

Sutureless Total Abdominal Hysterectomy Using Marclamp® IQ : A Prospective Cross-Sectional Study .

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ABSTRACT:

BACKGROUND:

Hysterectomy, the second most common surgical procedure performed in female patients, is associated with various complications like other major surgical procedure. To reduce such complications and shorten both the operating time and the intraoperative blood loss, sutureless hysterectomy was recently practiced using novel vessel sealing devices as marClamp® IQ and LigaSure.

OBJECTIVE:

To compare the outcomes of marClamp® total abdominal hysterectomy (TAH) versus total abdominal hysterectomies performed by LigaSure and suture ligation techniques of other studies.

PATIENTS AND METHODS:

A total of 47 female patients presenting with various benign and malignant uterine and malignant ovarian diseases were suturelessly hysterectomised using marClamp®.

Main outcome measures: The primary outcome measures were: the operating time and blood loss while the secondary outcome measures were: intraoperative and post-operative complications, hospital stay and histopathologic results of the removed specimens.

RESULTS:

Operating time of marClamp®: TAH only, TAH +bilateral salpingo-oophorectomy (BSO), TAH+BSO+ infracolic omentectomy and total study group were: mean±SD = 60.91±8.31minute (m) ,75.93±14.61m, 83.89±13.18 m and 73.94±15.11m respectively (P-value =0.001, it was statistically significant). The intraoperative blood losses of marClamp®: TAH only, TAH + BSO, TAH+BSO +infracolic omentectomy and total study group were: mean±SD = 64.09±8.61 milliliter (ml) , 85.74±17.30 ml ,103.33±20.62 ml and 84.04±20.71 ml respectively (P-value =0.000, it was statistically significant). Hospital stay of this study was mean±SD =2.08±0.59 day. This study had no intraoperative complications .Its postoperative complication rate was 10.63 %. Premenopausal simple endometrial hyperplasia with / without atypia was the most common histopathologic variety (51%) .This study had no mortality during the follow-up period.

CONCLUSION:

The use of marClamp® IQ device can reduce operating time, intraoperative blood loss, intraoperative and postoperative complication rates and the hospital stay. Thus it is cost-effective. It allows quick and secured hemostasis compared with the conventional suture ligation technique.

KEYWORDS: marClamp® IQ, LigaSure, Conventional, Hysterectomy, Sutureless.

INTRODUCTION:

Hysterectomy means surgical removal of uterus but, in practice it has a wider classification depending upon its indications. Hysterectomy may be performed without removal of the cervix (supracervical hysterectomy) or with removal of adnexa (hysterectomy with salpingo-oophorectomy).

It may be a part of staging laparotomy or radical hysterectomy. Hysterectomy can be performed abdominally, vaginally or laparoscopically. The approach depends on surgeon's preference, indication for surgery, nature of disease and patient characteristics.^[1]

Hysterectomy is the second most frequent performed major surgical procedure in female patients all over the world, following to the Caesarian Section (C/S).

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In USA, approximately 600,000 hysterectomies are yearly performed.^[2] Benign uterine diseases form more than 70% of the indications for hysterectomy including menstrual disorders, uterine fibroids, pelvic pain and uterine prolapse.^[3]

The rapid, safe and complete sealing of vessels remains an important part of a successful abdominal hysterectomy.^[4] Abdominal hysterectomy has the advantage of good intraoperative field, but the disadvantages are an abdominal wall scar and the long time for recovery.^[5] As any other surgical procedure, hysterectomy is also associated with intraoperative and postoperative complications. Rates of various hysterectomy complications have been reported in the range from 0.5% to 43%.^[6] Most of hysterectomies are performed either for benign conditions causing (menorrhagia, metrorrhagia, dysmenorrhea or pelvic pain), uterine fibroids, ovarian cysts or for uterine and ovarian cancers.

