Comparison of The Laparoscopic Approach Versus The Vaginal Route Closure of Vaginal Cuff during Total Laparoscopic Hysterectomy

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ABSTRACT

Background: One significant procedure in the field of gynaecology with several indications is the hysterectomy. Hysterectomy has become less intrusive and has less risks thanks to improvements in surgical technique and materials. Total laparoscopic hysterectomy (TLH) is currently a popular practise in gynecologic surgery.

Objective: To compare the effects of the laparoscopic approach versus the vaginal route for the management of vaginal cuff closure during total laparoscopic hysterectomy.

Patients and methods: The present study was a randomized controlled study conducted on 40 women attending the outpatient gynecology clinic of Al-Azhar University Hospital (New Damietta) and were planned to undergo hysterectomy for benign causes according to the inclusion/exclusion included in the study. The present study was conducted on two groups Group A had vaginal suturing for vaginal vault after total laparoscopic hysterectomy; Group B had laparoscopic suturing for virginal vault after total laparoscopic hysterectomy.

Results: Operative time in minutes and suturing time showed significant increase in group 2 (laparoscopic suture) when compared to group A (vaginal suture) (P=0.012 and >0.001) respectively. VAS score show significant increase in group A when compared to group 2 (p<0.001). Post-operative complications, post-operative vaginal bleeding, Vaginal cuff hematoma, Vaginal dehiscence, post-operative infection showed significant increase in group A when compared to group 2. Blood loss showed significant increase in group A when compared to group 2 (p=<0.001). Previous CS and BMI didn't significant correlation with operative time in minutes (p>0.05).

Conclusion: Laparoscopic vaginal cuff closure for complete laparoscopic hysterectomy appears to be secure, simple, and efficient. However, it requires more time than vaginal suture closure.

Keywords: Laparoscopic approach, Vaginal route closure of vaginal cuff, TLH.

INTRODUCTION

Following a caesarean birth, hysterectomy the most common kind of often performed surgical procedure on the female vaginal tract [(1)].

As the final stage of TLH, the vaginal cuff is sewn. Depending on the surgeon's preferences, a range of methods and sutures are available. Interrupted or continuous suturing, extracorporeal or intracorporeal procedures, and transvaginal cuff closure are among options for laparoscopic suturing [(2)].

Due to the challenging nature of laparoscopic suturing procedures, the most important part of the vaginal cuff closure challenging aspect of TLH. The need for specialized surgical skills, a steep learning curve, and a lengthy process are all significant drawbacks of surgery. In a questionnaire research, surgeons admitted that the technical challenges of TLH prevent them from conducting it as frequently as abdominal or vaginal hysterectomy [(3)].

Following TLH, vaginal cuff complications include dehiscence, infection, hematomas, and healing issues are rather common. The vaginal cuff dehiscence rate after laparoscopic and vaginal hysterectomies ranges from 0.1% to 0.2%. On the other hand, minimally invasive methods are thought to have a rate that is 5–10 times greater [(3)].

Early coit after surgery, early excessive exercise, diabetes, and corticosteroid usage all raise the chance of vaginal cuff problems. Nevertheless, cuff closure difficulties can be reduced by closing the vaginal cuff correctly and using the right suture material [(4)].

In the history of gynecologic surgery, there have been many different methods used to close the vaginal cuff during hysterectomy, including laparoscopic interrupted figure-of-eight suturing, interrupted suturing, knotted double-layer running suturing, and barbed running suturing are all used [(5)].

The vaginal cuff closure, which has several variants in surgical technique and materials, is an important part of hysterectomy. This article provides a summary of intracorporeal suturing and knot-tying techniques at the level of a junior resident in obstetrics and gynaecology and contains several validated models that have been developed to gauge resident competence level in vaginal cuff closure [(4)].

This study aimed to compared the outcomes of the vaginal and laparoscopic approaches for managing vaginal cuff closure after complete laparoscopic hysterectomy.

SUBJECTS AND METHODS

- **Study setting:** Al-Azhar University Hospital (New Damietta).
- **Study design:** Blind randomized controlled study.
- **Study population:** The patients were recruited from women attending the outpatient gynecology clinic of Damietta Hospital Al-Azhar University and were planned to undergo hysterectomy for benign causes according to the inclusion/exclusion

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included in the study.

