

**A 10-YEAR REVIEW OF TOTAL LAPAROSCOPIC HYSTERECTOMY
IN HOSPITAL SULTAN ABDUL HALIM
SUNGAI PETANI, KEDAH**

DR MUHAMMAD NOOR ASYRAF BIN ZAKARIA

Dissertation Submitted In Partial Fulfilment Of The
Requirement For The Degree Of Master Of Medicine
(Obstetrics & Gynecology)



Universiti Sains Malaysia, Kubang Kerian

2020

ACKNOWLEDGEMENT

I would like to take this opportunity to extend my full appreciations and gratitude to those who have helped me in many ways throughout the process of my dissertation.

- My dissertation supervisor, Dr Ahmad Amir Bin Ismail, Consultant Obstetrician and Gynaecologist, Department of Obstetrics and Gynaecology, School of Medical Science, Universiti Sains Malaysia for his continuous guidance, concern, feedbacks and advice in this study.
- My co-supervisors Dr Kunasegaran Kannaiah, Head Department and Consultant Obstetrician and Gynaecologist, Hospital Sultan Abdul Halim, Sungai Petani and Dr Harun Husin, Specialist Obstetrician and Gynaecologist, Hospital Sultan Abdul Halim, Sungai Petani for their guidance and supervision for my research
- To my parents and my family for their endless support and encouragement in ensuring the completion of this study
- To the staff nurse of Department Obstetrics and Gynaecology, Hospital Sultan Abdul Halim, Sungai Petani for facilitating in the study
- To the patients without whom the study is incomplete

CONTENT

1.0 PRELIMINARIES

<i>1.1 ACKNOWLEDGEMENT</i>	<i>i</i>
<i>1.2 CONTENT</i>	<i>ii</i>
<i>1.3 ABSTRACT IN MALAY</i>	<i>iv</i>
<i>1.4 ABSTRACT IN ENGLISH</i>	<i>vi</i>

2.0 INTRODUCTION 1

3.0 LITERATURE REVIEW 5

<i>3.1 OUTCOME OF TLH</i>	
<i>3.11 DURATION OF OPERATION</i>	5
<i>3.12 BLOOD LOSS</i>	6
<i>3.13 UROLOGICAL INJURY</i>	6
<i>3.14 BOWEL INJURY</i>	7
<i>3.15 VESSEL INJURY</i>	8
<i>3.16 VAGINAL VAULT DEHISCENCE</i>	9
<i>3.17 THROMBOEMBOLISM</i>	9
<i>3.2 SAFETY OF TLH IN PATIENT WITH PREVIOUS CAESARIAN SECTION</i>	10
<i>3.3 SAFETY OF TLH IN PATIENT WITH PREVIOUS PELVIC SURGERY</i>	10
<i>3.4 SAFETY OF TLH IN OBESE PATIENT</i>	11
<i>3.5 SAFETY OF TLH RELATED TO ANESTHESIA</i>	12

4.0 RATIONALE OF THE STUDY 13

5.0 OBJECTIVES OF THE STUDY 14

6.0 ABBREVIATIONS 15

7.0 RESEARCH METHODOLOGY	17
<i>7.1 STUDY DESIGN, STUDY VENUE AND STUDY DURATION</i>	17
<i>7.2 STUDY POPULATION</i>	17
<i>7.3 SAMPLE SIZE CALCULATION</i>	17
<i>7.4 INCLUSION CRITERIA</i>	18
<i>7.5 EXCLUSION CRITERIA</i>	18
<i>7.6 STATISTICAL ANALYSIS</i>	19
<i>7.7 STUDY PROCEDURE</i>	19
<i>7.8 CONCEPTUAL FRAMEWORK</i>	28
<i>7.9 ETHICAL ISSUES, CONFLICT OF INTEREST, CONFIDENTIALITY</i>	30
8.0 RESULTS	31
9.0 DISCUSSION	39
10.0 REFERENCES	46
11.0 APPENDICES	53
<i>10.1 DATA COLLECTION</i>	53
<i>10.2 STUDY APPROVAL</i>	55
<i>10.3 MEDICAL JOURNAL OF MALAYSIA (MJM) FORMAT</i>	57

1.3 ABSTRACT IN MALAY

KAJIAN ANALISA BERKAITAN PEMBEDAHAN PEMBUANGAN KESELURUHAN RAHIM SECARA LAPAROSKOPIK DALAM TEMPOH 10 TAHUN DI HOSPITAL SULTAN ABDUL HALIM, SUNGAI PETANI, KEDAH

Penulis : *Muhammad Noor Asyraf Zakaria, MD^{1,2}, Ahmad Amir Ismail, FRCOG¹, Kunasegaran Kannaiah² FRCOG*

¹Jabatan Obstetrik & Ginekologi , Hospital Universiti Sains Malaysia (HUSM)

²Jabatan Obstetrik & Ginekologi , Hospital Sultan Abdul Halim (HSAH), Sungai Petani

Objektif

Analisis berkaitan hasil pembedahan pembuangan keseluruhan rahim secara laparoskopik untuk ketumbuhan yang tidak berbahaya.

