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A RANDOMISED CONTROL STUDY ON OPEN VERSUS CLOSED VAGINAL CUFF CLOSURE TECHNIQUE FOLLOWING ABDOMINAL HYSTERECTOMY

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ABSTRACT **Introduction:** Hysterectomy is the most commonly performed gynecologic surgical procedure across the globe. It is recognized as one of the most frequently performed of all major surgical operations and is of great economic as well as medical and social importance **Aim and Objectives:** The aim of this study was to compare operating time, blood loss, length of hospital stay, and post-operative morbidities between open versus closed vaginal cuff closure technique following abdominal hysterectomy. **Materials and Methods:** This is a randomized controlled trial (open label). This study included patients who will undergo hysterectomy, with or without bilateral or unilateral salpingoophorectomy limited to benign lesions. Patients were assigned to either technique by simple randomized sampling using computer generated system. Group A was assigned as the Open Vaginal Cuff Technique. Group B was assigned as Closed Vaginal Cuff Techniques. **Results & Discussion:** A total of 88 patients were sequentially enrolled in the study; 44 were included in Group A (open technique) and 44 were included in Group B (closed technique). The mean and SD of age in Group A was 45.6 years and in Group B was 46.2 years. There was no statistically significant difference between the two groups. The indications for hysterectomy include Leiomyoma uteri (44%), AUB Leiomyoma uteri (24%), AUB adenomyosis (3%), and ovarian new growth (29%) in both Group A and Group B. The mean operating time, length of hospital stay and estimated blood loss were 118.6 min, 5.3 days and 326.8 mL in group A and 115.7 min, 5.4 days, and 321.5 mL in group B respectively. There were no statistically significant differences between the two groups. We evaluated bleeding, infection and pelvic hematoma between the two groups. In group A 10% had bleeding, 6.8% had infection and none had pelvic hematoma and in group B 2.27 % had bleeding, none had infection and pelvic hematoma. We found statistically significant differences in bleeding and infection between the two groups. **Conclusion:** Our study concludes that there was no significant difference between open versus closed vault in the incidence of operating time, length of hospital stay and estimated blood loss between the two groups and we found statistically significant differences in bleeding and infection between the two groups. In closed vault technique the incidence of bleeding and infection rate were less after one week of surgery, hence closed vault is superior to open vault technique. Further we conclude that more sample size is required to confirm our findings.

KEYWORDS : hysterectomy, open vault, close vault, bleeding, infection, length of hospital stay and duration of surgery.

INTRODUCTION

Hysterectomy is the most commonly performed gynecologic surgical procedure across the globe. It is recognized as one of the most frequently performed of all major surgical operations and is of great economic as well as medical and social importance [1]. In the India, it is the most common gynecologic procedure done as well. Therefore, trends to improve the surgical technique of hysterectomy with the goal of optimizing health, reducing hospital costs and decreasing morbidity and mortality of every woman undergoing hysterectomy should be considered.

Uterine myomas comprise the most common indication of all abdominal hysterectomies, the others being endometriosis, malignancy, abnormal uterine bleeding, pelvic inflammatory disease, and uterine prolapse [2].

The surgical technique of hysterectomy may include either open or a closed vaginal cuff. It is the surgeon's preference whether open cuff or closed cuff method technique is used. At present, there are no standard recommendations or guidelines regarding management of vaginal cuff following hysterectomy.

The classical method of abdominal hysterectomy allows retroperitoneal drainage to occur through an open vaginal cuff method. Open vaginal cuff method allows drainage thus preventing development of pelvic hematoma and decreases the risk of infection [3]. If the vaginal cuff is left open, the incidence of postoperative pelvic abscess is dramatically reduced [4,5]. However, some surgeons prefer closed vaginal cuff technique. Closed vaginal cuff method is believed to eliminate peritoneal contamination by vaginal flora decreasing the incidence of vaginal vault infection and peritoneal or ascending infection hence decreasing duration of hospital days [3].

Hence we have taken up this study to compare the outcomes of open versus closed vaginal cuff closure technique following abdominal hysterectomy.

OBJECTIVES

The aim of this study was to compare operating time, blood loss, length of hospital stay, and post-operative morbidities between open versus closed vaginal cuff closure technique following abdominal hysterectomy.