- **Sample size:** Based on the study population of 1395 and odds ratio of 0.18 as determined by **Uccella *et al.*** [1], the sample size calculation for this case control study resulted in 40 participants (20 subjects in each group) with at least 80% power at two-sided 95% significance level.

Inclusion criteria:

1) Age from 40 to 55 years.
2) BMI from 18 to 35
3) The existence of a benign reason for hysterectomy, such as fibroid uterus, unresponsive perimenopausal haemorrhage, adenomyosis, or complicated hyperplasia without atypia

Exclusion criteria:

1) Obese patients i.e., BMI> 35
2) Patients unfit for laparoscopy as patients with cardio-pulmonary compromise.
3) Known or suspected gynecological malignancy.

Ethical consent:

The study was authorised by Al Azhar University Hospitals (IRB00012367 - 21-03-003) ethical Institutional Review Board. All study participants provided written informed permission after being informed of our research's goals. The Declaration of Helsinki for human beings, which is the international medical association's code of ethics, was followed during the conduct of this study.

Methods:

All patients were subjected to:

1. **Full history taking**:
   a) Personal history: name, age and residence.
   b) Present history: symptoms of present problem.
   c) Past history: medical, surgical procedures and drug intake.
   d) Menstrual and obstetric history.
2. **Careful clinical examination:**
   a) General examination: BMI, anemia, chest and heart.
   b) Abdominal examination.
   c) Vaginal examination.
3. **Investigations:**
   a) **Laboratory investigations:**
      - CBC (Preoperative & 24hours after the operation).
      - Fasting & 2hr post prandial blood sugar.
      - Serum creatinine.
      - ALT, AST.
      - PT, PTT, INR.
      - PAP smear, End Pipelle.
   b) **Imaging:**
      - Transvaginal ultrasound using SonoAcer 5. Was done for all patients; any uterine or adnexal pathology was detected.
      - Echo-cardiography.

Randomization of patients: There were 40 patients in this research. They were simply randomised in a 1:1 ratio to have either laparoscopic or transvaginal closure of the vaginal cuff, and they were kept in the dark about the manner of closure until the trial was over. The postoperative follow-up investigators were blindfolded; however, it was not possible to blind the surgeons to the closure procedure.

Postoperative course:

1- The patient received IV fluids in the first 24 hours (3 litres).
2- Oral clear liquids intake began four hours following the procedure.
3- Postoperative analgesia was received as parenteral NSAIDs every eight hours for the first 24 hours, then as needed.
4- Cefotaxime 1gm every 12hrs for 3 days.
5- The urine catheter was taken out 4 hours after the operation and the drain was removed on discharge.
6- CBC was withdrawn 24 hours after the operation.

Postoperative recommendations and follow-up:

All patients were given the advice to refrain from vaginal sex for at least two months at the time of discharge, and they were checked on three months after surgery. The doctors doing the follow-up exams were blinded to the kind of vaginal cuff closure used during the intervention and were not engaged in the surgical procedures. Because it has been demonstrated that practically all vaginal cuff dehiscences following TLH take place within 2 months of surgery, a 3-month follow-up period was selected. Reabsorption of the suture material has also taken place at three months.

Outcome assessment:

a) Primary outcome:

- Vaginal dehiscence: Any separation at the level of the vaginal vault was considered to be a vaginal dehiscence.
- Suturing time was calculated from first holding the needle till cutting the thread after the last suture. The time measured in minutes using the video recording afterwards.

b) Secondary outcomes:

- Vaginal haemorrhage, a hematoma in the vaginal cuff, and postoperative infection, post- operative pain using VAS (the linear 10cm visual analogue scale) vaginal resuturing and any reoperation.

c) Possible factors:

- To offer more information, the risk factors for vaginal cuff dehiscence and any cuff complications were also examined. By using univariate analysis, factors that may be linked to the development of these issues were examined.

Statistical analysis: Statistical Package for Social Sciences (SPSS) version 27 for Windows was used to code, process, and analyse the obtained data (IBM SPSS

Inc, Chicago, IL, USA). Using the Shapiro Walk test, the distribution of the data was examined for normality.