Metodologi

Kajian analisis retrospektif dilakukan di mana 369 kes dikumpulkan dari Januari 2008 sehingga Disember 2017 membabitkan pesakit yang menjalani pembedahan pembuangan rahim secara laparoskopik di Hospital Sultan Abdul Halim, Sungai Petani. Maklumat klinikal, demografi dan data berkaitan pembedahan dan selepas pembedahan direkodkan.

Keputusan

Pesakit mempunyai purata umur 44.7 (± 2.6) tahun, purata 2.6 (± 1.5) bilangan kehamilan, dan purata BMI 31.2 (± 11.4) kg/m². Purata tempoh pembedahan adalah 89.1 (± 20.9) minit, purata kehilangan darah sebanyak 149 (± 152) mL dan purata penginapan di hospital selama 2.2 (± 0.5) hari. Purata saiz rahim adalah 13.7 (± 2.5) minggu kehamilan. Indikasi utama pembedahan adalah

ketumbuhan fibroid di rahim (55.6). Daripada keseluruhan 369 pesakit, sebanyak 10 (2.71%) pesakit terpaksa menjalani pembedahan secara 'laparotomy' di mana 6 kes disebabkan oleh perlekatan yang banyak, 3 kes disebabkan kecederaan pada usus dan 1 kes disebabkan ruang pembedahan yang terhad disebabkan ketumbuhan fibroid yang besar. Kecederaan pada pundi kencing membabitkan 4 (1.08%) pesakit. Tiada pesakit yang mengalami komplikasi pembedahan yang teruk. Tiada perbezaan yang signifikan berkaitan kadar komplikasi pembedahan di kalangan pesakit yang obese ($BMI \geq 30$ kg/m²) atau di kalangan pesakit yang mempunyai saiz rahim yang besar (≥ 12 minggu kehamilan). Di kalangan pesakit yang mempunyai sejarah pembedahan 'caesarian' atau di bahagian pelvik, perbezaan yang signifikan hanya membabitkan tempoh masa pembedahan.

Rumusan

Pembedahan membuang keseluruhan rahim secara laparoskopik terhadap pesakit yang mempunyai ketumbuhan yang tidak berbahaya dapat dilakukan dengan risiko komplikasi yang rendah.

Kata kunci : pembuangan rahim secara laparoskopik, hasil, komplikasi

1.4 ABSTRACT IN ENGLISH

A 10-YEAR REVIEW OF TOTAL LAPAROSCOPIC HYSTERECTOMY IN HOSPITAL SULTAN ABDUL HALIM, SUNGAI PETANI, KEDAH

Authors : *Muhammad Noor Asyraf Zakaria, MD^{1,2}, Ahmad Amir Ismail, FRCOG¹,*

Kunasegaran Kannaiah² FRCOG

¹Department of Obstetric & Gynaecology, Hospital Universiti Sains Malaysia (HUSM)

²Department of Obstetric & Gynaecology, Hospital Sultan Abdul Halim (HSAH), Sungai Petani

Objective

To analyse surgical outcomes of total laparoscopic hysterectomy (TLH) for benign disease.

Methods

Retrospective analysis of 369 cases collected from January 2008 to December 2017 of women who underwent TLH in Hospital Sultan Abdul Halim, Sungai Petani. Clinical, demographic, surgical, and intra and perioperative data were recorded.

Results

Patients had a mean age of 44.7 (± 2.6) years, a mean of 2.6 (± 1.5) pregnancies, and a mean BMI of 31.2 (± 11.4) kg/m². The mean surgical duration was 89.1 (± 20.9) minutes, with mean blood loss of 149 (± 152) mL and average hospital stay of 2.2 (± 0.5) days. Mean uterine size was 13.7 (± 2.5) weeks of gestation. Main indication for TLH was uterine fibroid (55.6%). Of 369 patients, 10 (2.71 %) were converted to laparotomy. Reasons for conversion were severe adhesive disease (6 patients), bowel injury (3 patients) followed by inadequate visualization secondary to fibroids (1 patient). Bladder injury occurred in 4 (1.08%) patients. No patient developed major

postoperative complication. No significant differences were seen in the intraoperative and postoperative complication rates of patients who were obese (body mass index ≥ 30 kg/m²) or patients with enlarged uterus (≥ 12 weeks gestation). There is significant difference in term of duration of operation in patients with previous caesarian section or pelvic surgery but there is no significant difference in term of intraoperative and postoperative complication rates.

Conclusions

Total laparoscopic hysterectomy can be performed successfully in most patients with benign indications. It is a procedure with a low incidence of complications.

