

Epidemiology of complications associated with gynecological laparoscopy procedures in Ukraine: results a multicenter study

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ABSTRACT

Aim: To estimate the frequency of complications during laparoscopic gynecologic surgery for benign diseases in women and identify associated risk factors in Ukraine.

Materials and Methods: A multicenter, prospective cohort study was performed in gynecological departments from 10 regional hospitals of Ukraine between January 1, 2020, to December 31, 2022. The study included gynecologic laparoscopies for benign diseases in women performed at these hospitals. To identify risk factors and variables associated with complications, crude and adjusted odds ratios were calculated with unconditional logistic regression. Surveillance was performed during 30 days after gynecological laparoscopy procedures.

Results: A total of 14,440 laparoscopic surgeries were performed, 2,340 (16.2%) complications cases were observed. Of all complication's cases, 74.9% were detected after hospital discharge. The overall frequency of major complications was 5.04%, and that of minor complications was 11.2%. The most frequently reported complications types were serious bleeding complications (20.6%), intestinal perforation (17.9%), mild anemia (16.7%), severe anemia (transfusion) (16.1%), failed laparoscopy (9.3%), minor bleeding complications (8.3%), postoperative hematoma (6.7%), urinary tract infection (5.6%), and fever (5.0%). The level of technical difficulty and existence of prior abdominal surgery, and obesity were associated with a higher risk of complications associated with gynecological laparoscopy procedures.

Conclusions: Results this study suggest a high frequency of complications associated laparoscopic gynecologic surgery in Ukraine. Greater technical difficulty and prior surgery were factors associated with a higher frequency of complications.

KEY WORDS: laparoscopic gynecologic surgery, complications, risk factors, outcomes, Ukraine

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INTRODUCTION

Laparoscopic surgeries have evolved over decades to become a safe and the standard of care for abdominal surgeries. Laparoscopic surgery has become widely accepted by surgeons and patients as an effective technique to treat gynecologic pathologies [1]. Although laparoscopic surgeries have evolved and have become the standard of care over the years, the rate of major complications, namely vascular, bowel, and urological injuries, have remained rare but constant over the last 3 decades. Complications associated laparoscopic

gynecologic surgery are comparatively rare, especially injuries of major vessels like the aorta, which is a retroperitoneal structure [2, 3].

Currently, as the technology has improved and surgical skills have increased, the nature and characteristics of laparoscopic procedures have also become more complex. At gynecological departments equipped for advanced laparoscopic surgery, procedures such as surgery for complex adnexal lesions, hysterectomies, pelvic floor repair, and resection for severe endometriosis are now performed by this approach [4].

It is an evidence-based fact that minimal access surgery is superior to conventional open surgery since this is beneficial to the women, community and the health-care system. Over the past 50 years, many techniques, technologies and guidelines have been introduced to eliminate the risks associated with laparoscopic entry. No single technique or instrument has been proved to eliminate laparoscopic entry associated injury [2]. Proper evaluation of the women, supported by surgical skills and good knowledge of the technology and instrumentation is the keystone to safe access and prevention of complications during laparoscopic surgery.

Laparoscopic gynecologic surgery is associated with a low frequency of complications but is a procedure that is not without risk. Greater technical difficulty and prior surgery were factors associated with a higher frequency of complications [1].

According to the literature, the incidence of complications decreases as surgeons gain experience with laparoscopy [5], the growing difficulty of some procedures in gynecologic surgery may increase the frequency of severe complications (visceral and great vessel injuries) [6].

It is important for major complications to be diagnosed promptly during laparoscopy so that corrective measures can be taken intraoperatively [7, 8]. However, shortened hospital stays and minimally invasive or outpatient surgery have led to the delayed diagnosis of complications in the gynecology department rather than during the postoperative hospitalization period.

The epidemiology of complications during laparoscopic gynecologic surgery and identify associated risk factors is not well understood and remains underestimated. The true incidence of complications during laparoscopic gynecologic surgery is not fully understood as outpatient surveillance data are lacking.

AIM

The aim this study to estimate the frequency of complications during laparoscopic gynecologic surgery for benign diseases in women and identify associated risk factors in Ukraine.

MATERIALS AND METHODS

DESIGN, SETTING AND PATIENTS

A multicenter, prospective cohort study was performed in gynecological departments from 10 regional hospitals of Ukraine between January 1, 2020, to December 31, 2022. The study including women who have undergone gynecologic laparoscopic surgery for benign

diseases. All patients were local residents. Inclusion criteria: any women who underwent gynecological laparoscopic procedures, and had relevant medical data. Exclusion criteria: subjects who malignant tumor, severe dysfunction in the heart, lung, liver, kidney, mental diseases, fever due to medical causes, infection after cesarean section, urinary tract infection or thrombophlebitis.

