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Risk Factors Associated with Major Complications of Total Laparoscopic Hysterectomy

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ABSTRACT

Objectives: To determine risk factors associated with major complications of Siriraj total laparoscopic hysterectomy (SiTLH) technique.

Materials and Methods: A case-control study was conducted in 275 women who underwent SiTLH at a university-based tertiary care hospital. Cases consisted of 55 women with major intraoperative complications. Controls were 220 women with the uneventful operation, randomly selected from those who underwent SiTLH during the same period as cases. Data were retrieved from medical records, including baseline and operative characteristics, diagnosis and indications, surgeon experience, and characteristics of the complications.

Results: Cases and controls were comparable in terms of baseline characteristics, including age, body mass index, diagnosis, and surgeon's experience. Cases were significantly more likely to have previous abdominal surgery and have preoperative diagnosis of endometriosis. (41.8% vs 25%, p = 0.013 and 47.3% vs 29.5%, p = 0.012, respectively). In addition, cases were significantly more likely to have higher specimen weight, longer operative time, and estimated blood loss (p < 0.001). Among those with major complications, internal organ injuries occurred in 30 cases (54.5%) including injuries to bowel (21.8%), bladder (18.2%), and ureters (16.4%). Conversion to abdominal operation occurred in 32.7%. Multivariate analysis showed that, after adjusting for potential confounders, having had previous abdominal surgery and preoperative diagnosis of endometriosis independently increased risk of major complications (adjusted odds ratio (OR) 2.2, 95% confidence interval (CI) 1.2-4.29, p = 0.015 and adjusted OR 2.1, 95%CI 1.1-4.1, p = 0.019, respectively).

Conclusion: Having had previous abdominal surgery and preoperative diagnosis of endometriosis independently increased the risk of major complications of SiTLH procedure.

Keywords: laparoscopic hysterectomy, complications, abdominal surgery, endometriosis.

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ปัจจัยเสี่ยงที่สัมพันธ์กับภาวะแทรกซ้อนที่สำคัญจากการผ่าตัดผ่านกล้องตัดมดลูก

จุฑามาศ ชูทอง, พิสุทธิ์ ศรีชัยกุล, ดิฐกานต์ บริบูรณ์หิรัญสาร

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาปัจจัยเสี่ยงที่สัมพันธ์กับภาวะแทรกซ้อนหลักของการผ่าตัดผ่านกล้องตัดมดลูกโดยวิธี Siriraj total laparoscopic hysterectomy (SiTLH)*

วัสดุและวิธีการ: *การศึกษาแบบ case-control โดยสตรี จำนวน 55 คน ที่มีภาวะแทรกซ้อนหลักจากการผ่าตัด เป็นกลุ่มศึกษาและสตรีที่ไม่มีภาวะแทรกซ้อนหลักจากการผ่าตัด จำนวน 220 คน เป็นกลุ่มควบคุม ข้อมูลจากเวชระเบียน ได้แก่ ข้อมูลพื้นฐานทั่วไป ข้อมูลการผ่าตัด การวินิจฉัยโรค และภาวะแทรกซ้อนจากการผ่าตัด จะนำมาใช้คำนวณเพื่อหาปัจจัยเสี่ยงในการผ่าตัดผ่านกล้องตัดมดลูก*

ผลการศึกษา: *กลุ่มศึกษามี ระยะเวลาในการผ่าตัด และปริมาณการเสียเลือดมากกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติ ในกลุ่มศึกษาภาวะแทรกซ้อนที่พบมากที่สุดคือการบาดเจ็บต่ออวัยวะข้างเคียงพบ 30 คน (54.5%) ประกอบด้วยการบาดเจ็บต่อลำไส้ (21.8%) กระเพาะปัสสาวะ (18.2%) ท่อไต (16.4%) และเส้นเลือด (3.6%) การศึกษา Multivariate analysis พบว่าการมีประวัติผ่าตัดในช่องท้อง (adjusted odds ratio (OR) 2.2, 95% confidence interval (CI) 1.2-4.29, p = 0.015) และการวินิจฉัยภาวะเยื่อบุโพรงมดลูกเจริญผิดที่ (adjusted OR 2.1, 95%CI 1.1-4.1, p = 0.019) เป็นปัจจัยเสี่ยงที่ทำให้เกิดภาวะแทรกซ้อนหลัก*

