TOTAL LAPAROSCOPIC HYSTERECTOMY WITH PRIOR UTERINE ARTERY CLIPPING VERSUS CONVENTIONAL LAPAROSCOPIC HYSTERECTOMY: A RANDOMIZED CONTROLLED TRIAL

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Abstract
Objective: To compare the efficacy of total laparoscopic hysterectomy (TLH) with prior uterine artery clipping versus conventional laparoscopic hysterectomy
Methods: A randomized controlled study was conducted at Ain Shams University Maternity Hospital. The study included 42 women who were admitted from the general gynecology outpatient clinic and were planned to undergo TLH. Patients participating in the study were randomized into 2 groups; the control group, including women who were subjected to conventional TLH, and the study group, including women who were subjected to TLH with prior uterine artery clipping at its origin.
Results The patient profiles in both groups were found to be similar, indicating a lack of confounding factors. No significant differences were observed between both groups in terms of age, BMI, parity, medical and surgical history, and the cause of hysterectomy. Regarding blood loss, no statistically significant difference was found between the two groups suggesting comparable outcomes in this aspect. However, a notable disparity was identified in terms of operative time. The study group had a mean operative time of 72.76±7.05 minutes, while the control group had a mean operative time of 63.76±6.28 minutes. This difference was highly statistically significant (p-value of < 0.001). All other outcomes (severe bleeding, post operative complications and operative time) were comparable between the two groups.
Conclusion: TLH with prior uterine artery clipping resulted in a longer operative time, without any added benefits regarding blood loss or other investigated outcomes.
Keywords: total laparoscopic hysterectomy, uterine artery, clipping, ligation, blood loss.

Introduction

Hyperplastic processes of the endometrium are one of the most common pathologies in women of premenopausal age and, depending on the presence of cytological atypia, are divided into non-atypical forms (NGE) and atypical (AGE)[1,2].
Total laparoscopic hysterectomy (TLH) is a minimally invasive surgical procedure that involves the removal of the uterus through small incisions in the abdomen. It offers several advantages over traditional open surgery, including reduced postoperative pain, shorter hospital stays, faster recovery, and improved cosmetic outcomes [3]

There are various techniques for TLH which depend on energy sources, the use of uterine manipulators, vaginal tubes, the method of uterine artery ligation, and the method of vault closure.[4]

Anatomically, the uterine artery divides into ascending and descending branches when it enters the uterus. The ascending branch may not be coagulated if the surgeon tries to handle this artery close to the uterus as in most of the laparoscopic hysterectomies and accordingly, this could lead to unexpected bleeding during the operation. In addition, the close proximity of the ureter to the uterine artery at this location during conventional TLH could result in unrecognized ureteric damage.[5]

New methods and techniques for ligation of the uterine vessels have been developed, including metal clips, the Hem-o-lok clip, endovascular staples, the suturing technique, bipolar electrocautery, the argon beam coagulator, and laser or ultrasonic dissectors.[4]

The classic technique of TLH includes attacking the uterine artery at the internal os. Attacking the uterine artery at its origin may be necessary to devascularize the uterus prior to TLH if bleeding is anticipated.[6]

Clipping the uterine artery may replace the classic ligature. As most of the blood enters the uterus through the uterine arteries, especially its ascending branch. From this surgical point of view, TLH with prior uterine artery clipping at its origin is proposed to reduce intraoperative blood loss. Accordingly, the purpose of this work was to compare TLH with prior uterine artery clipping versus conventional laparoscopic hysterectomy.[7&8]

Patients and Methods:
This was a randomized control study conducted at Ain Shams University Maternity Hospital. The study included 42 women who were admitted from the general gynecology outpatient clinic and were planned to undergo TLH according to the participant flow chart **Figure (1)** between Jan. 2022 and December 2022.This study was approved by the Institutional Review Board, Ain Shams University Maternity Hospital, and Research Ethics Committee, Faculty of Medicine, Ain Shams University (FWA 000017585): Approval Number MD64/2019. The study was registered in ClinicalTrials.gov (ID: NCT05028543) prior to initiation.

