the patient's own skin. They explained that contamination occurred via direct transfer by the hands of the OR staff or instruments 70% of the time. Knobben et al [10] reported transfer of bacteria between various biomaterial surfaces in the OR, including gloves, broaches, and light handles, at a rate of 17%-71% demonstrating the ability of bacteria to spread to all types of materials in the operative field. Given the evidence of transfer, the direct contact of OR personnel with the patient or prosthetic implant makes early contamination during surgery a likely cause of periprosthetic infection. They further noted that dipping the operative gloves into a chlorhexidine gluconate (CHG) solution prevented transfer.

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Furthermore, Maathuis et al [11] suggested that at least 30% of patients leave the operating suite with bacterial contamination.

The splash basin has been used for many years in the OR as a place to wash instruments and clean them of debris for potential reuse during the surgical case. Often, multiple instruments are placed within the basin in direct contact with previously used tools and debris. Anto et al [12] reported that an average of 45.7 instruments was placed in the splash basin per elective hip or knee arthroplasty case. Furthermore, several studies have shown evidence of bacterial contamination of these basins, with rates from 2% to 74% being reported [12–15]. Thus, the opportunity for bacteria to be transferred to the surgical wound upon reuse of an instrument from the basin is concerning.

Based on these findings, the most recent consensus statement of the Musculoskeletal Infection Society has recommended against the use of splash basins [16]. However, surgical technologists have been trained to use these basins, as a means of "intraoperative decontamination," and thus may still encourage their use in the operating theater [17]. It is recommended by the Association of Surgical Technologists that "a basin of sterile water should be available in the sterile field for the soaking and cleaning of instruments" [17]. Furthermore, a recent article has emphasized the importance of using a sterile water (SW) basin for "timely moisturization and removal of bioburden from reusable surgical instruments" [18]. This report also noted that the Association of Perioperative Registered Nurses along with the Association of Surgical Technologists AST have recommended the use of an SW basin. In summary, they note that reusable instruments should be kept clean and moist and may be placed in a basin of SW after wiping them down. Given our personal experience, and widespread recommendations for OR staff, we believe that the operative splash basin is still frequently used as a preference of the surgical support staff.

As has been suggested, the operative splash basin is a potential source of surgical wound contamination. Thus, we sought to eliminate the bacterial colonization of this source through the addition of an antimicrobial solution to the normal SW bath. To compare potential interventions, a randomized controlled trial comparing a 0.05% CHG antimicrobial solution to SW as a control was performed. This concentration of CHG followed by a saline rinse has been shown to decrease the risk of infection during wound irrigation without increasing the risk of adverse effects [19–22].

The primary objective of this study is to compare the efficacy of adding CHG (0.05% CHG solution) to the splash basin in reducing bacterial growth from splash basins at the end of a total joint replacement procedure. We hypothesized that the addition of CHG would eliminate bacterial growth within the operative splash basin. The secondary outcomes of differences in wound complications as well as superficial and deep surgical site infections were also monitored.

Materials and Methods

After obtaining institutional review board approval (IRB# 76754, NCT# 02434510, https://clinicaltrials.gov/ct2/show/NCT02434510?term=Gililland&rank=2) we began enrollment in a randomized controlled trial comparing 2 splash basin solutions. Enrollment occurred between April and October 2015 at a single academic medical center. Our current protocol includes the use of a splash basin at the back table during all surgical cases. All planned cases of primary TKA or THA during this time period were considered eligible for the study. Patients were excluded if they were scheduled for a revision total joint procedure, had a known history of periprosthetic joint infection, or had a known allergy to CHG. The patients were then randomized to either SW (SW group) or the experimental solution of 0.05% CHG with SW (CHG group). Randomized permuted blocks of 2, 4, and 6 along with stratification between TKA and THA were developed using Stata v.13.1 (College Station, TX) to allow for a balanced enrollment into the study. The study statistician generated the random allocation sequence. Each splash basin was randomized into the study using the Research Electronic Data Capture tool [23] (REDCap; Vanderbilt University, Nashville, TN) and was provided with a unique code. Protected health information was limited to that needed to complete the study. One hundred twenty-two patients scheduled for primary total joint arthroplasty of the hip or knee were approached to enter the study and ultimately 100 patients were included (Fig. 1). Of the 100 patients remaining in the study there was no difference in patient characteristics between the groups (Table 1).

The splash basin solution was made immediately upon opening of instruments and set up for the case at the time the surgical technician would normally assemble the splash basin. The surgical technicians were instructed on the mixing of the CHG solution prior to each surgical case. For the CHG solution, a 1:80 dilution of 4% Hibiclens (Mölnlycke Health Care, Norcross, GA) was needed to create the 0.05% CHG solution. Thus, 2 mL of Hibiclens from an unused freshly opened bottle was added to 2 L of SW (25 mL CHG:2 L SW). The surgical staff was instructed to use the splash basins as per their routine use during the case. One 20 mL aliquot was taken from the basin solution at the end of the surgical case using sterile technique and placed in a biohazard refrigerator prior to delivery to an independent laboratory (Nelson Laboratories, Salt Lake City, UT). Samples were maintained in the refrigerator for no longer than 24 hours. Neither the patient nor the laboratory was aware of the randomization allocation. However, due to the need to make the intervention in the operating theater, the OR staff was aware of the randomization.

The liquid samples were processed according to the laboratory's established protocol for environmental samples. The samples were plated on tryptic soy agar (medium) and incubated at 30°C-35°C to encourage growth. After 48-72 hours, the agar plates were pulled from incubation and examined for growth and a standard plate count of aerobic cultures was performed. When plate counts identified potential bacterial growth, subsequent Gram staining was performed to confirm bacterial growth vs filter debris using a Wescor Gram Stainer (Wescor Inc, Logan, UT). After growth was confirmed, DNA was extracted from the cell for genetic identification according to the laboratory protocols using a genetic analyzer from Applied Biosystems (Carlsbad, CA).

Culture data were collected for each group. A culture positive basin was defined as having positive growth. The proportion of samples with bacterial growth was compared between the SW and CHG groups. Additional data were collected for the purposes of describing the population. When evaluating for malnutrition, patients were considered malnourished if they had an albumin level of <3.5 g/dL or a total lymphocyte count <1500 cells/mm^3 [24,25]. We also recorded the number of scrubbed and other personnel in the OR, the total time the sterile solution was exposed to the environment, and the total duration of the procedure. Additionally, the participant charts were reviewed at their 6-week postoperative appointment to identify any early wound complications including superficial and deep surgical site infections. Finally, minimum 1-year follow-up (mean 1.96 years, range 1.00-2.28) was obtained clinically or via phone call (IRB# 103263) to further evaluate for reoperations due to infections or wound complications.

The total number of participants was determined through an a priori power analysis. Based on previous studies, bacterial contamination of 2.17%-74% has been identified in surgical splash