Keywords : Total laparoscopic hysterectomy, Complications, Outcomes

1.0 INTRODUCTION

Hysterectomy remains the most common major gynecological operation worldwide. It may be carried out by three different routes and its variations: vaginal, abdominal, and laparoscopic. Factors that may influence the route of hysterectomy include the indication for surgery, size of the uterus, presence or absence of associated pelvic pathology, surgeon's training and preference and patient's choice. With the advancement of laparoscopic technology, equipment, and training, hysterectomies are increasingly performed laparoscopically. The laparoscopic hysterectomy can be categorized into three main types including laparoscopic assisted vaginal hysterectomy (LAVH), laparoscopic supracervical hysterectomy (LSH), and total laparoscopic hysterectomy (TLH).

The laparoscopic hysterectomy was firstly performed by Reich et al in 1989 (1,2). Initially, laparoscopic hysterectomy was associated with a high complication rate, namely urinary tract lesions. Therefore, laparoscopic hysterectomy was only to be performed when the vaginal approach was not feasible, in order to avoid the abdominal hysterectomy. However, more recent studies have shown that laparoscopic hysterectomy is safe and related with a low complication rate.

The laparoscopic approach offers advantages over traditional total abdominal hysterectomy(TAH). These include significant lower analgesia requirements, shorter hospital stays, rapid recovery, greater patient satisfaction, and lower rates of wound infection and

hematoma infection. Disadvantageously, surgical time is lengthened, although the learning curve may be a factor.

In total laparoscopic hysterectomy (TLH) ,the uterus and cervix are removed. The entire procedure, including suturing of the vaginal vault, is performed laparoscopically. Alternately, some surgeons may prefer to suture the vaginal cuff using a vaginal approach. The uterine specimen is typically removed through the vaginal vault, either intact or after morcellation. In Laparoscopic subtotal (supracervical) hysterectomy (LSH), the uterus is removed; the cervix is conserved. The uterine specimen is extracted via the abdominal ports or incisions. In laparoscopic-assisted vaginal hysterectomy (LAVH), the laparoscopic approach is utilized to perform any needed adnexal surgery and control the adnexal blood supply (utero-ovarian ligament if ovaries are conserved or infundibulopelvic ligament blood supply if ovaries are removed). The remainder of the procedure is performed vaginally, including entry into the peritoneal cavity and ligation of the uterine vessels from below.

Instrument choice varies by institution and surgeon preference. Typical equipment for a laparoscopic hysterectomy includes grasping, dissection/cutting, and hemostatic devices. A monopolar or bipolar electro-surgical device, ultrasonic dissector, and/or an advanced vessel sealing/ligation device are commonly employed. Use of multiple disposable instruments generally adds to cost. Regardless of instrument choice, knowledge of electro-surgical principles is essential to a safe operation; unexpected injury may result from direct or capacitive coupling, insulation failure, and lateral thermal spread.

Among patients treated by laparoscopic hysterectomy, the intraoperative complications are as follows: bowel injury 2%, vascular injury 4%, bladder injury 1% and ureter injury less than 1% (3). Complications may arise during initial abdominal access, port placement, dissection, or use of electrosurgery. A Cochrane database review in 2006 by Johnson et al suggests that TLH should be preferred to abdominal hysterectomy for benign gynecological disease. As experience with total laparoscopic hysterectomy is increasing, gynecologists have begun to debate the role of laparoscopic hysterectomy in women otherwise suitable for vaginal hysterectomy. The superiority of vaginal hysterectomy over laparoscopic hysterectomy, particularly, total laparoscopic hysterectomy, has begun to be challenged.

With the progress of surgical techniques and improvements of laparoscopic instruments, hysterectomies for large uteri being performed by laparoscopy are increasingly more safe and effective (4). A large uterus will lead to several surgical difficulties during laparoscopic hysterectomy, such as limited operative field, restrictive instrument range of motion, and difficult removal of the specimen. The large uterus are often associated with higher risk of complications and morbidities, such as prolonged operation time and excessive blood loss from retrograde bleeding (5)

From a technical point of view, laparoscopic approach benefits include high-definition imaging and vision amplification, allowing for an easier access to the uterine vessels, ureter, rectum and vagina (6). Besides offering a better view, the laparoscopic approach also offers advantages in

terms of operative time, hospital stay, use of analgesia, and short-term patient satisfaction. Presently TLH is considered to be the day care surgery with minimal complication (7).