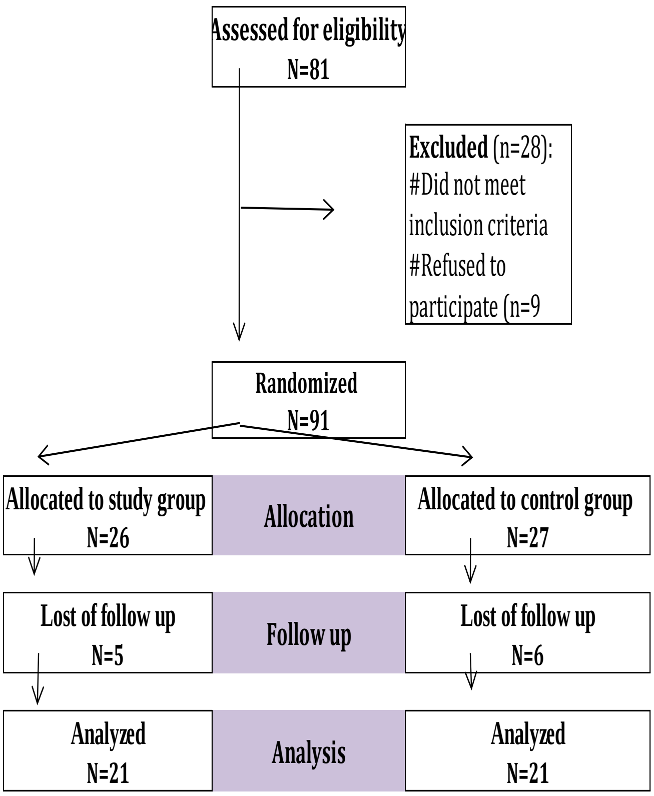


Figure (1): Consort Flow chart of the studied cases.

The objective of our study was to evaluate a range of patient outcomes, with particular emphasis on blood loss as the primary outcome, as well as secondary outcomes including clip failure, severe bleeding, post-operative re-exploration, intra-operative complications, postoperative complications, and total operative time.

Sample Size Justification: By using the PASS 11 program for sample size calculation, setting Power at 99%, alpha error at 5%, and reviewing previous study results by **Kale et al.[7]** that showed total blood losses in conventional TLH versus TLH with prior uterine artery clipping at its origin (TLH + UAL) were (109.38 ± 33.03 versus 47.50 ± 8.12 respectively); based on a sample size of at least 42 female patients underwent hysterectomy (21 patients in each group) were adequately powered for this primary outcome.

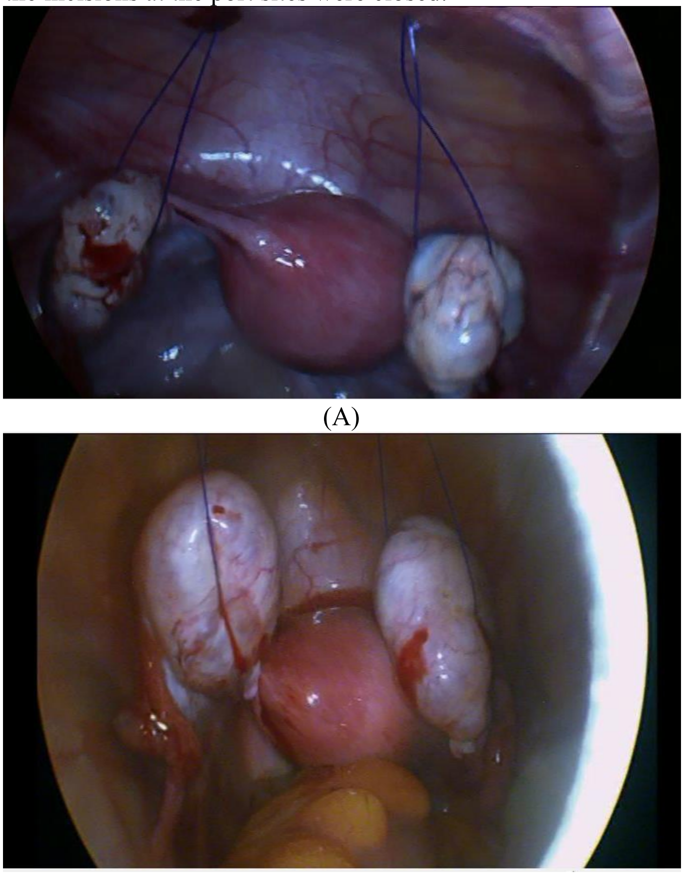
Randomization& Allocation Concealment: In this study, randomization of patients was conducted using a computer-generated randomization plan. The allocation concealment mechanism involved the use of consecutively numbered opaque sealed envelopes, with each envelope containing a letter corresponding to either group A (conventional TLH) or group B (laparoscopic clipping of uterine artery before TLH). Participating women were assigned to a group based on the letter inside the envelope. The randomization process was conducted blindly by the computer-generated plan, ensuring impartial allocation.

