Open Versus Closed Vaginal Cuff Closure Technique Following Elective Abdominal Hysterectomy for benign lesions: A Randomized Controlled Trial

[1] Jimmy A. Billod,MD, MHCA [2] Joella Gatchalian-Suare,MD

[1]Medical Specialist III, [2] Medical Officer,
[1,2] Department of Obstetrics and Gynecology,
[1,2] Baguio General Hospital and Medical Center, Baguio City, Philippines.

ABSTRACT

Background: Total abdominal hysterectomy is the most frequently performed gynecologic operation and surgical technique of hysterectomy may include either open or a closed vaginal cuff. There are no standard recommendations or guidelines regarding management of vaginal cuff. This study aimed to determine the advantages and disadvantages of open versus closed vaginal cuff closure technique following elective abdominal hysterectomies.

Methodology: This is a randomized controlled trial (open label) involving eighty eight women undergoing elective hysterectomy were randomized to either open or closed vaginal cuff technique. 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. Cramers v test were used to compare the gravidity and parity. A p value of <0.05 were considered statistically significant.

Results: Open and closed vaginal cuff techniques did not differ in terms of operating time (114 vs. 110 minutes; p= 0.53), length of hospital stay (4.67 vs. 4.54 days; p=0.64), estimated blood loss (306.90 vs. 338.13 ml; p=0.26) and surgical cost (5995.26 vs. 5862.94; p=0.55). Both techniques were similar in the clinical judgement of surgeons. This study showed that open and closed vaginal cuff technique techniques were comparable in terms of pain (5.40 vs. 5.42; p=0.53) vaginal discharge (40.48% vs. 23. 91 % respectively; p=0.11) and healing.

Conclusion: Both techniques of hysterectomy gave similar outcomes regarding length of hospital stay, operating time, estimated blood loss, surgical costs, post-operative morbidities and clinical judgement of surgeons. In terms of pain, bleeding, discharge and healing, both techniques showed no significant difference. Our study failed to show inferiority in favor of either of the surgical techniques.

Keywords: *hysterectomy, open vaginal cuff technique, closed vaginal cuff technique.*

INTRODUCTION

Hysterectomy is the most commonly performed gynecologic surgical procedure around 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 Philippines, it is the most common gynecologic procedure done as well. In 2005, out of 2376 gynecologic admissions at the Philippine General Hospital for example, 1512 or 63.6 % were for hysterectomies. In the year 2013- 2015, our sinstitution had an average of 263 hysterectomies per year. 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 [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].

In this study, advantages and disadvantages of open vaginal cuff technique versus closed vaginal cuff technique are determined in terms of operating time, blood loss, length of hospital stay, and post operative morbidities. This study also aims to compare the patient's response post-operatively in terms of pain, vaginal discharge and healing. The result of this study is geared towards providing optimum health and quality healthcare in patients undergoing hysterectomy.

METHODOLOGY

This is a randomized controlled trial (open label) 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.

It included women more than 40 years old undergoing elective hysterectomies with or without salpingoophorectomy for any benign gynecologic lesions regardless of parity was included in this study. Patients with post operative blood loss of more than the expected blood loss and operating time of more than 4 hours was included as an outcome in this study.

The sample size was computed using G power version 3 with the data adapted from the study done by Moustafa et al entitled Evaluation of closure versus non- closure of vaginal vault after hysterectomy where effect size is 0.5, error of probability is 0.05, power of 95 % and allocation ratio of 1. The total sample size computed were 88 where 44 will be included each group. Simple random sampling was utilized.

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 third year and/or fourth year residents of the Department of Obstetrics and Gynecology of the institution qualified to do hysterectomy using either closed or open vaginal cuff method under the supervision of the Consultants. 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 then after 1 month. During these follow ups, the healing of the vaginal vault as well as pain response were assessed. Follow-up was done pro-actively. Patients who are lost to follow-up was documented and reported as an outcome.

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. Cramers v test were used to compare the gravidity and parity. A p value of <0.05 were considered statistically significant.

RESULTS

Between 2018-2019, eighty eight patients were sequentially enrolled in the study; 44 were included in Group A (open technique) and 44 were included in Group B (closed technique). Patients' demographic and clinical characteristics were presented in Table 1. There was no significant difference between open and closed vaginal cuff Techniques in terms of age, gravidity, parity, comorbidities and procedure. The average age was 47-48 years old. The two groups were similar thus were suitable for comparison.