To represent qualitative data, frequencies and relative percentages were employed. The chi square test (2) and Fisher exact were used to compute the difference between the qualitative variables, as illustrated. Mean ± SD was used to convey quantitative data that were parametric, whereas median was used to express non-parametric data (Range).

Neutral samples the t-test was used to compare two independent sets of variables with regularly distributed distributions, whereas the Mann Whitney U test was used for non-normally distributed data (non-parametric data). With non-parametric quantitative data, Spearman's correlation was utilised to examine the relationship between two variables. The test's value, represented as r-values, is to be interpreted as follows: - A positive value denoted a direct proportion,

- Inverse correlation was indicated by a negative correlation.
- r from (0: 0.3) or (0: -0.3) …… weak correlation.
-r from (0.3: 0.6) or (-0.3: -0.6) …… moderate correlation. - r from (0.6: 1) or (-0.6: -1) …… strong correlation. Results from significance tests are shown as two-tailed probability. P value less than 0.05 was regarded as significant.

RESULTS

Mean age of patient in thee studied group was 52.15±5.63 while in the control group was 52.95±4.36. No significant difference between studied groups as regard age (p>0.05) (Table 1).

Table (1): Age characteristics of the studied groups

Socio-demographic data		Group A (vaginal suture) (N=20)	Group 2 (lap suture) (N= 20)	Total (N= 40)	Test of significance	P-value
Age	Mean ± SD	52.15±5.63	52.95±4.36	52.55±4.99	t = 0.502	0.618
	Median	52.5	53	53		
	Range	44-63	45-61	44-63		

Smoking, hypertension, diabetes mellitus, sexual activity, parity, previous CS, Previous open surgery and BMI didn't show significant difference between the two groups (p>0.05) (Table 2).

Table (2): History & clinical characteristics of the studied groups

History & clinical data	Group A (vaginal suture) (N=20)		Group 2 (lap suture) (N= 20)		Total (N= 40)		Test of significance	P-value
	N	%	N	%	N	%		
Smoking:								
Positive	1	5	1	5	2	5	-	-
Negative	19	95	19	95	38	95		
HTN:								
Positive	7	35	9	45	16	40	X^2= 0.417	0.519
Negative	13	65	11	55	24	60		
DM:								
Positive	7	35	7	35	14	35	-	-
Negative	13	65	13	65	26	65		
Sexual activity:								
Positive	12	60	14	70	26	65	X^2= 0.440	0.507
Negative	8	40	6	30	14	35		
Parity:								
Nullipara	1	5	1	5	2	5	-	-
Parous	19	95	19	95	38	95		
Previous CS:								
0	11	55	11	55	22	55	-	-
>1	9	45	9	45	18	45		
Previous open surgery:								
Positive	6	30	6	30	12	30	-	-
Negative	14	70	14	70	28	70		
BMI:								
Mean ± SD	27.80±3.11		27.55±2.37		27.68±2.73		t = 0.286	0.776
Median	27		27		27			
Range	22-34		23-33		22-34			

No significant difference was found between studied groups as regard PAP smear and End pipelle (p>0.05) (Table 3).

Table (3): Investigations in the studied groups

Investigations	Group A (vaginal suture) (N=20)		Group 2 (lap suture) (N= 20)		Total (N= 40)		Test of significance	P-value
	N	%	N	%	N	%		
PAP smear:								
Chronic inflammation	8	40	9	45	17	42.5	X^2= 0.102	0.749
Normal	12	60	11	55	23	57.5		
End pipelle:								
Atrophic	2	10	1	5	3	7.5	X^2= 1.454	0.693
Hyperplastic	6	30	7	35	13	32.5		
Secretory	0	0	1	5	1	2.5		
Normal	12	60	11	55	23	57.5		

The main indications for hysterectomy were fibroid (40%) in labaroscopic suture group and endometrial hyperplasia and adenomyosis in vaginal suture group (35% each). No significant difference was found between studied groups as regard indications for hysterectomy (p>0.05) (Table 4).

