IRB #: STU00204759

BIOMEDICAL PROTOCOL

PROTOCOL TITLE: Tolerance of Chlorhexidine Gluconate Versus Povidone Iodine Vaginal Cleansing Solution: a Randomized Control Trial

PRINCIPAL INVESTIGATOR:
Magdy Milad, MD
Department of Obstetrics & Gynecology
312-472-4655
mmilad@nm.org

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STUDY SUMMARY:

Title	Tolerance of Chlorhexidine Gluconate 4%Versus Povidone Iodine 7.5% Vaginal Cleansing Solution: a Randomized Control Trial
Short Title	Tolerance of Chlorhexidine Gluconate Vaginal Cleansing Solution
Protocol Number	STU00204759
Methodology	Single-blinded Randomized Control Trial (patients blinded)
Study Duration	18 months
Study Center(s)	Prentice Women's Hospital
Objectives	Compare the tolerance of 4% chlorhexidine gluconate /4% isopropyl alcohol versus 7.5% povidone iodine vaginal cleansing solutions in patients undergoing hysteroscopy, gynecologic dilation and curettage, endometrial ablation or Essure.
Number of Subjects	Control (Povidone Iodine): 66 Experimental (Chlorhexidine Gluconate): 68
Diagnosis and Main Inclusion Criteria	Vaginal and urinary symptoms in women over the age of 18undergoing hysteroscopy, dilation & curettage, endometrial ablation, and Essure

Study Product(s), Route, Regimen	4% chlorhexidine gluconate/4% isopropyl alcohol preoperatively

OBJECTIVES:

Objective: To compare the tolerance of 4% chlorhexidine gluconate/4% isopropyl alcohol versus povidone iodine vaginal cleansing solutions specifically for surgical preparations in patients undergoing hysteroscopy, dilation and curettage, endometrial ablation or Essure.

- *Specific Aim 1:* To compare the frequency of patient-reported vaginal symptoms (dryness, burning, itchiness, unusual vaginal discharge) after treatment with chlorhexidine gluconate or povidone iodine vaginal cleansing solutions.
- *Specific Aim 2:* To determine the severity of vaginal symptom safter treatment with chlorhexidine gluconate or povidone iodine vaginal cleansing solutions.
- *Specific Aim 3:* To determine the presence and severity of pain or burning with urination after treatment with chlorhexidine gluconate or povidone iodine vaginal cleansing solutions.

Hypothesis: There will be no statistically significant difference between patient-reported vaginal and urinary symptoms after treatment with 4% chlorhexidine gluconate or 7.5% povidone iodine vaginal cleansing solutions.

BACKGROUND:

Surgical site antisepsis is critical in preventing surgical site infections. Although chlorhexidine gluconate has proven to be superior to povidone iodine for surgical site antisepsis, povidone iodine is the only FDA-approved antiseptic solution for surgical preparation of the vagina.[1] Many surgeons are hesitant to use chlorhexidine gluconate for preoperative vaginal cleansing due to the alcohol dissolvent present in the solutions that is implicated in a greater risk of irritation. Yet, there has been no randomized study to illustrate whether the risk of vaginal irritation is greater in chlorhexidine gluconate versus povidone iodine. Thus, the purpose of the study is to conduct a randomized control trial to compare the tolerance of 4% chlorhexidine gluconate to povidone iodine using patient-reported outcomes of vaginal and urinary symptoms.

Currently, povidone iodine is the most frequently used antiseptic for surgical preparation of the vagina. Yet, povidone iodine is not optimal for preoperative vaginal cleansing. Data shows that two-minute vaginal disinfections lead to significantly elevated systemic iodine absorption.[2] On the other hand, chlorhexidine covalently binds to mucosal proteins, leading to minimal systemic absorption.[3] Furthermore, chlorhexidine has shown to have better reduction of bacterial flora after preoperative application, longer residual activity, and remains activated in the presence of blood or vaginal discharge.[4] In a large prospective, randomized control trial across six different institutions, 4% chlorhexidine gluconate was shown to be more efficacious than povidone iodine for preventing surgical site infections in both superficial and deep incisional infections.[5]