The enrolled patients were women who were indicated for hysterectomy due to benign conditions Laparoscopic Hysterectomy was indicated in this study for the following four categories: fibroids presenting with pain or bleeding, adenomyosis presenting with pain or bleeding, post-menopausal bleeding, and endometrial hyperplasia manifested by vaginal bleeding. e.g. polyp, adenomyosis, and uterine fibroids, with uterine size less than 16 weeks. On the other hand, we excluded women with 1) previous ureteric surgery that may increase possibility of ureteric injurey, 2) previous uterine artery embolization 3) suspected extensive pelvic adhesions based on previous history and examination. 4) known tube ovarian pathology requiring primary laparotomy, e.g., large adnexal masses, 5) factors that may delay vaginal vault healing as uncontrolled diabetes, prolonged corticosteroid therapy, or advanced liver diseases, 6) body Mass Index (BMI) > 35 kg/m^2, 7) conditions interfering with laparoscopic surgery e.g., significant cardiopulmonary disease, 8) broad ligament and cervical myoma hindering access to the lateral pelvic wall, 9) 2nd or 3rd-degree uterine descent.

Preoperative assessment: After taking informed and written consent the recruited patients were subjected to preoperative assessment, including detailed history taking, general and gynecological examination, laboratory testing, and ultrasonography scanning. Finally, to exclude malignancy, endometrial biopsy, and cervical smear were done. Twentyfour hours before the operation 2 units of Packed RBCs were prepared.

Intervention: All the study subject were operated by the same surgical team and all the patients received intravenous antibiotics 30 minutes before induction of anesthesia {Cefotaxime 1gm (Claforan®-Sanofi-Cairo-Egypt) & Metronidazole 500 mg (Flagyl®-Sanofi- Cairo-Egypt)}. We used the direct approach for the primary port insertion to enter the abdomen. After a thorough exploration of the pelvic cavity, the entire abdomen was surveyed before starting the procedure.

The size of the uterus, the presence of myomas, adnexa were visualized. In Group "A "women who underwent conventional TLH followed a specific sequence of actions. Initially, advanced bipolar diathermy LigaSur™ was used to coagulate the round and utero-ovarian ligaments. The broad ligament was opened to expose the uterine vessels, followed by the creation of a bladder flap to access the lower uterine segment. The posterior peritoneum at the lower uterine segment was opened, and the uterine vessels were coagulated using LigaSur. These steps were then repeated on the other side. The uterine vasculature was separated and coagulated using advanced bipolar cautery, and cutting the vaginal wall over V care cup. Subsequently, the uterus with its cervix was delivered through the vagina, the vault was closed via laparoscopic approach using the horizontal method using 0-vicryl sutures® with 40mm half circle tapering-point needle and intracorporeal knots was utilized. sutured, and the incisions at the port sites were closed.