During performance of hysterectomy, the vascular pedicles can be secured using usual mechanical techniques (sutures, clips or staples) or by vessel coagulation (high frequency electrocautery, ultrasound or laser).^[7] For rapid and secure hemostasis, the LigaSure vessel sealing apparatus was launched by Valleylab (Boulder, CO, USA)^[8] and marClamp® vessel sealing apparatus was launched by (Martin KLS, Germany). MarClamp® and LigaSure^[9] coagulate the vessels by recognizing the type of tissue to pass the right dose of pressure and energy. This dose alters the collagen and elastin fibers in the vessels to be sealed with minimal lateral thermal injury. MarClamp® and LigaSure are now popular in many operative procedures as thyroidectomy, splenectomy and urology procedures. They are more suitable for difficult surgical procedures because they can abandon need for vessel traction and shorten time needed for hemostasis.^[10]

Research data demonstrate that application of ligation-free techniques, such as LigaSure vessel sealing system, obviously improves surgical resection rate, reduces complication rate and shortens the operating time, so as to provide the optimal treatment and rehabilitation efficacy for patients.^[11]

AIM OF THE STUDY:

The objective of this study was to assess outcomes of sutureless TAH with /without BSO performed with marClamp® versus outcomes of other studies that used both, LigaSure device and conventional suture ligation technique for TAH with /without BSO.

PATIENTS AND METHODS:

This study began after the Ethical Committee of College of Medicine / Wasit University / IRAQ, approved its proposal in September 2016. All patients, enrolled in this study, had signed a written informed consent form before enrollment. The study included 47 consecutive female patients presented with various benign and malignant uterine diseases and malignant ovarian diseases. They underwent a sutureless TAH with / without BSO using marClamp® (produced by KLS martin group, Germany) in AL-Karama Teaching Hospital / College of Medicine / Wasit University/ IRAQ in cooperation with department of gynaecology and obstetrics in Kut hospital for Gynaecology Obstetrics and Pediatrics / Wasit / IRAQ during the period from September 2016 to December 2018.

The preoperative preparations, operative procedures and the postoperative follow-up were performed by the gynaecologist of the team using MarClamp under supervision of the trained surgeons of the research team. A proper preoperative evaluation of the study patients was performed including: history taking, thorough physical examination and investigations that included: chest X-ray, abdominal and transvaginal ultrasonography, pelvic MRI, dilation and curettage (D&C) for patients presented with abnormal uterine bleeding, electrocardiography and laboratory investigations (complete blood picture, PT, PTT, INR, fasting blood sugar, blood urea, serum creatinine, Hepatitis B, Hepatitis C and HIV and tumor marker CA 125 for patients with postmenopausal bleeding and those with ovarian tumors).

SUTURELESS TOTAL ABDOMINAL HYSTERECTOMY

Pfannnstiel incision was performed in patients with benign uterine diseases, while lower mid-line incision was performed for patients with malignant uterine and ovarian diseases. Intraoperative blood loss was calculated by measuring the blood on the sterile drapes, blood in the suction container and evaluating the blood in abdominal swabs and gauzes. The operating time was measured from moment of incising the abdominal skin to moment of completing skin closure.

The vaginal vault was closed with 1 Vicryl (Coated VICRYL® (polyglactin 910) Suture|Ethicon). The cardinal ligaments, at the level of vaginal cuff, were fixed to the round ligaments with 0 Vicryl, rectus sheath was closed with 1 Nylon and the skin was subcuticularly closed with 2/0 Nylon. The tuboovarian vascular pedicle, uterine vascular pedicle and the cervical vascular pedicle were sealed suturelessly using marClamp® IQ (Figure.1.).

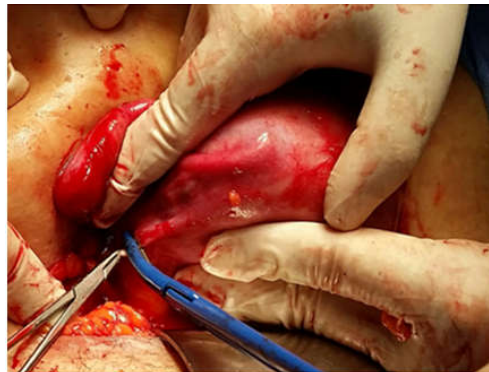


Figure.1.TAH using marClamp

Exclusion criteria were :

- Unfitness for general anaesthesia .
- Cervical cancers .

