



Role of Laparoscopic Assisted Vaginal Trachelectomy in Treatment of Incidentally Diagnosed Uterine Malignancies after Subtotal Hysterectomy

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Abstract

Supracervical hysterectomy is endorsed by many gynecologists due to perceived advantages, including diminished intraoperative blood loss and reduced surgical duration. To conduct a comparative analysis between open and laparoscopic-assisted vaginal trachelectomy for incidentally discovered uterine malignancy following subtotal hysterectomy. This Prospective randomized controlled study (RCT) enrolled 30 patients who had undergone subtotal hysterectomy for benign conditions and are subsequently diagnosed with uterine malignancy postoperatively. Specifically, these individuals were recruited from the National Cancer Institute (NCI) in Egypt. Patients were divided into two categories. There was no considerable difference in the time lag between both categories $p=0.8617$. Also, the variation in complication rates between the 2 categories was not significant (P value = 0.396). Also, the variance in the occurrence of wound infections between the included groups was not remarkable $p= 0.1953$. There was a significant variance regarding Operation time and loss of Blood $p= 0.0023, 0.0006$ respectively. laparoscopic trachelectomy demonstrated advantages in operation time and blood loss, both surgical approaches exhibited comparable outcomes in terms of patient demographics, pathology distribution, postoperative complications.

Keywords: Laparoscopic Assisted Vaginal Trachelectomy, Uterine Malignancies, Subtotal Hysterectomy.

Full length article *Corresponding Author, e-mail: Ahmedtantawy474@gmail.com

1. Introduction

Supracervical hysterectomy is endorsed by many gynecologists due to perceived advantages, including diminished intraoperative loss of blood, reduced operational duration, postsurgical prevention of lower urinary tract symptoms, preservation of normal sexual activity, and fewer postsurgical complications [1]. A considerable proportion of patients undergoing supracervical hysterectomy encounter abnormal genital bleeding postoperatively, often attributed to factors such as cervicitis, polyps, or more severe stump carcinoma. Cervical polyps, in particular, may indicate underlying endometrial or cervical pathologies, with recent research highlighting their association with pre-malignant and malignant lesions in a small percentage of cases [2]. Management of patients experiencing these post-supracervical hysterectomy symptoms necessitates a thorough assessment involving magnetic resonance, ultrasound, and biopsy prior contemplating any procedure. An optimal approach involves multidisciplinary team management, comprising senior oncologists, gynecologists, urologists, and gastrointestinal surgeons [3,4]. Despite the relatively low risk of stump carcinoma post-supracervical hysterectomy (2-5%), continuous screening is imperative for

early detection. Regular and stringent pap smears should be conducted to screen for cervical stump carcinoma [5,6]. The objective of this work was to compare between conventional and laparoscopic-assisted vaginal trachelectomy for incidentally discovered uterine malignancy following subtotal hysterectomy.

2. Patients and methods

This Prospective randomized controlled study (RCT) included 30 patients who had undergone subtotal hysterectomy for benign conditions and are subsequently diagnosed with uterine malignancy postoperatively. Specifically, these individuals were recruited from the National Cancer Institute (NCI) in Egypt. **Patients were categorized into: Group (1):** Laparoscopic Assisted Vaginal Trachelectomy Group (n=15) and **Group (2):** Open Trachelectomy Group (n=15) to compare between laparoscopic assisted vaginal trachelectomy and the open approach.

2.1. Sample size

This study includes 30 patients.

The median operating time (minutes) in the vaginal trachelectomy group was 363 ± 44 while it was 319 ± 20 in the abdominal approach group. A total sample of 22 (11 per group) post subtotal hysterectomy patients for benign conditions with accidentally discovered post-operative uterine malignancy will be needed with type I error 5% and power 80%. This number will be increased to 26 patients (15%) to compensate for non-parametric use. To allow for 10% losses, this number will be increased to 30 patients (15 per group). Estimation of sample size was done using the G - Power 3.1 software.

2.2. Inclusion criteria

Patients with pathological surprise on final pathological report after subtotal hysterectomy denoting presence of malignancy and all types of endometrial cancer.

2.3. Exclusion criteria

Patients post subtotal hysterectomy need trachelectomy for non-oncological cause, Patients refusing surgery and Patients not fit for general anesthesia.