The lack of professionals with enough training and experience was identified as the major restriction to the development of laparoscopic surgery. Gynecologists should acquire adequate skills and training in every approach to hysterectomy, allowing for an individualized choice, taking into consideration surgery indication, patient's characteristics and will. There are however evidences that the approach selection is rather based on surgeon's preference and experience than on evidence from the literature (8, 9)

3.0 LITERATURE REVIEW

3.1 OUTCOME OF TOTAL LAPAROSCOPIC HYSTERECTOMY (TLH)

3.11 DURATION OF OPERATION

Duration of operation mainly depend on complexity of the surgery itself and surgeon' s experience and technique. Wattiez et al (2002) compared woman undergoing TLH for uteri>300 g and ≤ 300 g, operative time was higher in the first group (156 vs 108 minutes, $p<0.001$). Using a cut off of 500g to define a bulky uterus, Wang et al. (2004) demonstrated a prolonged operative time (91.1 vs. 77.4 minutes; $p<0.01$) during TLH for uteri of increased size. Fanning et al. (2008) confirmed the feasibility of performing TLH for uteri above 1000g. They were able to successfully carry out 14 of 15 procedures (93%), with an average uterine weight of 1090g, a surgical time of 210 minutes. A study by Katherine et al (2007) showed the mean surgery duration was 130 minutes (SD=56; range, 28 to 355). Over one fifth (23.7%) of patients' surgeries were completed in 90 minutes or less. Neither age ($r=0.025$, $P=0.513$), body mass index ($r=0.060$, $P=0.115$), nor parity ($t=1.896$, $P=0.058$) impacted duration, but the increasing number of cases performed by the surgeon reduced duration ($r=-0.448$, $P<0.001$). Wann et al (2016) demonstrated the mean operation time and uterus removal time were significantly shorter in the morcellation group than in the transvaginal group (116.4 \pm 44.6 min versus 128.6 \pm 56.4 min and 15.8 \pm 6.6min versus 20.8 \pm 7.8 min,). Cristina et al (2014) showed the mean operating time during the total study period of 4 years was 77.7 \pm 27.5 minutes, but it decreased significantly as the surgical team's training increased.

3.12 BLOOD LOSS

A study by Catherina et al (2007) showed the average blood loss was 130 mL (SD=178; range, 0 to 1200, median 75) with 16% of patients (n=132) losing less than an estimated 10mL of blood. More than half of the patients lost less than 50 mL of blood. While age ($r = -0.018$, $P=0.633$) and BMI ($r=0.050$, $P=0.184$) did not correlate with blood loss, lower parity ($t = -2.91$, $P=0.004$) and increasing experience ($r = -0.247$, $P < 0.001$) correlated with reduced blood loss. Samina et al (2017) demonstrated no significant blood loss when comparing patient with previous caesarian section with no caesarian scar. Only 1 patient (0.3%) required blood transfusion (uterus weight of 1800 g) due to intraoperative blood loss of 500 ml and preoperative anemia (Hb 9.2 g/dl) as reported by Liliana et al (2017).

3.13 UROLOGICAL INJURY

Injury of the urinary tract is the most common major complication of gynaecological laparoscopic surgery. Injury to either bladder or ureter results in significant morbidity for the patient and may lead to litigation (10). The urinary bladder is at risk of injury during laparoscopic gynaecological surgery, either due to the entry process (for example during suprapubic port insertion) or due to its close association with the operating field (for example during hysterectomy). In complex cases the bladder can also be at risk because of its direct involvement in the disease process (utero-vesical endometriotic nodule). Most injuries occur during dissection of the bladder from the cervix and therefore the most common site is in the midline, above the inter-ureteric bar (11). Although not evidence-based, bladder catheterisation prior to peritoneal insufflation and insertion of trocars is recommended to avoid injury to a

bladder distended by urine. Kyung et al. also advise insertion of an indwelling catheter in long procedures. Keeping the bladder empty during surgery will protect it not only because its decreased size will keep it out of the surgeon's operating field, but also because an empty bladder cannot be penetrated as easily as a distended one (12,13). It is thought that approximately half of bladder injuries remain unrecognized during the primary operation (14).

Just like the bladder, the ureter's proximity to the female genital tract puts it at risk of injury during pelvic surgery. Most published studies quote a range of ureteric injury rates at laparoscopic gynaecological surgery from <1% to 2% (22). A Cochrane review reported a higher incidence of ureteric injuries associated with laparoscopic hysterectomies compared to abdominal and possibly vaginal hysterectomies (15). The most common sites of ureteric injury in laparoscopic surgery are at the pelvic brim (where the ureter comes into close proximity with the infundibulopelvic ligament which contains the ovarian vessels) and lateral to the cervix (during division or coagulation of the uterine artery or the uterosacral and cardinal uterine ligaments) (16).