Table 1. Patients' demographic and clinical characteristics

Parameter	Category	Open Vaginal Vault Closure		Closed Vaginal Vault Closure		p-value
		N	%	N	%	
Age		48.6		47.8		0.532
Gravidity	G0	5	11.90	8	17.39	0.156
	G1	7	16.67	5	10.87	
	G2	5	11.90	8	17.39	
	G3	3	7.14	9	19.57	
	G4	12	28.57	6	13.04	
	G5	4	9.52	6	13.04	

	G6	5	11.90	1	2.17	
	G7	1	2.38	3	6.52	
Parity	P0	1	2.38	1	2.17	
	P1	8	19.05	4	8.70	
	P2	5	11.90	14	30.43	
	P3	8	19.05	8	17.39	0.269
	P4	7	16.67	3	6.52	
	P5	7	16.67	6	13.04	
	P6	1	2.38	2	4.35	
c.Comorbidities		8	19.05	12	26.09	0.431
Procedure	TAHBSO	24	57.14	26	56.52	
	TAHBS	13	30.95	15	32.61	0.878
	TAHRSO/TAHLSO	4	9.52	3	6.52	

The indications for hysterectomy were shown in Table 2. Diagnosis of leiomyoma uteri was the most common indication of hysterectomy on both groups. There was no significant difference between open and closed vaginal cuff techniques in terms of indications. However, there was higher proportion of patients who had AUB- A (Adenomyosis) who underwent open vaginal cuff technique (14.29%) than those who underwent Closed Vaginal Cuff Technique (6.25%).

Table 2. Indications for Hysterectomy

	Open Vaginal Vault Closure		**Closed Vaginal Vault Closure**		**p-value**
	N	**%**	**N**	**%**	
Leiomyoma uteri (%)	20	47.62	21	43.75	0.7158
AUB Leiomyoma uteri (%)	9	21.43	6	12.50	0.2626
AUB Adenomyosis (%)	6	14.29	3	6.25	0.0211*
Adenomyosis (%)	0	0.00	3	6.25	0.0995
Ovarian new growth (%)	9	16.67	11	27.08	0.2399

*Significant at 5% level

Surgical outcomes were shown in Table 3. Findings showed no significant difference between open and closed vaginal cuff techniques in terms of each of the following: operating time, length of hospital stay, estimated blood loss and surgical costs. The operating time in closed vaginal technique was slightly shorter (110 minutes) than that of the open vaginal technique (114 minutes) but was not statistically significant. Estimated blood loss was 306 ml and 338 ml on open and closed vaginal cuff technique, respectively and was not statistically significant (p=0.26). Surgical costs are comparable on both groups (5995.26 vs. 5862.9;p= 0.55). The average length of hospital stay was about 4 days (4.67 vs. 4.54 days; p=0.64) on open and closed vaginal cuff technique, respectively.

Table 3. Comparison of Open and Closed Vaginal Cuff Techniques in Terms of Length of Hospital Stay, Operating Time, Estimated Blood Loss, and Surgical Costs

	Open Vaginal Vault Closure	**Closed Vaginal Vault Closure**	**p-value**
Operating time	114.90	110.96	0.538
Length of hospital stay (days)	4.67	4.54	0.648
Estimated blood bloss (mL)	306.90	338.13	0.269
Surgical cost	5995.26	5862.94	0.557

The surgeons' clinical judgement in terms of comfortability, easiness and adaptability were presented in Table 4. Results showed that surgeons were comfortable in doing either technique. Both open and closed vaginal cuff techniques were easy and adaptable.

Table 4. Comparison of Open and Closed Vaginal Cuff Techniques in Terms of Clinical Judgments of Surgeons

	Open Vaginal Vault Closure		**Closed Vaginal Vault Closure**		**p-value**
	N	**%**	**N**	**%**	
Comfortability	88	100	88	100	-
Easiness	88	100	88	100	-
Adaptability	88	100	88	100	-

Post operatively, patients' presentation of vaginal bleeding, granulation and presence of hematoma and dehiscence if any were evaluated after 1 week and after 1 month. On one month follow up, nine out of the forty- four patients did not follow up in the closed vaginal cuff technique and 11 patients out of 44 patients did not follow up in the open vaginal cuff technique. In terms of vaginal bleeding, we found no significant difference between the two groups after 1 week (21.43 % vs. 20.83%; p=0.95) and 1 month (2.38% vs. 2.08%; p=0.92) as shown in Table 5 and 6 respectively. In terms of presence of granulation tissues, both techniques have similar results after 1 week (27.27 % vs. 15.90%; p=0.25) and after 1 month (45.45% vs. 34.29 %; p=0.34). There were no noted incidence of dehiscence and pelvic hematoma on both groups. In terms of pain perception, there was no significant difference between open and closed vaginal cuff techniques in terms patients' response post-operatively of pain perception (5.4 on both groups; p=0.94) and vaginal discharge (40.48% vs. 23.91 %; p=0.11).

