Clinical Predictive Score of Major Complications in Total Laparoscopic Hysterectomy

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Objective: To evaluate the clinical factors associated major complications in total laparoscopic hysterectomy and to develop a score for a predictive model.

Materials and Methods: A retrospective cohort study was conducted. Reproductive women that underwent total laparoscopic hysterectomy for benign gynecological diseases at the Department of Obstetrics and Gynecology, Pranangklao Hospital between January 2009 and April 2017 were recruited. Major complications were defined by the presence of bowel injury and urological injury detected within six weeks after surgery and cases that had been converted to laparotomy. The predictive model and prediction score were developed by multivariate logistic regression analysis.

Results: Five hundred fourteen patients were enrolled, 493 had no major complications and 21 had incurred at least one of the major complications. In comparing the two groups, age was not statistically different, while BMI was statistically different (25.2±2.0 versus 27.6±1.9, respectively; p<0.001). The patients who had histories of lower abdominal surgery, had an ultrasonography finding of a maximal diameter of tumor mass greater than 5 cm, and had dense pelvic adhesion had significantly more major complications. The clinical score risk to predict major complications was developed with a ROC of 95.74%. Cut-off levels of total score at 4 and 11, which had positive likelihood ratios of 9.58 and 23.47, were selected. Each patient was then categorized as a low, moderate and high-risk case, respectively.

Conclusion: The present study demonstrated that clinical factors had high accuracy for predicting major complications of total laparoscopic hysterectomy. However, it is necessary for the model to have an external validation to provide sufficient evidence about its performance.

Keywords: Total laparoscopic hysterectomy, Major complication, Predictive score

Total laparoscopic hysterectomy (TLH) is one of most common procedures in gynecologic surgery. It is already useful as a surgical approach for benign diseases like fibroid, adenomyosis, and endometriosis. However, the role of TLH for malignant and gynecologic cancer is becoming more widely accepted. By definition, TLH means the surgical removal of all parts of the uterus, including the cervix, by laparoscopy. In addition, it entails ligation of the ovarian arteries and veins endoscopically with the removal of the pathologic tissues either vaginally or abdominally, along with laparoscopic closure of the vaginal cuff[(1,2)].

However, the complications of surgery are still a concern. The time of occurrence of complications could begin with the onset of anesthesia, patient position adjustment during port entry, and intra-operative procedures until post-surgery. The major complications are organ injuries such as bowel, urinary bladder, and ureteric complication. These serious, harmful complications often led to conversion of a surgical approach to laparotomy in many cases. In addition, these cases involved the use of more blood

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transfusion and prolongation of the operation[3].

There are clinical risk factors that are related to the major complications. Obesity and underlying diseases, including diabetes mellitus and hypertension, were demonstrated as having an association with higher complications in gynecological endoscopy[4,5]. Previous abdominal surgery also incurred an increased risk of complications. Uterine weight of more than 500 g or large uterine mass were also related to intra- and post-operative complications with prolonged hospital stays[6-8]. However, to the best of the authors' knowledge, there is no practical use of these risks for prediction of complications or for surgical planning.

The present study aimed to evaluate the clinical factors associated with the major complications in TLH and to develop a score for the predictive model.

Materials and Methods

Research design consisted of a retrospective cohort study. The present study had been approved by the Ethic Committee of the Hospitals. Women, 30 to 70 years of age that underwent TLH with or without oophorectomy for benign gynecologic disease between January 2009 and April 2017 were recruited. Findings of malignant diseases were excluded. The surgical team comprised of two main surgeons who had experience in the use of laparoscopy for more than five years. The TLH procedure involved a standard technique with an open entry technique and four ports. The procedure was not changed during the period under study.

The baseline characteristics such as age, body mass index (BMI), history of lower abdominal surgery, diameter of tumor measured by preoperative transvaginal ultrasound, and the degree of pelvic adhesion at the operative site, were recorded. The severity of adhesions was graded according to the modified Nair's classification and categorized as no adhesion, filmy or dense and vascular adhesions[9].

The outcome that had major complications, defined as organ injury, consisted of major vascular, bowel, and urinary tract injuries detected during surgery or within six weeks after surgery. Cases that required open abdominal surgery were also considered to be major complications.

Statistical analysis

All clinical variables were compared between the two groups that had been categorized by major complications. Descriptive statistics were applied to describe study participants' characteristics. Multi-variable logistic regression was used to evaluate risk

ratio. Then the risk ratio of each clinical risk factor or predictor was divided by the smallest coefficients and rounded to the nearest whole number, resulting in an item of the risk score or predictive score. Each clinical predictor was converted to a score for the predictor. The final scores were summed to derive the score of each predictor. The model was tested as an AUC discriminate prediction score within a 95% confidence interval. The appropriate cut-off values of the scores were selected. The studied patients were classified as low, moderate, or high-risk categories according to the cut-off levels of their scores.