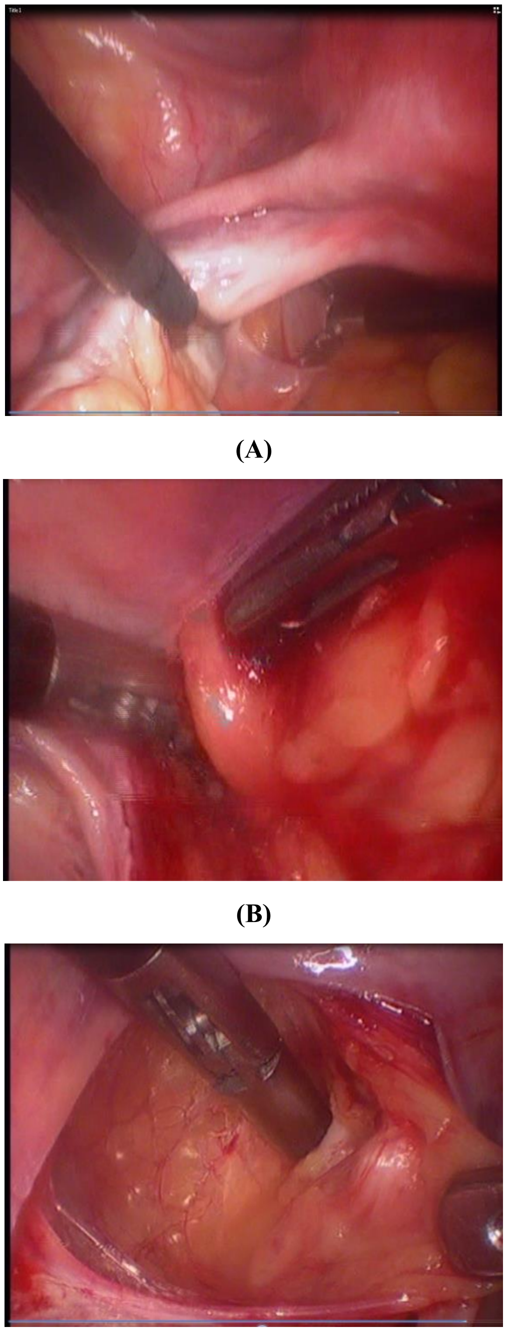


(A)

(B)

Figure(2): A&B Both ovaries were temporarily suspended to the anterior abdominal wall using atrnsfixing prolene 2-0 stitch ®

In Group "B," where uterine artery occlusion was performed prior to TLH, the following procedure was carried out: The uterine artery was dissected through a medial approach, starting from the posterior and medial regions of the infundibulopelvic ligament. The identification of the ureter was the initial step. By grabbing the obliterated umbilical artery at the anterior abdominal wall and retracting it, the origin of the uterine artery could be located. The uterine artery runs medially to the umbilical artery and nearly parallel to the ureter. This anatomical site was chosen to attack the uterine artery for clipping. To facilitate exposure at this specific anatomical site, both ovaries were temporarily suspended to the anterior abdominal wall using a transfixing prolene 2-0 stitch® inserted through a straight needle as showen in figure (2). This bilateral step was performed before proceeding with the remaining steps of the procedure, which followed the same approach as conventional TLH. The uterine vessels were clipped at their origin from the hypogastric vessels using a clip applier. Clipping of the artery was performed through the application of two 5 mm size titanium metallic clips in continuity, then the laparoscopic hysterectomy with the same steps as the conventional method was performed **figure(3).** Once the procedure was completed, this temporary suspension was released, allowing both ovaries to return to their normal position at the ovarian fossa**.**



(A)

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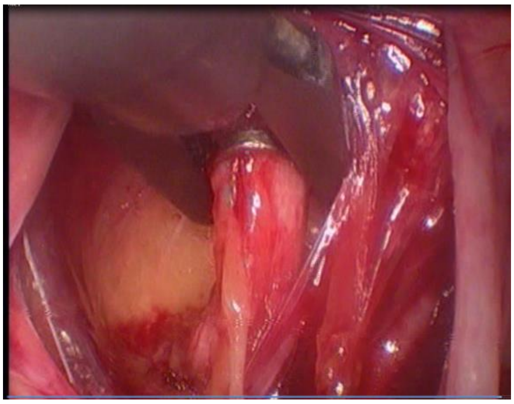

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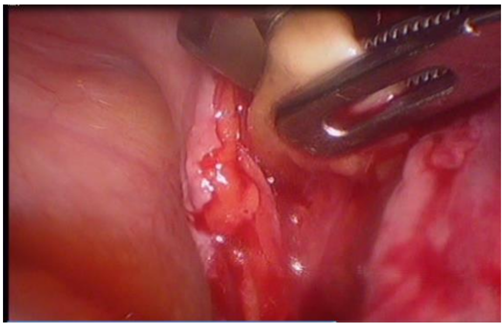