3.13 BOWEL INJURY

Bowel injury is thought to be a rare complication of laparoscopy but carries a high rate of morbidity and mortality, particularly when diagnosed postoperatively (17). The majority of bowel injuries (55%) occurred during initial abdominal access obtained using a Veress needle or trocar placement. A recent systematic review of 28 randomized controlled trials found no difference in major vascular or visceral complications between the open Hassan technique and

the closed Veress needle approach however, the open-entry technique resulted in fewer failed entries (18). It has been suggested that the open technique may facilitate intraoperative diagnosis of bowel injury, reducing mortality associated with delayed recognition (19). Managing bowel injury frequently requires laparotomy, although several studies support the safety of intraoperative laparoscopic repair (20,21,22). Bowel injuries diagnosed postoperatively almost always require laparotomy, because the entire abdomen must be evaluated (23,24).

3.15 VESSEL INJURY

Injuries involving the inferior epigastric vessel are the most common type of vascular complication. The incidence of abdominal wall bleeding is 0.3% to 0.5% (25). Epigastric and less commonly muscular vessels may be the origin of bleeding. These injuries usually occur in relation to the positioning of accessory ports, used principally to allow the insertion of the hand instruments necessary for dissecting and manipulating tissue. Blood dripping into the operative field may indicate intraoperative bleeding, but postoperatively diagnosed massive bleeding is also possible. Postoperative hematoma and abscess according to infection of the hematoma may be other consequences.

Retroperitoneal major vascular injuries are mortal complications and may be related to the Veress needle, trocar, or energy source. Of the cases reported, approximately 20% of the major vascular injuries resulted in death. The incidence is estimated to range from 0.04% to 0.5%. (26,27) Most injuries were entry related and independent of the complexity of the surgery (28).

In this situation, either the aorta, vena cava, or, more commonly, the common iliac vessel has been traumatized.

3.16 VAGINAL VAULT DEHISCENCE

Vaginal vault complications in laparoscopic surgery may occur, even though they are rare (29). It is believed that the risk of vaginal cuff dehiscence is correlated to the chosen approach to hysterectomy and to suture. The suture of the cuff by vaginal route is associated with a lower risk of complications and a shorter operative time (30). However, different sutures laparoscopically performed can differ in operative time and complications (31). Mereu et al (2018) reported, in 83.3% of cases, a laparoscopic vaginal cuff closure has been performed with a continuous barbed suture; 7 (1.9%) cases of bleeding and 3 (0.8) cases of dehiscence, 4 (1.1%) requiring reintervention without general anesthesia, while 6 (1.6%) had complications that were considered minor and did not require any medical or surgical intervention. These findings are in line with the 0–3.3 percentage of dehiscence reported in recent suture dehiscence literature (32,33).

3.17 THROMBOEMBOLISM

The most common cause of preventable deaths in hospitalized patient is venous thromboembolic events (VTEs), including deep venous thrombosis (DVT) and pulmonary embolism (PE) (34) It has been suggested that the risk of VTE may be reduced in patients undergoing minimally invasive gynecologic surgery compared to open surgery because minimally invasive surgery is associated with less surgical trauma, infrequent use of retractors, shorter hospital stay, and faster return to daily activities. There is a paucity of data on the incidence of VTEs in patients

undergoing minimally invasive surgery, including laparoscopic and robotic surgery. As a result, there are no definitive guidelines referring to prevention of VTEs in patients undergoing minimally invasive surgery. American College of Chest Physician (ACCP) recommends only early ambulation for patients undergoing laparoscopic surgery, unless they have other risk factors for VTE (35). ACOG recommends thromboprophylaxis on the basis of patient and procedure risk factors, regardless of whether the procedure is open or performed laparoscopically. (36)

3.2 SAFETY OF TLH IN PATIENT WITH PREVIOUS CAESARIAN SECTION

TLH in the presence of patients with previous cesarean section (CS) is becoming increasingly common. Currently, hysterectomy constitutes the second most common operation performed in women after CS (37) which accounts for up to 60 % of deliveries in some countries as estimated by the recent CORONIS trial (38). When performing TLH in these patients, bladder adhesions to the uterus may make dissection much more difficult with higher complication rates, principally related to major blood loss or urologic injuries (39). Surgical adhesions caused by previous CS or other pelvic surgery may cause distortion of pelvic anatomy, making the TLH technically difficult. This is of outmost importance when mobilizing the bladder off the cervix, a critical step during any hysterectomy. Alternatively, surgeons could prefer to perform a laparoscopic supracervical hysterectomy (LSH), instead of TLH to reduce the risk of urological injuries. So far, there is no evidence to support the election of LSH over TLH in patients with previous CS.

3.3 SAFETY OF TLH IN PATIENT WITH PREVIOUS PELVIC SURGERY

Many surgeons consider that previous experience of pelvic surgery (eg ovarian cystectomy, myomectomy, appendicectomy) increases the incidence of complications relating to hysterectomy. Since TLH allows improved exploration and an opportunity for more delicate dissection, Nadiye et al (2018) evaluated the reliability and safety of TLH in patients who had previously undergone pelvic surgery. They did not find any significant difference in terms of major complications between the previous pelvic surgery and no pelvic surgery groups. The results from this study demonstrated that TLH is not a risk factor regarding major complications or lower urinary system injuries in cases with a history of previous pelvic surgery (40).

