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Major Article

Safety and tolerability of chlorhexidine gluconate (2%) as a vaginal operative preparation in patients undergoing gynecologic surgery

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Background: The use of chlorhexidine gluconate (CHG) as an intraoperative vaginal preparation has been shown to be more effective than vaginal povidone-iodine (PI) in decreasing vaginal bacterial colony counts. However, PI remains the standard vaginal preparation because of concerns of CHG's potential for vaginal irritation. The primary outcome of this study is a comparison of the rate of patient-reported vaginal irritation between 2% CHG and PI.

Methods: Consecutive patients were enrolled in a pre-post study. Group 1 consisted of consecutive patients who received PI as a vaginal preparation. Group 2 consisted of consecutive patients who received 2% CHG as a vaginal preparation. Patients used a standardized instrument to report irritation to trained nurse practitioners 1 day after surgery.

Results: A total of 117 patients received vaginal operative preparation during the course of the study, with 64 patients in group 1 and 53 patients in group 2. Of the patients in group 1, 60 (93.7%) reported no vaginal irritation, 3 (4.69%) reported mild irritation, and 1 (1.56%) reported moderate irritation. In group 2 (2% CHG vaginal preparation), all of the patients (100%) reported no vaginal irritation ($P = .38$).

Conclusions: The use of 2% CHG as a vaginal operative preparation is not associated with increased vaginal irritation compared with PI in gynecologic surgery. It can safely be used, taking advantage of its efficacy in reducing vaginal bacterial colony counts.

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Despite recent advances in antiseptic and surgical techniques, postoperative infections after abdominal surgery remain a major cause of morbidity and mortality.[1] Surgical site infections (SSIs), specifically pelvic cellulitis and abscesses, occur in 1%-3% of patients after hysterectomy.[2] Decreasing the vaginal bacterial burden prior to surgery has been shown to lower the risk of SSI.[3] Chemical vaginal cleansing (vaginal preparation) lowers the vaginal bacterial burden and is commonly done using povidone-iodine (PI).

Although PI has a long history of safe and effective use, allergy to PI may preclude its use, and alternatives are needed for additional safe and more effective agents. Two percent chlorhexidine gluconate (CHG) is a common substitute. CHG has several advantages; it is not inactivated by blood or serum products or vaginal pH and is not readily absorbed by mucous membranes.[4,5] However, hospitals and surgical centers may be reluctant to adopt CHG as a vaginal preparation because of labeling warnings against use in mucous membranes and the potential for postoperative patient discomfort secondary to vaginal and perineal irritation.

When used as a skin preparation, CHG has been shown to lower SSI rates.[6] However, limited data exist regarding the use of CHG as a vaginal preparation. Culligan et al showed greater reductions in vaginal bacterial colony counts after using 4% CHG when compared with 10% PI as a vaginal preparation.[4] Such a reduction in the vaginal bacterial colony count may potentially lower SSI rates.[5,6]

We undertook a quality improvement study to evaluate the tolerability of 2% CHG compared with PI as a vaginal and vulvar surgical preparation on postoperative patients' reported vaginal and vulvar irritation and discomfort. Our hypothesis was that there would be no difference in postoperative vaginal irritation when using 2% CHG compared with PI. The primary outcome of this study was to report the rate of postoperative vaginal and perineal irritation after using vaginal preparation with the newly adopted 2% CHG compared with the use of PI.

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METHODS

This was a pre-post study conducted in gynecology patients at our 592-bed tertiary care medical center. Institutional review board approval at the University of Wisconsin was obtained for this study. We adopted 2% CHG as vaginal preparation for surgery in the operating room.

At the end of each surgery, the vagina was rinsed with sterile water per the manufacturer's instructions. To ensure patients' safety, we monitored the rate of postoperative vaginal and perineal irritation as reported by patients after adopting the aforementioned practice change. This study was conducted over a period of 3 months. Postoperative irritation was monitored in each patient by applying a numerical visual analog scale of vaginal irritation as reported by the patients on the first day after surgery. This numerical visual analog scale was administered by trained nurse practitioners.

Group 1 consisted of all consecutive patients undergoing gynecologic procedures from July 1, 2012-September 30, 2012. These patients had vaginal preparation by a 7.5% povidone-iodine surgical scrub (Allegiance Healthcare, McGaw Park, IL). Group 2 included all consecutive patients undergoing gynecologic procedures from October 1, 2012-December 31, 2012. Patients in group 2 had a vaginal preparation of 2% chlorhexidine gluconate scrub solution (CareFusion).

Inclusion criteria were all consecutive patients who had gynecologic surgery during the aforementioned time frames. Patients could choose not to respond to the questions about vaginal irritation.

Patients' data included the following: patient demographics (age and body mass index), preexisting vulvar disease, patient medical (preexisting vulvar disease) and surgical history (previous vulvar surgery), surgical data, and pathology outcome.

The primary outcome was vaginal irritation as reported by the patients on the day after surgery. The patients were blinded to the intervention, which occurred in the operating room.

Secondary outcomes included, allergic reaction, postoperative fever (defined as >100.5°F twice over 6 hours apart up to the date of discharge), and SSI defined according to the Centers for Disease Control and Prevention criteria.[7]

Statistical analysis was performed using the Fisher exact test. The *P* values <.05 were considered statistically significant.