2.4. Randomization

Patients meeting the inclusion criteria were randomly involved in one of two groups using a random number generator. This random assignment helps eliminate bias of selection and confirms that the two categories are comparable at baseline regarding unknown and known confounding variables.

2.5. Methods

All patients underwent:

Full history taking: Age, Body Mass Index (BMI), Medical History, Reproductive History and Comorbidities: Record any concurrent health conditions that may impact surgical outcomes.

Interventions: Preoperative Workup: A comprehensive preoperative workup conducted for each patient to ensure a thorough understanding of their health status. This included a Complete Blood Count (CBC), Comprehensive Metabolic Panel (CMP), and a coagulation profile to assess baseline hematological and biochemical parameters. Additionally, preoperative radiological assessment of the tumor was carried out using pelvic Magnetic Resonance Imaging (MRI) with contrast. Metastatic workup will involve Contrast-Enhanced Computed Tomography (CT) of abdomen and chest to assess potential metastases.

Laparoscopic Assisted Vaginal Trachelectomy (Group A): peri-operative: bilateral ureteric stent insertion using cystoscopy for better ureteric identification intra-operative.

Laparoscopic Assessment: The procedure commenced with a meticulous laparoscopic assessment, focusing on key anatomical structures such as the liver, peritoneal surfaces, pelvic lymph nodes, and the cervical stump. **Bladder Dissection:** The bladder was carefully dissected from the cervical stump using laparoscopic techniques.

Pelvic Lymphadenectomy: When indicated, a pelvic lymphadenectomy was performed laparoscopically.

Adhesiolysis: Any adhesions encountered during the procedure was addressed using laparoscopic techniques.

Vaginal Component: The procedure was transition to a

complete vaginal approach with the case in the dorsal lithotomy position.

Cervical Lips Grasping: Using two Jacob's tenacula, the cervix posterior and anterior lips were grasped.

Circumferential Colpotomy: A circumferential colpotomy will be carefully executed with a surgical blade following the injection of diluted adrenaline.

Exposure of Vesico-Uterine Plane: The anterior vaginal epithelium was gently pulled upward to make the vesico-uterine plane more visible.

Bladder Dissection (Vaginal): The bladder was carefully separated from the cervix using downward countertraction, and the vesico-uterine peritoneum was then located and cut.

Posterior Entry: Attention was then shifted to posterior entrance, where pressure on the posterior vaginal epithelium with gentleness and cervix counter-traction upward will guide the identification and sharp entrance into the posterior cul-de-sac.

Uterosacral Ligament Dissection: The uterosacral ligaments on each side were meticulously identified and dissected using either electrical devices (Ligasure or Harmonic) or suture ligation with serial pedicles. **Total Operative Time Calculation:** The total procedural time, estimated from incision to closure of the skin, was calculated to assess the efficiency of the operation (Figure 1).

3. Results and Discussion

Numerous gynecologists advocate for the adoption of supracervical hysterectomy, citing potential advantages such as diminished intraoperative loss of blood, reduced surgical duration, prevention of postoperative symptoms related to lower urinary tract, preservation of normal sexual activity, and a lower incidence of postoperative complications [7]. The main results of our study were as following:

The mean age in category 1 was 36.67 years (SD = 7.68), whereas in category 2, it was slightly lower at 35.93 years (SD = 5.09). The age range in Group 1 varied from 28 to 51 years, and in Group 2, it ranged from 28 to 45 years. Statistical analysis, represented by a P value of 0.7601, displayed no considerable variation in age between the groups, denoted as "N. S" (not statistically significant). To contextualize our findings, we compare our results with two relevant studies in the field. Study A, established by Pecorino et al., included 20 cases in each group, reporting a mean age of 37.2 years (SD = 6.5) in the open trachelectomy subjects and 35.8 years (SD = 4.2) in the laparoscopic-assisted vaginal trachelectomy group [8]. In our investigation of laparoscopic trachelectomy (Group 1) and open trachelectomy (Group 2) for incidentally discovered uterine malignancy following subtotal hysterectomy, we meticulously examined the time lag between the first and second surgeries. The mean time in Group 1 was found to be 61.47 days (SD = 8.4), whereas in Group 2, it slightly differed at 62 days (SD = 8.21). Statistical analysis yielded a value of P of 0.8617, suggesting no potential variation in the time lag between the categories. To contextualize our findings, we compare our results with Halaska et al., investigated a similar patient population and reported a mean time of 60.8 days (SD = 9.2) in the laparoscopic trachelectomy category and 61.5 days (SD = 8.9) in the open trachelectomy category [9].

