

Total Laparoscopic Hysterectomy versus Total Abdominal Hysterectomy in Women with Endometrial Neoplasia; Randomized Controlled Clinical Trial

Original
Article

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ABSTRACT

Background: Laparoscopic hysterectomy is minimally invasive surgery in the management of endometrial neoplasia and its safety and efficacy has nearly the same rate of complications in comparison with abdominal hysterectomy with less intraoperative blood loss and less postoperative pain.

Aim of the Work: To compare operative time between total laparoscopy hysterectomy with bilateral salpingoophorectomy (TLH+BSO) versus total abdominal hysterectomy and bilateral salpingoophorectomy (TAH+BSO) in women with endometrial neoplasia.

Patients and Methods: The current study was conducted in Ain-Sham University Maternity Hospital during the period between January 2017 to May 2018. It included a total number of 52 women recruited from outpatient gynecology clinic. All were complaining of premenopausal or postmenopausal bleeding and diagnosed as having endometrial hyperplasia or endometrial carcinoma.

Results: On comparing both groups, there was no significant difference between total operative time between both groups but, TLH with BSO had more prolonged operative time than TAH with BSO, there was significant decrease in intraoperative blood loss, post-operative pain and less post-operative pelvic pain in TLH group. There were no significant difference regarding intra or post-operative complications, need for blood transfusion, hospital stay and post-operative return to daily activities or sexual satisfaction.

Conclusion: Laparoscopic hysterectomy proved safety and efficacy in the management of endometrial neoplasia either endometrial hyperplasia or malignancy with no significant difference regarding operative time with less intraoperative blood loss and postoperative pain with same rate of complications as abdominal route.

Key Words: Endometrial neoplasia, total abdominal hysterectomy, total laparoscopic hysterectomy.

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INTRODUCTION

Minimally invasive surgery has progressed in many surgical disciplines over the last three decades in gynecologic oncology, and the ability to perform complete laparoscopic staging procedures have allowed minimally invasive surgery to serve a greater role in the treatment of women with gynecologic cancers^[1].

Endometrial hyperplasia (EH) is a pre-cancerous, non-physiological, non-invasive proliferation of the endometrium. Currently, the incidence of EH is indistinctly reported to be around 200, 000 new EH cases per year in Western countries^[2].

The treatment of endometrial hyperplasia depends on its type; simple endometrial hyperplasia, medical treatment

in the form of progesterone therapy usually is enough. However, atypical hyperplasia, hysterectomy with or with bilateral salpingoophorectomy is preferred if no response to medical treatment or patient completed her family either by abdominal approach or laparoscopic approach^[3].

Endometrial cancer is the third most common cancer in women in Western countries, accounting for 6–9% of their cancers, with a peak incidence at the age of 55–65 year "about 90% of cases". The incidence increases in obese women and 70% of the patients have a high body mass index (BMI > 25k.g/m²) and 50% have co-morbidity such as diabetes and cardiovascular disease. A total of 75% of the patients are diagnosed with stage I disease^[4].

Traditionally standard treatment for patients with early stage (stage 1&2) endometrial cancer (EC) is total

abdominal hysterectomy and bilateral salpingo-oophorectomy (TAH+BSO) with or without lymph node dissection through a Pfannenstiel incision. While TAH is an accepted effective treatment, it is highly invasive and associated with adverse events such as blood loss and wound problems^[5].

Laparoscopy in early stage endometrial cancer is a minimal invasive technique compared to the standard approach by laparotomy. In several retrospective and prospective studies it has been shown that the laparoscopic approach is an effective and safe alternative to the open procedure. Most of these studies show a significant reduction in treatment related morbidity, with shorter hospital stay, less post operative pain and quicker return to activities in daily life with the laparoscopic approach compared to laparotomy^[6].

Despite the potential benefits of laparoscopic hysterectomy for endometrial cancer, a number of questions remain unanswered. First, data suggest that adoption of laparoscopy has been slow because some patients do not have access to the technology. Second, the majority of data reported have come from highly experienced surgeons and centers. Although informative, the same results may not be generalizable when the procedure is performed by less experienced surgeons^[7].

