Official Title: The Value of Home Chlorhexidine Pre-Surgical Wash before Spine Surgery

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Study Purpose and Rationale:

Surgical site infections lead to significant morbidity and mortality. These complications lead to severe clinical, and economic, burdens across surgical disciplines, and may have especially harmful consequences in spine surgery, where they can lead to extensive revision surgeries as well as neurologic sequelae, or even death.

Other trials have examined the effects of presurgical cleansing with chlorhexidine with mixed results. For example, Murray et al. performed a prospective, randomized study examining the effect of CHG cloth treatment at home preoperatively (1). Their study, which was industry sponsored, concluded that pre-cleansing led to decreased bacterial culture positivity preoperatively. However, they reported only on the results of their sample taken in the preoperative holding area. The most relevant data is arguably the bacterial burden after preoperative prep, to determine whether the level equalizes in both groups after the chlorhexidine is applied immediately preoperatively. Additionally, they looked at its use before shoulder surgery, while we are looking at the effects prior to spine surgery.

Another study by Ng et al. prospectively studied the effect of chlorhexidine foot washes on patients prior to foot and ankle surgery and found reductions in bacterial burden after washing (2). They analyzed bacterial flora qualitatively rather than quantitatively, reporting only culture positivity rather than bacterial colony counts. They claim that CHG decreased flora intraoperatively, however their "intraoperative" sample took place after washing and before prep and drape; it could more precisely be labeled a preoperative sample. It was taken about twenty minutes after washing, so it is not surprising that the burden was decreased in this actually preoperative sample. There was a reduction postoperatively in the chlorhexidine footbath group. However, this was not statistically significant.

Significant effort has been put forth by surgeons in the past few decades to decrease the rate of surgical site infections. One intervention has been the adoption of chlorhexidine use by the patient at home preoperatively. There has been conflicting evidence about its potential efficacy in decreasing bacterial loads and infection rates across surgical populations. This intervention has been a subject of numerous trials and reviews over the last several years and has recently been a topic of interest in the orthopedic surgery literature as well. However, no prior study has analyzed the benefit of such an intervention with regards to the field of spine surgery.

1. Murray MR, Saltzman MD, Gryzlo SM, Terry MA, Woodward CC, Nuber GW. Efficacy of preoperative home use of 2% chlorhexidine gluconate cloth before shoulder surgery. J Shoulder Elbow Surg. 20(6):928-33, 2011

2. Ng AB, Adeyemo FO, Samarji R. Preoperative footbaths reduce bacterial colonization of the foot. Foot Ankle Int. 30(9):860-4, 2009.

Scientific Abstract:

To our knowledge no prior study has evaluated the effects of preoperative skin cleansing on the cutaneous bacterial burden for patients undergoing spine surgery. Surgeons use various methods to decrease the risk of infection in patients perioperatively. We would like to conclusively determine whether or not at-home preoperative skin cleansing with chlorhexidine decreases the bacterial burden pre-operatively for patients undergoing spine surgery, and if these effects are eliminated after the pre-surgical chlorhexidine prep. We will perform a prospective, randomized clinical trial to assess the impact of home chlorhexidine wipes and evaluate whether this intervention leads to a change in bacterial counts on patients pre- and intra-operatively. Validating their efficacy will allow optimal protocols to be

designed that contribute to improved outcomes without adding undue mental or financial burden on patients.

Lay Abstract:

To our knowledge no prior study has evaluated the effects of cleaning the skin at home before surgery in patients undergoing spine surgery. We will perform a clinical trial to see if patients who use the chlorhexidine cleansing wipe have decreased amounts of bacteria on their skin when they arrive for their scheduled spine surgery. Spine surgeons strive to decrease infections in their patients, so it is important to see if this intervention helps to do this.

Research Question/Hypothesis:

We plan to assess the effect of preoperative chlorhexidine skin cleansing on cutaneous bacterial loads.

1. We hypothesize that preoperative washing will decrease overall bacterial burden upon patient arrival to the pre-operative holding area and before the pre-surgical prep.

2. We also believe that the immediate pre-operative and the intra-operative bacterial counts will be unaffected by this intervention.

Study Design:

We will perform a prospective, randomized clinical trial at Columbia University, specifically the Allen Pavilion as our test site.

Clinical Trial:

We will prospectively analyze 40 patients undergoing spine procedures at Columbia University. After attaining IRB approval, and confirming that all surgeons included in this study will abide by the standardized preoperative protocol, we will begin trial enrollment.

Patients undergoing spine surgery will be included after informed consent with the surgical team during their preoperative clinical evaluation. Randomization will occur through use of numbered envelopes with cards inside with detailed instructions for patients in the chlorhexidine versus placebo groups; grouping will be determined by a random number generator matching to the envelope numbers. The attending surgeon, as well as the microbiology lab analyzing the sample, will be blinded to the selected intervention.

