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Solutions for Surgical Preparation of the Vagina

ABSTRACT: Currently, only povidone-iodine preparations are approved for vaginal surgical-site antisepsis. However, there are compelling reasons to consider chlorhexidine gluconate solutions for off-label use in surgical preparation of the vagina, especially in women with allergies to iodine. Although chlorhexidine gluconate solutions with high concentrations of alcohol are contraindicated for surgical preparation of the vagina, solutions with low concentrations of alcohol (eg, 4%) are both safe and effective for off-label use as vaginal surgical preparations and may be used as an alternative to iodine-based preparations in cases of allergy or when preferred by the surgeon.

Surgical-site antisepsis is an important step in preventing surgical-site infections, which occur in 300,000–500,000 patients who undergo surgery in the United States each year (1). Iodine-based preparations and alcohol skin preparations were approved decades ago by the U.S. Food and Drug Administration, but newer agents are gaining popularity. Chlorhexidine products have considerable advantages over other preparations by reducing a greater number of microflora and achieving longer residual activity. Solutions with high concentrations of alcohol are contraindicated for surgical preparation of the vagina. Currently, only povidone-iodine (PVP-I) preparations are approved for use in the vagina. There are compelling reasons to consider chlorhexidine gluconate solutions for off-label use in surgical preparation of the vagina, especially in women with allergies to iodine. The purpose of this Committee Opinion is to review what is known about the use of these preparations in vaginal surgery to guide their use by obstetrician–gynecologists.

Povidone-Iodine

Povidone-iodine is the most commonly used antiseptic for surgical preparation of the vagina in the United States. However, this is not the case in other countries. Of 43 hospitals that participated in the Swedish National Register for Gynecologic Surgery between 2000 and 2008, none used PVP-I to prepare the vagina, and chlorhexidine gluconate was preferred (2). Iodine is a recognized antibacterial agent, but local skin irritation and skin staining limited its use, which was overcome by the introduction of a stabilizing moiety, povidone. Povidone, which is water soluble, does not require a dissolvent such as alcohol and, thus, is less irritating to skin and mucosal surfaces. Unlike other surgical antiseptics, PVP-I is nonsensitizing and does not cause irritation or pain when applied to skin and mucous membranes (3); nonetheless, some patients may still develop sensitivity.

Povidone-iodine is not the ideal solution for surgical preparation of the vagina. Safety concerns include incorporation of iodine in body cavities unprotected by a keratinized epithelium, such as the vagina. A 2-minute vaginal preparation with 10% PVP-I can result in absorption of iodine (4). Because of the risk of iodine absorption, PVP-I solutions should not be used in patients with severe iodine allergy. In normal vaginal pH (3.8–4.5), iodine's disinfecting properties are somewhat diminished. In addition, iodophors are inactivated in the presence of blood (5).

Chlorhexidine Gluconate

Chlorhexidine gluconate acts by causing destruction of bacterial cell membranes, leading to the leakage of cellular components and a decrease in bacterial counts (6). Some studies show greater reduction in skin flora after application of chlorhexidine (0.5% and 4%) compared with iodine agents (5). Also, chlorhexidine gluconate may have a greater residual activity after application than other preparations and, unlike iodine, is not inactivated in the presence of blood (5, 7).

Chlorhexidine gluconate is available in several concentrations and is often combined with 70% isopropyl alcohol for skin preparation. Chlorhexidine gluconate with alcohol has greater and more persistent antimicrobial activity than an alcohol-free solution (8). In a retrospective study of women undergoing laparotomy for gynecologic surgery, skin preparation with 2% chlorhexidine gluconate followed by 70% isopropyl alcohol resulted in a significant decrease in surgical-site infection compared with the use of 10% PVP-I scrub followed by 10% PVP-I paint with 65% alcohol (9).

In a multicenter randomized trial of 849 patients undergoing clean-contaminated surgery, the chlorhexidine gluconate–alcohol skin preparation (2% chlorhexidine gluconate and 70% isopropyl alcohol) was twice as effective at preventing superficial incisional infections and three times as effective at preventing deep wound infections when compared with standard 10% PVP-I preparation (1). Approximately 10% of the participants in this study underwent "non-abdominal gynecologic surgery"; however, the protocol for surgical preparation of the vagina was not specified. There were no serious adverse events associated with the use of either type of antiseptic. The decrease in infectious morbidity was attributed to the rapid onset and persistent antimicrobial activity of chlorhexidine gluconate compared with PVP-I.

