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Hysterectomy Surgical Site Infection Rates After Conversion to Chlorhexidine Gluconate for Vaginal Antisepsis: A Prospective, Multi-site NSQIP Study

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ABSTRACT

Background: *Contamination of the surgical site by vaginal flora may lead to surgical site infection (SSI) after hysterectomy. While vaginal preparation to reduce this risk is standard, there is conflicting evidence regarding the appropriate choice of preparation.*

Objective: *The aim of this study was to assess whether a large-scale transition of vaginal antisepsis prior to hysterectomy from povidone iodine (PI) to 4% aqueous chlorhexidine gluconate (CHG) across multiple sites would improve SSI rates.*

Methods: *This was a prospective, multi-center, observational quality improvement (QI) study performed at six sites. Each site collected risk-adjusted SSI rates based on NSQIP smoothed rates models for one year prior and two years following large-scale transition to CHG for vaginal antisepsis.*

Results: *The average pre-intervention SSI rate was 4.09%, and post-intervention rate was 3.88% with individual sites reporting rates ranging from 2.19% to 5.13%. Four out of six participating sites demonstrated trends of lower SSI rates.*

Conclusion: *CHG may contribute to reductions in the incidence of surgical site infections, and vaginal antisepsis with CHG should be considered within an institution's efforts to reduce surgical site infections after hysterectomy.*

Keywords
Gynecology, Infection, Surgery.

Background
Surgical site infections are a well-known cause of patient morbidity and increased healthcare costs. Despite being identified as a patient safety priority by both the Centers for Medicaid and Medicare Services and the Joint Commission on the Accreditation of Healthcare Organizations, many hospitals continue to struggle with higher than average SSI rates after hysterectomy. While there are many risk factors for infection, one well known risk factor in gynecologic surgery is contamination of the surgical site by vaginal flora. At this time, there remains a lack of consensus on a preferred specific vaginal antisepsis agent. While PI has been traditionally used for vaginal antisepsis, there is moderate evidence to suggest that CHG, which is being increasingly used off-label, may be superior [1-4]. Two studies have demonstrated significant reductions in overall SSI rate of 20% to 3% in one study [2] and 12.1% to 5.4% in the other [3] with the implementation of preventative SSI bundles, which included the conversion from PI to CHG for vaginal preparation. However, the majority of literature comparing infection rates between CHG and PI focuses on different outcomes and settings, such as wound infection rates in cesarean delivery or urinary tract infection rates in urogynecologic surgeries [4,5]. To our knowledge, there is no literature evaluating SSI rates following an isolated change from PI to CHG for vaginal preparation prior to hysterectomy. As such, the aim of this study was to assess whether a large-scale transition to CHG across

multiple sites would improve SSI rates.

Methods

This was a prospective, multi-center observational QI study performed at six sites. The sites were recruited from the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) Gynecologic Surgery Collaborative, which includes 24 hospitals ranging from small community hospitals to large academic centers across North America. A total of six sites, which had previously been using PI for vaginal antisepsis, agreed to participate in the large-scale transition to 4% CHG. As a quality improvement study to improve patient care, review by the IRB was not required.

Each site independently secured supplies and coordinated the transition from PI to CHG with specific date of implementation varying between April to December of 2021. The first step in the process of converting from PI to CHG involved getting all the surgeons (and trainees, if applicable) on board and working with perioperative leadership for approval. A letter detailing current guidelines and the evidence-based rationale behind the decision to change from CHG to PI for vaginal preparation was distributed. Once agreement had been reached, operating room (OR) leadership worked to update the sterile vaginal preparation kits in each OR. Once supplies were obtained and a method to replace PI with CHG was established, the next step in the implementation process was the educational component. Residents and/or OR staff were re-trained on proper technique for vaginal preparation. CHG was used for vaginal antisepsis for all routes of hysterectomies performed for any indication by any specialty or subspecialty with the exception of patients with documented CHG allergies.