Table (4): Indications of hysterectomy in the studied groups

Indications of hysterectomy	Group A (vaginal suture) (N=20)		Group 2 (lap suture) (N= 20)		Total (N= 40)		Test of significance	P-value
	N	%	N	%	N	%		
End hyperplasia:								
Positive	7	35	5	25	12	30	X^2= 0.476	0.490
Negative	13	65	15	75	28	70		
Adenomyosis:								
Positive	7	35	7	35	14	35	-	-
Negative	13	65	13	65	26	65		
Fibroid:								
Positive	6	30	8	40	14	35	X^2= 0.440	0.507
Negative	14	70	12	60	26	65		
Ovarian mass:								
Positive	3	15	2	10	5	12.5	FE= 0.229	1
Negative	17	85	18	90	35	87.5		
Postmenopausal bleeding:								
Positive	2	10	2	10	4	10	-	-
Negative	18	90	18	90	36	90		

Operative time in minutes and suturing time showed significant increase in group 2 (laparoscopic suture) when compared to group A (vaginal suture) (P=0.012 and >0.001) respectively. While blood loss didn't show significant difference between the two groups (p>0.05) (Table 5).

Table (5): Operative data of the studied groups

Operative data	Group A (vaginal suture) (N=20)	Group 2 (lap suture) (N= 20)	Test of significance	P-value
Operative time in minutes:				
Mean ± SD	71.3±10.34	81.00±12.85		
Range	55-92	61-106	t = 2.630	**0.012***
Suturing time:				
Mean ± SD	5.40±1.67	9.85±2.16	t = 7.296	**<0.001 ****
Range	3-8	6-14		
Blood loss (ml):				
Mean ± SD	222.00±114.41	197.00±120.49	U= 0.827	0.408
Range	80-500	70-550		

U: Mann-whitney test. * P <0.05: Significant, ** P <0.001: Highly significant

VAS score show significant increase in group A when compared to group 2 ($p<0.001$) (Table 6).

Table (6): Pain assessment of the studied groups

pain assessment	Group A (vaginal suture) (N=20)	Group 2 (lap suture) (N= 20)	Test of significance	P-value
VAS score:				
Mean ± SD	5.80±1.47	4.05±1.19	t = 4.132	**<0.001****
Range	3-8	2-6		

**Highly Significant

Post-operative complications, Post-operative vaginal bleeding, vaginal cuff hematoma, vaginal dehiscence, Post-operative infection showed significant increase in group A when compared to group 2. Reintervention, post-operative sexual activity, Vaginal evisceration and blood transfusion didn't show significant difference between the two groups ($p>0.05$) (Table 7).

Table (7): Analysis of post-operative complications

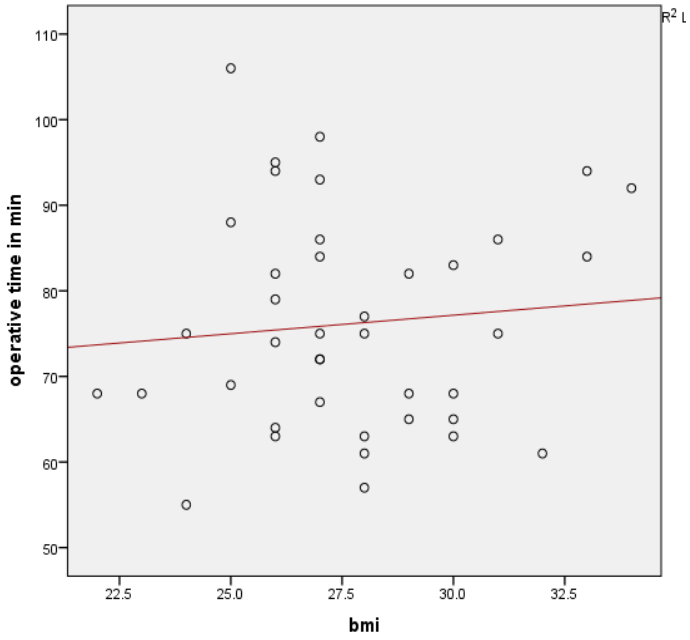
Post-operative complications	Group A (vaginal suture) (N=20)		Group 2 (lap suture) (N= 20)		Test of significance	P-value
	N	%	N	%		
Post-operative complications:						
Positive	14	70	6	30	X^2= 6.400	**0.011***
Negative	6	30	14	70		
Post-operative vaginal bleeding:						
Positive	11	55	3	15	X^2= 7.033	**0.008***
Negative	9	45	17	85		
Vaginal cuff hematoma:						
Positive	7	35	1	5	FE= 5.625	**0.044***
Negative	13	65	19	95		
Vaginal dehiscence:						
Positive	5	25	0	0	FE= 5.714	**0.047***
Negative	15	75	20	100		
Post-operative infection:						
Positive	10	50	3	15		
Negative	10	50	17	85	X^2= 5.584	**0.018***
Reintervention:						
Negative	20	100	20	100	-	-
Vaginal evisceration:						
Negative	20	100	20	100	-	-
Post-operative sexual activity						
Total	11	55	13	65		
Positive	6	30	7	35		0.64
Negative	5	25	6	30		
Blood transfusion:						
Positive	5	25	5	25	-	-
Negative	15	75	15	75		