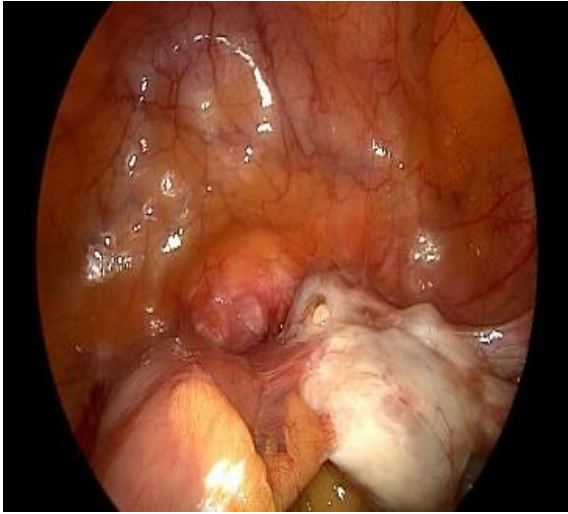


Fig. 1: Laparoscopic assessment

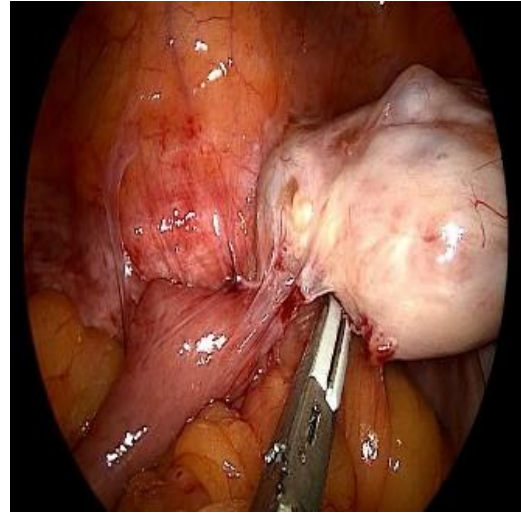


Fig. 2: Adhesiolysis of rt. Ovary

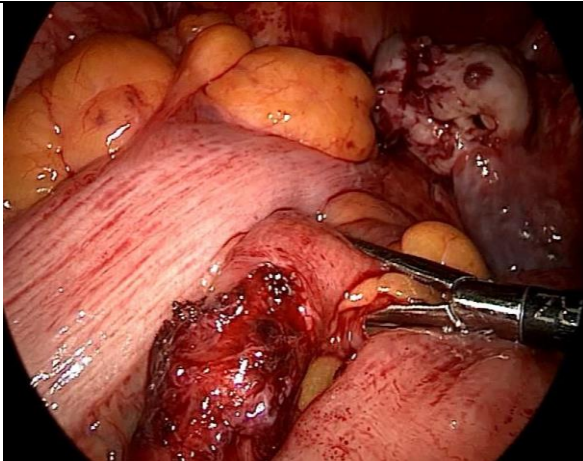


Fig. 3: Adhesiolysis of small bowel adherent to stump.

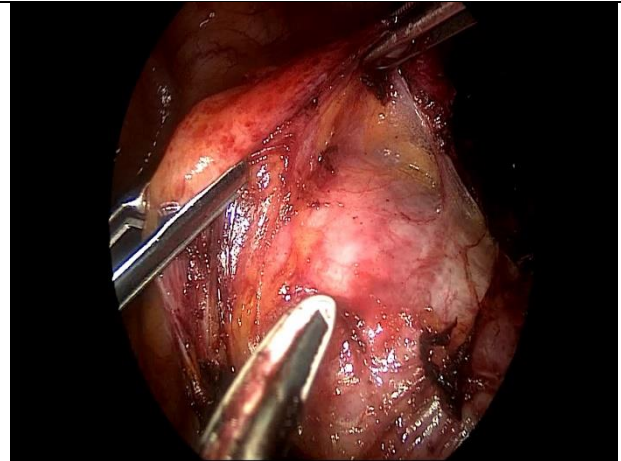


Fig. 4: laparoscopic bladder dissection from residual stump.