3.4 SAFETY OF TLH IN OBESE PATIENT

Obesity and comorbidities associated with it, are well known factors that negatively affect surgical outcomes. Body mass index was calculated by dividing a person's weight in kilograms by the square of their height in meters. Ideal BMI has been defined as between 18.5 to 24.9 kg/m², overweight is having a BMI between 25 to 29.9 kg/m², and obese patients are those with a BMI of 30 kg/m² or more (41). Laparoscopic techniques may be particularly well suited to obese patients as they can avoid the poor healing of surgical wounds and infection especially when diabetes is present, and also afford more rapid recovery and shorter period of hospitalization than open procedures (42). However, laparoscopic surgery in the obese gynecologic patient can be technically challenging. Establishment and maintenance of the pneumoperitoneum pose significant difficulty, given the thickness of the abdominal wall and the amount of preperitoneal fat (43). Although large women tolerate increased intraperitoneal

pressure well with regard to cardiac function, respiratory mechanics can be adversely affected for the duration of the pneumoperitoneum. In particular, large women often need higher than usual inspiratory pressures, especially in Trendelenburg position, because the weight of the abdominal wall, bowel, and omentum reduces ventilatory compliance during the surgery (44).

3.5 SAFETY OF TLH RELATED TO ANESTHESIA

The aim of anaesthetic management of patients undergoing laparoscopic surgery should be to allow the physiological changes during surgery with minimal effects on body's vital systems and rapid recovery from anaesthesia with minimal residual effects. The physiological changes during laparoscopic surgery occur mainly due to two reasons: a) creation of pneumoperitoneum and b) position of patient during surgery. The major problems during laparoscopic surgery are related to the cardiopulmonary effect of pneumoperitoneum, systemic carbon dioxide absorption, venous gas embolism, unintentional injuries to intra-abdominal structures and patient positioning. (45)

The pneumoperitoneum leads to an increase in the intra-abdominal pressure with a consequent elevation of the diaphragm. This results in collapse of basal lung tissue ultimately causing decreased functional residual capacity (FRC), ventilation perfusion ratio (V/Q) mismatch, increase intrapulmonary shunting of blood which all lead to hypoxemia and increased alveolar arterial oxygen gradient. The cardiovascular changes occurring during laparoscopic procedure are because of both mechanical and chemical effects of CO₂-induced pneumoperitoneum. The mechanical effect of pneumoperitoneum is compression of the inferior vena-cava, which causes reduction in venous return leading to decrease cardiac output and increase in the central venous pressure, resulting in increased vascular resistance in the arterial circulation. In Trendelenburg

position, there is an increase preload due to an increased in the venous return from lower extremities. This position results in cephalic shifting of viscera, which accentuates the pressure on the diaphragm.

4.0 RATIONALE OF THE STUDY

Currently there is paucity of data on Total Laparoscopic Hysterectomy (TLH) and operation outcome in Malaysia. The aim of this study to describe Hospital Sultan Abdul Halim's experiences in performing TLH and to evaluate complication rates related to TLH. Issues such as pain score, patient satisfaction and return to work were not considered due to retrospective nature of the study long term. Postoperative quality of life, urinary incontinence and sexual function require further study.

5.0 OBJECTIVES OF THE STUDY

General objective :

To study the outcome of Total Laparoscopic Hysterectomy in Hospital Sultan Abdul Halim

Specific objectives :

1. To describe the demographic data of patients undergoing TLH in HSAH
2. To determine the outcome of TLH in HSAH, which include
 - a. Duration of operation
 - b. Intraoperative blood loss
 - c. Perioperative complication
3. To assess the safety of TLH in patients with one or more previous caesarian section (CS) or pelvic surgery compared to those without previous surgery
4. To estimate the risk of operative and postoperative complications for obese patients undergoing TLH compared with non obese patients.

6.0 ABBREVIATIONS

Adenomyosis is defined as the presence of endometrial tissue (both gland and stroma) deep within the myometrium.

Age is defined as age in completed years at the year of surgery.

Blood loss is defined as volume of blood in the negative pressure suction bottles (mL).

Body mass index (BMI) is defined as a person's weight in kilograms divided by the square of height in meter (kg/m^2) : Underweight < 18.5 , Normal weight 18.5-24.9 , Overweight 25-29.9 ,Obesity > 30 .

Caesarian section is defined as surgical procedure in which the fetus or fetuses are delivered abdominally (through incision in maternal abdomen and uterus).

Deep vein thrombosis (DVT) is defined as formation of blood clot in deep vein, commonly in the legs or pelvis.

Duration of operation is define as time from the insertion of the trocar to skin closure of the last port site (minutes).