Data of this study were statistically analysed using IBM SPSS ver. 22.0 (IBM Co., Armonk, NY, USA). P-values less than 0.05 were statistically significant.

RESULTS:

This study included 47 patients whose ages ranged 38-75 years with mean±SD =49.26±7.95 y (Table.3.) .They presented with various benign and malignant uterine diseases and various malignant ovarian tumors.

They were surgically treated according to type and the stage of the underlying uterine or ovarian disease .The study variables were statistically analyzed and tabulated in the following tables 1,2,3 and 4.

Table.1.Pathologic distribution of the study patients.

Pathology	No=	Percentage
Premenopausal simple endometrial hyperplasia with/without atypa .	24	51
Postmenopausal simple endometrial hyperplasia with / without atypa .	9	19.15
Primary ovarian cancers .	6	12.8
Uterine fibroids .	4	8.5
Premenopausal uterine carcinoma .	2	4.3
Metastatic ovarian cancers.	1	2.1
Postmenopausal uterine carcimoma.	1	2.1
Total	47	100.0 %

NO = number of the patients

SUTURELESS TOTAL ABDOMINAL HYSTERECTOMY

Table.1. shows the pathological distribution of the study patients .The most common pathological types were : 24 patients out of 47 (51%) had simple premenopausal endometrial hyperplasia with / without atypia , 9 patients out of 47 (19.15%) had postmenopausal simple endometrial hyperplasia with / without atypia and 6 patients out of 47 (12.8%) had primary ovarian cancers.

Table.2. Type of TAH performed by using marClamp® .

Type of the surgical technique.	No=	Percentage
TAH only .	11	23.40
TAH + BSO .	27	57.45
TAH + BSO + infracolic omentectomy .	9	19.15
Total	47	100.0

NO = number of the patients

Table.2. shows the distribution of the study patients according to the surgical technique :11patients (23.40%) were surgically treated by TAH only , 27 patients (57.45%) were surgically treated by TAH + BSO and 9 patients (19.15 %) were surgically treated by TAH + BSO+infracolic omentectomy according to type and stage of the underlying disease .

table .3. Perioperative descriptive statistical analysis of the study variables

The StudyVariables	No:	Minimum	Maximum	Mean±SD or %
Age/year .	47	38	75	49.26±7.95
Associated co-morbidities .	47	21		44.7%
Previous abdominal surgery.	47	16		34 %
Operating time/m.	47	50	120	73.94±15.11
Intraoperative blood loss/ml.	47	50	130	84.04±20.71
Intraoperative complications.	47	0.00		0.00%
Postoperative complications.	47	5		10.63%
Hospital stay/day.	47	1.5	3.5	2.08±0.59
Follow up /month.	47	1.00	34.00	18.24±9.49

NO = number of the patients

Table.3. shows descriptive statistical analysis of the study variables. Twenty one (44.7%) patients out of 47 had chronic medical diseases including: hypertention ,diabetis mellitus and cardiac diseases that were medically controlled before surgery. Five patients(10.6%) had preoperatively severe anemia due to severe uterine bleeding, their anemias were preoperatively corrected by blood transfusion.

Table 4. Type of previous abdominal surgery versus operating time & intraoperative blood loss of this study.