Each site collected risk-adjusted SSI rates based on NSQIP smoothed rates models, which use years of historic data to adjust for each site's varying patient populations, characteristics, and risk factors. The risk adjustment method utilizes logistic regression for estimation of risk-adjusted observed-to-expected ratios which are adjusted to reference population rates [5]. Each site was also required to report any additional site-wide interventions implemented during the intervention period. Data was collected from one year prior to intervention to approximately two years after intervention when data was submitted for review. Sites have been kept anonymous in the collective review process.

Results

The six sites that participated in this quality improvement project represent a diverse mix of rural and urban as well as academic and community sites across the United States and Canada. The average pre-intervention SSI rate was 4.09% with individual sites reporting rates ranging from 2.72% to 6.23%. The average post-intervention SSI rate was 3.88% with individual sites reporting rates ranging from 2.19% to 5.13% (Figure 1). Four out of the six sites demonstrated a decrease in SSI rate following conversion from PI to CHG. The highest reduction in SSI rate was 1.1%, a decrease from 6.23% pre-intervention to 5.13% post-intervention. The average reduction in SSI rate was 0.21%.

Conclusion and Discussion

Much of the literature comparing SSI rates with PI and CHG vaginal antisepsis involves single institution studies and lacks generalizability. Thus, the purpose of this study was to evaluate whether a large-scale conversion from PI to CHG would decrease SSI rates across multiple sites. The findings demonstrated reductions in SSI rates at four of the six participating sites, with these reductions being noted specifically at the four academic sites included.

At this time, PI is the only vaginal antisepsis approved by the U.S. Food and Drug Administration (FDA). The regulation of antiseptics by the FDA began in the late 1970s.

At that time, CHG was not included due to the lack of data; this has not been re-reviewed in the near 50 years since then. Although manufacturer warning labels for CHG state it should not be used in the genital area, there is no documentation explaining why that warning exists. The FDA currently requires companies whose

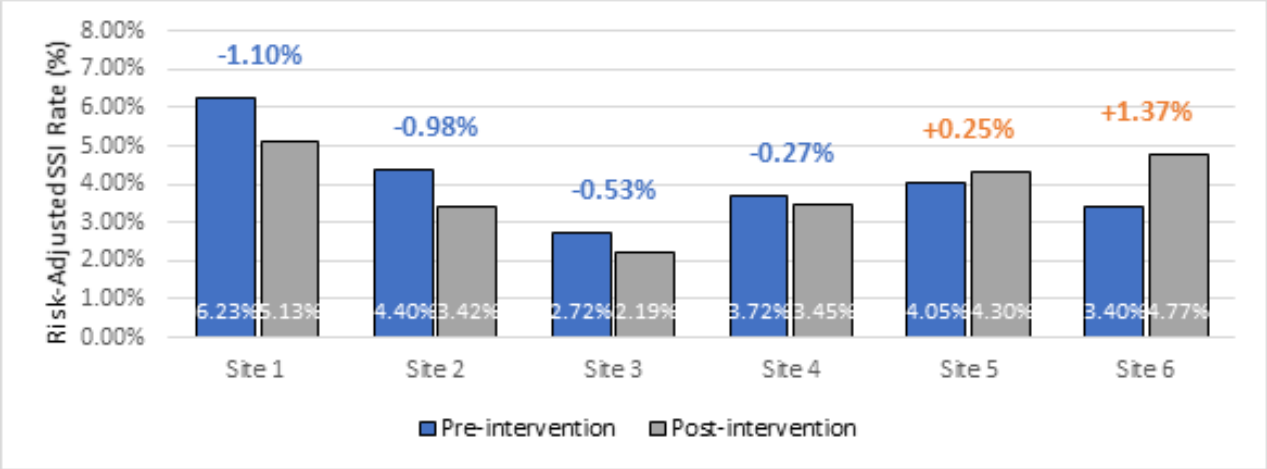

Figure 1: Risk-Adjusted SSI rates Pre- and Post-Intervention. Sites have been kept anonymous but are organized here by hospital type. Sites 1-4 represent academic hospital centers, while sites 5 and 6 represent community hospitals.

products were not included in the initial approval process in the 1970s to apply for approval through a more rigorous process. Although CHG has since been approved for skin preparation, due to the lack of FDA-established vaginal tissue testing criteria and the additional expense, CHG manufacturers have not pursued any changes in labeling [2].