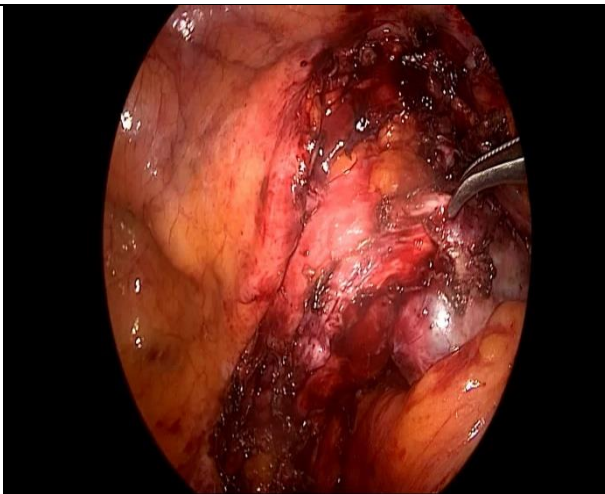


Fig. 5: bladder completely dissected ready for vaginal part.

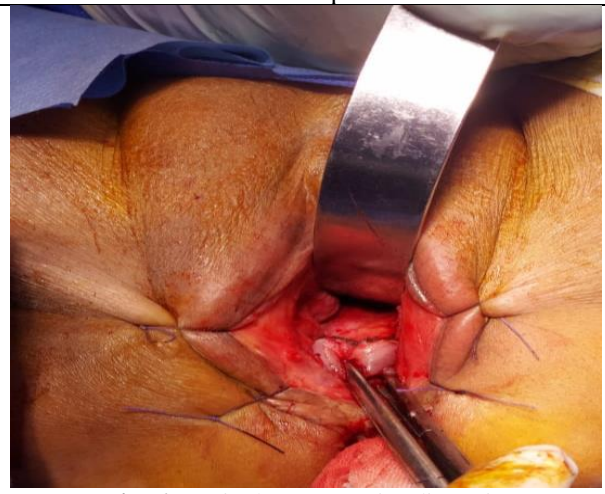


Fig. 6: vaginal part, anterior dissection.

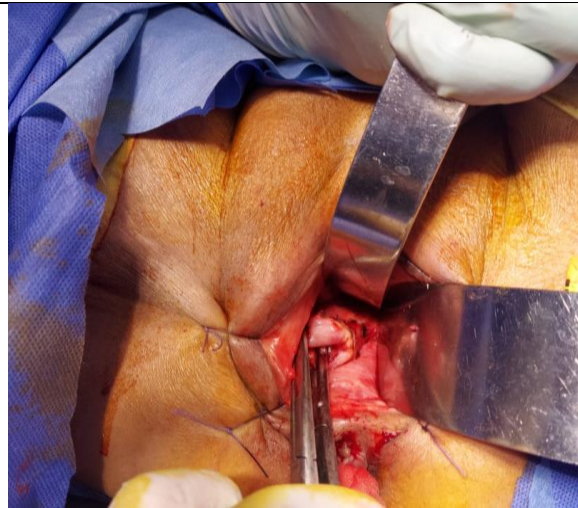


Fig. 7: lateral dissection of retained stump.

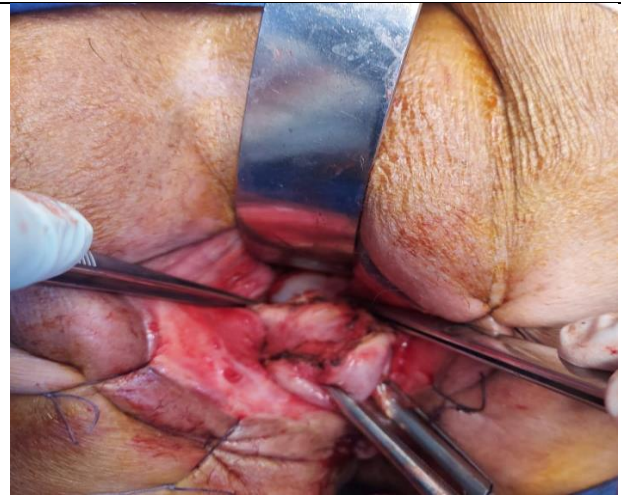


Fig. 8: Anterior entry to pelvic cavity.