The Study Variables	Type of previous abdominal surgery	No=	Mean±SD	Range	P-value
Operating time / m.	Caesarian Section.	12	82.50±16.17	65-120	0.042
	Other pelvic operation.	2	85.00±21.21	70-100	
	Other non-pelvic abdominal operation.	2	80.00±14.14	70-90	
	No previous operation	31	69.52±13.13	50-100	
	Total	47	73.94±15.11	50-120	
Intraoperative blood loss/ml.	Caesarian Section	12	88.33±18.38	70-130	0.045
	Other pelvic operation	2	100.00±28.3	80-120	
	Other non-pelvic abdominal operation	2	115.00±7.07	110-120	
	No previous operation	31	79.35±19.86	50-120	
	Total	47	84.04±20.71	50-130	

Table 4. compares between patients that had history of previous abdominal versus those that had no previous abdominal surgery in regard to

the operating time and intraoperative blood loss of this study.

DISCUSSION:

MarClamp® IQ is reusable bipolar electro-surgical device which can seal blood vessels with diameters up to 6mm by denaturing collagen and elastin fibers of the vessel wall and surrounding connective tissue with a minimal lateral thermal injury limited to 2 millimeters over the surgical site. The coagulation zone can withstand blood pressure up to 3 times of the systolic blood pressure.^[11]

Every surgeon aims to implement the least invasive, quickest, least complicated, and most effective operative techniques necessary for the shortest operating time and hospital stay, least blood loss and the lowest surgical cost.^[12] The sutureless techniques hypothetically reduce the operating time, the intraoperative blood loss, perioperative complications and hospital stay, thus they are cost effective.

Regarding the patients' ages, this study included 47 female patients whose ages ranged 38-75 y with mean±SD of 49.26±7.95 y. İgin TURKCUOĞLU *et al*^[13] reported that their study patients' ages mean±SD of suture ligation TAH group and LigaSure TAH were: mean 50.4±7.3 y and 54.3 ±12.7y respectively.

Jorge MLL *et al*^[14] study included 133 women treated by suture ligation TAH and 134 women treated by LigaSure TAH. Mean of age of their study patients was of 55 years (39 to 71 years).

In this marClamp® abdominal hysterectomy study the most common indication of hysterectomy was premenopausal simple endometrial hyperplasia with / without atypia 51 %, while the most indication of hysterectomy of Rinku Girija *et al*^[15] study was uterine fibroid : suture ligation TAH and ligaSure TAH were 80% and 88.6% respectively. Aşkın YILDIZ *et al*^[16] study included 173 women underwent TAH using LigaSure and suture ligation TAH technique, the most common indication of hysterectomy was uterine fibroids, 74 out of 173 (42.8 %). Jorge MLL *et al*^[14] study reported that the main indication of hysterectomy of their study was uterine myomatosis (91.4%) of their study patients).

.Chen B *et al*^[17] study reported that uterine fibroid was the main indication of hysterectomy, 61.8 % of patients were treated by TAH with suture ligation and 66.4 % of patients were treated by vaginal hysterectomy.

Regarding the operating time of this marClamp® abdominal hysterectomy study: TAH only, TAH+BSO, TAH+BSO+ omentectomy and total study group were: Mean±SD = 60.91±8.31m , 75.93±14.61m, 83.89±13.18 m and 73.94±15.11m respectively (P-value =0.001,it is statistically significant) . İgn TURKCUOĞLU *et al* ^[13] reported that, operating time of suture ligationTAH was 92.1±21.1m and that of LigaSure TAH was 90.2±20.6m . Jorge MLL *et al* ^[14] study reported operating time of 145 m for the suture ligation TAH and 130 m for LigaSure TAH (p < 0.05) .Aşkın YILDIZ *et al* ^[16] reported that operating time (Median/Min.-Max) of LigaSure TAH was 105.0m (70-175m) while that of suture ligation TAH was 130m (60-230m) . Chen B *et al* ^[17] reported that operating time of vaginal hysterectomy (VH) was 65.2±10.6m while that of suture ligation TAH was 95.6 ±15.9 m. Robert McLellan *et al* ^[18] reported operating time mean of LigaSure TAH was 30.6 m (range: 18m-62m) versus 48.2 m (range: 30m-109m) of the suture ligation TAH .Thus the mean±SD of operating time of this marClamp® hysterectomy study was shorter than both, LigaSure TAH and suture ligation TAH of the studies ^[13,14,16,17] but longer than those of study . ^[18]