The American College of Obstetricians and Gynecologists (ACOG) notes that despite the lack of FDA approval, 4% CHG is often used off-label in cases of iodine allergy and is used preferentially at many institutions in the U.S. While CHG with high concentrations of alcohol (70% isopropyl alcohol, often used in preparations intended for skin antisepsis) is contraindicated due to concerns regarding vaginal irritation, solutions with lower concentrations of 4% are well tolerated and may be used in cases of allergy or when preferred by the surgeon [1].

Despite the lack of clarity in these guidelines, there is moderate evidence to suggest that CHG may be superior to PI for vaginal antisepsis. Unlike PI, CHG is not inactivated by blood, which inevitably contacts the vagina during a routine hysterectomy [10]. Similar to studies regarding skin antisepsis, CHG has been shown in multiple RCTs to be more effective than PI at decreasing bacterial colony counts in vaginal cultures [13,14]. Additionally, multiple studies involving the use of 2% or 4% CHG vaginal preparation reported either no adverse events or no difference in vaginal irritation when compared to PI [4,13-15]. A RCT of 117 patients who received vaginal preparation prior to gynecologic surgery assessed the number of patients who reported any amount of vaginal irritation postoperatively and found that CHG was not associated with more vaginal irritation than PI [3]. While literature evaluating infection rates remains mixed demonstrating either an improvement or no change with a conversion from PI to CHG, we feel comfortable with continuing to use CHG for vaginal preparation and will continue to closely monitor patient outcomes.

Due to the nature of an anonymous QI study, individual patient data was not collected and did not allow for detailed statistical analysis. However, one strength of this study is that the NSQIP reported rates are already risk-adjusted for patient-level confounders such as medical comorbidities. Although we cannot tease out the details of which co-morbidities have the most impact, they are ultimately accounted for. Thus, the results of this study are limited to data trends only.

Another common challenge in SSI research involves isolating specific interventions that impact infection rates. Interventions to reduce SSI rates are often introduced as part of larger bundles to more efficiently improve outcomes. In this study, five out of the six sites performed an isolated conversion from PI to CHG. Site two, which demonstrated a reduction in SSI rate, also included the addition of routine metronidazole prophylaxis for all hysterectomies. Other trials involving isolated conversion from PI to CHG have demonstrated varying results. One of the larger retrospective trials involving 2935 propensity score matched pairs demonstrated no statistically significant difference in SSI, readmission, or reoperation rates but did show an increased risk of UTI infection and ED visits [7]. Two studies demonstrating large reductions in SSI rates, from 20% to 3% and 12% to 5% respectively, implemented bundles which in addition to a switch to CHG for vaginal antisepsis also included preoperative CHG skin preparation, warming devices, improved glycemic control, restricted operating room traffic, separate closing trays, and cefazolin and metronidazole for prophylaxis with appropriate redosing as indicated intraoperatively [9,10]. CHG for vaginal antisepsis can be an impactful addition to any QI bundle aimed at reducing SSI rates after hysterectomy.

Upon review of the data and current literature by each site's quality improvement and infection control committees, all six sites participating in this study have independently elected to continue with CHG for vaginal antisepsis at this time and will work to address other known risk factors for SSI to better improve patient outcomes.

Conclusion

Our data suggests a widespread conversion from PI to CHG for vaginal antisepsis prior to hysterectomy can lead to reductions in SSI rates. While further studies are indicated to assess more granular patient level data, this multi-center study demonstrates a promising trend to help improve patient outcomes after hysterectomy.

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