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Comparative Study between Laparoscopic and Open Modified Radical Hysterectomy in Early-Stage Cervical Cancer

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ABSTRACT

Background: Radical hysterectomy is the standard surgical approach for treatment of early-stage cervical cancer. The debate still exists whether laparoscopic or open surgery is the best. This study aimed to compare the feasibility, the intra-operative and immediate postoperative outcomes in patients who undergo modified open radical hysterectomy and laparoscopic radical hysterectomy in early-stage cervical cancer. **Methods:** A prospective comparative trial included 34 patients with early stage cervical cancer stage IA2 to IIA, divided to two equal groups 17 patient each; group (A) underwent open radical hysterectomy and group (B) underwent laparoscopic radical hysterectomy. **Results:** Mean operation time was longer in group B (268.52±41.9 min vs. 200.35±57.55 min), Blood loss and HB defect were significantly higher in group A (521.76±152.7 ml vs. 274.0±61.05 ml), and (1.87±0.58 gm/dl vs. 0.82±0.27 gm/dl). Hospital stay and Pain score were significantly longer in group A than B, also intra-operative complications; were significantly higher in group A. **Conclusion:** Conventional open radical hysterectomy has shorter operative time than laparoscopic hysterectomy but with more intraoperative and immediate post-operative complications.

Keywords: Radical Hysterectomy; Early Stage; Cervical Cancer; Laparoscopic hysterectomy.



INTRODUCTION

Cervical cancer is the most common cause of cancer death in women all over the world and comes in the fourth place in rank of the most common diagnosed cancers among women [1]. The standard treatment for patients diagnosed with early-stage cervical cancer who do not want to preserve fertility is radical hysterectomy associated with pelvic lymphadenectomy [2]. Modified radical hysterectomy removes the cervix, proximal vagina, and parametrial and paracervical tissue between the uterus and the ureter with removal of the uterosacral ligament midway between the rectum and uterus with resection of upper 2cm of vagina. This maneuver is well suited for tumors in patients with stage IA1 cervical cancer [3]. On the other hand laparoscopically assisted radical

hysterectomy with lymphadenectomy had shown more advantages over the open surgical approach such as; lower blood loss, shorter hospital stay, and better quality of life for patients [4]. Several previous studies had suggested that both approaches the laparoscopic surgery and the open surgery showed matched short and long oncologic outcomes [5-9]. Depending on these studies, laparoscopic radical hysterectomy became the standard of treatment for early-stage cervical cancer especially in well-equipped centers with well-trained specialists [10-11]. Unexpectedly, a recent prospective, international trial, demonstrated that increase rate of recurrence and decrease survival rate were associated with minimally invasive surgery (laparoscopic and robotic) as compared with open surgery in patients with early stage cervical

cancer [12]. In addition, a large retrospective study including 2461 patients from the National Cancer Database (NCDB) had shown a similar unfavorable risk of cancer death in minimally invasive surgery group [13]. The current National Comprehensive Cancer Network (NCCN) guidelines and European Society of Gynecological Oncology (ESGO) guidelines recommends open radical hysterectomy as the standard surgical approach for treatment of early-stage cervical cancer⁽²⁾. The debate still exists whether laparoscopic or open surgery is safer with better outcome for patients with early stage cervical cancer. Therefore, we aimed to compare the feasibility, the intra-operative and immediate postoperative outcomes in patients who undergo modified open radical hysterectomy and patients who undergo laparoscopic radical hysterectomy in early-stage cervical cancer.

PATIENTS AND METHODS

This is a prospective nonrandomized operative trial that was held in Obstetrics and Gynecology Department, at Zagazig University Hospitals, Egypt and Egyptian National Cancer Institute between March 2016 and April 2020. The study included 34 patients aged between 30 to 60 years and diagnosed as cervical cancer stage IA2 to IIA by examination under general anesthesia, cervical biopsy and radiological studies. Patients were allocated into two equal groups; group (A) underwent open modified radical hysterectomy (ORH), and group (B) underwent laparoscopic radical hysterectomy (LRH). Patients were excluded if they had; stage of the disease more than IIA, associated with other malignancies, previously treated by surgery, radiotherapy or chemotherapy and /or medical conditions contraindicating laparotomy or laparoscopy. Written informed consent was obtained from all participants with explanation of the management strategy, possible hazards and follow up plan. The study was approved by the research ethical committee of Faculty of Medicine, Zagazig University with Institutional review board (IRB) number (2684). The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

All patients were subjected to full history taking, complete physical and gynecologic examination, radiological imaging by pelvi-abdominal

ultrasound, CT scan and/or MRI and chest radiography. Routine preoperative laboratory investigations such as; CBC, coagulation profile, fasting blood glucose, hepatitis markers screening, liver and kidney function tests, ECG and Staging (clinical and radiological) by preoperative examination under general anesthesia. The patient's assigned stage was based on the clinical staging set by the International Federation of Gynecology and Obstetrics (FIGO) [14].