สรุป: *ปัจจัยเสี่ยงที่สัมพันธ์กับภาวะแทรกซ้อนหลักจากการผ่าตัดผ่านกล้องตัดมดลูกด้วยวิธี SiTLH คือการมีประวัติผ่าตัดในช่องท้อง และการวินิจฉัยเยื่อบุโพรงมดลูกเจริญผิดที่*

คำสำคัญ: *การผ่าตัดผ่านกล้องตัดมดลูก, ภาวะแทรกซ้อน, การผ่าตัดในช่องท้อง, ภาวะเยื่อบุโพรงมดลูกเจริญผิดที่*

Introduction

Laparoscopic surgery is considered as an alternative surgical approach in gynecologic surgery. The advantages of laparoscopic surgery over laparotomy include a smaller incision, better visualization, less tissue trauma, shorter hospital stay, and less blood loss and fibrosis[1]. Moreover, surgical outcomes after laparoscopic surgery have been reported to be equivalent to or better than laparotomy[2]. Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital, Mahidol University, has begun laparoscopic hysterectomy since 2004 and developed a novel technique for laparoscopic hysterectomy (SiTLH) in 2006. The objectives of this technique are to reduce surgical complications and blood loss during surgery[3].

The overall complication rate in gynecologic laparoscopic surgery ranged from 0.2-10.3% but higher rates were noted in major laparoscopic operations such as hysterectomy ranging from 0.6-18%[4]. Major complications were identified as death, organ injuries that need the surgical correction, unintended laparoconversion, or massive blood loss, whereas minor complications include complications that have a low impact on patient's quality of life, such as postoperative fever, mild bleeding, postoperative urinary retention[5]. Data from most studies showed possible specific risk factors for laparoscopic surgery, including history of previous laparotomy, presence of adhesions, intra-operative technical difficulty, level of laparoscopic complexity, suspicion of malignancy ,and surgeon's experience[6-9]. However, there were the discrepancies in these results. It possibly due to study design, cohort size, and surgeon's expertise.

Currently, there is no information regarding this specific issue in Siriraj Hospital. Therefore, this study aimed to identify the risk factors of major complications from gynecologic laparoscopic surgery. The results could provide more information to identify those with higher risk and help raise awareness among surgeons to prepare better and further minimize the risk of major complications.

Materials and Methods

After approval from Siriraj Institutional Review Board, a case-control study was conducted on 2,858 women who underwent SiTLH as a major laparoscopic procedure at the Department of Obstetrics and Gynecology, Faculty of Medicine Siriraj Hospital between February 2014 and December 2020. Details of the SiTLH surgical technique have been previously reported elsewhere[3]. This technique begins with retroperitoneal dissection, an avascular area, at the beginning of the procedure to locate and ligate the uterine artery to minimize blood loss during surgery and improve surgical exposure. Furthermore, ureters and bladder were clearly identified before hysterectomy began.

Sample size was estimated based on pilot study that 25% and 10% had previous abdominal surgery among those with and without major complications, respectively. At 95% confidence level and 80% power with 4:1 control-to-case ratio, at least 50 cases and 200 controls were required.

Cases were identified as patients with acute major complications that occurred in 30 days postoperative period, including critical blood loss, organ injuries, unintended conversion to laparotomy, death, vaginal cuff dehiscence requiring surgical intervention, wound infection, re-admission, re-operation, and postoperative ureteric stenosis. Critical blood loss was defined as estimated blood loss that required intraoperative blood transfusion or total blood loss of ≥ 1000 mL[3,10]. Organ injuries are defined by Clavien–Dindo classification of grade > 3[11]. Controls were patients who underwent SiTLH and did not have any major complications. Controls were selected from those with uneventful operations during the same period of cases by two controls above and two controls below case as shown in

Fig. 1. All the operations were performed by surgeons who had laparoscopic surgery experiences of more than five years at the time of the operations.