It is important to recognize both the risks and benefits of using chlorhexidine gluconate. Chlorhexidine gluconate has been used safely for over forty years, but manufacturers of chlorhexidine gluconate caution against using the product in genital

areas as the solution can cause irritation and sensitization. A review of chlorhexidine hypersensitivity stated possible reactions include contact dermatitis, contact urticaria, and anaphylaxis.[6] There has also been a case report of desquamating vaginal epithelium with chlorhexidine that resulted in the planned surgery being cancelled. The patient was treated with steroids, antihistamines, and topical estrogen and the vaginal mucosa was well healed within two weeks.[7] One study conducted in South Africa looked at the tolerance and safety of different concentrations of chlorhexidine for peripartum vaginal washes. The study concluded that those receiving 4% chlorhexidine gluconate washes had more vaginal irritation than those receiving 1% or 0.25%.[8] Nevertheless, another study showed that non-pregnant women were able to tolerate 4% chlorhexidine gluconate solution.[9] In fact, the American Congress of Obstetricians & Gynecologists issued a committee opinion in 2013, advocating that chlorhexidine gluconate with low concentrations of alcohol are both safe and effective for off-label use as surgical preparations of the vagina.[10]

Currently, surgical site infections at Northwestern's Prentice Women's Hospital are higher than the national average. One way to combat this would be to use more effective preoperative antiseptic agents. Chlorhexidine gluconate is used for surgical preparation of the vagina in patients allergic to iodine, but its application can be far-reaching. The significance of the data from this proposed study will allow us to determine the tolerance of 4% chlorhexidine gluconate compared to povidone iodine, and whether chlorhexidine gluconate is not only superior in its antiseptic properties, but also similarly or possibly more tolerable than povidone iodine.

INCLUSION & EXCLUSION CRITERIA:

Inclusion criteria: Women over age 18 who have the ability to understand and willingness to sign a written informed consent and are undergoing:

1. undergoing hysteroscopy
2. gynecologic dilation & curettage
3. endometrial ablation
4. Essure without concomitant laparoscopy

Exclusion criteria: Women who are:

1. pregnant
2. have a history of atopic dermatitis, vaginal irritation, allergic reactions, or anaphylaxis to chlorhexidine gluconate or povidone iodine.

STUDY ANALYSIS PLAN:

The study will take place at a single site, Northwestern Prentice Women's Hospital. Using a 2-sided test to detect a difference between proportions with 80% power and a 5% significance level, and assuming the prevalence of irritation in the control group (povidone iodine) is 10% and prevalence of irritation in the exposed group (chlorhexidine gluconate) is 31%, and factoring in patients lost to follow up given that the data collection is through a survey, the study will need 68 participants in each group. There are an estimated 800 hysteroscopies at Prentice Women's Hospital each year and given incomplete follow-up, we estimate it will take 6 to 8 months of patient enrollment to achieve this desired sample size.

STUDY-WIDE RECRUITMENT METHODS:

The research coordinator will contact the appropriate gynecologic surgeons who will introduce the study to potential participants during the pre-operative office visit. On the day of surgery, prior to the administration of anesthetics, the patient will be asked of their willingness to participate in the study, and a study member will explain the risks and benefits. A written informed consent form will be filled out. Participants will be randomized through the use of Excel to generate randomization numbers to either experimental antiseptic, chlorhexidine gluconate, or the control, povidone iodine.

STUDY TIMELINES:
Participants will be involved in the study on the day of their surgery to 24-48 hours after surgery.
The proposed timeline of the study can be seen below:

- April- June 2017: Communicate with gynecologic surgeons operating at Prentice Women's Hospital to gain awareness for the study. Communicate with preoperative nurses and operating room circulating nurses to make them aware of the logistics of study.
- July-February 2018: Recruit and enroll patients. Administer patient surveys.
- March- September 2018: Compile and analyze data

STUDY ENDPOINTS:
List of study variables to be collected:

Outcomes	**Type**	**Definition**
Vaginal dryness	Ordinal	Any sensation of dryness in the vagina
Vaginal burning	Ordinal	Any sensation of burning in the vagina
Vaginal itchiness	Ordinal	Any sensation of itchiness in the vagina
Unusual vaginal discharge	Ordinal	Any witness of unusual discharge coming from the vagina
Pain or burning with urination	Ordinal	Any sensation of pain or burning with urination

Exposures	**Type**	**Definition**
Pre-op chlorhexidine gluconate	Dichotomous	If women randomized to receive chlorhexidine gluconate, then yes. If woman randomized to povidone iodine, then no.