Method of intervention was adopted according to patient's desire after a thorough explanation and description of the planned procedure, its potential risks and benefits, and the possibility of conversion to laparotomy in the laparoscopic group. Patients are informed that general anesthesia will be used with proper explanation of the procedure and its risks by the anesthesiologist. Each patient in the modified LRH group will be matched to one patient in the modified ORH group using the following matching criteria: Age group (5 years interval), tumor size, tumor stage. Modified (ORH) was done under general anesthesia. We started our procedure with midline incision that extended from the umbilicus to symphysis pubis then the peritoneal cavity was explored for any metastasis, cutting and ligation of round and infundibulopelvic ligaments was done which allowed us to open the pelvic spaces then pelvic lymphadenectomy and uterine artery ligation at its origin was done with deroofting of the ureter and cutting of Mackenrodt's ligament. Lastly the uterus, cervix and upper 3 cm of vagina were excised. On the other hand in Modified (LRH) we started by opening of 10mm incision for primary entry just below the umbilicus then two additional 10 mm incisions were done for secondary trocars. These trocars were placed lateral to the inferior epigastric vessels approximately two fingerbreadths above the pubis then the same steps for modified ORH was done using Ligasure vascular sealing system (figure 1). Data were collected on both the laparoscopic cases and the matched open cases. These data included patient age, body mass index (BMI), tumor histological characteristics, length of removed vagina, number and positivity of lymph nodes. Additionally, we collected operative outcomes including operating time, conversion to laparotomy, transfusion

requirement, operative complications and intraoperative blood loss (in laparotomy group as 150 cc of blood in soaked towel and 5 cc of blood in soaked sponge in addition to the amount of blood in the suction container, while in laparoscopy the blood loss was estimated by the amount in the suction container after subtracting the amount of fluid used for washing). Postoperative follow-up included postoperative wound infections, length of stay in hospital, postoperative twelve hours pain score according to revised face pain scale (figure 2), intestinal injury, bladder injury, vascular injury, ureteric injury, 2ry suture and mortality.

STATISTICAL ANALYSIS

Data collected, coded, entered, and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 24.0) software for analysis. According to the type of data qualitative represent as number and percentage, quantitative continues group represented by mean \pm SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi square test (X^2) or Fisher. Differences between quantitative independent groups by t test when normally distributed or Mann Whitney U test when non-normally distributed, P value was set at <0.05 for significant results & <0.001 for high significant result.

RESULTS

This study included 34 patients divided into two groups 17 patients each. The mean age of group A (open radical hysterectomy) was 48.82 ± 8.99 years and the mean age of group B (laparoscopic radical hysterectomy) was 53.11 ± 11.81 years with no significant difference between them, while the mean BMI of group A (ORH) was 29.11 ± 5.79 kg/m² and the mean BMI of group B (LRH) was 27.88 ± 6.5 kg/m² with no significant difference between groups (table 1).

In group A modified (ORH), 6 cases were diagnosed as adenocarcinoma and 11 cases

were squamous cell carcinoma diagnosed by biopsy before the operation and 10 cases were stage 1A2 and 7 cases were stage 1B1 diagnosed by examination under anesthesia, while in Group B modified (LRH), 4 cases were diagnosed as adenocarcinoma and 13 cases were squamous cell carcinoma diagnosed by biopsy before operation and 4 cases were stage 1A2 and 13 cases were stage 1B1 diagnosed by examination under anesthesia, there was no statistically significant difference regarding histological classification and staging between both studied groups (table 2).

Regarding operative characteristics, the mean number of removed LNs was 13.52 ± 5.25 in group A with median number of 13 ranged from 6 to 22 LNs whereas, in group B the mean number was 11.11 ± 3.8 with 12 LNs as a median ranged from 4 to 18, with no statistically significant difference between them. The mean Length of removed vagina was 3.5 ± 0.25 cm and 2.5 ± 0.5 cm in group A and B respectively with no significant difference between them (table 3).