Data were reviewed and extracted from medical records, including baseline and operative characteristics such as age, body mass index (BMI), diagnosis and indications, surgeon's experience, characteristics of the complications, and surgical outcomes. Body weight was categorized as normal weight (BMI 18.5-22.9 kg/m^2), underweight (BMI < 18.5 kg/m^2), overweight (BMI 23-24.9 kg/m^2), and obese (BMI ≥ 25 kg/m^2).

Descriptive statistics, including mean, standard deviation, number, and percentage were used to describe various characteristics as appropriate. Student t-test, Mann-Whitney U test, Chi-square test, and Fisher's Exact test were used to compare characteristics between cases and controls. Odds ratios (OR) and 95% confidence intervals (CI) were estimated to determine the association between major complications and various characteristics. Multivariate logistic regression analysis was performed to evaluate independently associated factors for major complications, adjusted for potential confounders. A p value of < 0.05 was considered statistically significant. All analyses were performed using IBM SPSS Statistics for Windows®, Version 21.0. Armonk, NY: IBM Corp.

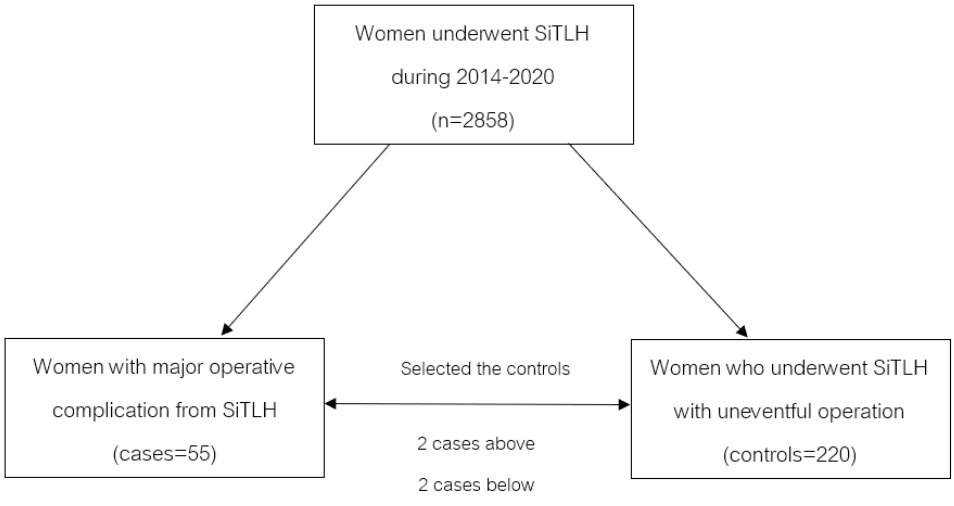

Fig. 1. Flow chart of the study population.

Results

A total of 2,858 women who underwent SiTLH at Siriraj hospital 275 women were enrolled in this study. Cases consisted of 55 women with major complications, and controls consisted of 220 women with uneventful operations. The prevalence of major complications from the SiTLH occurred 1.9%. Baseline characteristics between the two groups were compared, and the results are shown in Table 1. Both groups were comparable concerning age, BMI, diagnosis, primary pathologic site, and surgeon's experience. However, cases were significantly more likely to have previous abdominal surgery (41.8% vs 25.0%, p = 0.013)

Comparisons of operative characteristics between the two groups are shown in Table 2. Cases were significantly more likely to have endometriosis (47.3% vs 29.5%, p = 0.012). Compared with controls, cases had significantly longer operative time (190 vs 150 minutes, p < 0.001) and higher estimated blood loss (150 vs 30 mL, p < 0.001).

Table 1. Comparison of baseline characteristics between the 2 groups.

