TITLE

A randomized trial of vaginal prep solutions to reduce bacteria colony counts in patients having a vaginal surgery.

INVESTIGATORS

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SUMMARY OR ABSTRACT

This is a randomized trial comparing the effectiveness of 4 vaginal prep solutions (betadine, baby shampoo, TechniCare and Peridex) on reducing bacterial colony counts during surgery preparation. Women undergoing a vaginal surgery will be enrolled into the trial prior to surgery. Target sample size per group is 15 patients. During standard surgical prep, a vaginal swab will be taken to assess the initial colony counts for aerobic and anaerobic bacteria. After the initial swab, the vagina will be prepared using one of the prep 4 solutions (betadine, baby shampoo, TechniCare or Peridex). After a predefined 10 minutes, the area will be re-swabbed to determine pre-procedure colony counts. A third swab will be taken following completion of the procedure to determine post-procedure colony counts. Laboratory analyses for raw colony counts, sensitivities, identification (using MALDI-TOF) will be performed. We expect that there will be reduced colony counts at the pre-procedure point with baby shampoo having the least reduction, followed by betadine and TechniCare, then Peridex. Patient reported outcomes for vaginal itching and burning as well as patient report of any treatment for vaginal infection will be collected by telephone at 2 days, 2 weeks and 1 month post-surgery.

BACKGROUND AND LITERATURE REVIEW

Antiseptic preparation for surgical incision sites has greatly reduced postoperative infections. However, surgical site infections (SSI) are still the leading cause of hospitalizations after

surgery. With the application of antiseptic preparation, a reduction in bacterial counts follows. The rate at which the bacterial counts rise between preparation and incision may be of variation depending on the surgical antiseptic scrub.

Betadine (Povidone- iodine), Peridex (Chlorhexidine), baby shampoo and TechniCare (chloroxynel) are all surgical scrubs approved for the preparation of vaginal access surgeries. While there has been controversy on the use of Chlorohexidine for vaginal preparation surgery, due to its labeling as a cause for irritation, studies have shown that when 2-4% Chlorhexidine is used in the vaginal area there are little to no signs of irritation and the bacteria counts post incision are less than the bacterial counts for povidone iodine[1,2]. Baby shampoo can also be used as an effective antiseptic scrub with no irritation and no statistical difference in bacterial count reduction as compared to povidone-iodine[3]. Little research has been done to look at the antiseptic power of Chloroxylenol in vaginal surgeries. However, when used as a root canal antiseptic it can reduce bacteria counts by 99.9%[4]. This is illustrative of its capability to reduce bacteria on a mucus membrane similar to the vagina.

There is literature that shows the antiseptic power of Betadine, Peridex, Baby shampoo and TechniCare for post-incisional bacteria counts, but little is known about the pre-incisional power of these scrubs for vaginal access surgeries.

SPECIFIC AIMS OR OBJECTIVES

The aim of this study is to understand the power of vaginal surgical scrubs before and after procedure completion. This will be done by collecting bacterial samples before antiseptic preparation, 10 minutes after antiseptic preparation, and after completion of the procedure along with follow-up data of irritation, infection post-surgery, and infection risk factors of each patient.

SIGNIFICANCE TO PATIENT, INSTITUTION, PROFESSION, OR ALL

Vaginal preparation research provides beneficial knowledge to hospitals and physicians in the prevention of surgical site infections (SSI). This specific project will provide insight regarding the bacteria-eliminating power of four different surgical scrubs used on the vaginal mucous membrane. There is potential for this study to determine the most effective scrub for vaginal surgeries, as well as correlate pre-procedure bacterial counts and likelihood of surgical site infections. The information collected from this study could benefit future patients and hospitals alike in terms of reducing the risk of SSI's. The risks of this study could be unidentified allergies to any of the surgical scrubs, or a loss of patient data. These are unlikely risks due to the protocol of the study.