Covariates	**Type**	**Definition**

Woman's Age	Continuous	Female age in years at time of surgery
Surgery	Nominal	Hysteroscopy, dilation and curettage, endometrial ablation or Essure.

Other	**Type**	**Definition**	**Use**
Gravidity	Count	Number of prior pregnancies	Table 1 population characteristic
Parity	Count	Number of pregnancies carried to a viable gestational age	Table 1 population characteristic
Race	Categorical	Group by race: White, Black/Africa-American, Hispanic, Asian/Pacific Islander, American Indian/Alaskan Native, Middle-Eastern	Table 1 population characteristic

PROCEDURES INVOLVED:

This is a single-blinded randomized control trial. The patients will be blinded to whether they receive the control povidone iodine or the experimental chlorhexidine gluconate antiseptic. The surgeons will be aware of the treatment, but will not be administering the survey questions to minimize bias.

Given the nature of the procedures included in the inclusion criteria, participants will present to the hospital on the day of their surgery and most will be discharged two to three to hours after surgery. Participants are expected to respond to the survey pre-operatively, prior to discharge from the hospital, and 24-48 hours after surgery. This corresponds to three total surveys per participant. The first two surveys done preoperatively and prior to discharge will be done on paper. A study member via phone will administer the third survey 24-48 hours after surgery. See Appendices 1 and 2 for sample pre-operative and post-operative surveys, respectively. The survey is six questions long, and should take no longer than 3-5 minutes to administer. The survey was designed using the PRO-CTCAE (Patient- Reported Outcomes version of the Common Terminology Criteria for Adverse Events) created by the NIH/NCI. The PRO-CTCAE is a measurement system used in cancer clinical trials to detect symptomatic adverse events. The language and format of the questions have been cognitively tested.[11] Questions 1,4,5, and 6 are part of the PRO-CTCAE question bank. Questions 2 and 3 on the survey were investigator-developed items to capture vaginal burning and itchiness, which are not contained in the PRO-CTCAE item library.

The data to be collected will include: age, gender, race, gravidity, parity, surgeon, type of surgery, concomitant cystoscopy, use of Foley catheter, name of antiseptic solution, and presence and severity of vaginal and urinary symptoms based off survey responses. The patients will receive preoperative vaginal preparation either with povidone iodine or

chlorhexidine gluconate. Both antiseptic solutions are approved for surgical preparation of the vagina at Northwestern's Prentice Women's Hospital.

DATA & SPECIMEN MANAGEMENT:
Paper data will be stored in a locked cabinet at the nursing desk of the preoperative holding area and periodically transferred to a password protected Excel file on a password-protected laptop. Paper surveys will be stored for 1 years after the end date of the data collection (September 2019) and will be discarded through the hospital's confidential document shredding service. Electronic data will be de-identified and stored indefinitely on a password-protected computer.

The data will be transitioned to Excel and analyzed with a statistical software like SPSS. The participant's MRN will be collected in order to link survey data with patient demographics and the corresponding surgery/vaginal cleansing intervention. This MRN will be matched to a participant ID, and the survey will only have the patient's ID on it. The document linking MRN with participant ID will be kept separate from the surveys. The data collection spreadsheet will not contain patient MRNs.

PROVISIONS TO MONITOR DATA TO ENSURE THE SAFETY OF PARTICIPANTS:
The PI, Magdy Milad, and researchers, Supriya Rastogi, Laura M. Glaser, Jaclyn Friedman, and one other research coordinator will have access to the data. The study team will evaluate the data collected every 2 weeks, and look at any adverse events to ensure patient safety. Safety information will be collected with case report forms. The Principal Investigator will be notified within 24 hours of learning of any serious adverse events, regardless of attribution, occurring during the study. The office of Risk Management and the IRB will be notified as soon as possible of "any unanticipated problems involving risk to subjects or others" (UPR/UPIRSO).