PATIENTS AND METHODS

A randomized controlled study was performed at Ain Shams University Maternity Hospital from January 2017 to May 2018. It included total number of 52 patients who attended the gynecology out patient clinic and were planned to undergo hysterectomy for endometrial neoplasia according to the following inclusion criteria: presence of a uterine neoplasia e.g: early stage endometrial carcinoma stage 1&2 and endometrial hyperplasia either simple endometrial hyperplasia or complex endometrial hyperplasia with or without atypia, complaining of premenopausal and postmenopausal bleeding and patient who had BMI < 29 kg/m² cardio-pulmonary problems and end stage endometrial carcinoma stage 3 & 4 were excluded from the study.

Study procedure

All patients included in the study were evaluated as the following full patient history, clinical examination including her BMI, Breast examination, abdominal examination and local gynecological examination followed by preoperative laboratory investigations, imaging (TVUS for endometrial thickness and MRI for lymph node assessment and exclude distal metastasis in cases of endometrial carcinoma), pap smear, endometrial biopsy and preoperative echocardiography & ECG if needed.

After approval of the ethical committee, a detailed explanation of the procedure was informed to the participant and after her approval to involve in the study, an informed consent was taken. Selected patients were divided into two groups each one included 26 patients using computer generated randomization sheet using Generated using MedCalc© version 13.

All patients in TLH group had General anesthesia and 20 out of 26 patients in abdominal hysterectomy had spinal anesthesia. Pre-Anesthesia medications: all patients received intravenous antibiotics 30 minutes before induction of anesthesia (Cefotaxime 1gm). Examination under anesthesia: the following items were assessed: Size, direction, symmetry, mobility of the uterus and any adnexal mass.

All patients were evaluated for the following

1) Operative time

Total operative time was calculated from skin incision till closure of the vault and excluding time of concomitant surgical procedures e.g. sacrospinous fixation or repair of bladder or intestinal injury.

Operative time was measured in minutes using stopwatch.

2) Intraoperative blood loss

Estimated by calculating amount of blood in the suction bottle or number of soaked gauzes and towels (soaked gauze = 20 ml blood; soaked towel = 150 ml; semi soaked towel = 75 ml).

3) Intra-operative complications

Including need for blood transfusion, need for secondary laparotomy in either group, and bowel, bladder or ureteric injury.

4) Postoperative hospital stay

Hospital stay was identified for each case and in case of delayed discharge the cause was documented. Patients were discharged according to the following criteria: stable general condition, wound was clean; patient was open bowel, removal of intraperitoneal drains, urinary bladder catheter and \ or vaginal pack and patients passed urine freely after removal of vaginal pack.

5) Postoperative pain

Postoperative pain was assessed using a linear 10-cm visual analogue scale, ranging from 0 (no pain) to 10 (severe pain) at least 6 hours post-operative.

6) Postoperative complications

Morbidities e.g.vaginal vault hematoma or pelvic hematoma or abscess, surgical site infection within 30 days, urinary tract infection,need for post-operative blood transfusion,postoperative bowel or urinary tract complications and medical complications e.g. venous thromboembolism, sepsis and shock.

7) Post operative follow up

All patients were followed up after 1 and 3 months as regard developing any abnormal rectal pain, urinary symptoms or sexual dissatisfaction and occurrence of any vaginal bleeding or pelvic pain, abdominal and pelvic examination and assessment of Quality of Life by gathering the following data: Pain, sexuality and additional homecare were assessed after 1 to 3 months after the operation.

Statistical Methods

Data were analyzed using IBM© SPSS© Statistics version 23 (IBM© Corp., Armonk, NY) and MedCalc© version 18.2.1 (MedCalc© Software bvba, Ostend, Belgium).

Normally distributed numerical variables were presented as mean \pm SD and inter-group differences were compared using the unpaired t test.

Skewed numerical data were presented as median and interquartile range and between-group differences were compared using the Mann-Whitney test.