Regarding intraoperative blood losses of TAH only, TAH + BSO, TAH+BSO + omentectomy and total study group of this marClamp® abdominal hysterectomy were were: Mean±SD = 64.09±8.61ml , 85.74±17.30ml, 103.33±20.62 ml and 84.04±20.71ml respectively (P-value =0.00, it is statistically significant) . İgn TURKCUOĞLU *et al* ^[13] reported that intraoperative blood loss of LigSure TAH was 42.3±40.5ml while that of suture ligation TAH was 157.1±89.1ml . Jorge MLL *et al* ^[14] reported in their study that included 133 patients intraoperative blood loss mean was 475 ml in suture ligation TAH and 330 ml in LigaSure TAH (p < 0.05). Chen B *et al* ^[17] reported intraoperative blood losses of VH and TAH of 65.2±10.6ml and 95.2 ±15.9ml respectively .

Robert McLellan *et al* ^[18] reported that blood loss was significantly less in the LigaSure TAH with an average of 74.2 ml (range: 32-50ml) versus 118.7 ml (range: 25-250 ml) in suture ligation TAH (p-value = 0.02). Thus, the intraoperative blood loss of this marClamp® hysterectomy study was more than intraoperative blood losses of LigaSure TAH of the studies ^[13,18] but less than that of study ^[14]. The mean±SD of intraoperative blood loss of this marClamp® hysterectomy study was less than that of the suture ligation TAH of the studies . ^[13,14,17,18]

Hospital stay of this marClamp® hysterectomy study was 2.08±0.59 day . İgn TURKCUOĞLU *et al* ^[13] reported hospital stay of suture ligation TAH was 3.2 ±1.0 day while that of LigaSure TAH was 3.6 ±2.4day (p-value =0.53) . Aşkın YILDIZ *et al* ^[16] reported hospital stay (Median/Min.-Max) of LigaSure TAH was 5day (2-17day) and that of suture ligation TAH was 5days (3-17day) . Chen B *et al* ^[17] reported hospital stay of VH andTAH were 4.5±0.5day and 6.3 ±1.5 days respectively .Mean±SD of hospital stay of this marClamp® hysterectomy study was less than those of ligaSure TAH and suture ligation TAH of the studies ^[13,16] and that of suture ligation TAH of the study ^[17] .

Regarding patients with history of previous abdominal surgery, this marClamp® hysterectomy study had 16 patients (34%) out of 47 patients with previous pelvic surgery, 12 patients had Caesarian Section (C/S), 2 patients had other pelvic operations and 2 patients had upper abdominal operations . Aşkın YILDIZ *et al* ^[16] reported 85 patient out of 173(49.1%) had previous abdominopelvic surgery,20 patients (11.6 %) had caesarian section.

This marClamp® hysterectomy study had no intraoperative complications. Its postoperative complication rate was 10.63 % (5 patients out of 47 patients) . Aşkın YILDIZ *et al* ^[16] reported total complications of LigaSure TAH was 1.2% and of suture ligation TAH was 6.5%. Complication rate of this marClamp® hysterectomy study was higher than that of the study ^[16] .

CONCLUSION:

The use of marClamp® IQ device in performance of total abdominal hysterectomy can reduce operative time ,intraoperative blood loss, intraoperative and postoperative complication rates and the hospital stay. It also reduces consumption of surgical sutures .Thus it is cost-effective . It allows quick and secured hemostasis compared with the conventional suture ligation techniques . MarClamp® IQ device is technically comparable with LigaSure but it is economically superior to both ; suture ligation technique and LigaSure because it is reusable while ligaSure is disposable .

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Conflict of interest: We declare we have no conflict of interest .

Ethical approval: The study was approved by Ethical Committee of College of Medicine / Wasit University/ IRAQ .

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