BMI didn't significant correlation with operative time in minutes (p>0.05) (Table 8).

Table (8): Correlation between BMI and operative time

	Operative time in minutes	
	R	P-value
BMI	0.094	0.562

r: Pearson correlation coefficient.



DISCUSSION

In our study, mean age of patient in the studied group was 52.15±5.63 while in the control group was 52.95±4.36. This was comparable to **Aydogmus *et al.* [2],** who found the average age of women having hysterectomy procedures was 48.1 (38-71) years old. Additionally, this is consistent with what other facilities have reported **[6, 7].**

Smoking, hypertension, diabetes mellitus, sexual activity, parity, previous CS, Previous open surgery and BMI didn't show significant difference between the two groups (p>0.05).

Bastu *et al.* [5] discovered that the laparoscopic method and vaginal route groups were comparable for age, parity, BMI, and haemoglobin decline during operation. This finding is consistent with our findings.

Eighty women who underwent complete laparoscopic hysterectomy for benign lesions were the subjects of a prospective randomised controlled research. Regarding BMI, weight, and height, the study's two groups did not differ statistically significantly from one another **[8]**.

In our study no significant difference was found between studied groups as regard PAP smear and End pipelle (p>0.05). The main indications for hysterectomy were fibroid (40%) in laparoscopic suture group and endometrial hyperplasia and adenomyosis in vaginal suture group (35% each).

In a similar vein, **Butt *et al.* [9]** evaluated 335 patients who had hysterectomy in South Africa, with fibroid-related menorrhagia (23% of cases) and abnormal uterine haemorrhage (14.9%) being the most frequent indications.

Additionally, 251 elective abdominal hysterectomy cases were among the 7632 major gynaecological surgeries that **Rabiu and Habib [10]** conducted, at a rate of 3.3%. Uterine fibroid was the most typical symptom (51.8%).

The present study showed that operative time in minutes and suturing time showed significant increase in group 2 (laparoscopic suture) when compared to group A (vaginal suture) (P=0.012 and >0.001) respectively. While blood loss didn't show significant difference between the two groups (p>0.05).

According to **Aydogmus *et al.* [2],** vaginal method resulted in a mean cuff closure time that was much quicker than endoscopic suturing at 5.8 minutes (2-18), which is consistent with our findings.

Additionally, **Hwang *et al.* [11]** discovered that patients who underwent laparoscopic sutures experienced considerably shorter median operating times than those who underwent vaginal sutures.

When compared to group 2, the VAS score for group A significantly increased (p < 0.001). This is explained by the fact that the vaginal approach involves more tugging of the uterosacrals and vaginal tissues.

In line with our findings, **Singh *et al.* [12]** discovered that only four patients required greater analgesia when using the laparoscopic technique, compared to twelve patients who had vaginal suturing and experienced substantial discomfort while receiving normal analgesia.

In contrast to our findings, **Lee *et al.* [13]** discovered that VH was linked to a quicker recovery period and less discomfort 24 hours after surgery than LH.

The current study revealed that post-operative complications, post-operative vaginal bleeding, vaginal cuff hematoma, vaginal dehiscence, post-operative infection showed substantial increase in group A compared to group 2. Reintervention, vaginal evisceration and blood transfusion didn't show significant difference between the two groups (p>0.05).