Results

Five hundred fourteen women underwent TLH during the studied period and provided complete data for analysis. Altogether, 493 patients had no major complications and were categorized as the "non-case" group, 21 (4.1%) patients had major complications and were categorized as the "case" group. Main indication for benign hysterectomy was myoma uteri, which consisted of 326 cases (73.15%). Other indications were adenomyosis, endometriosis, endometrial hyperplasia, and benign ovarian cyst with 9.15%, 8.8%, 7%, and 1.95%, respectively.

The major complications were bowel injury in two cases (0.39%), urinary bladder injury in eight cases (1.56%), ureteric injury in three cases (0.58%), and conversion to laparotomy in eleven cases (2.14%). There was no major vascular injury in the present series.

Table 1 compares the group of patients having major complications to the group having no major complications. The mean ages were not significantly different, but the BMI in the "case" group was significantly higher than the "non-case". The percentage of patients who had histories of lower abdominal surgery was significantly higher in the "case" group. The dense adhesion was found significantly higher in the "case" group than in the "non-case" group (42.9% versus 8.1%). The proportion of patients who had maximal diameter of mass more than 5 cm in transvaginal ultrasonogram was significantly higher in the "case" group.

The clinical factors causing increased risk of major complications by multivariate regression analysis are shown in Table 2. There were four clinical factors having significantly higher values of risk ratio, BMI above 25 kg/m², previous lower abdominal surgery, maximal diameter, and dense adhesion. When their risk ratios were adjusted to round numbers, the score were 3, 8, 5, and 1, respectively.

Table 1. Comparison of baseline characteristics of patient group that had no major complications with group that had major complications

	No major complications (non-case, n=493)	Having major complications (case, n=21)	p-value
	n (%)	n (%)	
Age (year), Mean±SD	45.5±5.3	43.4±5.7	0.081
BMI (kg /m^2), Mean±SD	25.8±2.0	27.6±1.9	<0.001
Previous lower abdominal surgery	15 (3.0)	11 (52.4)	<0.001
Ultrasound finding of maximal diameter of tumor size >5 cm	12 (2.4)	10 (47.6)	<0.001
Adhesion			<0.001
No adhesion	448 (90.9)	7 (33.3)	
Filmy adhesion	5 (1.0)	5 (23.8)	
Dense adhesion	40 (8.1)	9 (42.9)	
Blood transfusion	16 (3.2)	10 (47.6)	<0.001
Duration (minute), Mean±SD	108.2±30.5	181.7±51.9	<0.001
Blood loss (cc), Mean±SD	119.4±78.5	337.9±294.5	<0.001

BMI=body mass index; SD=standard deviation

Table 2. Relationship between clinical factors and major complications by multivariate binary logistic regression analysis, and score derived from adjusted risk ratio

Factors	Risk ratio	95% conference interval	p-value	Score
Age above 45 years	0.54	0.17 to 1.79	0.317	-
BMI above 25 kg/m^2	10.12	1.13 to 90.64	0.038	3
Previous lower abdominal surgery	31.64	8.43 to 118.82	<0.001	8
Ultrasound finding of maximal diameter of tumor mass >5 cm	20.71	5.37 to 79.88	<0.001	5
Dense pelvic adhesion	3.75	1.01 to 13.88	0.048	1

BMI=body mass index

Table 3. Performances of the predictive model as classified by selected total score

Total score	Sensitivity	Specificity	Corrected classified	LR+	Risk
3	100%	38.74	41.25	1.63	Low
4 to 11	95.24 to 47.62	90.06 to 97.97	90.27 to 95.91	9.58 to 23.48	Intermediate
12	23.81	99.39	96.30	39.13	High

LR+=positive likelihood ratio

The final score was their sum. Regression analysis was then used to demonstrate whether this final score worked with major complications. The predictive model had an enclosed area of the AUROC curve of 95.74%, with a confidence interval between 92.35 and 99.13%, and showed a statistical significance as shown in Figure 1. When using the score to demonstrate the distributions of the "case" and "non-case", the "non-case" was shown to have a greater accumulation at a lower total score of 4.

As shown in Table 3, the cutoff point of the total score was analyzed to show the effect of sensitivity, specificity, and positive likelihood ratio (LR+) on the prediction of major complications. A cut-off score of 3 has 100% sensitivity and a 38.74% specificity, with positive likelihood ratio at 1.63 and a categorized
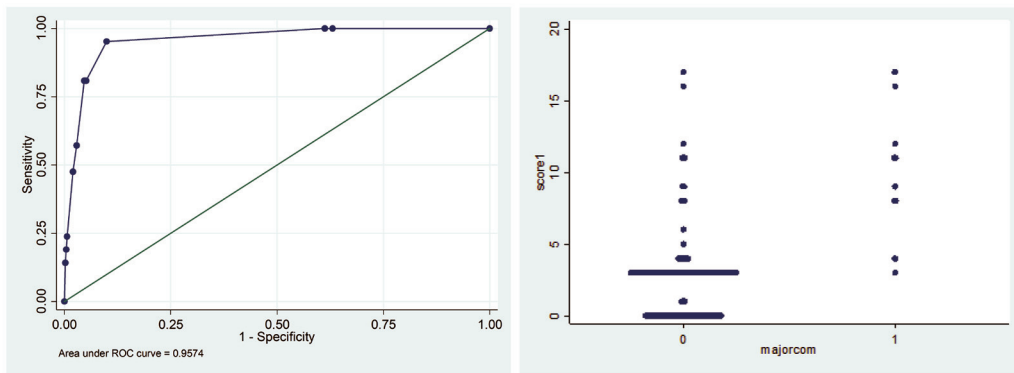
Figure 1. AUROC curve of the predictive model (left), the distribution of cases of having major complication (1) and non-case (0) by developed score (right).