METHODS

This study will use block randomization. There will be four arms of the study one for each of the four surgical scrubs. There will be approximately 15 patients per arm. Patients undergoing surgeries which require a vaginal antiseptic preparation will be recruited from Wright State Physicians Obstetrics and Gynecology as well as other participating groups at Miami Valley Hospital. Procedures included in the study are procedures in which a vaginal preparation is performed, including procedures with a vaginal incision (hysterectomy, incontinence procedures), as well as general laparoscopic procedures (diagnostic laparoscopy, salpingectomy, oophorectomy, etc). Procedures excluded from the study are procedures which involve: any local infectious process such as cellulitis or abscess, have significant risk of washout of the vaginal preparation (hysteroscopy or vaginoscopy), any procedures for invasive cancer diagnoses, or procedures with significant risk of bleeding such as dilation and curettage (both for sampling or pregnancy-related), or endometrial ablation. Revision surgeries will also be excluded to decrease any complications. Patients who consent to the study will be given a ID and

will be randomly assigned to one of the four arms. Patients will be excluded if an allergy to any of the scrubs is listed or found. Each recruited patient will be over the age of 18 with ability to consent on their own.

Each patient will be given a standard prophylaxis 30 minutes before surgery. After prophylaxis administration and before surgical antiseptic preparation, a 10 second swab will be taken of the vagina making sure to span the surface area of the vaginal canal with avoidance of the cervix. The swab will then be broken off into a tube labeled with the patient ID, date, and "pre-scrub." The patient will then undergo antiseptic preparation with the assigned surgical prep. A standard procedure of application will be done for each of the arms. Ten minutes after application, another swab will be taken using the same procedure as the "pre-scrub" swab. This swab will be broken off in a tube labeled with the patient ID, date, and "post-scrub."[1] Following the conclusion of the procedure, a third swab will be taken using the same procedure as the two pre-incision swabs. The third swab will then be broken off into a tube labeled with the patient ID, date, and "post-procedure-swab." The swabs will then be transported to CompuNet where they will be analyzed for aerobic, anaerobic bacteria and fungal colonies using Matrix Assisted Depolarization/Ionization Time of Flight mass spectrometry (MALDI-TOF).

The data of colony counts will be collected from CompuNet. BMI, age, prophylaxis, postmenopausal information, diabetic information, smoking history, surgical duration, complication in surgery, and length of hospital stay will all be collected from patient records. No patient identifiers will be collected[5]. Patients will be followed up on their surgery approximately two days, two weeks and a month after surgery to get information on irritation and/or surgical infection. This data will be collected either be phone call or at post-surgical follow-up appointment at Wright State Physicians. The South Hampton Grading Scheme for Surgical

Wounds will be used to Quantify Each patients level of irritation and/or infection. The scale is a Zero to Five score, with Zero being no irritation or infection and Five being severe irritation or infection[15].

One potential obstacle of this study could be recruitment of patients. Patients will not be given incentive for participation and will not acquire any direct benefit from the study. Another potential issue may arise from the size of the study; there may not be enough subjects recruited for each arm of the study to find a detectable and significant difference in the use of one surgical scrub over another. There may also not be sufficient power to detect a difference in the risk of post-operative surgical site infections.

Precautions will need to be taken for allergies. A recruited patient may not be aware of personal allergies to the surgical scrubs. This would put the patient in harm if they are assigned to a scrub that they are allergic to. Since data will be collected from the patient's medical records, precautions will be taken to avoid loss of patient identifiers. All research investigators will only utilize the patients assigned research ID. This will both protect the patient and avoid bias.

Statistical Analysis Plan

Bacterial and fungal colony counts will be coded as positive if counts are ≥5000 colonies/mL and negative if < 5000 colonies. Statistical analyses will be conducted as follows:

Baseline charasteristics will be compared with Chi square (categorical data) and ANOVA (continuous data) to determine potential differences for demographic and clinical characteristics and for colony counts (positive vs negative) at the pre-scrub sample collection.

Each of the 3 target scrubs (baby shampoo, chlorhexidine and chloroxynel) will be compared to povidone-iodine as the standard of care using Fisher's Exact tests for each pair comparison at the

post-scrub and post-procedure collections.

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