Characteristics	Cases n = 55	Controls n = 220	p value
Mean age ± SD (years)	44.9 ± 8.2	45.5 ± 10.5	0.709
Mean BMI ± SD (kg/m^2)	23.9 ± 4.6	24.4 ± 4.8	0.550
BMI category			0.897
Normal	31 (56.4%)	123 (55.9%)	
Underweight	5 (9.1%)	14 (6.4%)	
Overweight	13 (23.6%)	57 (25.9%)	
Obese	6 (10.9%)	26 (11.8%)	
Diagnosis condition			1.00
Benign pathology	51 (92.7%)	203 (92.3%)	
Malignant pathology	4 (7.3%)	17 (7.7%)	
Primary pathologic site			0.282
Uterus only	46 (83.6%)	193 (88.9%)	
Uterus with others	9 (16.4%)	24 (11.1%)	
Previous abdominal surgery			0.013
No	32 (58.2%)	165 (75%)	
Yes	23 (41.8%)	55 (25.0%)	
Surgeon's experiences			0.673
≥ 10 years	30 (54.5%)	113 (51.4%)	
5 - 10 years	25 (45.5%)	107 (48.6%)	

SD: standard deviations, BMI: Body Mass Index

Table 2. Comparison of operative characteristics between the 2 groups.

Operative characteristics	Cases n = 55	Controls n = 220	p value
Existence of endometriosis			0.012
No	29 (52.7%)	155 (70.5%)	
Yes	26 (47.3%)	65 (29.5%)	
	Median (IQR)	**Median (IQR)**	
Specimen weight (grams)	250 (160-453)	221 (150-380)	0.191
Operative times (minutes)	190 (150-250)	150 (115-188)	< 0.001
Estimated blood loss (mL)	150 (50-450)	30 (20-73.7)	< 0.001

IQR: interquartile range

Characteristics of major complications are shown in Table 3. Internal organ injuries occurred in 54.5%, including bowel, bladder, ureter, and vessel injuries. Other complications consisted of unintended conversion to laparotomy (32.7%), critical blood loss (16.4%), and vaginal cuff dehiscence (7.3%). Re-operation was required in 30.9% and re-admission was needed in 32.7% which included organ injuries for fourteen patients including ureter injury for nine patients, bladder injury for two patients, bowel injury for two patients, blood vessel injury for one patient, and vaginal cuff dehiscence for four patients. Patients with ureter and bladder injuries presented with abdominal pain and fever or watery discharge from

the vagina. Patients with ureteral injuries underwent ureteral reimplantation for three patients and others were treated with ureteral stenting. Patients with bladder injuries were repaired vaginally. For bowel injury, patients presented with fever and intraabdominal collection. Exploratory laparotomy with repair bowel and colostomy was done in both cases. Patient with blood vessel injury presented with a large vaginal stump hematoma with active bleeding from the vagina and anemia one week postoperatively. Angiographic embolization was successfully done at the vaginal branch of the uterine artery.

Table 3. Characteristics of major complications (n = 55).

Major complications	n (%)
Re-operation	17 (30.9%)
Re-admission	18 (32.7%)
Critical blood loss	9 (16.4%)
Organ injury	30 (54.5%)
Ureter injury	9 (16.4%)
Bladder injury	10 (18.2%)
Bowel injury	12 (21.8%)
Vessel injury	2 (3.6%)
Conversion to TAH	18 (32.7%)
Vaginal cuff dehiscence	4 (7.3%)

TAH: total abdominal hysterectomy

Multivariate logistic regression analysis was performed to determine independently associated factors for major complications of SiTLH, and the results are shown in Table 4. After adjusting for potential confounders, independently associated risks for major complications were previous abdominal surgery (adjusted OR 2.21, 95%CI 1.17-4.17, p = 0.015) and the existence of endometriosis (adjusted OR 2.15, 95%CI 1.13-4.06, p = 0.019).

Table 4. Multivariate logistic regression analysis to determine independent associated factors for major complication of SiTLH, adjusted for potential confounders.