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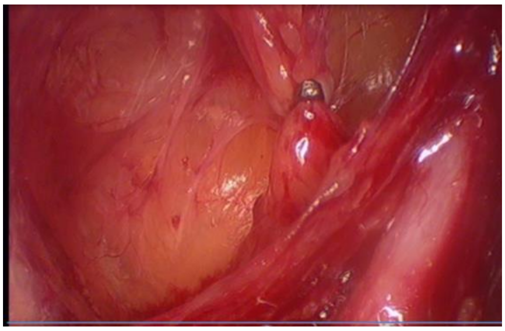

(F)

Figure (3): A) The peritoneum of the ovarian fossa (B, C) Dissection uterine artery. (D) Placement of vascular clip using clips applicator over the uterine artery. (E&F) metallic clipping of uterine artery at its origin in our study included patient.

Postoperative assessment: Vital signs were assessed and followed up Postoperative analgesia, antibiotics, and IV fluid were prescribed as per the hospital protocol. Blood loss was estimated via the amount of intraoperative blood in the suction bottle, excluding the volume of saline wash as well as the drop-in postoperative hemoglobin& hematocrit 24 hours after the end of the procedure through the following formula:

$$V_L = \text{EBV} \times \frac{HCT_o - HCT_f}{HCT_{av}}$$

VL, volume lost; **EBV,** estimated blood volume (65 mL/Kg for adult women); **HCTo,** initial hematocrit; **HCTf,** final hematocrit; **HCTav,** an average of initial and final hematocrit.[10]

Finally, any postoperative complications as severe bleeding and bowel injurey or failed procedures as clips failure and conversion to laparotomy were recorded.

Statistical analysis: Recorded data were analyzed using the statistical package for social sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean± standard deviation and ranges when their distribution was parametric (normal) while non-normally distributed variables (non-parametric data) were presented as median with inter-quartile range (IQR). Also, qualitative variables were presented as numbers and percentages. Data were explored for normality using the Kolmogorov-Smirnov and Shapiro-Wilk Tests. The t-test of significance was used when comparing two means. The Comparison between groups with qualitative data was done by using the Chi-square test while Fisher's exact test was applied when the expected count in any cell less than 5. Pearson's correlation coefficient (r) test was used to assess the degree of association between two sets of variables. Probability P-value <0.05 was considered significant.

Results:

Participants were mean age of 47.69±4.02 years and the mean BMI was 30.29±1.57. Baseline characteristics, previous history, and medical conditions did not show statistically significant differences between the study and control groups **(Table 1).**

Table (1): Comparison between groups according to baseline characteristics.

Baseline characteristics	Control Group (n=21)	Study Group (n=21)	Test value	p-value
Age (years)				
Mean±SD	47.29±3.68	48.10±4.39	0.420	0.521
Range	38-55	38-56		
BMI [wt/ (ht)^2]				
Mean±SD	30.33±1.62	30.24±1.55	0.038	0.847
Range	29-34	28-35		
Obstetric History				
Mean±SD	2.67±1.53	2.48±0.87	0.246	0.623
Range	0-6	1-4		
Parity				
NG	2 (9.5%)	0 (0.0%)	x^2= 4.800	^{FE}0.187
P1-2	8 (38.1%)	12 (57.1%)		

P3-4	9 (42.9%)	9 (42.9%)		
P5-6	2 (9.5%)	0 (0.0%)		
Medical History				
Anemia	0 (0.0%)	1 (4.8%)	x^2:1.008	FE0.315
Controlled HTN	6 (28.6%)	3 (14.3%)	x^2:1.244	FE0.265
Controlled DM	6 (28.6%)	3 (14.3%)	x^2:1.244	FE0.265

Using: t-Independent Sample t-test for Mean±SD;
x^2: Chi-square test for Number (%) or Fisher's exact test, when appropriate
p-value >0.05 is insignificant

Regarding operative time, there was statistically high significant difference observed. The study group had a mean operative time of 72.76±7.05 minutes, while the control group had a mean operative time of 63.76±6.28 minutes (p<0.001) **(Table 2).** However, there were no significant differences between the groups in terms of postoperative hemoglobin, postoperative hematocrit, and hematocrit drop (Table 3).the mean estimated blood loss (EBL) was slightly higher in the control group (173.86±119.32 ml) compared to the study group (130.75±113.69 ml), but this difference was not statistically significant (p=0.238) **(Figure 4).**

