# Pre-Post Pilot Study: Investigating the Role of Rectovaginal Contamination in Laparoscopic Hysterectomy-Related Infectious Morbidity

Tarek KHALIFE[1], Jason J DEWITT[1], and Amy L. Brien[1]

[1]Mayo Clinic Health System in Mankato

June 5, 2023

**Title: Pre-Post Pilot Study: Investigating the Role of Rectovaginal Contamination in Laparoscopic Hysterectomy-Related Infectious Morbidity**

**Tarek KHALIFE, MD**

Mayo Clinic Health System MANKATO, MINNESOTA, United States

**Jason J DEWITT, MD**

Mayo Clinic Health System MANKATO, MINNESOTA, United States

**Amy L. Brien, MD**

Mayo Clinic Health System MANKATO, MINNESOTA, United States

This study was conducted after obtaining Institutional Review Board approval.

**Financial disclosure** : The authors report no conflict of interest.

**Funding** : The study was funded by the Mayo Clinic OBGYN Quality Committee grant for department quality improvement projects. Awarding body had no role in the study design, collection and analysis of data, interpretation or writing of the report.

**Corresponding author:** Tarek Khalife, MD; email: khalife.tarek@mayo.edu; 1025 Marsh Street, Mankato, MN 56001. Cell phone: 313-680-4224

**Word count:** 497

**Keywords:** Hysterectomy, Infection, Uterine Manipulator, Rectovaginal, contamination.

**Objective:** About 538,793 hysterectomies are performed annually in the US alone and 62% of those are done laparoscopically.[1] Surgical site infection (SSI) following a hysterectomy is a recognized complication and rates range from 1.8-3.9% with a lower rate being associated with minimally invasive surgery (MIS) routes. [2] Surgical site infection is associated with significant morbidity, mortality, and high healthcare expenditure. Thereby, its closely scrutinized by the Centers for Disease Control and the National Surgical Quality Improvement Program (NSQIP).[3] Research endeavors with a focus on the reduction of surgical infectious morbidity resulted in several bundles and care pathways that are aimed to minimize that risk.

Laparoscopic benign hysterectomy surgeons commonly use a uterine manipulator to reduce the risk of genitourinary tract injuries and improve visualization during the procedure, especially in patients with complex pathology. Nonetheless, the utilization of the tool is not without risks.[4]

Due to the proximity of the uterine manipulator handle and shaft from the anal orifice during the manipulation maneuvers, contact contamination of the tool by coliform bacteria from the anus is highly likely. A recent study reported that 60.7% of bacteria causing intra-abdominal infections are from intestinal or vaginal bacteria which highlights the rectovaginal contamination hypothesis as a risk factor.[5]

In this pilot study our aim was to evaluate the effect of applying an anal occlusive drape (AOD) prior to the laparoscopic hysterectomy prep to decrease the risk of potential rectovaginal contamination and resultant risk of infectious morbidity after laparoscopic hysterectomy.

**Study Design:** A quality improvement study using a pre-post-intervention study design was conducted at a community health system in Minnesota. The study was reviewed and approved by the Institutional Review Board. Figure 1 demonstrates the AOD components and application instructions. Baseline SSI rates were calculated from January 1$^{st}$, 2020, till December 31$^{st}$,2021 through chart review and the National Surgical Quality Improvement Program data registry for 178 patients. All total laparoscopic or robotic hysterectomy patients done between March 1$^{st}$, 2022, and March 1st, 2023, were included and followed for the 30-day surveillance period (post-intervention group). The primary outcome measure was the reduction of the risk of SSI by 20%. A similar reduction in urinary tract infections (UTI) and use of antibiotics in the 30-day postoperative period would be expected.

**Results:** Eighty-one patients were included in the study period. SSI rates dropped from 3.4% to 1.2% (63%) (Fischer exact test P= 0.4397). Similar decreases in UTI rates from 4.5 to 2.5% (45%) and the use of post-operative antibiotics prescribing from 17.4% to 6.2% were noted. No perianal skin irritation or allergic reaction was reported. The preparation process did not increase the average In-Room to Incision time of 35 min.

**Conclusion** : Rectovaginal contamination may be a factor in the pathogenesis of hysterectomy-related infectious morbidity. Applying an Anal Occlusive Drape may help reduce this risk. The study is underpowered to detect statistical significance and plans for accumulating additional patients are underway Future research efforts will focus on the widespread implementation of the AOD prep across the health system sites to confirm validity and generalizability.

**References:**

1- Wright JD, Huang Y, Li AH, Melamed A, Hershman DL. Nationwide Estimates of Annual Inpatient and Outpatient Hysterectomies Performed in the United States. Obstet Gynecol. 2022 2- Gandaglia G, Ghani KR, Sood A, Meyers JR, Sammon JD, Schmid M, Varda B, Briganti A, Montorsi F, Sun M, Menon M, Kibel AS, Trinh QD. Effect of minimally invasive surgery on the risk for surgical site infections: results from the National Surgical Quality Improvement Program (NSQIP) Database. JAMA Surg. 2014 Oct;149(10):1039-44. doi: 10.1001/jamasurg.2014.292. PMID: 25143176.

3-Daneman N, Lu H, Redelmeier DA. Discharge after discharge: predicting surgical site infections after patients leave hospital. *J Hosp Infect* . 2010;75(3):188-194

4-Abdel Khalek Y, Bitar R, Christoforou C, Garzon S, Tropea A, Biondi A, Sleiman Z. Uterine manipulator in total laparoscopic hysterectomy: safety and usefulness. Updates Surg. 2020 Dec;72(4):1247-1254. doi: 10.1007/s13304-019-00681-w. Epub 2019 Oct 12. PMID: 31606857.

5- Cowley ES, Jacques L, Powell AM, Al-Niaimi A, Pop-Vicas A. Characterization of bacterial composition of surgical site infections after gynecologic surgery. Am J Obstet Gynecol. 2022 Aug;227(2):345-347. doi: 10.1016/j.ajog.2022.02.033. Epub 2022 Mar 3. PMID: 35248576; PMCID: PMC9308663.

**Figure 1** – Anal Occlusive Drape applied to a patient.

*Legend:* The perianal area is prepared with chlorhexidine swabs prior to securing a gauze over the anus with a Band-Aid to protect the anal mucosa from the adhesive. Duraprep Surgical prepping solution (3M St Paul, Minnesota, USA) is applied to the perineum and perianal skin to enhance the adhesive properties

of the Ioban 2 drape (3M Antimicrobial Incise Drape, St Paul, Minnesota, USA) that is applied at the end as shown in the picture. Avoid applying to the pink vaginal or vulvar skin.

Picture Courtesy of Mayo Clinic- Taken by Khalife, T after obtaining patient consent.