Factors	Adjusted OR	95% CI	p value
Age	1.0	0.97-1.04	0.852
BMI category			
Normal	1.0		
Underweight	1.28	0.40-4.10	0.677
Overweight	0.94	0.45-1.99	0.88
Obesity	1.17	0.39-3.43	0.776
Previous abdominal surgery	2.21	1.17-4.17	0.015
Diagnosis of malignancy	1.06	0.27-4.15	0.929
Existence of endometriosis	2.15	1.13-4.06	0.019
Uterine pathology only	0.52	0.21-1.29	0.156
Surgeon's experience of 5-10 years	0.87	0.46-1.62	0.653

SiTLH: Siriraj total laparoscopic hysterectomy, OR: odds ratio, CI: confidence interval, BMI: body mass index

Discussion

Over the past decades, laparoscopy has been the gold standard for diagnosis and therapeutic purposes. Many patients prefer TLH over total abdominal hysterectomy due to the benefits of TLH. Laparoscopic surgery remains an intra-abdominal procedure. Therefore, it shares all the intraoperative and postoperative risk of laparotomy, such as infection and injury to the adjacent intraabdominal organs. Recognizing risk factors of major complications from TLH is thus important in improving care process and aiding physicians to identify high-risk women and provide proper information to decide mode of surgical access.

The results of this study showed that independently associated risks for major complications of the SiTLH were previous abdominal surgery and the existence of endometriosis. A previous study has also reported that serious complications were significantly more frequent in patients with prior abdominal surgery with a similar adjusted OR.5,9 While the other study focusing on risk of unintended laparoscopic conversion as a major complication also found that patients with previous laparotomy had an increased risk of laparoscopic surgery failure.6 Previous abdominal surgery might increase the chance of abdominopelvic adhesions that could limit visualization during laparoscopic surgery and increase the risk of organ injuries during adhesiolysis procedure. A previous study showed that umbilical adhesion was presented in 0.68% of patients without history of surgery and 19.8% in patients with previous Pfannenstiel and 51.7% with vertical abdominal incision[12].

In this study, the presence of endometriosis also significantly increased the risk of major complications of the SiTLH. A recent study has reported that the independent risk factors for severe TLH complication events was endometriosis, with OR of 3.51[13]. Another study has reported similar results.14 The nature of endometriosis might be explained that it can cause continuous inflammation and scaring that lead to adhesion formation, derangement of normal tissue neovascularization, and anatomical distortion. Furthermore, these can lead to inadequate exposure, uterine immobility, and bleeding during the procedures, especially for large uterus.

Some studies have reported that postoperative hemoglobin drop was an independent risk factor for postoperative morbidity and mortality[14,15]. However, as postoperative hemoglobin is not included as a routine test according to our institutional guideline, such association could not be evaluated. Further studies might be required to determine if hemoglobin is of value in predicting major SiTLH complications. Other risk factors for TLH complications that have been reported including age, obesity, malignant condition, non-uterine pathology as a major surgical indication, and surgeon's experiences[6-8]. This study evaluated these factors but did not reach a statistical significance level in multivariate analysis. The discrepancy might be from the differences in TLH technique in different settings and the surgeon's experiences. The technique used in Siriraj Hospital includes the proper port placement according to body habitus, use of retroperitoneal space, and early ligation of uterine blood supply before initiation of hysterectomy.

Re-admission occurred in as many as 32.7%, possibly because some postoperative complications were unrecognized intraoperatively and required in-patient admission to treat and re-evaluate properly. The bowel, bladder, and ureter were common intraoperatively injured organs. The previous study has also reported that most internal organ injuries occurred in the bowel, especially in case of endometriosis[16].

The strengths of this study included that data were from a single tertiary center where all patients were operated on with similar surgical techniques by the experienced surgeons. All SiTLH-related data were routinely recorded and collected systematically. However, some limitations should be mentioned. Due to retrospective nature of the data, some information was unavailable in detail, such as severity or stage of

endometriosis, number and types of previous abdominal surgical procedures. The results might have limited generalizability due to population characteristics between settings. Further larger studies are needed to evaluate and identify significant associated risks of SiTLH complications and to determine if those complications are related to adverse surgical outcomes in more detail.

Nevertheless, the results of this study provide more insights into the management of women undergoing SiTLH. Understanding the significant risk factors will help physicians identify women at higher risk for the procedure. Awareness of both conditions will make the surgery safer and more effective.

Conclusion

Independently associated risks of major complications of SiTLH included having had previous abdominal surgery and diagnosis of endometriosis.

Potential conflicts of interest

The authors declare no conflicts of interest.

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