

COMPARISON OF CONVENTIONAL TOTAL LAPAROSCOPIC HYSTERECTOMY VERSUS MINI- TOTAL LAPAROSCOPIC HYSTERECTOMY: A PROSPECTIVE RANDOMISED TRIAL

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ABSTRACT

Objectives: Total laparoscopic hysterectomy (TLH) represents one of the most frequently performed gynecological procedures nowadays. The aim of this study was to compare the feasibility and clinical outcomes of patients who underwent total laparoscopic hysterectomy via mini-laparoscopic or conventional laparoscopic techniques.

Methods: During the period between January 2013 and December 2015, 64 laparoscopic hysterectomies were performed in our clinic. All hysterectomies were performed by the same laparoscopic surgeon. Thirty of these patients had TLH by traditional laparoscopic hysterectomy and 34 women had a mini-laparoscopic hysterectomy. Operating time for the hysterectomy, estimated blood loss, preoperative and postoperative complications, postoperative analgesic requirement and length of hospital stay were recorded.

Results: The first-ranked indication was abnormal uterine bleeding and the second was symptomatic leiomyoma. A total of eight hysterectomies was performed for premalignant and malignant conditions. Patients were generally discharged home the day following surgery and seen in the office for a postoperative visit from three to four weeks after surgery. The patients were then followed up annually. On average from 2 to 36 months following surgery, there was no vaginal vault dehiscence or any other late postoperative complications in either group.

Conclusions: Mini-laparoscopy can be safely and effectively used to perform TLH.

KEYWORDS: Laparoscopic Hysterectomy & Micro-Laparoscopy

INTRODUCTION

The first total laparoscopic hysterectomy was performed over 25 years ago [1]. Today, as a result of the development of minimally invasive surgical techniques, the use of mini-laparoscopic instruments in endoscopic surgery is becoming increasingly common. Current multi-port laparoscopic surgery, which uses 5-10mm ports are now called conventional or traditional laparoscopy. Mini-laparoscopy is defined as surgery with instruments that are 2-5mm in diameter, with the sole possible exception of using larger diameter optics at the umbilicus [2]. The benefits of minimal

invasive surgery are less tissue trauma and scar burden, less blood loss, shorter recovery time, and increased patient comfort.

The aim of this study was to compare the feasibility and clinical outcomes of patients who underwent total laparoscopic hysterectomy via mini-laparoscopic or conventional laparoscopic techniques.

METHODS

Subjects and Methods

This prospective study was conducted at Izmir Katip Celebi University Hospital between June 2012 and December 2015. Ethics approval was obtained from Izmir Katip Celebi University's Ethical Committee (2013- 145) for the study. This study adhered to the Declaration of Helsinki for Medical Research involving Human Subjects. Informed consent was obtained from each patient. A total of 64 consecutive patients who needed a hysterectomy for benign gynecological conditions or premalignant and malignant uterine pathologies were enrolled in the study. The exclusion criteria were: (a) patients who were unable to tolerate Trendelenburg position or pneumoperitoneum, and (b) patients who had an incision scar on their anterior abdominal wall. All hysterectomies were performed by the same experienced laparoscopic surgeon (SK).

The patients were divided into two groups. Randomization was made by using computerized random numbers. Thirty women had TLH by conventional laparoscopic hysterectomy and 34 women had mini-laparoscopic hysterectomy. Group A underwent conventional laparoscopy with one 12-mm port for a 10-mm laparoscope and three 5-mm ports. Group B underwent mini-laparoscopy with one 5-mm port for a 5-mm laparoscope as well as two or three 3-mm ancillary trocars.

Surgical Method

Operative laparoscopy was performed under general anesthesia for all women. Bladder catheterization was performed for all patients. After the pneumoperitoneum was created using a Veress needle, a 0-degree 5-mm laparoscope (Karl Storz, Tuttingen, Germany) was introduced through the umbilicus. Two or three 3-mm ancillary trocars were inserted under direct visualization in the lower abdomen. One 3-mm trocar was always inserted in the midline approximately 3 cm above the symphysis. The other trocars were inserted under laparoscopic visualization laterally to the medial umbilical ligament. The mini-TLH was performed in the manner described by Ghezzi [3-4]. In general, the procedure was performed most commonly using bipolar coagulation and scissors. After electrocauterization of the infundibulopelvic ligaments or the ovarian ligaments and Fallopian tubes, the anterior peritoneal fold of the broad ligament was dissected and the bladder dissected from cervix. After electrocauterization of uterine arteries, circumferential colpotomy was performed on the rim of Clermont-Ferrand (Germany – KARL STORZ GmbH & Co. KG, Germany) or RUMI Uterine manipulators (Cooper Surgical, USA) by using mono polar electrocauterization.