The U.S. product labeling of chlorhexidine gluconate specifies to avoid genital use; however, solutions with low concentrations of alcohol may be used off-label in the vagina as an antiseptic for both obstetric and gynecologic procedures.

In the United States, 4% chlorhexidine gluconate soap (containing 4% isopropyl alcohol) is often used off-label to prepare the vagina in cases of iodine allergy, and some U.S. institutions prefer it for routine cases. To avoid irritation, chlorhexidine gluconate with high concentrations of alcohol (eg, 70% isopropyl alcohol, commonly used for skin preparation) should not be used in the vagina. Solutions that contain lower concentrations, such as the commonly used 4% chlorhexidine gluconate soap containing 4% alcohol, are usually well tolerated and may be used for vaginal preparation.

Only one randomized trial compared the efficacy of 4% chlorhexidine gluconate with 4% isopropyl alcohol to a 10% PVP-I solution for vaginal preparation (10). Fifty women who underwent vaginal hysterectomy were randomized to a preoperative vaginal scrub with one solution, and serial vaginal culture specimens were obtained to assess bacterial contamination throughout surgery. No cases of vaginal irritation occurred. Thirty minutes after the vaginal preparation, those in the iodine group were more than six times more likely to have contaminated cultures compared with the chlorhexidine gluconate group. Because no participant in either group developed a postoperative infection or complication, the clinical significance of this finding remains unclear.

Benefits and Risks Associated With the Use of Vaginal Preparation Solutions

Potential problems with vulvar and vaginal application of antiseptic preparations include irritation and safety concerns. Alcohol-based preparation solutions are flammable and carry the risk of electrosurgical burns unless the prepared area is allowed to dry completely, which is difficult to ensure because of vaginal pooling. All surgical preparation solutions have the propensity to irritate local tissues and may cause irritant dermatitis, allergic dermatitis, and delayed or immediate hypersensitivity reactions. The vaginal epithelium does not contain mucous glands and, thus, is not a classic mucous membrane. However, like the oral mucosa, the vaginal epithelium lacks keratin and, thus, is more susceptible to irritation from an antiseptic than other cutaneous surfaces prepared before surgery (11). Of note, the oral mucosa tolerates 0.12% chlorhexidine gluconate found in prescription mouth rinses.

Manufacturers of chlorhexidine gluconate products warn that they may cause irritation, sensitization, and allergic reactions when used in the genital area; U.S. product labeling specifies that these products should not be used in this area. Although chlorhexidine gluconate has been safely used for the past 40 years on skin and mucous membranes, there are case reports of serious adverse events including, anaphylaxis and epithelial desquamation associated with vaginal use of chlorhexidine gluconate (12, 13). Most case reports, however, have not investigated the potential of possible allergic reactions to other substances within the skin preparation solution. Data from the obstetric literature suggest that the risk of irritation may be related to concentration of the antiseptic. In a trial that used repeated vaginal washes of various concentrations of chlorhexidine gluconate in women in labor, 1% chlorhexidine gluconate was much better tolerated than the 2% solution (14). More than twice as many women in the higher strength group reported vaginal burning or requested cessation compared with the lower strength group (14). However, other studies of women who were not pregnant note that a single application of 4% chlorhexidine gluconate is well tolerated (10, 15).

Conclusions and Recommendations for Use

Although chlorhexidine gluconate more effectively decreases the bacterial colony counts on the vaginal operative field than PVP-I, there is still reluctance to use it for a surgical preparation of the vagina based on the product labeling. Despite manufacturer warnings, many hospitals and surgeons have found the use of 4% chlorhexidine gluconate with 4% isopropyl alcohol to be acceptable on the vaginal surface in patients with or without an iodine allergy. As with iodine-based preparations, serious topical reactions and anaphylaxis occur

rarely. Because of increased risk of irritation, as well as electrosurgical burns, the formulations of chlorhexidine gluconate with 70% isopropyl alcohol preferred for surgical skin-site antisepsis should not be used for surgical preparation of the vagina. Solutions of chlorhexidine gluconate with low concentrations of alcohol (eg, 4%) are both safe and effective for off-label use as vaginal surgical preparations and may be used as an alternative to iodine-based preparations in cases of allergy or when preferred by the surgeon. It is the opinion of the American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice that additional randomized studies are needed to determine whether chlorhexidine gluconate with 4% alcohol is more effective at preventing surgical-site infection than PVP-I for standard surgical preparation of the vagina.

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