Inclusion Criteria:

- 18 years old or older
- Scheduled for elective spine surgery at Columbia University Medical Center

Exclusion Criteria:

- Unable to apply at-home chlorhexidine wipe by themselves
- Deemed "high risk" preoperatively by the treating surgeon
- Diagnosed with spine trauma
- Undergoing deformity correction surgery
- Unable to consent to the terms of the surgery
- Known infection at time of the index procedure
- Hospitalized within 1 week pre-operatively
- Allergic to chlorhexidine
- Immunocompromised
- End stage renal disease on dialysis

- Local or systemic skin disease (such as psoriasis, eczema, etc.)
- Open skin wounds

Patient Criteria

Adult patients 18 years of age and older who are undergoing elective primary spine surgery will be included in the surgery. Patients included in the study also will agree to perform the intervention of washing their surgical site by themselves (rather than through the help of an assistant). Patients who are deemed "high risk" preoperatively by the treating surgeon, as well as spine trauma patients and those undergoing deformity correction surgery, will be excluded from this study. Patients will also be excluded if they are unable to consent to the terms of the study, or if they are physically unable to wash their surgical site due to physical constraints, e.g., shoulder pathology that prohibit them from reaching the site of their spine surgery. Patients will be excluded if they had known infection at time of the index procedure, hospitalized within 1 week pre-operatively, or are known to have allergies to chlorhexadine. Patients will also be excluded if they had immune compromise, end stage renal disease on dialysis, local or systemic skin disease (such as psoriasis, eczema) or open skin wounds.

Data will be collected for patients regarding demographic variables such as age, gender, race, BMI, as well as compliance with cleansing protocol (washed once, twice, or not at all), occurrences of side effects from cleansing, whether they had shaved their surgical site or needed shaving in the OR, and presence of diabetes, rheumatoid arthritis, or chronic renal insufficiency, as well as other comorbid medical conditions.

Intervention

Patients will be randomized to the chlorhexidine or no additional intervention groups. Patients will be randomized to use 4% chlorhexidine cloths, while the other half receive no additional intervention. Those randomized into the CHG home-application group will be asked to shower the night before surgery, and to use a standardized pre-packaged chlorhexidine gluconate wipe (that they would receive at their pre-surgical consultation) on their surgical site after thoroughly drying those areas. They will be asked to use a second wipe in each area the morning of surgery. Those who forget to use the wipe in the morning are allowed to use the wipe in the pre-operative area and included if this occurs more than one hour before skin prep. The surgical sites will be analyzed in two groups: anterior cervical and posterior spine. Each of these two groups will be randomized separately. All patients will undergo a standardized preoperative cleansing regimen. Once positioned, they will be cleansed with an alcohol solution. Then, the surgical site (either the anterior portion of the neck or the posterior area of the spine) will be scrubbed with chlorhexidine-soaked brushes and then painted with chlorhexidine solution. Perioperative antibiotics will be given per attending surgeon preference.

Specimen Sampling

Cutaneous samples will be taken from the surgical site of each patient at each time point. Initial skin sample would be taken in the office at the preoperative clinical visit at time of booking. The next specimen will be acquired pre-operatively after the patient is positioned on the operating table, before the skin prep. A third sampling occurs immediately before draping, after the skin prep had been given adequate time to completely dry. The fourth sample will be taken 1hr after the start of the case from superficial subcutaneous tissue. All specimens were taken by a sterile BD E-Swab, which will be rubbed 10 times (five times in one direction, five times in the other) lightly along a 5cm site the surface of the site being used for the incision. This swab will be then placed in the ESwab collection system. All samples will be sent immediately after acquisition to the microbiology lab for analysis within twenty-four hours.

Statistical Procedures:

Data will be analyzed in intent-to-treat manner. All patients will be asked in the preoperative holding area about their compliance to the home cleansing regimen. Those who are noncompliant or only partially compliant with their treatment will still be included in the intent-to-treat analysis and will also be removed for subsequent analysis of only patients who were fully compliant with treatment. Power analysis will be performed before the start of the trial in order to achieve adequate power to detect significant decreases in the bacterial burden after intervention. The standard deviation of the data will be assessed after the pilot trial so that this calculation can be performed. Data analysis will be done through multivariate analysis with logistic regression and chi squared analysis, using SPSS.

Recruitment:

Patients will be enrolled prospectively as they present to the medical practice of the spine practice. If they are eligible based on inclusion criteria and exclusion criteria, they will be offered informed consent and enrollment into the trial. Only patients who present to the offices of the spine attendings included in the study and who are eligible will be identified and the study discussed with them. Pilot trial patients will be recruited from word-of-mouth discussion with study investigators and healthcare staff within Columbia.

Potential Benefits:

Patients undergoing adult spine surgery at CUMC do not currently receive at-home chlorhexidine wipes. They are an additional anti-microbial measure that possibly decrease the amount of bacteria on the skin. Through this trial, half of the enrollees will obtain this additional potentially anti-microbial step in their preoperative regimen, which could potentially decrease their risk of developing surgical site infections.