Table (2): Comparison between groups according to operative time and pre and post-operative hemoglobin

	Control Group (n=21)	Study Group (n=21)	Test value	p-value
Operative time (min)				
Mean±SD Range	63.76±6.28 55-80	72.76±7.05 60-90	19.074	<0.001**
Preoperative hgb 1 (mg)				
Mean±SD Range	10.15±0.41 9.5-10.8	10.15±0.64 8-11	0.001	0.977
Drop of Hgb (mg)				
Mean±SD Range	0.41±0.32 0-1	0.32±0.25 0-1	1.039	0.314
Postoperative hgb (mg)				
Mean±SD Range	9.81±0.28 9-10.2	9.95±0.44 9.3-10.8	1.462	0.234

Using: t-Independent Sample t-test for Mean±SD;

p-value >0.05 is insignificant

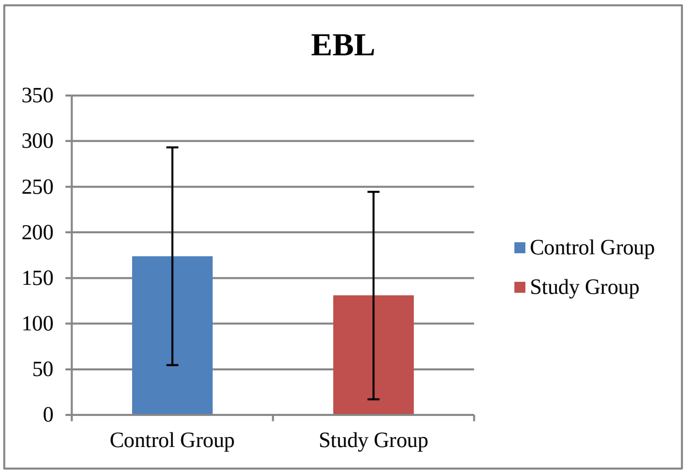

Figure (4): Comparison between groups according to EBL.

In the control group, there was a positive correlation between blood loss and operative time (r-value -0.456, p-value 0.038). Additionally, positive correlations were found between operative time and preoperative hemoglobin and drop in hemoglobin (r-value 0.524, p-value 0.015; r-value 0.540, p-value 0.012. In the study group,positive correlations were observed between operative time and preoperative hemoglobin (mg) and uterus weight (gm) (r-value 0.533, p-value 0.013; r-value 0.617, p-value 0.003).These findings indicate a relationship between blood loss, operative time, and specimen weight, with heavier specimens associated with increased blood loss and longer operative time. The correlation between operative time and preoperative hemoglobin and uterus weight was statistically significant (**Table 3).**

Table (3): Correlation between blood loss "ml" and operative time with all different parameters, using Pearson Correlation Coefficient among study group, among control group

Control group	**Blood loss (ml)**		**Operative time (min)**	
	r-value	**p-value**	**r-value**	**p-value**
Blood loss (ml)			-0.456	0.038*
Age (years)	-0.165	0.475	0.382	0.088
BMI [wt/(ht)^2]	0.342	0.129	-0.193	0.402
Parity	0.073	0.754	-0.285	0.211
Operative time (min)	-0.456	0.038*		

Preoperative hgb (mg)	-0.105	0.650	0.524	0.015*
Post-operative hgb (mg)	-0.128	0.580	0.247	0.281
Drop of Hgb (mg)	-0.233	0.310	0.540	0.012*
Uterus weight (gm)	0.074	0.749	0.127	0.583
Hospital stay (days)	-0.124	0.593	0.045	0.846
Study group				
Blood loss (ml)			0.185	0.422
Age (years)	-0.039	0.868	-0.211	0.359
BMI [wt/(ht)^2]	-0.004	0.985	-0.178	0.440
Parity	-0.078	0.738	0.239	0.297
Operative time (min)	0.185	0.422		
Preoperative hgb (mg)	0.030	0.897	0.533	0.013*
Postoperative hgb (mg)	-0.099	0.669	0.428	0.053
Drop of Hgb (mg)	-0.123	0.595	-0.335	0.138
Uterus weight (gm)	0.350	0.120	0.617	0.003*
Hospital stay (days)	-0.166	0.472	-0.415	0.062

r-Pearson Correlation Coefficient

*p-value >0.05 is insignificant; *p-value <0.05 is significant; **p-value <0.001 is highly significant*

Intra-operative complications did not show statistically significant differences between the groups (p>0.05) **(Figure5)** and the mean hospital stay was similar between the control group and the study group (p=1.000).

