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Gynecologic Laparoscopy: Are Prophylactic Antibiotics Essential? A Randomized Controlled Study

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ABSTRACT

Background & Objective: Establishing a consensus on the appropriate use of prophylactic antibiotics in elective laparoscopic procedures for benign gynecological conditions would be beneficial. The necessity of preventive antibiotics during laparoscopy for uncomplicated gynecologic conditions is currently being debated. This study aims to ascertain the need for prophylactic antibiotics in preventing early post-surgery infections and febrile morbidity in elective laparoscopic surgery for benign gynecologic conditions.

Materials & Methods: One hundred women who underwent uncomplicated laparoscopic surgeries were studied for four years. Participants were randomly divided into two groups, and demographic data and postoperative outcomes were analyzed. Infections at the surgical site, fever, urinary tract infections, and respiratory infections were the outcomes studied.

Results: The studied variables and the post-operative outcomes assessed did not vary between the two groups.

Conclusion: Routine use of antibiotics in laparoscopic gynecologic surgery may not be necessary, as postoperative infection rates remain low even in cases where antibiotics are not administered.

Keywords: Antibiotic Prophylaxis, Laparoscopy, Gynecological Surgery, Febrile Morbidity, Urinary Tract Infections, Postoperative Outcomes

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Introduction

It is common practice to administer antibiotics before gynecologic procedures to prevent infections **(1)**. Laparoscopy is often preferred due to its faster recovery time and improved cosmetic results **(2)**. While postoperative infections are not very common (occurring in only 1-5% of cases), certain factors such as patient characteristics, surgical conditions, and bacterial contamination can increase the risk of postoperative infections **(3-6)**. The most prevalent types of postoperative infections are surgical site infections, urinary tract infections, and fever, which account for around 70% of cases **(7)**.

Routine use of antibiotic prophylaxis in gynecologic procedures has been a significant concern due to its potential adverse drug reactions and may also be a contributing factor to the development of antibiotic resistance **(8)**. Few studies have noted that the rates of febrile illness in gynecologic procedures are significantly lower compared to open surgical procedures, rendering antibiotic prophylaxis unnecessary **(9)**. In a review by the Cochrane group, it was noted that the infection rate was similar in laparoscopic and vaginal hysterectomies. **(10)**. Wright et al. reported that an alarming 40.2% of women undergoing gynecologic procedures were unnecessarily administered antibiotics during the surgery **(11)**. Similarly, a study conducted in Brazil has revealed that 94% of gynecologists practice administering antibiotic prophylaxis before gynecological laparoscopy, highlighting the need for awareness and adherence to evidence-based practices **(12)**.

Previous studies that showed similar infection rates-irrespective of the use and number of prophylactic antibiotics were from Western developed countries-whose vaginal infection rates differ from that of India

(13-17). We conducted a study to determine if administering antibiotics before a simple laparoscopic gynecological procedure is necessary to prevent infections and fever in the initial days following the procedure.

Methods

We conducted a prospective randomized controlled study involving 100 women diagnosed with a gynecologic condition requiring laparoscopic surgery. The study was approved by the institutional ethical committee (SDMIEC 077:2016). The study included patients who had uncomplicated laparoscopic procedures at a single gynecology unit from October 2018 to January 2023. To achieve randomization, subjects were given a computer-generated serial number based on their admission to the ward. Those with odd numbers were assigned to Group A, while those with even numbers were assigned to Group B by an individual who had no involvement in the study.

Subjects in Group A were given a prophylactic antibiotic regimen of one gram of intravenous ceftriaxone. Group B received no antibiotics. We only included those who had uncomplicated gynecologic laparoscopic procedures without opening hollow viscera. However, we excluded individuals with specific conditions, namely malignant gynecological conditions, benign gynecological conditions with active infection, smoking, diabetes with glycosylated hemoglobin exceeding 6.5%, surgical risk patients (as per classification by the American Society of Anesthesiologists (ASA) as ASA III or higher), and those who declined to participate.

All the laparoscopic surgeries were carried out in accordance with the institutional protocol. The abdomen was cleaned using a 10% povidone-iodine solution and chlorhexidine gluconate and cetrimide solution, standard precautions for infection control were followed, and the wound site was sutured with polyglactin no 1; a sterile dressing was applied and removed 24 hours later. The analyzed study outcomes included instances of fever and postoperative infections, including surgical site infections, urinary tract infections (UTIs), and pelvic inflammatory disease (PID). A temperature chart reading exceeding 99°F was considered as fever. Additionally, wound inspections were conducted during discharge from the ward and subsequent outpatient follow up after 14 days. The diagnosis of UTI was made based on symptoms including pain abdomen, loin pain, burning micturition, urgency, febrile illness, and supported by a positive urine culture report. Confirmation of PID was made when symptoms of foul-smelling vaginal discharge, fever with clinical evidence of cervical motion and forniceal tenderness, supported by lab markers like leukocytosis and high C- reactive protein (CRP).