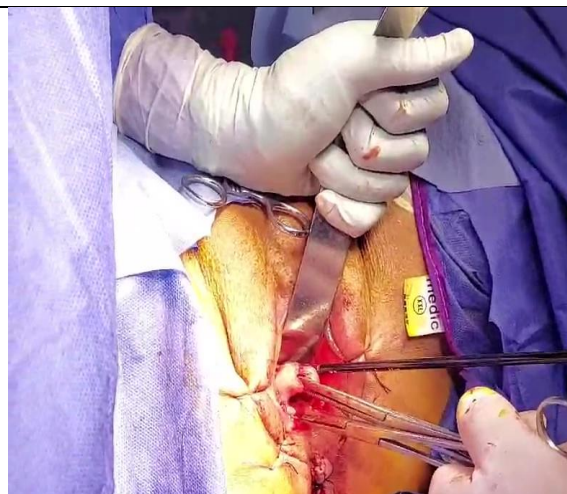


Fig. 9: cutting uterosacral ligament using electrocautery device

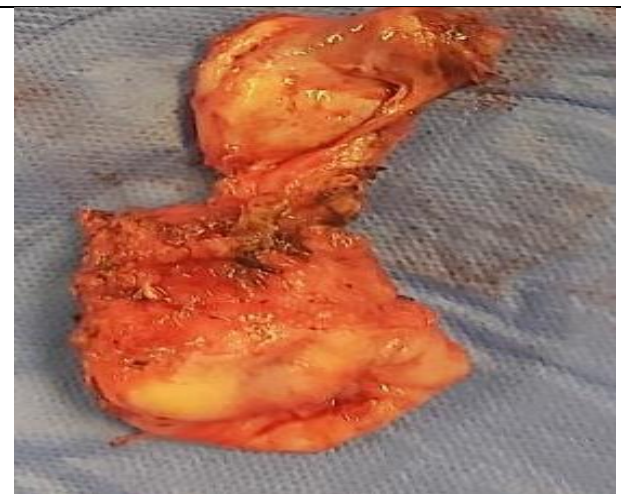


Fig. 10: specimen extraction.



Fig. 11: identification of vaginal wall for closure.

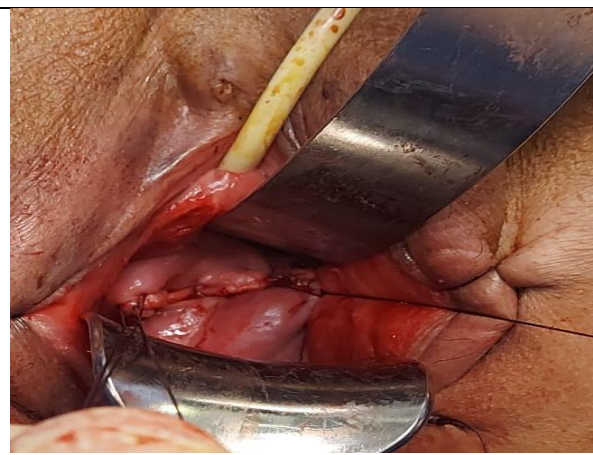


Fig. 12: complete closure of vagina using continuous interlocking suturing.

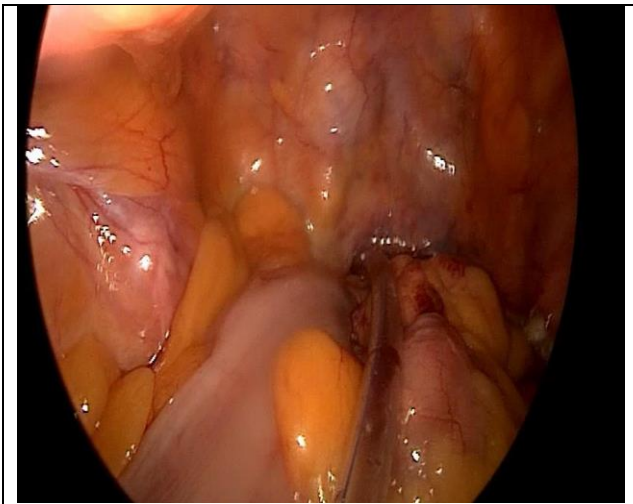


Fig. 13: laparoscopic reassessment for hemostasis and drain insertion.