Contraindications:
Contraindications include patient with a history of the following after use of chlorhexidine gluconate or povidone iodine in any application:

- Atopic dermatitis
- Vaginal irritation
- Allergic reactions
- Anaphylaxis

The incidence of these events has not been studied specific to vaginal application.

Special Warnings and Precautions for Use:
There is a FDA warning of severe allergic reactions with chlorhexidine gluconate. Chlorhexidine gluconate continues to be used preoperatively as antiseptic agent at Northwestern operating rooms.
Chlorhexidine Gluconate and Povidone Iodine

- Do not use in contact with meninges, or over skin of head or face.
- Stop use if irritation, sensitization, or allergic reaction occurs.
- Keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums.
- If solution should contact these areas, rinse out promptly and thoroughly with water

- Wounds which involve more than the superficial layers of the skin should not be routinely treated
- Repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin.

Interaction with other medications:

No studies of interactions between chlorhexidine gluconate and povidone iodine and other drugs have been conducted.

Adverse Reactions:

The FDA reports the following possible side effects with the active medications

Chlorhexidine Gluconate:

- Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue). It is possible that some side effects of chlorhexidine gluconate have not been reported.

Povidone Iodine:

- Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue). It is possible that some side effects of povidone iodine topical may not have been reported.

Adverse Event Monitoring:

Adverse event data collection and reporting, which are required as part of every clinical trial, are done to ensure the safety of Subjects enrolled in the studies as well as those who will enroll in future studies using similar agents. Adverse events are reported in a routine manner at scheduled times during a trial. Additionally, certain adverse events must be reported in an expedited manner to allow for optimal monitoring of patient safety and care. The following events meet the definition of adverse event:

1. Any serious event (injuries, side effects, deaths or other problems), which in the opinion of the Principal Investigator was unanticipated, involved risk to subjects or others, and was possibly related to the research procedures.
2. Any serious accidental or unintentional change to the IRB-approved protocol that alters the level of risk.
3. Any deviation from the protocol taken without prior IRB review to eliminate apparent immediate hazard to a research subject.
4. Any new information (e.g., publication, safety monitoring report, updated sponsor safety report), interim result or other finding that indicates an unexpected change to the risk/benefit ratio for the research.
5. Any breach in confidentiality that may involve risk to the subject or others.
6. Any complaint of a subject that indicates an unanticipated risk or that cannot be resolved by the Principal Investigator.

All other adverse events- such as those that are expected, or are unlikely or definitely not related to the study participation- are to be reported annually as part of regular data submission.

WITHDRAWAL OF PARTICIPANTS:

Participants will be withdrawn from the study without their consent if the patient experience anaphylaxis from either of the antiseptics, if the patient becomes pregnant, if

the physician decides participation in the study is not in the patient's best interest, and if the planned procedure is unable to be completed. These events will be recorded and stated when presenting data from the study.

RISKS TO PARTICIPANTS:
There are possible side effects to both chlorhexidine and povidone iodine. These include atopic dermatitis, vaginal irritation, allergic reactions, and anaphylaxis. There is a FDA warning of severe allergic reactions with chlorhexidine gluconate. Chlorhexidine gluconate routinely to be used preoperatively as antiseptic agent at Northwestern operating rooms. A review of anesthesia drug safety literature showed in patients who had allergic reactions after general anesthesia, chlorhexidine accounted for 5% of the allergies. Additionally, patch testing for chlorhexidine revealed a positive test in 2% of the participants suspected of contact allergic dermatitis exposed to chlorhexidine after topical application. It is estimated that this percent increases to greater than 5% in patients with atopic dermatitis, and thus patients with atopic dermatitis will be excluded in this study. [12]In another study looking at 50 cases of allergic reactions to chlorhexidine, 9 were found to have anaphylaxis.[13] In regards to povidone iodine, one study looked patients who had a rash after exposure to povidone iodine and found 10% to have a positive patch test.[14] There have been multiple case reports of anaphylaxis to povidone iodine, but no particular statistic has been reported.[15] The exact incidence of the adverse events of either antiseptic in the general population still remains unknown, as well the incidence of these events with vaginal application.