DEFINITIONS

In this study the surgical indications for laparoscopy were classified into 3 groups according to the level of technical difficulty. These 3 groups were chosen based on the classifications of Chapron et al [7], Leonard et al [9], and Härkki-Sirén and Kurki [10], although in this study, groups 1 and 2 together were considered technically simple procedures, group 3 was considered moderate difficulty, and group 4 was considered complex surgery. In this study, the simple surgery group included tubal electrocoagulation, coagulation of bleeding areas without other procedures, and diagnostic laparoscopy with or without biopsy. The moderate difficulty group comprised ovarian surgery, including endometriosis (management of ectopic pregnancy, adnexectomy, cystectomy, salpingectomy, tubal plasty, and ovarian drilling), and removal of an intrauterine device that had migrated to the abdominal cavity. The complex surgery group included total and subtotal hysterectomy with or without pelvic lymphadenectomy and myomectomy.

DATA COLLECTION

In our study surveillance was performed during 30 days after gynecological laparoscopy procedures for to detect complications cases. All clinical records of patients undergoing laparoscopy procedures were included in the study. Data were collected from hospital records.

Data were collected by a questionnaire given to the women in ambulatory setting and combined with data from general practitioner and hospital records. Clinically relevant data of subjects with complications during laparoscopic gynecologic surgery were analyzed, and all clinical data were collected by obstetricians and related investigators receiving unified training. Information about patient characteristics, surgical procedure, laparoscopy-related complications, and length of hospital stay was entered into a database for later analysis. The following variables for patients' characteristics were recorded: age, morbid obesity (body mass index >35 kg/m²), prior abdominal surgery, year of surgery, and length of hospital stay (in days). Age was classified into 3 categories: <30 years, 30 to 60 years, and >60 years.

Table 1. Characteristics of 14,440 gynecological laparoscopy procedures in perinatal centers of Ukraine, 2020-2022

Variable	No (%)
Age group (yrs.)	
<30	3,915 (27.1)
30–60	10,050 (69.6)
>60	475 (3.3)
Morbid obesity	255 (1.8)
Prior surgery	2,275 (15.8)
Level of technical difficulty	
Simple	5,370 (37.2)
Tubal ligation	4,435 (30.7)
Diagnostic laparoscopy	785 (5.4)
Laparoscopy and biopsy	80 (0.6)
Coagulation	70 (0.5)
Moderate	7,820 (54.2)
Unilateral adnexectomy	1,490 (10.3)
Bilateral adnexectomy	755 (5.2)
Salpingectomy	1,470 (10.2)
Cystectomy	3,770 (26.1)
Tubal plasty	30 (0.2)
Adhesiolysis	205 (1.4)
Ovarian drilling	25 (0.2)
Complex	1,245 (8.6)
Subtotal hysterectomy	190 (1.3)
Total hysterectomy	520 (3.6)
LAVHa	420 (2.9)
Myomectomy	190 (1.3)
Length of hospital stay	
0–3 d	12,215 (84.6)
4–5 d	1,950 (13.5)
≥6 d	275 (1.9)

LAVH, laparoscopy-assisted vaginal hysterectomy.

ETHICS

Approval was granted by the Ethics Committee of Shupyk National Healthcare University of Ukraine. Consent was obtained by all participants in this study.

STATISTICAL ANALYSIS

All data were collected with Microsoft Excel. The statistical analysis was performed using IBM SPSS (Version 21.0, IBM SPSS Inc., Chicago, IL, USA). A descriptive analysis was produced for each variable. Differences between groups were identified with the χ^2 test for qualitative variables. In all analyses based on bilateral comparisons, $P < 0.05$ was considered statistically significant. To identify the factors associated with major

and minor complications, conversion to laparotomy, or failed laparoscopy, a specific logistic regression model was constructed for each dependent variable, and the crude and adjusted odds ratios were calculated together with their 95% confidence interval (CI).