Mean operation time was significantly longer in group B (268.52 ± 41.9 min) than group A (200.35 ± 57.55 min), Blood loss was significantly higher in group A (521.76 ± 152.7 ml) while in Group B (274.0 ± 61.05 ml), also deficiency in HB was significantly higher at Group A (1.87 ± 0.58 gm/dl) than group B (0.82 ± 0.27 gm/dl). Hospital stay was significantly longer in group A (7.11 ± 5.02 days) than group B (3.82 ± 1.12 days) also Pain score was significantly higher in group A than B (6.7 ± 2.11 vs. 3.64 ± 1.2) respectively (table 4).

As regards intra-operative complications; vascular injury, Wound infection, Blood transfusion, Mortality and 2ry suture were significantly higher in group A than group B as shown in (table 5).

Table (1): Age and Bmi Distribution Between Studied Groups

VARIABLE	GROUP A (N=17)	GROUP B (N=17)	T	P
AGE	48.82±8.99	53.11±11.81	1.193	0.242
BMI KG/M2	29.11±5.79	27.88±6.5	0.584	0.563

T= STUDENT T TEST, BMI= BODY MASS INDEX

Table (2): Histological Findings and Stage Distribution Between Studied Groups

VARIABLE		GROUP (A)		GROUP (B)		X ²	P
		NO.	(%)	NO.	(%)		
HISTOLOGY	ADENOCARCINOMA	6	35.2%	4	23.6%	0.56	0.45
	SQUAMOUS CELL CARCINOMA	11	64.8%	13	76.4%		
STAGE	1A2	10	58.8%	13	76.4%	1.21	0.27
	1B1	7	41.2%	4	23.6%		

X²= CHI SQUARE TEST

Table (3): Ln Removal and Length of Vagina Removed Distribution Between Groups

VARIABLE	GROUP A (N=17)	GROUP B (N=17)	TEST	P
LN REMOVAL MEAN±SD MEDIAN(RANGE)	13.52±5.25 13.0 (6-22)	11.11±3.8 12.0 (4-18)	1.532*	0.135
LENGTH OF VAGINA REMOVED IN CM	3. 5±0.25 CM	2. 5±0.5 CM	1.4**	0.46

*=MANN WHITNEY TEST, **= STUDENT T TEST, LN= LYMPH NODES

Table (4): Comparison Between Both Groups in Intraoperative and Postoperative Criteria

VARIABLE	GROUP A (N=17)	GROUP B (N=17)	T	P
OPERATION TIME BY MINUTES	200.35±57.55	268.52±41.9	3.261	0.002*
BLOOD LOSS(ML)	521.76±152.7	274.0±61.05	6.111	0.00**
HB DEFICIENT (GM/DL)	1.87±0.58	0.82±0.27	3.016	0.008*
HOSPITAL STAY (DAYS)	7.11±2.02	3.82±1.12	2.345	0.00**
PAIN SCORE	6.7±2.11	3.64±1.2	4.737	0.00**

T = STUDENT T TEST, * = P<0.05 =SIGNIFICANT TEST, ** P<0.001 = HIGHLY SIGNIFICANT TEST.

Table (5): Complication Distribution Between Studied Groups

COMPLICATION	GROUP A		GROUP B		CHI SQUARE OR FISHER	P
	NO.	(%)	NO.	(%)		
BLADDER INJURY	2	11.6%	1	5.8%	5.9‡	0.01*
VASCULAR INJURY	3	17.6%	1	5.8%	5.9‡‡	0.01*
WOUND INFECTION	7	41.1%	0	0.0%	57.1‡‡‡	0.00**
CONVERSION TO LAPAROTOMY			3	17.6%		
BLOOD TRANSFUSION	17	100.0%	10	58.8%	5.9‡‡‡	0.00**
MORTALITY	1	5.8%	0	0.0%	3.94‡	0.048*
2RY SUTURE	3	17.6%	0	0.0%	45.2‡‡‡	0.00**
TOTAL	17	100.0%	17	100.0%	----	-----