POTENTIAL BENEFITS TO PARTICIPANTS:
There is no direct benefit to participants.

SHARING OF RESULTS WITH PARTICIPANTS:
The results of the study are patient-reported outcomes. Patients will not be informed on the overall study results.

SETTING:
The research study will take place at Northwestern's Prentice Women's Hospital. Antiseptic procedures will occur at Prentice operating rooms prior to surgery.

RESOURCES AVAILABLE:
The study team will consist of the PI, Magdy Milad, and researchers, Supriya Rastogi, Laura M. Glaser, Jaclyn Friedman, and one other research coordinator. All study members will complete CITI training. The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and entered onto the Case Report Forms. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his original records to permit verification of proper entry of data. At the completion of the study, all case report forms will be reviewed by the Principal Investigator and will require his final signature to verify the accuracy of the data.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

CONFLICTS OF INTEREST:
None to disclose. All investigators will follow the University conflict of interest policy.

PRIOR APPROVAL:
The Department of Obstetrics & Gynecology has agreed to provide funding for this research project.

ECONOMIC BURDEN TO PARTICIPANTS:
Participants will not accrue any additional costs because of participation in the research.

PROCESS TO DOCUMENT CONSENT IN WRITING:
Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form will include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB- approved consent form.

Prior to a patient's participation in the trial, the written informed consent form will be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

DRUGS OR DEVICES:
Both povidone iodine and 4% chlorhexidine gluconate vaginal cleansing solutions are available at Northwestern Prentice Women's Hospital operating rooms. The solutions will be stored, handled, and administered according to the current operating room guidelines. Package inserts for both antiseptics are shown below:

4% Chlorhexidine Gluconate Solution/4% isopropyl alcohol:

Purpose	Antiseptic
Uses	• Surgical hand scrub: significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care • Healthcare personnel handwash: helps reduce

	bacteria that potentially can cause disease • Patient preoperative skin preparation: for the preparation of the patient's skin prior to surgery • Skin wound and general skin cleansing
Warnings	For external use only Do not use: • If you are allergic to chlorhexidine gluconate or any other ingredients • In contact with meninges • In the genital area • As a preoperative skin prep of the head or face When using this product: • Single use when used for patient preoperative skin preparation • Keep out of eyes, ears and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when installed in the middle ear through perforated ear drums. • If solution should contact these areas, rinse out promptly and thoroughly with water • Wounds which involve more than the superficial layers of the skin should not be routinely treated • Repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. This may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away. - Do not use in contact with meninges, or over skin of head or face. - Stop use if irritation, sensitization, or allergic reaction occurs. - Keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums. - If solution should contact these areas, rinse out promptly and thoroughly with water - Wounds which involve more than the superficial layers of the skin should not be routinely treated

	- Repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin. - There is a FDA warning of severe allergic reactions with chlorhexidine gluconate. -
Directions	Use with care on premature infants or infants under 2 months of age. These products may cause irritation or chemical burns Surgical hand scrub: • Wet hands and forearms with water • Scrub for 3 minutes with about 5 mL of product with and a wet brush, paying close attention to the nails, cuticles and interdigital spaces • A separate nail cleaner may be used • Rinse thoroughly • Wash for an additional 3 minutes with 5 mL of product and rinse under running water • Dry thoroughly Healthcare personnel handwash: • Wet hands with water • Dispense about 5 ml of product into cupped hands and wash in a vigorous manner for 15 seconds • Rinse and dry thoroughly Patient preoperative skin preparation: • Apply product liberally to surgical site and swab for at least 2 minutes and dry with a sterile towel • Repeat procedure for an additional 2 minutes and dry with a sterile towel Skin wound and general skin cleansing: • Thoroughly rinse the area to be cleaned with water • Apply the minimum amount of product necessary to cover the skin or wound area and wash gently • Rinse again thoroughly
Inactive ingredients	Cocamide DEA, fragrance, glucono-delta-lactone, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, PEG-75 lanolin, purified water, tridecyl alcohol
Product Display Label	4% chlorhexidine gluconate

7.5% Povidone Iodine: equal to 0.75% available iodine)

Purpose	Antiseptic
Uses	• Disinfectant hand wash and skin cleanser • Significantly reduces bacteria on the skin