RESULTS

INCIDENCE OF COMPLICATIONS

During the study period (2020–2022), a total of 14,440 laparoscopic surgeries were performed, 2,340 complications cases were observed. Of all complication's cases, 74.9% were detected after hospital discharge. The mean age was ± 35.8 years, and 70% of the patients were aged between 30 and 60 years. Prior abdominal surgery was recorded in 15.8% of the patients in this group. Most of the laparoscopies during the study period were of moderate technical difficulty (54.2%). The mean length of hospital stay was ≤ 3 days, and 84.6% of the patients were discharged during the first 3 days after the procedure. Patient characteristics and the indications for the laparoscopic approach are presented in Table 1.

Incidence of complications associated with gynecological laparoscopy procedures was 16.2% (95% CI, 15.9–16.5). Of these cases, 5.04% (95% CI, 4.8–5.6) were major complications and 11.16% (95% CI, 10.9–11.5) were minor complications. Bleeding was the most frequent major complication, with 13 due to a major vessel injury. The distribution of 2,340 complications associated with gynecological laparoscopy procedures in regional (tertiary care) hospitals is shown in Table 2.

RISK FACTORS

In our study, patients with prior abdominal surgery had significantly more ($P < 0.001$) serious complications (21.1% vs 10.9%) and more failed attempts at laparoscopy. A greater level of difficulty of the procedure was associated with both complications and failed laparoscopy ($P < 0.001$). Obesity and age were also significantly associated with failed laparoscopy ($P < 0.001$) and serious complications ($P = 0.02$), respectively. The factors associated with major and minor complications, conversion, and failed laparoscopy are shown in Table 3.

Multiple logistic regression analyses (Table 4 and Table 5) showed that serious complications were significantly more frequent in patients with prior abdominal surgery (adjusted odds ratio, 2.78; 95% CI, 1.54–4.95), and the adjusted odds ratio tended to increase with increasing level of technical difficulty of the procedure. Level of difficulty was also directly associated with conversion to laparotomy and failed laparoscopy.

Table 2. Distribution of 2,340 complications associated with gynecological laparoscopy procedures in perinatal centers of Ukraine, 2020-2022

Type of complications	No. (%)	95% CI
Major complications	728 (31.1)	30.1-32.1
Intestinal perforation	130 (17.9)	17.1-18.7
Bladder perforation	52 (2.2)	1.9-2.5
Serious bleeding complications	481 (20.6)	19.8-21.4
Serious complications from infection	52 (2.2)	1.9-2.5
Acute pulmonary edema	39 (1.7)	1.4-2.0
Minor complications	1,612 (68.9)	67.9-69.9
Mild anemia	390 (16.7)	15.9-17.5
Severe anemia (transfusion)	377 (16.1)	15.3-16.9
Minor bleeding complications	195 (8.3)	7.7-8.9
Minor complications from infection	52 (2.2)	1.9-2.5
Wall abscess	13 (0.6)	0.4-0.8
Vaginal vault abscess	26 (1.1)	0.9-1.3
Pelvic abscess	13 (0.6)	0.4-0.8
Nerve lesion	13 (0.6)	0.4-0.8
Fever	117 (5.0)	4.5-5.5
Pain of undetermined cause	52 (2.2)	1.9-2.5
Subcutaneous emphysema	13 (0.6)	0.4-0.8
External genitalia edema	26 (1.1)	0.9-1.3
Paralytic ileum	39 (1.7)	1.4-2.0
Hernia at laparoscopy trocar	13 (0.6)	0.4-0.8
Urinary tract infection	130 (5.6)	5.1-6.1
Urinary retention	26 (1.1)	0.9-1.3
Hematoma (postoperative)	156 (6.7)	6.2-7.2
Postoperative wall hematoma	143 (6.1)	5.6-6.6
Postoperative vaginal vault hematoma	13 (0.6)	0.4-0.8
Uterine perforation	13 (0.6)	0.4-0.8
Failed laparoscopy	1,053 (9.3)	8.7-9.9
Conversion to laparotomy because of complications	468 (4.2)	3.8-4.6

CI, confidence interval.

In this study we found 130 cases of intestinal perforation, 39 of which were diagnosed intraoperatively and 91 postoperatively. In all 130 cases conversion to laparotomy was necessary to manage the perforation. There were 52 cases of injury to the bladder; 13 was managed during laparoscopy. Among the severe bleeding complications, 13 great vessel injury occurred during insertion of the Veress needle into the abdominal cavity, and urgent laparotomy was required. There were 39 cases of serious infection that required further surgery.

We found that obesity played an important role as a risk factor for failed laparoscopy. Women with obesity were likely than women without obesity to require open surgery because laparoscopy could not be initiated ($P < 0.001$).