‡ FISHER’S EXACT TEST, ‡‡= CHI SQUARE TEST, * = P<0.05 =SIGNIFICANT TEST, ** P<0.001 = HIGHLY SIGNIFICANT TEST

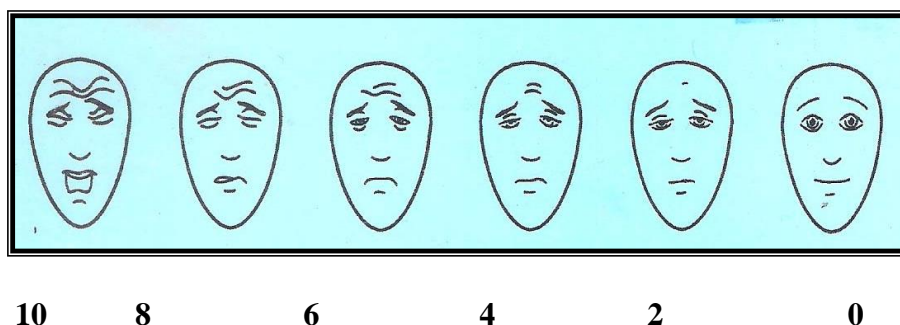


Figure (1) Revised Faces Pain Scale (R-FPS)



Figure (2) Ligasure vascular sealing system

DISCUSSION

In this study the mean age of group A (ORH) is 48.8 years while the mean age for group B (LRH) is 53.1 with no significant difference between both groups. In the study of Frumovitz et al.[15] the mean age group was 42.5 for group A (ORH) and 40.8 years for group B (LRH) while in Malzoni et al. [16] study the mean age for group A(ORH) 40.5 while in group B (LRH) it was 42.7 years, so the mean age group in our study is higher than

the mean age group of the different studies. The mean BMI for group A (ORH) is 29.11 kg/m² while the mean BMI in group B (LRH) is 27.88kg/m² with no significant difference between them. However, in the study of Park et al.[17] the mean BMI for the first group (ORH) is 23.7 kg/m² and for the second group (LRH) is 23.1 kg/m² also in the study of Taylor et al. [18] The mean BMI in the first group (ORH) is 24.1 kg/m² while in the second group (LRH) it is 23.4 kg/m², so the BMI of the cases

of our study is relatively higher due to different lifestyles of population of different studies. In this study, the mean operative time in minutes in Group A (ORH) was 200.35 ± 57.55 minutes being significantly shorter than Group B (LRH) that was 268.52 ± 41.9 minutes. It deserves mentioning that the operative time in laparoscopic group showed considerable shortening with repetition of cases and progression in the learning curve, starting by 280 minutes in the first case and declining to reach 220 minutes in the last case. So the operative time of ORH in this study was shorter and that reported by Bogani et al. [19] (245 ± 21 min), but it is longer than the operative time reported by Malzoni et al. [16] (145 min) and similar to the operative time reported by Taylor et al. [18]. The operative time in the second group (LRH) is shorter than that reported by Frumovitz et al. [15] (344 ± 45 min), but longer than that reported by Park et al. [17] (221 ± 41 min) and also reported by Taylor et al. [18] (231 min). In most of the studies the operative time of laparoscopic radical hysterectomy is longer than that of open radical hysterectomy due to more difficult preparation and accurate, precise steps done by laparoscopy and it needs a long learning curve [20]. The mean amount of Blood loss was significantly higher in group A as it was distributed as 521.76 ± 152.7 ml while in Group B only 274.0 ± 61.05 ml. Regarding blood loss in the conventional (ORH) group, there is a wide variation between the literatures the mean blood loss in this study was more than that reported by park et al. [17] (400 ml), while it was less than that reported by Lee et al. [21] (836 ml).

Regarding mean blood loss in the laparoscopic group (LRH), it was less than that reported by Frumovitz et al. [15] (319 ml) and Nam et al. [22] (379 ml).

As a consequence of blood loss, the mean hemoglobin deficit 12 hours after surgery was significantly lower in LRH group 0.82 ± 0.27 gm/dl than conventional ORH group 1.87 ± 0.58 gm/dl, this finding is similar to that found by Malzoni et al. [16] as the mean HB deficit in the conventional (ORH) group is 1.1 gm/dl and the mean HB deficit in the (LRH) group is 0.5 gm/dl and also the results found by park et al, [17] in which the mean HB

deficit in the (LRH) group is 0.7 gm/dl and the mean HB deficit in the (ORH) group is 1.9 gm/dl.