In line with our findings, the laparoscopic route vault closure had a statically substantially lower rate of post-operative problems (28.5%) compared to the vaginal route vault closure (88.5%), and the difference was statistically significant (Z= 6.42, p <0.000) **[12]**.

Additionally, TV closure at the conclusion of a TLH is linked to a much increased risk of any vaginal cuff issue as well as vaginal dehiscence, according to research by **Uccella *et al.* [1]**.

According to **Naveiro-Fuentes *et al.* [14]**, patients who had their vaginal cuff sutured through the vaginal method required reconstruction more frequently as a result of vaginal cuff healing issues.

On the other hand, **Uccella *et al.*** [15] revealed that there was a higher incidence of cuff dehiscence in patients who had suture utilising transvaginal knots as opposed to laparoscopic knots.

Previous studies may have drawn false findings as a consequence of the inherent constraints of a retrospective design, which is one explanation for the discrepancy in results. Additionally, a surgeon's skill level and working environment are directly and inescapably related to the results of surgery.

The current study demonstrated a statistically significant link between a history of diabetes mellitus and post-operative complications (p=0.008). Inhibited baseline pulmonary, cardiovascular, and renal system dysfunction are among the DM-related factors that may contribute to these consequences [16, 17].

In line with our finding, the number of 56,640 laparoscopic hysterectomies was recorded by **Corrigan *et al.*** [18] Nevertheless, compared to the non-diabetes group, both the cohorts with insulin-dependent diabetes mellitus and those without insulin-dependent diabetes mellitus had a higher risk of postoperative complications.

Moreover, we found that age, Smoking, hypertension, sexual activity, parity, previous CS, previous open surgery and BMI didn't show significant correlation with post-operative complications (p>0.05).

On the other hand, **Pepin *et al.*** [19] looked at individuals who had laparoscopic hysterectomies for benign reasons. Seven characteristics were found using the hysterectomy risk prediction tool using logistic regression complications: history of laparotomy, age, body mass index, parity, and race.

Additionally, obesity was linked to a higher risk of significant bleeding after surgery, major bleeding complications, and infection, according to research by **Osler *et al.*** [20]. Women with a BMI under 20 also had a higher risk of re-operation and any type of bleeding issues.

Endometrial hyperplasia showed significant correlation with post-operative complications (p=0.038). Adenomyosis, Fibroid, ovarian mass and PMB didn't show significant correlation with post-operative complications (p>0.05).

According to **Butt *et al.*** [9] study of 335 hysterectomy patients in South Africa, patients with malignant illness experienced intraoperative difficulties at a rate that was six times higher than that of patients with benign conditions.

Blood loss showed significant increase in group A when compared to group 2 (p=<0.001). Operative time in minutes and Suturing time didn't show significant correlation with post-operative complications (p>0.05).

Contrarily, **Catanzarite *et al.*** [21] reported that complications rose gradually with longer surgical times among patients who underwent robotic or laparoscopic hysterectomy for a benign condition.

Patients receiving robotic-assisted radical hysterectomy for cervical cancer were the subject of a study by **Park *et al.*** [22]. Perioperative complications and surgery time were substantially correlated (p = 0.026).

Previous CS and BMI didn't significant correlation with operative time in minutes (p>0.05).

On the other hand, prior research shown that obesity was linked to a lengthier operating time and more difficulties following hysterectomy [23, 24, 25].

Hesselman and colleagues [26] carried out a population-based longitudinal register research on 25354 women who had benign hysterectomy surgeries at 46 Swedish medical institutions. Previous caesarean birth was associated with bladder damage, but not ureter injury.

This research has certain limitations. Because the complete laparoscopic hysterectomy approach is highly dependent on surgeon expertise, surgical outcomes may differ depending on the surgeon. Furthermore, our study was constrained by a small sample size and was conducted at a single centre, limiting the generalizability of our findings.

CONCLUSION

Laparoscopic vaginal cuff closure for complete laparoscopic hysterectomy appears to be secure, simple, and efficient. However, it requires more time than vaginal suture closure.

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