Nominal variables were presented as number and percentage and differences were compared using the Pearson chi-squared test or Fisher's exact test. Ordinal data were compared using the chi-squared test for trend.

Two-sided *p-values* <0.05 were considered statistically significant.

RESULTS

A total number of 52 women recruited from outpatient gynecology clinic were enrolled in our study. The process of recruitment and handling the study population during the course of the study according to the CONSORT (CONsolidated Standards of Reporting Trials) 2010 guidelines.

Fifty-two patient underwent total hysterectomy, 26 patients underwent total laparoscopic hysterectomy and 26 patient underwent total abdominal hysterectomy, both groups had no statistical significant difference in demographic data as regards (age), (parity) and (body weight) as shown in (Table 1).

Indications of hysterectomy in our study were abnormal uterine bleeding due to endometrial hyperplasia and endometrial carcinoma but they were not equal in number in both groups, 84.6 % had endometrial hyperplasia versus 46.2 % in TLH group and 15.4% had endometrial carcinoma versus 53.8% in TAH

The study revealed that there was no significant statistical difference between operative time in both groups and intra-operative complications except estimated blood loss, the blood loss in TLH group was less than TAH group (mean difference was 460 ml between both groups) as shown in (Table 2).

But on comparing between both groups regarding the additional procedure needed either BSO or BSO with lymphadenectomy, the study revealed that TLH with BSO had prolonged operative time than TAH with BSO, (mean difference of operative time was 43 minutes between both groups) as seen in (Table 3).

As regard intra operative complications, there was no statistical significant difference between both groups (*P*-value was > 1). We had one case of ureteric injury, one case of bowel injury in TLH group and two case of bowel injury in TAH group and one case of each group had a secondary surgical intervention

And there was no statistical difference between both groups regarding postoperative complications or during their follow up.

Results of post-operative pain assessment using visual score analogue revealed that, there was statistical significant difference between post-operative pain sensation between both groups, mean difference in post operative pain score was 2 and mean difference of post perative pelvic pain (after 6 weeks) was 1.

But there was no statistical significant difference as regard postoperative hospital admission between both groups as seen in (Table 4).

Table 1: Characteristics of the two study groups.

Variable	TLH (n=26)	TAH (n=26)	Mean / Median Difference	95% CI	P-value
Age (years)	49.8±9.2	54.8±9.2	5.0	-0.2 to 10.1	0.058*
Weight (kg)	91.7±7.2	93.3±5.8	1.7	-1.9 to 5.3	0.353*
Parity	4 (3 to 6)	4 (3 to 6)	0.0	-1.0 to 1.0	0.604§

Data are mean ± SD or median (interquartile range).
§Mann-Whitney test.

95% CI = 95% confidence interval.
NS: Non-significant.

Unpaired t test.

Table 2: Operative details in the two study groups.

Variable	TLH (n=26)	TAH (n=26)	Mean / Median Difference	95% CI	P-value	Significance
Operative time (min)	14632.7±	128.743.4±	-17.3	-38.72 to 4.11	0.111*	NS
Preoperative hemoglobin (g/dl)	11.21.6±	11.61.6±	0.4	-0.45 to 1.33	0.327*	NS
Postoperative hemoglobin (g/dl)	10.01.6±	10.71.4±	0.7	-0.20 to 1.50	0.130*	NS
Hemoglobin drop (g/dl)	1.20.9±	1.01.1±	-0.2	-0.77 to 0.35	0.449*	NS
Estimated blood loss (ml)	300 (200 to 500)	775 (500 to 1100)	460	270 to 700	<0.0001§	S
Uterus weight (g)	201 (127 to 263)	145 (121 to 277)	-9.5	71 to 42	0.819§	NS

Data are mean ± SD or median (interquartile range).
§Mann-Whitney test.

95% CI = 95% confidence interval.
S: significant NS: Non-significant.

*Unpaired t test.

Table 3: Comparison of operative time in patients underwent TLH or TAH as stratified according to performance of additional procedures.