After removal of the uterus, adnexa, or both, through the vagina, the vaginal cuff was closed with a running delayed absorbable suture (No.1 Vicryl; Ethicon, Livingston, UK) by vaginal approach [5]. Operating time of the hysterectomy, estimated blood loss, preoperative and postoperative complications, postoperative analgesic requirements and hospital stay time were recorded. Patients were generally discharged home the day following surgery and seen in the office for a postoperative visit three to four weeks after surgery. Each patient was then followed yearly. After at least three

months following surgery all patients were assessed by the same two physicians about skin scar development. At the same time, all patients evaluated themselves about their skin scar formation using the POSAS Patient scale.

Statistical Analysis

Data were analyzed in SPSS Version 22.0 (IBM, Armonk, NY, USA). Categorical variables were compared via Pearson Chi-square and Fisher's exact tests. Comparisons between the two groups of continuous variables with normal distribution were made by using independent sample t-test. Variables with non-normal distribution (Kolmogorov-Smirnov $p < 0.05$) were compared by using a Mann-Whitney U test. A P value of less than 0.05 was considered statistically significant.

RESULTS

The patient demographics and indications of surgery are shown in Table 1. No significant differences between groups were observed in terms of operating time, blood loss, intra-operative and postoperative complication rates, and uterine weight. The most common indications for both groups were abnormal uterine bleeding and uterine leiomyoma. There was one conversion to laparotomy in each group. The one case in the TLH Group was due to technical reasons; and the case in the MLH Group was due to an advanced stage endometrial carcinoma in a frozen section. Bladder injury occurred in one patient in the TLH Group. There were no intra-operative complications in either group. One of the patients in the traditional laparoscopy group (3,3%) had vaginal cuff hematoma and one patient in the mini-TLH group (2,9%) had cuff cellulitis postoperatively. Duration of hospital stay and need for analgesia were significantly shorter in the MLH Group (Table 2). Both patient and observer PSOAS scar scores were better in the MLH Group ($p < 0, 05$). On average 23, 98 (2-36) month follow-up there was no vaginal vault dehiscence or any other late postoperative complications in either group.

DISCUSSIONS

Our results demonstrate that there were no significant differences between conventional laparoscopic hysterectomy and MLH in terms of operative time, blood loss, intra-operative and postoperative complications. However duration of hospital stays, need for analgesia and cosmetic results were better with MLH.

As a result of the rapid development of modern laparoscopic surgery, surgeons can now use minimally invasive techniques for almost all kinds of surgeries. Hysterectomy, which is the one of more common gynecological surgeries has been performed laparoscopically for a long time. TLH has been associated with better pre-operative and postoperative results, and a more rapid return to normal life than laparotomy [6-7]. Today, all these factors have become more important for surgeons and patients alike. Moreover a patient's preferences regarding the cosmetic results of surgery are compelling surgeons to use minimally invasive techniques [8].

The main aim of using smaller instruments for surgery is to cause less tissue trauma, improve the patient's comfort and achieve better cosmetic results. Although mini-laparoscopic surgeries began in early 1990's, because of some limitations of the initial instruments common use of mini-laparoscopy has been achieved only recently [9-10]. Nowadays surgical procedures which demand advanced surgical skills like TLH can be performed via mini-laparoscopy.

The main advantage of mini-laparoscopy is a reduction in tissue damage on the abdominal wall and, as a result, decreased-pain. In the current study, our results suggest postoperative analgesic requirement is lower in the mini-TLH Group than conventional TLH (Table 2). The literature comparing mini-laparoscopy versus conventional laparoscopy in terms of postoperative pain reports conflicting results. Some studies suggest decreased postoperative pain; others have not verified that. [11-16]. It is speculated that postoperative pain occurs due to the rectus sheath suture, which has to be made with incisions of 10 mm and wider trocars to reduce the risk of hernia formation [17]. Although the mean analgesic requirement was greater in our conventional laparoscopy group than in the mini-TLH group, it is difficult to say that increased postoperative pain is due only to umbilical trocar size.

By using mini-laparoscopy it can also be possible to reduce subcutaneous or subfacial bleeding and hematoma formation [16]. The other advantage of mini-laparoscopy is a reduction in the risk of postoperative hernia formation. It has been shown that 86,3% of all trocar hernias occur with 12 mm or bigger trocars. Conversely, only 2.7% of all trocar hernias occur with 5 mm trocars. Any patient did not have incisional hernia or subfacial bleeding in our study [18-20]. Although evaluations of skin scar formation is challenging because of inadequate objective scales, the majority of studies in the literature demonstrate that cosmetic results are better when smaller trocar sizes are used [21-25]. We used both observer and patient score scales for evaluation of scar formation. Both scores were better in the mini-TLH group than in the conventional laparoscopic hysterectomy. Nowadays, according to patients the cosmetic results of surgery are almost as treatment of the main pathology. The development of abdominal scar formation nearly invisible by mini-laparoscopy . (Image 1).-

Enlarged uteruses also can be removed via mini-laparoscopy. It has been shown that even uteruses weighing more than 1 kg can be removed via mini-TLH. The biggest uterus removed by laparoscopy was 3313grams. In the current study, largest uteruses in the conventional TLH and mini-TLH groups were 1076grams and 1025grams, respectively [26].