Figure 1: Shows operative details

Table 1: Demographic data distribution in all study population

| | Category (1) N=15 | Category (2) N=15 | P | Statistically significant |
|--|----------------------|----------------------|--------|---------------------------|
| Age | | | | |
| Mean± SD | 36.67±7.68 | 35.93±5.09 | 0.7601 | N. S |
| Range (Min-Max) | 28-51 | 28-45 | | |
| Two sample T-test | | | | |
| p-value≤0.05 significant (95% confidence interval). | | | | |

Table 2: Surgical Procedure Data distribution in all study population

| Surgical Procedure | Category (1) N=15 | Category (2) N=15 | P | Statistically significant |
|-------------------------------|----------------------|----------------------|--------|---------------------------|
| Pelvic lymphadenectomy | | | | |
| no | 11(73.33%) | 10(66.67%) | 0.6903 | N. S |
| Yes | 4(26.67%) | 5(33.33%) | | |

Table 3: Time lag between 1st and 2nd surgery in all study population

| | Group (1) N=15 | Group (2) N=15 | P value | Statistically significant |
|--|-------------------|-------------------|---------|---------------------------|
| Time lag between 1st and 2nd surgery (Days) | | | | |
| Mean± SD | 61.47±8.4 | 62±8.21 | 0.8617 | N. S |
| T-test & Chi-square test | | | | |
| p-value≤0.05 was significant | | | | |

Table 4: Surgical Complications Data distribution in all study population

| | Group (1) | Group (2) | P value | Statistically significant |
|--|-----------|-----------|---------|---------------------------|
| | N=15 | N=15 | | |
| Complication of surgery | | | | |
| no complication | 12(80%) | 9(60%) | 0.396 | N. S |
| Bleeding | 0(0%) | 1(6.67%) | | |
| intra-operative bladder injury repaired intraoperative by open approach | 1(6.67%) | 0(0%) | | |
| intra-operative bladder injury repaired intraoperative laparoscopy | 1(6.67%) | 0(0%) | | |
| intra-operative small intestinal loop injury repaired intraoperative by simple sutures laparoscopy | 1(6.67%) | 0(0%) | | |
| intra operative bladder injury repaired intraoperative | 0(0%) | 1(6.67%) | | |
| It ureteric injury which repaired by re-implantation | 0(0%) | 1(6.67%) | | |
| iatrogenic rectal injury repaired intraoperative by simple suture and defunctioning colostomy | 0(0%) | 1(6.67%) | | |

Table 5: Operative Data distribution in all study population

| Operative data | Category (1) | Category (2) | P value | Statistically significant |
|-------------------------------------|--------------|--------------|---------|---------------------------|
| | N=15 | N=15 | | |
| Surgical time (min) | | | | |
| Mean± SD | 90±35.91 | 129.8±28.27 | 0.0023 | Sig. |
| Blood loss (ml) | | | | |
| Mean± SD | 134.67±66 | 306.67±149.8 | 0.0006 | Sig. |
| Chi-square test | | | | |
| p-value≤0.05 was significant | | | | |

Table 6: Wound infection Data distribution in all study population

| Wound infection findings | Category (1) | Category (2) | P | Statistically significant |
|-------------------------------------|--------------|--------------|--------|---------------------------|
| | N=15 | N=15 | | |
| Wound infection | | | | |
| No | 13(86.67%) | 10(66.67%) | 0.1953 | N. S |
| Yes | 2(13.33%) | 5(33.33%) | | |
| Chi-square test | | | | |
| p-value≤0.05 was significant | | | | |