Dysfunctional uterine bleeding (DUB) is defined as irregular uterine bleeding that occurs in the absence of pelvic pathology and medical disease.

Endometrial hyperplasia is defined as endometrial thickening with proliferation of irregularly sized and shaped glands and an increased gland to stroma ratio.

Fibroid is defined as a benign smooth muscle neoplasms that typically originate from myometrium.

Iatrogenic injury is defined as unintentional injury to tissue or organ during operation.

Parity is defined as number of pregnancies reaching 24 weeks.

Pelvic surgery is defined as any surgery procedure involving organ/structure within pelvic cavity or at pelvic area.

Pneumonia is defined as a form of acute respiratory infection that affect the lungs.

Port site infection is defined as an infection involving area over the ports insertion.

Pulmonary embolism (PE) is defined as obstruction of the pulmonary artery or one of its branches by material (thrombus, tumor, or air) that originated elsewhere in the body.

Subcutaneous emphysema is defined as presence of gas or air under the skin

Uterine size is defined as the size of the uterus by abdominal or bimanual examination.

Vaginal vault dehiscence is defined as separation of the vaginal edges following hysterectomy.

7.0 RESEARCH METHODOLOGY

7.1 Study design, study venue and study duration

This is a retrospective observational study, which was conducted in gynaecology clinic Hospital Sultan Abdul Halim (HSAH) for period of 10 years duration from 1st January 2008 to 31st December 2017.

7.2 Study population

Patients undergoing Total Laparoscopic Hysterectomy (TLH) in HSAH from 1st January 2008 to 31st December 2017.

7.3 Sample size calculation

Sample size is calculated by using the previously reported 40% of the indication of surgery was uterine fibroid – Pattanaik T, Mishra SP, Das S. Total Laparoscopic Hysterectomy: A Retrospective Observational Study in a Teaching Hospital Ann. Int. Med.Den. Res. 2017;3(1) OG10-OG13

The following formula (Daniel,1999) was used

$$n = \frac{Z^2 P (1-P)}{d^2}$$

$$d^2$$

n = sample size

Z = statistic for a level of confidence

P = expected prevalence or proportion

d = precision

Z = 1.96 (For the level of confidence of 95%, which is conventional, Z value is 1.96)

P = 40% (0.4)

d = 5% (0.05)

Thus estimated sample size = 369

7.4 Inclusion criteria :

1. All patients undergoing TLH in HSAH for benign disease

7.5 Exclusion criteria :

1. Patients who undergoing TLH for malignant disease

2. TLH associated with cystectomy/oophorectomy

7.6 Statistical Analysis

All statistical analysis was performed using Statistical Package for Social Sciences for Windows (SPSS 17.0 for Windows). Count data was expressed as number and percentage and compared using χ^2 or Fisher's exact test. Numeric data are presented as means \pm standard deviation (SD) and were compared using *t* tests. A *P* value of less than 0.05 was considered statistically significant.

7.7 Study Procedure

Patients were identified from hospital's registry. The written consent was obtained from the Hospital Director to gain access to the medical records. Case notes of the patients were traced from the record office.

For each patient the baseline characteristics, including age, parity, medical history, previous caesarean section, other previous pelvic surgery, body mass index (BMI); uterine size (gestation week) and the indication for hysterectomy.

Intraoperative parameters including conversion to laparotomy, time of surgery, blood loss, complications such as injury to bowel, bladder, ureter and blood vessel and major complication related to anesthesia.

Operative time was calculated from the insertion of the trocar to skin closure of the last port site. Estimation of blood loss was made on the volume in the negative pressure suction bottles (mL).

Postoperative parameters including duration of hospital stay, infections, vault haematoma or bleeding, deep vein thrombosis (DVT) or pulmonary embolism and vesicovaginal fistula or dehiscence. Patients attended a follow-up visit at 1 and 3 months after surgery.

Surgeon

TLH procedure done by a consultant with experience in gynaecology laparoscopic surgery more than 10 years assisted by specialist/medical officers more than 5 years experience in laparoscopic surgery.

Steps in Total Laparoscopic Hysterectomy

1. Patient Positioning.

Following anesthesia induction, the patient is placed in low dorsal lithotomy position in booted support stirrups to permit manipulation of the uterus. The patient's arms are tucked at her sides. Correct patient positioning is critical to avoid nerve injury. A bimanual examination is completed to determine uterine inclination. Inclination will direct positioning of the uterine manipulator. The vagina and abdomen are surgically prepared, and the bladder is drained. If a longer procedure is anticipated, a Foley catheter may be required as a full bladder can obstruct the operating view or increase the risk of bladder injury. Occasionally an orogastric or nasogastric tube may be inserted.