DISCUSSION

This multicentre, prospective cohort study is the first Ukrainian study to estimate the frequency of complications during laparoscopic gynecologic surgery for benign diseases in women and identify associated risk factors in different regions of the country. This study also provides information about the relative proportion of gynecological laparoscopy procedures for the different types of benign diseases in Ukrainian women. The association between socio-demographic characteristics, different type of laparoscopic gynecologic procedures, and clinical profile for women with complications was analyzed in this study.

Results our study suggest a high (16.2%) frequency of complications associated laparoscopic gynecologic surgery in Ukraine. Of all complication's cases, 5.04%

Table 3. Factors associated with complications in gynecological laparoscopy procedures in perinatal centers of Ukraine, 2020-2022

Variable	Serious complications (n = 728)	Minor complications (n = 1,612)	Conversion (n=468)	Failed laparoscopy (n=1,053)
	No. (%)	No. (%)	No. (%)	No. (%)
Age (yrs.)				
<30 (3,915)	78 (2.0)	578 (14.8)	40 (1.0)	286 (7.3)
30–60 (10,050)	598 (5.9)	955 (9.5)	408 (4.1)	702 (7.0)
>60 (475)	52 (10.9)	79 (16.6)	20 (4.2)	65 (13.7)
P value	0.02	0.12	0.14	0.22
Prior abdominal surgery				
Yes	481 (21.1)	1183 (52.0)	312 (13.7)	741 (32.6)
No	247 (10.9)	429 (18.9)	156 (6.9)	312 (13.7)
P value	< 0.001	0.01	0.013	0.004
Obesity				
Yes	602 (29.5)	1290 (63.2)	381 (18.7)	823 (40.3)
No	126 (6.2)	322 (15.9)	87 (4.3)	230 (11.3)
P value	0.011	0.004	0.013	< 0.001
Level of difficulty				
Simple	130 (2.4)	208 (3.9)	26 (0.5)	130 (2.4)
Moderate	403 (5.2)	585 (7.5)	273 (3.5)	572 (7.3)
Complex	195 (15.7)	299 (24.0)	169 (13.6)	351 (28.2)
P value	< 0.001	< 0.001	< 0.001	< 0.001

Table 4. Multiple logistic regression analyses factors associated with serious and mild complications in gynecological laparoscopy procedures in perinatal centers of Ukraine, 2020-2022

Variable	Serious complications		Mild complications	
	cOR (95% CI)	aOR (95% CI)	cOR (95% CI)	aOR (95% CI)
Age group (yrs.)				
<30	Ref	Ref	Ref	Ref
30–60	2.41 (0.98–5.80)	2.43 (1.03–5.89)	0.69 (0.44–1.09)	0.56 (0.34–0.93)
>60	1.28 (0.13–1.14)	1.51 (0.68–3.11)	1.59 (0.47–5.42)	0.95 (0.26–3.45)
Prior abdominal surgery (Yes vs No)	2.68 (1.48–4.78)	2.78 (1.54–4.95)	0.57 (0.28–1.60)	0.59 (0.29–1.26)
Obesity (Yes vs No)	2.11 (0.51–8.88)			
Level of difficulty				
Simple	Ref	Ref	Ref	Ref
Moderate	2.7 (1.24–5.96)	2.85 (1.27–6.41)	1.97 (1.12–3.49)	1.89 (1.02–3.44)
Complex	7.67 (3.17–8.45)	8.58 (3.39–1.82)	6.74 (3.51–12.95)	7.65 (3.71–15.75)

aOR, adjusted odds ratio; cOR, crude odds ratio; CI, confidence interval.

(95% CI, 4.8–5.6) were major complications and 11.16% (95% CI, 10.9–11.5) were minor complications. Estimating the incidence of complications associated with gynecological laparoscopy procedures is a challenge since many women with minor complications are asymptomatic, while others may report non-specific symptoms. In addition, shortened hospital stays have led to the delayed diagnosis of complications in the gynecological department. The most cases (74.9%) of

complications were detected after hospital discharge. The most frequently reported complications types were serious bleeding complications (20.6%), intestinal perforation (17.9%), mild anemia (16.7%), severe anemia (transfusion) (16.1%), failed laparoscopy (9.3%), minor bleeding complications (8.3%), postoperative hematoma (6.7%), urinary tract infection (5.6%), and fever (5.0%). The level of technical difficulty and existence of prior abdominal surgery, and obesity were associated

Table 5. Multiple logistic regression analyses of factors associated with conversion to laparotomy to laparotomy and failed laparoscopies in perinatal centers of Ukraine, 2020–2022