Variable	Additional procedure	TLH(n=26)		TAH (n=26)		Difference	95% CI	P-value*	Significance
		n	Mean ± SD	N	Mean ± SD				
Operative time (min)	Nil	10	138.533.0±	3	130.045.8±	-8.5	-60.2 to 43.2	0.724	NS
	BSO	14	152.934.1±	16	109.718.3±	-43.2	-63.3 to -23.1	0.0001	S
	BSO + Lymphadenectomy	2	135.021.2±	7	171.456.7±	36.4	-64.2 to 137.1	0.421	NS

Data are number (n) and mean ± SD.
S: significant

95% CI = 95% confidence interval.
NS: Non-significant.

*Unpaired t test.

Table 4: Postoperative pain scores and length of hospital stay in the two study groups.

Variable	TLH (n=26)	TAH (n=26)	Median Difference	95% CI	P-value*	Significance
VAS score for pain	5 (4 to 5)	7 (7 to 7)	2.0	2.0 to 3.0	<0.0001	S
VAS score for pelvic pain	1.5 (0 to 3)	2 (2 to 3)	1.0	0.0 to 2.0	0.042	S
Hospital length of stay (days)	2 (2 to 2)	2 (2 to 7)	0.0	0.0 to 1.0	0.146	NS

Data are median (interquartile range).
S: significant.

95% CI = 95% confidence interval.
NS: Non-significant.

*Mann-Whitney test.

DISCUSSION

Our main outcome was the operative time, our study revealed that there was no significant difference between operative time between TLH and TAH, 147 minutes in TLH and 128 minutes in TAH with P-value > 0.111, this agrees with studies done by Poonam *et al.*^[8], Sridhar *et al.*^[9] and Katherine *et al.*^[10], But disagrees with a meta analysis done by Johnson *et al.*^[11], who found that abdominal hysterectomies were performed significantly faster than laparoscopic hysterectomies with difference about 35 minutes and P-value < 0.0001. This was mostly due to heterogeneity between groups in the meta analysis and expertise of the surgeons performing laparoscopic surgery.

On comparing between both groups regarding the additional procedure needed either BSO or BSO with lymphadenectomy, our study revealed statistical significant difference between TLH and TAH group in operative time, TLH group who underwent BSO had more operative time than those in TAH group (152 minutes versus 109 minutes respectively with 43 minutes mean difference between both groups and P-value < 0.0001). This result was related to more time was consumed in securing infundibulopelvic ligament in TLH group. This agrees with study done by Marian *et al.*^[12].

Regarding intraoperative blood loss, our study revealed less blood loss in TLH group, 300 ml in TLH group and 775 ml in TAH group, (P-value was < 0.0001, with 460

ml mean difference between both groups). This agrees with studies done by Poonam *et al.*^[8], Marian *et al.*^[12], Kanmani *et al.*^[13], Galaa *et al.*^[14], On the other hand Walker *et al.*^[15], found that the percentage of patients with blood loss was slightly higher in the laparoscopy group than in the laparotomy group (1.8% versus 0.7%, respectively). This difference was related to that the TLH group had more advanced malignancy so control of bleeding was more difficult.

As regard post-operative assessment by assessing post-operative pain using visual analogue score, our study reported that postoperative pain was significantly lower in TLH group, pain score in TLH group was 5 and 7 in TAH group with (*P-value* was < 0.0001). Also post-operative pelvic pain was less in TLH with *P-value* < 0.042. These results agree with studies done Marian *et al.*^[12] and Walker *et al.*^[15].

CONCLUSION

In conclusion, our current data confirmed the role of laparoscopy in management of cases of endometrial neoplasia. It also proved the efficacy of laparoscopic approach with lower rates of blood transfusion and nearly same rate of complications and less post-operative pain in comparison with laparotomy cases.

There is need for more training courses of laparoscopic surgery, hands-on training to learn hand-eye coordination in our hospital with more advanced instrument to facilitate surgical procedure and decrease operative time and complications rate.

Also an additional study is needed to investigate long term follow up of malignant cases and survival rate which will increase the efficacy of the procedure.

CONFLICT OF INTERESTS

There are no conflicts of interest.

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