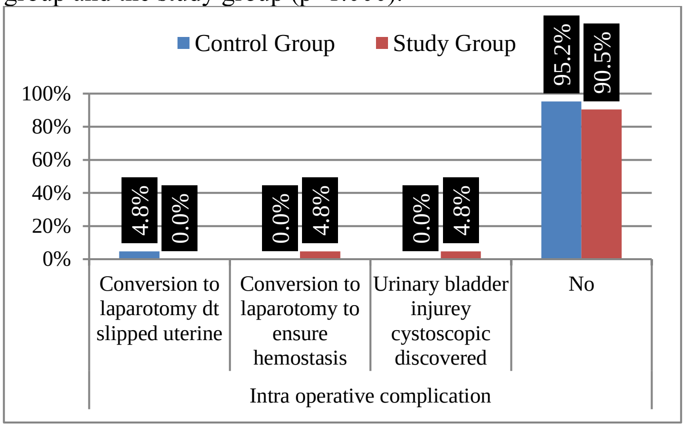

Figure (5): Comparison between groups according to intra operative complication.

Discussion

The occlusion of uterine arteries prior to total laparoscopic hysterectomy (TLH) is a technique that involves blocking the blood supply to the uterus by placing clips or sutures on the uterine arteries, which are the main blood vessels supplying the uterus. Devascularization has been shown to decrease blood loss during surgery, enhance surgical field visibility, and potentially reduce the risk of complications. Theoretically it should be beneficial in cases involving a large uterus, fibroids, or a history of heavy menstrual bleeding. [11].

In our study, we compared two groups: the first group underwent TLH with uterine artery clipping, and the second group underwent conventional TLH. The analysis of blood loss between the groups revealed no significant difference. The mean blood loss in the first group was 132.14±22.50 ml compared to 140.67±17.48 ml in the second group, with an insignificant difference (p-value > 0.05).A similar finding was reported by **Abo-Hashem et al**[9], who found no significant difference in blood loss between the two groups in their study comparing TLH with uterine clipping at its origin and conventional TLH. The mean blood loss in their study was 97.67±34.31 ml in the TLH with uterine clipping group and 104.33±39.19 ml in the conventional TLH group.

The study by **Pan et al**[12],also supports our findings, as they observed no significant difference in blood loss betweenTLH (177.2±80 ml) and TLH with coagulation of the uterine artery at its origin (154.9±30.2 ml). (p >0.05).

In contrast to our findings **Poojari et al**[6]**.** yielded dissimilar results regarding blood loss where The conventional total laparoscopic hysterectomy (TLH) group in our study exhibited a mean blood loss of 70 ml, whereas the TLH group with prior uterine artery ligation demonstrated a mean blood loss of 43 ml (p<0.001).

Similarly, **Sinha et al.**[13]reported contrasting outcomes in their study, where the total laparoscopic hysterectomy with early uterine ligation group experienced a mean blood loss of 50 ml compared to 60 ml in the classical TLH group, indicating a significant distinction (p <0.05).

Notably, **Kale et al.** [7]documented significant differences in their study, with TLH resulting in a mean blood loss of 109.38±33.03 ml, while TLH with uterine artery ligation at the beginning of surgery resulted in a mean blood loss of 47.50±8.12 ml (p <0.001).

These discrepancies may be attributed to variations in the technique employed for securing the uterine artery, as the aforementioned studies utilized uterine artery ligation instead of clipping. Additionally,the population chereacteristics,as well as,the uterine pathologies were different from our study.