score less than 4 as being at low risk. Scores between 4 and 11, categorized as intermediate risk, had a high specificity of 90.06% to 97.97% with LR+ of 9.58 to 23.48. The total score cut-off at 12 had high specificity and corrected classified at 99.39% and 96.30%, respectively, with LR+ at 39.13. If total score of a patient was greater than 11, the patient was categorized as being at high risk.

Discussion

TLH has been proven to cause less post-operative pain, shorter hospital stays, and more rapid recoveries when compared to abdominal laparotomy, but some evidence has shown that complications might occur more often. Meta-analysis study demonstrated that urinary complications are higher in laparoscopic by 2.7%, versus 0.8% in abdominal hysterectomy[10]. These complications occur mainly depending on techniques employed and the experience of surgeons. Some highly experienced laparoscopists declare that there is no absolute contraindication of laparoscopic hysterectomy for benign gynecologic disease. However, in the real world, distortion of pelvic anatomy by tumors and complexity of disease are the most important factors that increase the difficulty of surgery and lead to unexpected complications. Therefore, this matter has to be weighted with benefits and must be delineated from any clear medical indications for surgery.

Major organ injuries and complications are related to the complexity of the laparoscopic type. Bowel injuries had incidences of only 0.08% with diagnostic laparoscopy, but up to four times when laparoscopy was used for surgical treatment[11]. In the present series, the incidence was 0.39%, and these two cases were detected during surgery and had to be

corrected by open laparotomy. As regards to the major vascular injury associated to the port entry, the present study had none. A possible explanation is that the authors used the open technique of port entry. Urinary tract injuries were one of the most frequently occurring complications in the series and were associated with histories of lower abdominal surgeries with dense adhesion in the pelvis organs. This was consistent with the review of Adelman et al[12].

By using the multivariate regression analysis, the authors developed a score model to forecast chances of major complications. The history of previous abdominal surgery (open laparotomy) had the highest score of 8, which could be associated with pelvic adhesion. However, the dense adhesion score is surprisingly only 1. This result could be explained by the surgeon's awareness of complications, when a severe or dense adhesion was found during the initially laparoscopic visualization.

The authors proposed and categorized the total scores of the patients into three groups. A total score of 3 was chosen as the cut-off point because LR+ had a sudden six-fold increased from 1.63 to 9.58. For a patient who had a total score lower than 3, complication was unlikely to occur. The patient was categorized as a low-risk case. Hence, standard care and management are appropriate.

A patient having a total score of 12 had a very high probability of complications of almost 40 times when compared to the patient who had no score. In a high-risk case, the patient will receive serious counseling about the complications. The experienced surgeon must be available on site, and, in some cases, it is safer to undertake open surgery.

A total score between 4 and 11 is classified as an intermediate case. The chance of complications

rises, so these cases need to be meticulously investigated, employing such methodologies as computed tomography (CT) or magnetic resonance imaging (MRI) to see whether the operative field could be harmful to adjacent organs.

There are several limitations of the present study. The retrospective design of the present study could lead to recalling bias error and incomplete data. Some clinical factors such as history of lower abdominal symptoms were not clearly defined. Most of the surgery consisted of cesarean section, and the incision type was low midline, although some had a Pfannenstiel's incision. The multiple laparotomy is one factor which causes significant risk[13]. However, the data thus-far compiled are not sufficient for a complete analysis. Moreover, the present model was generated in a single center with a small group of surgeons. It requires an internal validation by another group of surgeons and finally it has to be applied under actual conditions and with external validation to enhance the confidence in the predictive scoring model before implementing in actual clinical practice.

Conclusion

The present study identified significant clinical factors related to the major complications of TLH and converted them into the new tool, the predictive score. The score had high performance for predictions of the major complications of TLH and might be useful for clinicians to consider appropriate TLH surgical plan. However, it is necessary to have an external validation to provide strong evidence about its performance before implementing into the clinical practice.

What is already known on this topic?

Major organ injuries and complications of TLH are related to risk factor such as obesity, tumor size, and dense pelvic adhesion.

What this study adds?

Clinical risk factors, namely histories of lower abdominal surgery, an ultrasonographic finding of maximal diameter of tumor mass greater than 5 cm, and dense pelvic adhesion had strongly associated with major organ injuries and complications of TLH.

These clinical factors could be developed into the score and a new tool for prediction of the major complications of TLH.

Acknowledgement

Conflicts of interest

The authors declare no conflict of interest.

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