Table 1
Patient characteristics

Characteristic	Group 1: PI (n = 64)	Group 2: CHG (n = 53)	*P* value
Age, mean (y)	53	56	.48
BMI, mean (kg/m^2)	38	36	.53
Pathology			
Benign	14	12	.37
Malignant	50	41	.32
Surgery			
Hysterectomy (laparoscopic/abdominal)	47	42	.61
Hysterectomy (vaginal)	6	5	.51
No hysterectomy (laparoscopic BSO/USO/others)	9	6	.79
Preexisting choric vulvar disease	3	2	.43

NOTE. Values are the number of patients or as otherwise indicated.
BMI, body mass index; *BSO*, bilateral salpingo-oophorectomy; *CHG*, chlorhexidine gluconate; *PI*, povidone-iodine; *USO*, unilateral salpingo-oophorectomy.

Table 2
Reports of vaginal irritation

	Patient reports on postoperative day 1	
Vaginal irritation score	Group 1: Povidone-iodine vaginal preparation (n = 64)	Group 2: 2% CHG vaginal preparation (n = 53)
0 = No vaginal itching or burning	60 (93.75%)	53 (100%)
1 = Mild vaginal itching or burning	3 (4.69%)	0 (0%)
2 = Mild to moderate vaginal itching or burning	0 (0%)	0 (0%)
3 = Moderate vaginal itching or burning	1 (1.56%)	0 (0%)
4 = Moderate to severe vaginal itching or burning	0 (0%)	0 (0%)
5 = Severe vaginal itching or burning	0 (0%)	0 (0%)

NOTE. Values are n (%).
CHG, chlorhexidine gluconate.

RESULTS

A total of 121 patients received vaginal operative preparation during the course of the study. Four patients were excluded because of a lack of data on outcomes, leaving 117 patients in both arms. There were 64 patients in group 1 (PI vaginal preparation) and 53 patients in group 2 (2% CHG vaginal preparation). Table 1 shows the patients' characteristics. Groups 1 and 2 had a mean age of 53 and 56 years and a body mass index of 38 and 36 kg/m^2, respectively. Preexisting chronic vulvar disease was observed in 3 patients (4.6%) and 2 patients (3.7%) in groups 1 and 2, respectively ($P = .43$). There was no previous vulvar surgery in either group.

The primary outcome, vaginal irritation, is reported in Table 2. We dichotomized the scale into 2 categories: no irritation (0 on the scale) versus any other rating. In group 1, 60 patients (93.7%) reported no vaginal irritation compared with all 53 patients (100%) in group 2 (2% CHG vaginal preparation; $P = .12$). Four patients in group 1 reported some irritation: 3 (4.69%) reported mild irritation and 1 (1.56%) reported moderate irritation.

There were no differences in the secondary outcomes, including postoperative fever, allergic reaction, and SSI, in either group. Postoperative fever was reported in both groups to be 3 patients (4.6%) in group 1 and 3 patients (5.6%) in group 2. Postoperative SSI was observed in 2 patients (3%) in group 1 and 1 patient (1.8%) in group 2. The difference was not statistically significant between the 2 groups. No allergic reactions were observed in either group.

DISCUSSION

We found that using 2% CHG as a vaginal operative preparation was not associated with vaginal irritation when compared with PI in our patient population. Furthermore, no allergic reactions or vaginal desquamation were reported.

Our findings have relevance for surgeons and infection control practitioners because of the desirable qualities of CHG that make it superior to PI as a surgical preparation. However, most of the existing data comparing CHG with PI in surgery stems from use as a skin preparation agent,[6,8] not from use as a vaginal preparation agent. Intermediate outcomes of interest include vaginal bacterial counts, which have been found to be lower with CHG than PI.[9]

Although concerns about vaginal irritation from CHG historically prohibited its routine use as a vaginal preparation, recent research has helped to allay these concerns. Culligan et al found use of CHG as a vaginal preparation solution might not be associated with an increased risk of vaginal irritation; however, the latter was not the primary outcome of the study.[4] From the obstetric literature, using CHG as a vaginal preparation has demonstrated that a single application of 4% CHG is well tolerated without increased rates of vaginal irritation.[8-10] Only one case study reported vaginal desquamation after use of 4% vaginal CHG,[11] and although significant, this is likely a rare event. Additionally, a recent committee opinion

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of the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice stated that CHG solutions with low concentrations of alcohol are safe and effective for use as vaginal operative preparations and may be used as an alternative to iodine-based preparation.[12] CHG is distinct from and unrelated to 3% hexachlorophene, which has been associated with neurologic toxicity when used in mucous membranes and has been removed from the market.

Taking into consideration that CHG lowers bacteria load, theoretically decreases SSI rates, and is now an acceptable alternative surgical preparation as stated by the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice, we adopted the routine use of CHG as a surgical vaginal preparation. After this change in protocol, our study showed that adopting the routine use of CHG as a vaginal preparation does not increase the rate of vaginal irritation compared with PI.

Our study has several strengths. Patients reported vaginal irritation through the questionnaires immediately after surgery, eliminating recall bias. The patients in both arms were consecutive, reducing selection bias.

Our study has limitations. First, this was a single-center study; therefore, the results may not be generalizable. Second, irritation to CHG was assessed at only 1 time point. However, irritation reactions are expected to occur right after application; therefore, we do not expect that additional irritation reactions were missed. Third, our study was not powered to examine vaginal bacterial colonization or SSI. Fourth, differences in patient populations in the pre- and postintervention period may explain differences in irritation rates. However, patient populations were very similar in both periods. Finally, this study was not a randomized controlled trial.

In conclusion, 2% CHG can safely be used as a surgical vaginal preparation when compared with PI. Future randomized controlled trials of vaginal CHG preparation should be undertaken to examine its impact on SSI in patients undergoing hysterectomy.

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