In this study the number of the lymph nodes removed in (ORH) is 13.52 ± 5.25 slightly larger than the number removed in (LRH) which is 11.11 ± 3.8 , also length of vagina removed was distributed as 3.5 ± 0.25 cm and 2.5 ± 0.5 cm respectively between groups that may be due to better exposure in the open group and lack of sufficient experience with the laparoscopic approach, but this goes with the results of the study performed by Taylor et al, [18] in which the mean number of lymph nodes removed in (ORH) group is 13.9 and in the (LRH) group is 11.2 but actually most of the results of similar studies show larger number of the lymph nodes removed as the study performed by Frumovitz et al, [15] the mean number of L.N removed in (ORH) group is 19.6 and in (LRH) is 13.2, so that difference between this study and other studies may be due to lack of sufficient experience and facilities. However, in the current study no difference in pathologic specimens with respect to vaginal cuff obtained from both groups.

The mean duration of hospital stay in conventional (ORH) group was significantly longer (7.11 ± 2.02 days) than that in the (LRH) (3.82 ± 1.12 days), that may be due to less wound infection, less intraoperative complication, less pain score and early intestinal motility in the (LRH) group than (ORH) group. Almost all the results of all studies show less hospital stay in the laparoscopic group than the open group as the study of Bogani et al, [19] at which the mean hospital stay was 8 ± 1.3 days in (ORH) and 4 ± 2.03 days in (LRH) group, also Malzoni et al, [16] show the mean hospital stay in (ORH) group is 7 days (4-9 days) and 4 days (3-7 days) in (LRH) group, so the hospital stay in the (ORH) group in our study is much longer than other studies due to possibility of wound infection that necessitated secondary suture in 2 cases.

As it can be seen from the complication rate, there were no major postoperative complications in the laparoscopic group which gave the impression of safety of this strategy. This can be ascertained by Chalkoo et al, [23]

who confirmed in their study that this strategy is safe.

Pain score after 36 hours observation was significantly higher in the (ORH) group (6.7 ± 2.11) than the (LRH) group (3.64 ± 1.2) mostly due to less manipulation, smaller laparoscopic entry incisions than midline incision, less incidence of wound infection in laparoscopic group, less intra and postoperative complications. These results are similar to that reported by Campos et al, [24], who reported that pain score in the (ORH) group was (5.8 ± 2.01) and in the (LRH) group was (2.45 ± 2.2)

Regarding intraoperative and postoperative complications, there was no intestinal injuries in both groups, similar to that reported by Frumovitz et al, [15] bladder injuries in the (ORH) group was (11.6%) (2 cases) and in (LRH) group was (5.8%) (one case), approaching to that reported by Park et al, [17] (12% in the open group and 2% in the laparoscopic group, vascular injury the (ORH) group was (17.6%) and in (LRH) group was (5.8%). Vascular injury in the ORH group was in the form of; injury to external iliac vein in one case that necessitated vascular surgeons' interference, injury of internal iliac artery in one case that necessitated its ligation, and injury of uterine artery during opening of the paravesical space that necessitated ligation of internal iliac artery. While vascular injury in the LRH group was in one case in the form of injury of the internal iliac artery that necessitated conversion to laparotomy and its ligation. Vascular injuries in both groups were more than that reported by Taylor et al, [18] (5% in (ORH) group and 2% in (LRH) group). In this study conversion to laparotomy was done in 3 cases (17.6%) less than that reported by Li et al, [25] (4%), conversion to laparotomy was done in that 3 cases due to; injury of Internal iliac artery that necessitated exploration and its ligation, injury of urinary bladder and difficulties in the operative technique. So that high incidence of conversion to laparotomy mostly due to lack of sufficient experience regarding dealing with the complications by laparoscopic approach and lack of experience about laparoscopic suturing and lack of facilities and equipment.

Blood transfusion was done in all cases of (ORH) group and 58% of cases in the laparoscopic group, this was more than that reported by Lee et al, [21] and Bogani et al [19]. One case died post operatively in the (ORH) group due to extensive vascular injury (injury of external iliac vein with re-exploration and repair of the injury by vascular surgeons) and no mortality in the laparoscopic group. About 41% of the cases in ORH group had wound infection from those 17.6% needed secondary suture with no wound infection in the laparoscopic group which represented a great advantage. The percent of the cases with wound infection in ORH group in our study is higher than that in the study of Park et al, [17] (33%) and less than the study of Campos et al, [24] (50%). High rate of wound infection was mostly due to large midline incision and more blood loss in ORH group.

CONCLUSION

Conventional open modified radical hysterectomy took slightly shorter operative time than laparoscopic modified radical hysterectomy but had more intraoperative blood loss, increased HB deficit, increased the need for blood transfusion, more postoperative pain scoring and longer hospital stay, with increased incidence of wound infection and the need of secondary suture.

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