CONCLUSIONS

The strengths of our study are the prospective study design, and the use of relatively objective assessment methods like scar assessment scales and haemoglobin changes. The weak points of our study are the failure to use pain assessment scales and patients co-morbidities.

In conclusion, a mini-laparoscopy can be safely and effectively used to perform TLH. Although performing mini-TLH requires advanced surgical skills and a relatively long learning curve, in our opinion, this procedure could be performed by all laparoscopic surgeons.

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APPENDICES

Figure 1: Flowchart

Figure 2: PSOAS Patient Scale

Figure 3: PSOAS Observer scale

Image 1: Postoperative Day1 appearance of the skin and Clermont-Ferrand uterine manipulator

Table 1: Patient demographics, and indications of surgery

Table 2: Surgical parameters

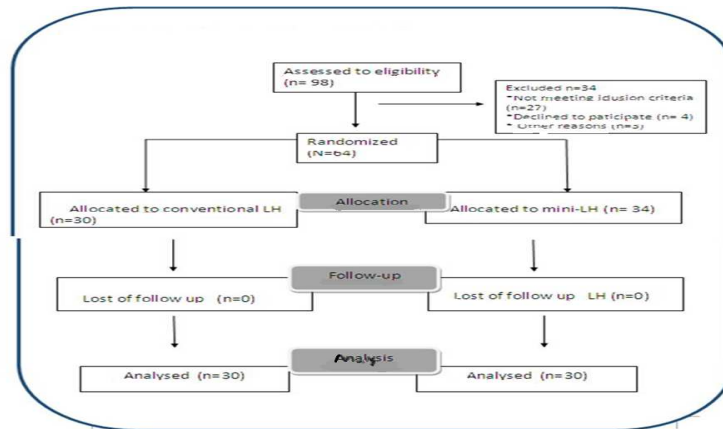


Figure 1: Flow chart

	1 2 3 4 5 6 7 8 9 10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
	1 = no, as normal skin yes, very different = 10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?	○ ○ ○ ○ ○ ○ ○ ○ ○ ○
	1 = as normal skin very different = 10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?	1 2 3 4 5 6 7 8 9 10 ○ ○ ○ ○ ○ ○ ○ ○ ○ ○

Figure 2: PSOAS Patient Scale (6-60)

	1 = normal skin	worst scar imaginable = 10									
PARAMETER	1	2	3	4	5	6	7	8	9	10	CATEGORY
VASCULARITY	○	○	○	○	○	○	○	○	○	○	PALE PINK RED PURPLE MIX
PIGMENTATION	○	○	○	○	○	○	○	○	○	○	HYPH HYPER MIX
THICKNESS	○	○	○	○	○	○	○	○	○	○	THICKER THINNER
RELIEF	○	○	○	○	○	○	○	○	○	○	MORE LESS MIX
PLIABILITY	○	○	○	○	○	○	○	○	○	○	SUPPLE STIFF MIX
SURFACE AREA	○	○	○	○	○	○	○	○	○	○	EXPANSION CONTRACTION MIX
OVERALL OPINION	○	○	○	○	○	○	○	○	○	○	

Figure 3: PSOAS Observer Scale



Image 1: Postoperative Day 1 Appearance and Clermont-Ferrand Uterine Manipulator

Table 1: Patient Demographics and Indications of Surgery

	Conventional TLH (n=30)	Mini TLH (n=34)	P
Characteristics			
Age (years)	49,3±5,8	47,1±8,2	0,06
Gravity	3,9±1,9	2,8±1,2	0,14
Parity	3,1±1,6	2,5±1,2	0,22
Body mass index (kg/m ²)	25,9 (21,8-41)	23,9 (20,-31,9)	0,93
Premenopausal n,(%)	10 (33,3%)	16 (47,1%)	
Postmenopausal n,(%)	20 (66,7%)	18 (52,9%)	
Indication			
Abnormal Uterine Bleeding n,(%)	15 (50%)	11 (32,3%)	
Uterine fibroids n,(%)	8 (26,6%)	11 (32,3%)	
Premalignant-malignant conditions of uterus n,(%)	1 (3,3%)	7 (20,5%)	
Adnexal mass n,(%)	6 (20%)	5 (14,7%)	

Table 2: Surgical Parameters

	TLH (n=30)	Mini-TLH N=34)	P value
Operative time (min)	132,4±36,6 (68-230)	131,9±32,3 (82-200)	0,95
Haemoglobin change (mg/dl)	-1,8±0,9	-1,8±1,1	0,87
Intraoperative complications	1	0	1,00
Postoperative complications	1	1	0,43
Conversion to laparotomy	1	1	0,43
Uterus weight (g)	360 (98-1076)	314,1 (105-1025)	0,54
Need for analgesia (day)	4,1 (1-10)	2,8 (1-6)	0,003
Hospital stay (day)	3,7±1,1 (2-10)	2,3±1,6 (1-15)	0,001
Patient scar scale	30,7±3,4	18,1±8,9	0,001
Observer scar scale	27,9±35,3	16,6±27,1	0,001