2. Uterine Manipulator

A uterine manipulator with its attached cervical cup is placed vaginally to assist uterine manipulation and delineate the cervicovaginal junction. A Sim speculum or vaginal retractors are used to display the cervix. To stabilize the cervix, a single-tooth tenaculum is placed on the anterior cervical lip. To permit manipulator insertion, the cervical os may need to be dilated using Hegar dilator. The uterus is also sounded to determine cavity depth for correct manipulator placement.

3. Primary Trocar Entry.

Abdominal access may be attained by any of the four basic techniques. These include Veress needle insertion, direct trocar insertion, optical-access insertion, or open entry methods. The umbilicus is usually chosen as the site of abdominal entry. However, if a patient's history suggests periumbilical adhesions, then entry at Palmer point may be preferred. A 5-mm or 10-mm umbilical port will house a suitable laparoscope examination. Generally, starting with a 5-mm incision and laparoscope will allow or adequate visualization of the abdominopelvic cavity. Should improved optics be desired, this can be easily changed to a 10-mm size. Once safe initial entry is confirmed, the abdomen is insufflated to reach an intraabdominal pressure of 15 mm Hg or less.

4. Additional Port Site Selection

In most cases, three additional 5-mm ports are inserted under direct visualization, example one suprapubic and two just medial and superior to the anterior superior iliac crests. Number and placement of secondary ports varied depend on surgeon preference.

5. Upper Abdomen Evaluation

All laparoscopic procedures begin with a systematic and thorough diagnostic inspection of the entire peritoneal cavity, including the pelvis and upper abdomen. Once safe initial entry is confirmed, the area directly below the primary trocar entry site is evaluated for bleeding or other signs of entry trauma. Prior to Trendelenburg positioning, the upper abdomen is examined. Specifically, the liver surface, gallbladder, falciform ligament, stomach, omentum, and right and left hemidiaphragms are inspected. The ascending, transverse, and descending colon are also viewed. During inspection of the ascending portion, the appendix is identified. After Trendelenburg positioning, bowel and omentum all toward the upper abdomen to expose the retroperitoneal structures. Now free of intestines, the area directly beneath the initial entry site is examined again. Previously unappreciated trauma to this area from initial abdominal entry might then be seen.

6. Examination of Pelvis

After examination of the upper abdomen, attention is turned to the pelvis. First, with the aid of the uterine manipulator the uterus is retroflexed and anteflexed, manipulate to left and right to view anterior and posterior cul-de-sac and also pelvic side walls. Uterine size, shape, and texture are also noted. To examine both fallopian tubes and ovaries, a surgeon may place a blunt probe into the cul-de-sac and sweep the probe forward and laterally. In doing so, the tubes and ovaries are lifted from the posterior cul-de-sac or ovarian fossa for inspection. Both ureters are visualized coursing from the pelvic brim, along the pelvic sidewall, and to the cervix. Both peristalsis and caliber are assessed.

7. Round Ligament Transection.

The proximal round ligament is grasped and divided.

8. Oophorectomy.

The infundibulopelvic (IP) ligament is grasped and pulled up and away from retroperitoneal structures. The presence and path of the ureter is identified. The IP ligament is isolated and dissected away from the ureteral course. The pedicle is coagulated, desiccated, or and then divided.

9. Broad Ligament Incision.

Following transection o the round ligament, the leaves of the broad ligament all open and between these leaves. The anterior leaf is incised sharply. This incision is directed caudally and centrally to the midline above the vesicouterine fold. The posterior leave requires incision caudally to the level of the uterosacral ligament. The loose areolar tissue separating the anterior and posterior leaves is dissected as well. Ultimately, opening the broad ligament provides access to lateral uterine anatomy, which is important for subsequent uterine artery ligation.

10. Bladder Flap Development.

After broad ligament incision bilaterally, the vesicouterine fold is grasped with atraumatic forceps, elevated away from the underlying bladder, and incised. This exposes connective tissue

between the bladder and underlying uterus in the vesicouterine space. Loosely attached connections can be bluntly divided by gently pushing against the cervix and caudally to move the bladder caudad. Denser tissue in the vesicouterine space is better divided sharply. With this, the tissue is elevated, and the scissors are kept close to the surface of the cervix to minimize inadvertent cystotomy risk. As this tissue is dissected, the vesicouterine space is opened. Electrosurgery may be needed to coagulate small bleeding vessels. Creating cephalad traction on the uterus with the uterine manipulator may also help with this dissection. Development of this space allows the bladder to be moved caudally and of the lower uterus and upper vagina. This mobilization of the bladder is necessary for final colpotomy and uterus removal.

11. Uterine Artery Transection.

After the uterine arteries are identified, the areolar connective tissue surrounding them is grasped, placed on tension, and incised. This skeletonizing of the vessels leads to superior occlusion on the uterine artery and vein. The arteries are then coagulated and transected.

12. Cardinal Ligament Transection.

Following uterine artery coagulation, the cardinal ligaments are transected on each side to reach the level of the uterosacral attachments.

13. Colpotomy