Table 5. Comparison of Open and Closed Vaginal Cuff Techniques in Terms of Post-operative Morbidities After 1 Week

	Open Vaginal Vault Closure		Closed Vaginal Vault Closure		p-value
	N	%	N	%	
a. Bleeding	9	21.43	10	20.83	0.9541
Dehiscence	0	0.00	0	0.00	-
Granulation	12	27.27	7	15.90	0.250
Pelvic Hematoma	0	0.00	0	0.00	-

Table 6. Comparison of Open and Closed Vaginal Cuff Techniques in Terms of Post-operative Morbidities After 1 Month

	Open Vaginal Vault Closure		Closed Vaginal Vault Closure		p-value
	N	%	N	%	
Bleeding	1	2.38	1	2.08	0.9240
Dehiscence	0	0	0	0	-
Granulation	15	45.45	12	34.29	0.3429
Pelvic Hematoma	0	0.00	0	0.00	-

DISCUSSION

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. In the Philippines, there are no available researches that compared these two surgical techniques. 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 hemostasis 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]. According to the study done by M.Anate et. Al (2001), open vaginal cuff method allows drainage thus preventing development of pelvic hematoma and decreases the risk of infection [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 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 appose 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 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.

This study compared the open vs. closed vaginal cuff technique in terms of its advantages and disadvantages which did not show significant difference between two techniques in terms of length of hospital stay, operating time, estimated blood loss, surgical costs, clinical judgement of surgeons, pain, vaginal discharge and healing. With these results, we found that open and closed vaginal cuff techniques are comparable on both intraoperative and postoperative course. Similarly, in a prospective study by Anate et. al, 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, this study showed no significant difference in terms of operating time. In terms of estimated blood loss, this study did not show significant difference between the two techniques in contrast to the study done by Rockowiak where in the open cuff method resulted in approximately 15 percent less blood loss than did the closed cuff method [7]. In a randomized controlled trial by Tsafrir et. Al. (2017), the outcomes of different vaginal cuff closure techniques in robotic-assisted total laparoscopic hysterectomy was evaluated and revealed no significant impact on patient outcomes [12].

Surgical costs were also similar on both techniques. Hence, costs in both techniques were cost-effective. However, there were no published studies done to compare the cost effectiveness of either open or closed vaginal cuff technique.

Post operative morbidities such as pelvic hematoma, abscess, vaginal vault dehiscence and cellulitis are rare [15].These morbidities were not observed in this study.

Most surgeons utilize the open vaginal vault cuff technique in the local setting. In our institution, majority of gynecologic surgeons use the open vaginal vault technique. However, some surgeons prefer closed vaginal vault technique. This present study showed the clinical judgement of the surgeons based on comfortability, easiness and adaptability were similar in both techniques. Comments regarding open vaginal cuff technique include " easy to do" and "provide adequate hemostasis". Comments regarding closed vaginal cuff technique include "very easy" and "requires shorter time to close the vaginal vault". Both techniques of vaginal vault closure are therefore acceptable. However, at present, there are no published researches to negate or favour these findings.

Pain perception, vaginal bleeding, discharge and healing were similar in both open and closed vaginal cuff technique. This shows that both procedures are safe but further studies are needed to validate these findings. In this study, neither technique showed an advantage over the other. Either technique can be utilized depending on the surgeon's preference.

Open and closed vaginal cuff technique have been practiced for decades, there is no consensus as to the preferred procedure. According to Ahorni et. al, advocates of the open cuff technique stress the importance of retroperitoneal drainage in order to reduce the risk of hematoma formation and subsequent infection. On the other hand, the authors who call for closure of the vaginal cuff decreases the possibility of ascending infection.

CONCLUSION

In conclusion, both techniques of vaginal closure for hysterectomy gave similar outcomes regarding length of hospital stay, operating time, estimated blood loss, surgical costs, post-operative morbidities (pelvic hematoma, abscess, and dehiscence). In terms of pain, vaginal bleeding, discharge and healing, both techniques showed no significant difference. Our study failed to show some benefit in favor of either of the surgical techniques in terms of the clinical judgement of surgeons. A surgeon's competence, careful and meticulous surgical technique, and antibiotic prophylaxis seem to remain the most important factors to prevent postoperative complications such as infection, dehiscence and pelvic hematoma.

LIMITATIONS AND RECOMMENDATIONS

Postoperative pain, vaginal discharge, healing and clinical judgement of surgeons of either techniques are not well studied hence additional researches are recommended. It is recommended that further studies should be done with larger populations and other outcome such as sexual function may be included for evaluation. Long term follow up and limitation to one surgeon are also recommended to further assess and evaluate both vaginal cuff techniques.

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