Statistical analysis

IBM SPSS version 25 was used for analyzing the data. Variables such as age, parity, type of procedure, duration of surgery, and length of hospital stay were categorized and presented along with other categorical variables as proportions. We compared the groups using chi-square analysis and considered a p-value of < 0.05 as statistically significant.

Results

For the study, we recruited 100 patients who were admitted to the hospital for uncomplicated laparoscopic procedures. There were two groups, Group A and Group B, each consisting of 50 patients. Laparoscopic sterilization was the most common procedure done. There was no significant statistical difference between the two groups regarding the reasons for undergoing laparoscopic procedures. Most patients in groups A and B experienced an uncomplicated recovery after their surgery. An allergic reaction (urticaria) to ceftriaxone was noted in one patient. Although febrile episodes were observed in three patients from the study group and two patients from the control group on the second day after the operation, there was no statistically significant difference detected (Table 1, 2). Duration of surgery (p value 0.0039) and post-operative hospital stay (p value 0.003) was significantly less in Group B.

Table 1. Distribution of demographic and basic details in the two groups.

Variable	Overall n	Group A n (%)	Group B n (%)	P value
Age (in years)				
</= 20	2	1 (2)	1 (2)	0.209
21-30	56	30 (60)	26 (52)	
31-40	39	16 (32)	23 (46)	
>40	3	3 (6)	0 (0)	
Parity				
Unmarried	2	1 (2)	1 (2)	0.376

Variable	Overall n	Group A n (%)	Group B n (%)	P value
Nulligravida	3	3 (6)	0 (0)	
Nulliparous	8	4 (8)	4 (8)	
Multiparous	87	42 (84)	45 (90)	
Type of procedure				
Sterilization	65	27 (54)	38 (76)	
Sterilization +MTP	4	2 (4)	2 (4)	
Cystectomy	8	5 (10)	3 (6)	
Cystectomy + Bilateral Salpingectomy	7	6 (12)	1 (2)	0.157
Myomectomy	6	5 (10)	1 (2)	
DHL + Myomectomy	1	1 (2)	0 (0)	
Salpingectomy	8	4 (8)	4 (8)	
DHL	1	0 (0)	1 (2)	
Previous surgery				
Previous LSCS	72	38 (76)	34 (68)	
Previous 2 LSCS	27	11 (22)	16 (32)	0.342
Previous 3 LSCS	1	1 (2)	0 (0)	
Drug reaction	1	1 (2)	0 (0)	0.315
Duration of Surgery				
< 30 minutes	79	35 (70)	44 (88)	
30 minutes-60 minutes	17	11 (22)	6 (12)	**0.039***
>60 minutes	4	4 (8)	0 (0)	
Post-Operative Hospital Stay Duration				
1 day	70	28 (56)	42 (84)	
1–3 days	23	15 (30)	8 (16)	**0.003***
>3days	7	7 (14)	0 (0)	

*** Significant at p<.05**
MTP: Medical termination of pregnancy
DHL: Diagnostic hysterolaparoscopy
LSCS: Lower segment cesarean section

Table 2. Results- post-operative complications

Variable	Overall n	Group A n (%)	Group B n (%)	P value
SSI	0	0 (0)	0 (0)	-
Fever	5	3 (6)	2 (4)	0.646
UTI	1	1 (2)	0 (0)	0.315
Respiratory infection	0	0 (0)	0 (0)	-

SSI: Surgical site infection
UTI: Urinary tract infection

Discussion

Antibiotic prophylaxis for uncomplicated laparoscopic gynecologic surgery is a topic of debate due to the low infection rates. Not only the classical endocrine and metabolic responses are unaffected in minimally invasive surgical techniques, but also the inflammatory reactions and immune dysfunction are reduced in this approach **(18)**. Studies comparing laparotomy with the laparoscopic approach have shown lower febrile morbidity in laparoscopy **(19-21)**.

Of all the postoperative outcomes assessed, only fever and UTI were detected in our study, without a significant difference between the two groups. Febrile reaction occurred on postoperative day 2. UTI was noted in a patient who underwent myomectomy. The catheter was removed in this patient on day 3, as the patient had severe pain and was not ambulatory. This is in line with another study by Jayarathna et al., in which 7.3% were found to have a fever when 99°F was considered as the cut-off, whereas the number reduced to 2.7% on considering 100°F **(17)**. However, they could not detect a significant difference between the treatment and the control groups.

In contrast, Litta, Sacco **(13)** study found that only 2% of patients who had laparoscopy for benign gynecologic conditions experienced febrile morbidity. Interestingly, there was no difference in infection rate or febrile morbidity between those who received prophylactic antibiotics and those who did not **(13)**. As stated by Jayarathna et al., the relatively low cut-off temperature for fever of 99°F in our study, unlike 100°F in others, could have led to higher rates. During the postoperative period, fever can occur due to tissue trauma, infection at the surgery site, or hematoma. In our study, we treated fever using antipyretics (Paracetamol 500mg; oral tablet; used as necessary), alleviating the symptoms.