METHODOLOGY

This is a randomised control trial conducted at RAMA MEDICAL COLLEGE, Mandhna, Kanpur from January 2019 to December 2021 designed to evaluate the advantages and disadvantages as well as to compare patients' response following elective hysterectomy using open versus closed vaginal cuff technique. Patients who consented for elective hysterectomies for any benign lesions were recruited in this study. Qualified patients signed an informed consent for the study and subsequent randomization was initiated to classify between open and closed vaginal vault technique. Patients classified to undergo open vaginal cuff technique served as the control group in this study. Comparison of the advantages and disadvantages of both techniques were evaluated in terms of length of hospital stay, operating time, estimated blood loss, surgical costs, post-operative morbidities. Pain, vaginal discharge and healing were the factors assessed to evaluate the patients' post-operative response regarding the designated procedure

Inclusion Criteria:

It included women more than 40 years old undergoing elective hysterectomies with or without salpingoophorectomy for any benign gynecologic lesions regardless of parity were included in this study.

Exclusion Criteria:

those not willing to give consent were excluded from the study.

Study Procedure:

This is a randomized controlled trial (open label). This study included patients who will undergo hysterectomy, with or without bilateral or unilateral salpingoophorectomy limited to benign lesions. Patients were assigned to either technique by simple randomized sampling using computer generated system. Group A was assigned as the Open Vaginal Cuff Technique. Group B was assigned as Closed Vaginal Cuff Technique. Consent for the procedure and research was secured by the surgeon or researcher on admission. The following data will be extracted and recorded in the Data Extraction Form.

Hysterectomy was performed by a same surgeon of the Department of Obstetrics and Gynecology of the institution qualified to do hysterectomy using either closed or open vaginal cuff method. Pre-operative antibiotics was the same on all patients. Cardio pulmonary clearance was required prior to procedure.

Patient's participation in this study was entirely voluntary. Once the patient consented, the participants received the appropriate treatment

or intervention of her condition according to national guidelines. Patients were closely monitored before, during and after the procedure. After discharge, participants of the study were asked to follow up after 1 week. During these follow ups, the healing of the vaginal vault as well as pain response were assessed. Follow-up was done pro-actively. Risks and benefits were explained to the participants. Any surgical procedure such as hysterectomy poses the risk of acquiring complications such as surgical wound infection, injury to the bowel, bladder, ureter or major blood vessel. Post-operative morbidities related to vaginal cuff closure were clearly explained to the patients which include pelvic hematoma, pelvic abscess and dehiscence. The participants were assured that any possible complications that may arise during and after hysterectomy will be managed accordingly.

Statistical Analysis

The independents sample t test was used to compare differences between continuous variables namely age, operating time, length of hospital stay, estimated blood loss, allowable blood loss and surgical costs. Statistical tool used to compare bleeding, dehiscence, granulation and pelvic hematoma was z test on two proportions. A p value of <0.05 were considered statistically significant.

RESULTS & DISCUSSION

A total of 88 patients were sequentially enrolled in the study; 44 were included in Group A (open technique) and 44 were included in Group B (closed technique). The mean and SD of age in Group A was 45.6 years and in Group B was 46.2 years. There was no statistically significant difference between the two groups.

The indications for hysterectomy include Leiomyoma uteri (44%), AUB Leiomyoma uteri (24%), AUB adenomyosis (3%), and ovarian new growth (29%) in both Group A and Group B.

Table 1: Shows comparison of operating time, length of hospital stay and estimated blood loss both the groups.

Parameters	Group A Open Vaginal Vault Closure	Group B Closed Vaginal Vault Closure	p value
Operating time	118.6	115.7	NS
Length of hospital stay (days)	5.3	5.4	NS
Estimated blood loss (mL)	326.8	321.5	NS

The mean operating time, length of hospital stay and estimated blood loss were 118.6 min, 5.3 days and 326.8 mL in group A and 115.7 min, 5.4 days, and 321.5 mL in group B respectively. There were no statistically significant differences between the two groups.

Table 2: Shows comparison of post-operative outcomes between the two groups post-operative one week

Parameters	Group A Open Vaginal Vault Closure		Group B Closed Vaginal Vault Closure		p value
	Number	Percentage	Number	Percentage	
Bleeding	4	10%	1	2.27%	S
Infection	3	6.8%	0	0	S
Pelvic hematoma	0	0	0	0	-

We evaluated bleeding, infection and pelvic hematoma between the two groups. In group A 10% had bleeding, 6.8% had infection and none had pelvic hematoma and in group B 2.27 % had bleeding, none had infection and pelvic hematoma. We found statistically significant differences in bleeding and infection between the two groups.