Peng et al[14],presents contrasting findings regarding uterine artery occlusion during laparoscopic myomectomy (LUAO). they reported that the amount of blood loss during the LUAO +

LM group was significantly less than without occlusion (177.97 ± 104.09 mL vs 258.10 ± 119.55 mL) this significant impact of LUAO +LM may be explained by the different blood supply pattern of uterine fibroids where the blood is solely dependant on uterine artery However the case is different in case of hysterecyomy where the uterus receives its blood supply from an extensive anastomosing net work of blood vessels incorbulated not only the uteine artery but also anastomosis with vaginal,cervical and ovarian branches this might be the explanation why uteine artery occlusion in the TLH is not as effective as its in the case of laparoscopic myomectomy.

In our study, we observed a significant disparity in operative time between the study and control groups. The study group exhibited a substantially longer mean operative time of 72.76±7.05 minutes, while the control group had a mean operative time of 63.76±6.28 minutes. This discrepancy was found to be highly statistically significant ($p<0.001$). The longer operative time in the study group can be attributed to several factors. Firstly, the placement of clips required more time. Moreover, ovarian suspension and anatomical exposure of the uterine artery at its origin,discriminating it from the ureter,was rather time consuming.

Abo-Hashem et al.[9] conducted a similar study and found that TLH with prior uterine artery clipping had a mean surgery time of 48.93±8.3 minutes compared to 58.83±9.26 minutes in conventional TLH, showing a significant difference which similar to our study results.

Our findings however, differ from the study by **Poojari et al**[6],where the TLH group had a mean surgery time of 71 minutes, while the TLH with earlier uterine artery ligation group had a mean surgery time of 60 minutes, indicating a statistically significant difference between the two groups. Similarly, **Kale et al**[7],reported significant differences in their study, with TLH resulting in a mean surgery time of 99.16±7.01 minutes, while TLH with uterine artery ligation at the beginning of surgery resulted in a mean surgery time of 63.16±7.16 minutes.

The findings of the above studies that with prior uterine artery ligation were less time consuming may be attributed to the difference in occlusion technique (coagulation or ligation,rather than clippings).

During our study, a few intraoperative complications were observed in both groups. In the study group, one patient experienced an intraoperative urinary bladder injury, which was diagnosed using a cystoscope and repaired laparoscopically during the same surgical session. Additionally, one case in the study group required conversion to laparotomy to achieve proper hemostasis. In the control group, one case had to be converted to laparotomy due to bleeding caused by the slipping of the uterine artery. **Poojari et al**[6],reported similar findings, where one patient in the TLH with prior uterine artery ligation group experienced an injury to the urinary bladder**. Sinha et al.**[13] reported one patient in the classical TLH group suffering from secondary hemorrhage and vault sutures, and in the same group, two patients experienced blood loss requiring 4-unit blood transfusions.

Strengths: This study had several points of strength. Firstly, it had a well-designed protocol with proper randomization and a concealed allocation process. Additionally, the study had sufficient statistical power to detect the primary outcome of operative blood loss. Additionally, the UA occlusion technique involved the use of a non-costly, readily-available, reusable metal clip applier, which is widely used in laparoscopic cholecystectomy and appendectomy. In contrast, some other studies utilized more expensive, disposable clipping devices.

Limitations: There are several limitations to this study. Firstly, only one technique of uterine artery occlusion, specifically uterine artery clipping at its origin using a metallic clip, was implemented. Other occlusion techniques, such as clipping using hemostatic clips or temporary ligation, were not investigated. Additionally, alternative approaches to uterine artery occlusion, such as the lateral or anterior approach, were not examined in this study. Lastly, the study was not adequately powered to detect rare complications, including adverse effects.

Conclusion:TLH with prior uterine artery clipping did not effectively reduce blood loss. However, it resulted in a longer operative time compared to conventional TLH. Our study findings are consistent with some previous studies but differ from others, highlighting the need for further research and larger studies to validate these results and assess long-term outcomes.

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Author contributions: Protocol design: Professor Sabry Elsayed Hassan & Assistant professor Mohamed Hamed Abdelaziz Salma **Data collection, and analysis:** Yasmeen Ahmed Mohamed Taha, Rania Gamal Anwar Elskaan; **Manuscript writing:** Yasmeen Ahmed Mohamed Taha, Rania Gamal Anwar Elskaan, Mohamed Hamed Abdelaziz Salama, **Revision and approval:** all authors.

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