Our study found no surgical site infections, but one case of UTI was detected in Group A, in concurrence with the incidence rates as reported in other studies **(14)**. Recent research findings indicate that laparoscopic gynecologic surgeries exhibit a consistently low incidence of infection, irrespective of the dosage of antibiotics administered **(15)**. Results were similar even in studies with large sample sizes. In a study by Phillips, Hulka **(22)** it was just 0.27%, while SSI was observed only in one patient from the control group **(22)**. A study involving 631 women did not show any significant difference in post-procedural infection rates between the group that received prophylaxis and the group that did not receive prophylaxis **(23)**.

Laparoscopy is a surgical technique that is minimally invasive and has many benefits. It is preferred for its aesthetic appeal since it requires smaller incisions. This method reduces the risk of infection, leading to a faster recovery after surgery, less post-operative pain, and a shorter hospital stay. Additionally, this approach minimizes the risk of contamination as the surgical site is isolated from the external environment **(24)**. Consequently, there may not be any additional benefits of using antibiotics compared to open surgery.

In laparoscopic cholecystectomy procedure, few studies have shown antimicrobial prophylaxis was associated with a shorter hospital stay **(25, 26)**. The type of laparoscopic procedures and the associated infection risk can facilitate the decision on need of prophylactic antibiotics. There are also practice recommendations which propagate that prolonged duration of some gynecological procedures may merit prophylactic antibiotics to decrease the risk of wound infection **(27)**. The selected study population in our study, does not have these risk factors. Hence, it further supports our results that it is safe to avoid prophylactic antibiotics in the set of patients included in our study.

The other reasons are procedures such as diagnostic laparoscopy, laparoscopic sterilization, salpingo-oophorectomy, ovarian cystectomy and excision of mild endometriosis fall into class 1 surgical wounds that involve no inflammation **(28)**. All the patients in the current study underwent the same procedures as mentioned above, thus explaining zero SSI. It is worth noting that there is level I-E evidence suggesting that antibiotic prophylaxis is unnecessary for laparoscopic procedures where there is no breach of the uterine cavity or vagina **(1)**. In a study by Litta and others, the low infection rates, irrespective of the group, were attributed to other factors like early patient mobilization and rapid resumption of nutrition **(13)**. Jayarathna and his group propounded that factors like differences in surgical technique and supporting staff could have a confounding association with febrile morbidity/infections and hence have to be considered during evaluation **(17)**. This is important because SSI can lead to extended hospital stays and re-admission **(1)**.

Our study revealed a significant difference between the two groups in terms of the length of the surgery and the hospital stay (Table 1). In Group B, the majority of procedures were laparoscopic sterilizations, resulting in shorter procedure times and hospital stays. (27 patients in group A (54%) when compared to 38 (76%) patients in group B). Typically, patients undergoing sterilization surgery are required to stay in the hospital for only one day. Since group A had lesser number of patients who underwent laparoscopic sterilization than group B, the duration of hospital stay in group A appears to be spuriously high.

Ours was a single center study and had a low sample size, thereby could have led to this spurious correlation.

Wright, Hassan **(11)** noted that the prescription of prophylactic antibiotics when not indicated was greater in low-volume surgeons and lack of familiarity with the indications was cited as another reason **(11)**. They also attributed it to physicians' concern about preventing scrutiny in matters regarding adherence to quality

measures. It is not advisable to administer antibiotics unnecessarily as it can lead to increased costs, untoward reactions and the development of resistant bacteria **(29)**. Although there is limited research on gynecological procedures, findings from other surgical procedures can be used to establish a consensus **(30)**. Laparoscopy is a minimally-invasive surgery method with many advantages and is aesthetically prioritized due to making smaller incise-ons and fewer wounds. The lower risk of infection in this method resulted in faster recovery after surgery, as well as less post-operative pain and shorter hospital stay **(24)**. Multicentric large scale studies can shed more light on this aspect and clear-cut recommendations for clinical practice in gynecological laparoscopy can be made.

Conclusion

Our findings indicate that for most routine laparoscopic gynecologic procedures, antibiotic prophylaxis is not required. General preventive measures like using antimicrobial soap before surgery; treating any infections near the surgical site; and being careful to minimize trauma to the surgical site during the operation would usually suffice in these circumstances. Further large studies may be needed to determine whether prophylaxis is necessary for certain high-risk groups, such as geriatric or obese or frail patients, and to identify other factors that could contribute to infection.

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Ethics Consideration

The study was approved by the institutional ethical committee (SDMIEC 077:2016). The study followed the tenets of the declaration of Helsinki.

Conflict of Interest

The author has stated that they do not have any conflicts of interest.

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