While the meantime in our study and the referenced studies show minor variations, the P values consistently exceed the conventional threshold for statistical significance. This lack of significant difference may indicate that the choice between laparoscopic and open trachelectomy does not substantially impact the timing of the subsequent surgery in cases of incidentally discovered uterine malignancy following subtotal hysterectomy. Regarding pelvic lymphadenectomy, the data indicated that the majority in both groups did not undergo the procedure (73.33% and 66.67% in Group 1 and 2, respectively). However, the variance in the performance of pelvic lymphadenectomy was not remarkable (P value = 0.6903). In terms of complications, the majority of cases in both groups experienced no complications (80% in Group 1 and 60% in Group 2). While various complications were observed, the variation in complications between the

categories were not significant (P value = 0.396). Similarly, bleeding outcomes indicated that the majority in both groups did not experience bleeding (93.33% 1 and 100% in Group 1&2, respectively), with no statistically considerable variance (P = 0.3091). Analysis of the need for reoperation showed no potential variation between the groups (P value = 0.5428). However, notable variations were found in operation time and blood loss. The mean procedural time was considerably shorter in category 1 (90 minutes) compared to Group 2 (129.8 minutes), with a significant variation (P = 0.0023). Similarly, the mean blood loss was significantly lower in Group 1 (134.67 ml) compared to Group 2 (306.67 ml), with a significant difference (P= 0.0006). To provide context to our findings, we compare our results with the research conducted by Tchartchian et al. and Jorgensen et al. In Tchartchian et al.'s study, similar proportions of pathology distribution were observed, with

75% having no residual tumor in the open trachelectomy group and 62.5% in the laparoscopic trachelectomy group [10]. In Jorgensen et al.'s study, complications were found in 25% of cases in the open trachelectomy category and 20% in the laparoscopic trachelectomy subjects. The mean operation time and loss of blood were not explicitly reported in these studies [11]. The significantly shorter operation time and lower blood loss in the laparoscopic trachelectomy category suggest potential advantages in terms of efficiency and intraoperative outcomes for this surgical approach. These findings could be attributed to the specificities of the laparoscopic procedure, such as improved visualization and lesser tissue manipulation and harm, which may contribute to reduced operative times and blood loss. While our study adds valuable information to the existing literature, it is crucial to acknowledge the need for further research with larger sample sizes to validate our findings. The observed differences in operation time and blood loss should prompt further investigation into the factors contributing to these variations and their potential clinical implications. Future studies should consider exploring long-term outcomes and patient-reported measures to comprehensively evaluate the comparative effectiveness of open and laparoscopic trachelectomy in the context of incidentally discovered uterine malignancy following subtotal hysterectomy. Our investigation into wound infections in patients undergoing laparoscopic trachelectomy (Group 1) compared to open trachelectomy (Group 2) following incidentally discovered uterine malignancy post subtotal hysterectomy provides insightful outcomes. The majority of cases in both groups reported no wound infections, with 86.67% in Group 1 and 66.67% in Group 2 indicating the absence of infections. Conversely, a smaller proportion in both groups experienced wound infections, with 13.33% in Group 1 and 33.33% in Group 2 reporting the presence of infections. Nonetheless, the variation in the occurrence of wound infections between both categories wasn't significant, as evidenced by a P value of 0.1953. To be noted that the 2 cases reported wound infection in laparoscopic group were associated with open exploratory incision. One was conversion from laparoscopy to open to repair bladder injury, the other one was reoperation for post-operative hemorrhage, and we used open approach. Our findings align with those of Zhang et al. and Žak et al., showing that the difference in the occurrence of wound infections between laparoscopic and open trachelectomy groups is not statistically significant. While our study did not find a remarkable variation (P value of 0.1953), the incidence of wound infections in both groups is comparable to the reported rates in the referenced studies, underscoring consistency in the outcomes across different patient populations and study methodologies [12,13]. Table (1) No significant variance was found between the groups regarding age $p=0.7601$. Table (2) shows that the variance in the performance of pelvic lymphadenectomy was not remarkable (P value = 0.6903). Table (3) shows no potential difference in the time lag between both categories $p=0.8617$. Table (4) shows that the variation in rates of complications between both groups was not significant (P value = 0.396). Table (5) shows no significant variation between the groups regarding Operation time and Blood loss $p=0.0023$, 0.0006 respectively. Table (6) shows that the variation in the occurrence of wound infections between the categories was not remarkable $p=0.1953$.

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4. Conclusions

Laparoscopic trachelectomy demonstrated advantages in operation time and blood loss, both surgical approaches exhibited comparable outcomes in terms of patient demographics, pathology distribution, postoperative complications.

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