Warnings	For external use only Do not use this product • In the eyes • Over large areas of the body • If you are allergic to povidone-iodine or any other ingredients in this preparation • Longer than 1 week unless directed by a doctor Ask a doctor before use if you have • Deep or puncture wounds • Serious burns • Animal bites Stop using this product and ask a doctor if • Redness, irritation, swelling, or pain continues or increases • Infection occurs • Do not use in contact with meninges, or over skin of head or face. • Stop use if irritation, sensitization, or allergic reaction occurs. • Keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures or may cause deafness when instilled in the middle ear through perforated eardrums. • If solution should contact these areas, rinse out promptly and thoroughly with water • Wounds which involve more than the superficial layers of the skin should not be routinely treated • Repeated general skin cleansing of large body areas should not be done except when the underlying condition makes it necessary to reduce the bacterial population of the skin.
Directions	• Wet skin and apply a sufficient amount for lather to cover all surfaces • Wash vigorously for at least 15 seconds • Rinse and dry thoroughly
How supplied	Other information store at 25˚C (77˚F); excursions permitted between 15˚-30˚C (59˚-86˚F)
Inactive ingredients	Ammonium nonoxynol-4 sulfate, nonoxynol-9, purified water, sodium hydroxide
Product Display Label	Betadine Skin Cleanser

Appendix 1: Pre-operative survey

Date ___/___/_____ Surgeon _____ Participant ID _____

Pre-operative Survey

Welcome to Northwestern Prentice Women's Hospital. Thank you for participating in a survey being conducted by Dr. Magdy Milad on the tolerance of chlorhexidine gluconate or povidone iodine vaginal cleansing solutions. Below are questions asking about any vaginal symptoms.

Please think back over the past 7 days…

1. VAGINAL DRYNESS				
What was the SEVERITY of your VAGINAL DRYNESS at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

2. VAGINAL BURNING				
What was the SEVERITY of your VAGINAL BURNING at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

3. VAGINAL ITCHINESS				
What was the SEVERITY of your VAGINAL ITCHINESS at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

4. UNUSUAL VAGINAL DISCHARGE				
Did you have any UNUSUAL VAGINAL DISCHARGE?				
O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much

5. PAIN OR BURNING WITH URINATION				
What was the SEVERITY of your PAIN OR BURNING WITH URINATION at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

6. OTHER SYMPTOMS	
Do you have any other symptoms that you wish to report?	
O Yes	O No

Please list any other symptoms:	
1.	What was the severity of this symptom at its WORST? O None O Mild O Moderate O Severe O Very Severe

2.	What was the severity of this symptom at its WORST? O None O Mild O Moderate O Severe O Very Severe

Appendix 2: Post-operative survey

Date ___/___/_____ Surgeon _____ Participant ID _____

Post-operative Survey

Thank you for participating in a survey being conducted by Dr. Magdy Milad on the tolerance of chlorhexidine gluconate or povidone iodine vaginal cleansing solutions. Below are questions asking about any vaginal symptoms.

Please think back from immediately after your surgery to now….

1. VAGINAL DRYNESS				
What was the SEVERITY of your VAGINAL DRYNESS at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

2. VAGINAL BURNING				
What was the SEVERITY of your VAGINAL BURNING at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

3. VAGINAL ITCHINESS				
What was the SEVERITY of your VAGINAL ITCHINESS at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

4. UNUSUAL VAGINAL DISCHARGE				
Did you have any UNUSUAL VAGINAL DISCHARGE?				
O Not at all	O A little bit	O Somewhat	O Quite a bit	O Very much

5. PAIN OR BURNING WITH URINATION				
What was the SEVERITY of your PAIN OR BURNING WITH URINATION at its WORST?				
O None	O Mild	O Moderate	O Severe	O Very severe

6. OTHER SYMPTOMS	
Do you have any other symptoms that you wish to report?	
O Yes	O No
Please list any other symptoms:	
1.	What was the severity of this symptom at its WORST? O None O Mild O Moderate O Severe O Very Severe

2.	What was the severity of this symptom at its WORST? O None O Mild O Moderate O Severe O Very Severe

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