Hysterectomy is well-known as one of the most frequently performed of all major surgical operations and is of great economic, medical and social importance [1]. Most surgeons performing the abdominal hysterectomy use the open cuff method of vaginal dome closure. At present, there are no standard recommendations or guidelines regarding management of vaginal cuff following hysterectomy.

In open cuff technique, the edges of the vaginal mucosa are sutured with a running locking Vicryl 1-0 synthetic absorbable suture starting at the midpoint of the vagina underneath the bladder and carried around to the stumps of the cardinal and uterosacral ligaments, which are sutured into the angle of the vagina [7]. Straight Ochsner clamps were applied to the anterior vaginal mucosa, the lateral angles of the vagina, and the uterosacral ligaments. One lateral corner of the vaginal dome is closed with a Vicryl 1-0 suture with the stitch passing from front to back through the anterior vaginal mucosa, back out through the lateral aspect of the mucosa, transfixing the stump of the cardinal ligament, brought again through the lateral aspect of the mucosa and back out posteriorly. The suture was then tied. The opposite lateral corner of the vaginal dome is closed in a similar manner. Both corners were then tagged to ensure haemostasis and held in traction. The remainder of the vaginal dome is allowed to remain open. However, the vaginal mucosa and adjacent perivaginal fascia were approximated with the use of continuous lock suture [7].

In the closed vaginal cuff technique, the closure of the vaginal cuff is accomplished with the use of no. 1 Vicryl, either from one end of the vaginal dome or from its central portion. When suturing from the central portion, a suture was passed to envelop all surfaces of the vaginal dome. The closure was done in a continuous interlocking fashion of the entire length to adequately oppose the vaginal cuff and control all bleeding points. Closed vaginal cuff method is believed to eliminate peritoneal contamination by vaginal flora decreasing the incidence of vaginal vault infection and peritoneal or ascending infection hence decreasing duration of hospital days [3].

In 1997, Wheeless, Jr., and M. Roenneburg stated that if the vaginal cuff is left open, the incidence of postoperative pelvic abscess is dramatically reduced [5]. In the study done by Rochowiak (1980), open vaginal cuff method allows retroperitoneal drainage leading to elimination of a culture medium for bacterial growth resulting to a reduction of pelvic-visceral irritation and hence, a notable reduction of infection, fever, and other kinds of operative morbidity [7].

In a study done by Miskry et al, mass closure of the vaginal vault ensures hemostasis, decreases vault hematoma and vaginal cuff infections.

This is a randomized controlled trial (open label) involving patients undergoing elective total abdominal hysterectomy for a benign disease. The two groups were similar with respect to age and to variables related to the surgical procedure and thus were considered suitable for comparison.

The studies conducted by Anate et. Al concluded that there was no significant difference between open versus closed vault in the incidence of blood loss, duration of operation, postoperative pyrexia, wound infection, vaginal vault granulation tissue formation, length of hospitalization and dyspareunia, however, there was increased incidence of pelvic fluid collection in closed vaginal cuff method favouring open vaginal cuff method [3].

A prospective study done by Arahoni et al, both techniques of hysterectomy produced a similar postoperative course despite the fact that the closed vaginal cuff technique resulted a shorter operating time compared to open vaginal cuff technique [13].

In contrast, in our study we found that the mean operating time, length of hospital stay and estimated blood loss were 118.6 min, 5.3 days and 326.8 mL in group A and 115.7 min, 5.4 days, and 321.5 mL in group B respectively. There were no statistically significant differences between the two groups. We evaluated bleeding, infection and pelvic hematoma between the two groups. In group A 10% had bleeding, 6.8% had infection and none had pelvic hematoma and in group B 2.27 % had bleeding, none had infection and pelvic hematoma. We found statistically significant differences in bleeding and infection between the two groups.

CONCLUSION

Our study concludes that there was no significant difference between open versus closed vault in the incidence of operating time, length of hospital stay and estimated blood loss between the two groups and we found statistically significant differences in bleeding and infection between the two groups. In closed vault technique the incidence of bleeding and infection rate were less after one week of surgery, hence closed vault is superior to open vault technique. Further we conclude that more sample size is required to confirm our findings.

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