Variable	Conversion to laparotomy		Failed laparoscopy	
	cOR (95% CI)	aOR (95% CI)	cOR (95% CI)	aOR (95% CI)
Age group (yrs.)				
<30	Ref	Ref	Ref	Ref
30–60	2.75 (0.96–7.84)	2.07 (0.69–6.22)	0.92 (0.55–0.52)	0.62 (0.36–1.09)
>60	2.95 (0.32–26.91)	1.66 (0.17–15.78)	2.21 (0.73–0.69)	0.75 (0.21–2.63)
Prior abdominal surgery	2.37 (1.17–4.78)	2.35 (1.13–4.91)	2.02 (1.24–3.30)	2.17 (1.29–3.65)
Obesity	2.86 (0.67–2.29)		8.20 (3.93–17.14)	7.04 (3.09–16.03)
Level of difficulty				
Simple	1	1	1	Ref
Moderate	5.91 (1.38–25.26)	12.25 (1.61–93.25)	2.49 (1.25–4.98)	2.52 (1.23–5.17)
Complex	22.57 (5.05–98.79)	47.14 (5.86–98.99)	9.94 (4.73–20.89)	10.81 (4.76–24.59)

aOR, adjusted odds ratio; cOR, crude odds ratio; CI, confidence interval.

with a higher risk of complications associated with gynecological laparoscopy procedures. We believe that this study constitutes a unique addition to the currently available literature on surgical complications since it has included and analysed even minor complications.

Laparoscopic surgery has evolved over the past two decades to now be accepted as the method of first choice for tackling most gynecological problems. Better recovery, a shorter hospital stay, less postoperative pain, and lower blood loss are the main arguments in favor of this approach [11]. Gynecologic laparoscopic surgical procedures are increasing throughout the world, and with this increase in its utilization, a renewed interest in its possible complications. Diagnostic and sterilization laparoscopies appear to be safe, but more complex laparoscopies are associated with an unacceptably high number of serious complications requiring continuous follow-up and expertise. Despite advanced technology and experience, complications during the installation phase of laparoscopy remain a major cause of significant morbidity and most operative complications occurred in advanced operative procedures. Complications associated with all types of laparoscopic procedures should not be underestimated.

Complications during gynecologic laparoscopic surgical procedures result from the proximity of the uterus and ovaries to other critical pelvic structures. These structures include the urinary tract, bowel, nerves, and vasculature. Knowledge of pelvic anatomy is important when performing these procedures and is critical in cases of altered anatomy from adhesive disease and during intraoperative hemorrhage. Recognition and repair of an unintended injury gives the best chance for minimizing sequelae from these complications.

Complications of gynecologic laparoscopic proce-

dures are relatively uncommon but may be devastating. As the number of endoscopic procedures has increased tremendously over the years, several different complications may arise affecting different systems. According to the literature, the overall rate of complications ranges from 0.4% to 5.57% [4, 7, 8, 12, 13]. Although the incidence of complications decreases as surgeons gain experience with laparoscopy [5, 6, 14, 15], the growing difficulty of some procedures in gynecologic surgery may increase the frequency of severe complications. Vascular structures, gastro-intestinal organs and urinary tract are the most common affected sites [14, 16]. As well as being the rarest, major vascular complications occurring after closed or direct trocar entry are observed in approximately 0.04–0.1% of laparoscopic procedures [17]. During laparoscopic entry, gastrointestinal system injuries may also be observed (0.06%) [18].

Surgical complications can arise either intraoperatively or postoperatively. The factors that lead to complications in gynecological surgeries could be both patient-related or surgeon-related [19]. There are several patient and surgeon related factors that might influence complications, however in the presence of adequate expertise, most of these complications can be avoided. In the researchers' reports majority of the cases where major vascular complications were encountered was overweight or obese patients [20, 21]. Furthermore, inadequate surgical experience and inappropriate patient positioning may also contribute to increased complication rates. It is crucial to determine the site of the aortic bifurcation conjecturally before starting the procedure. This region may not always be palpated or detected according to the umbilicus. Sub-specialization fellowship training and high surgical volume have previously been linked to improved gynecological surgical

outcomes. [22-24]. Conversely, this additional training narrows a physician's scope of practice and, on a larger scale, could limit access to routine or preventive health care from general Obstetricians Gynecologists. [25]. Many surgeons in our study are sub-specialty-trained in urogynecology and/or minimally invasive surgery. However, surgeon training and/or experience was not a factor assessed in this study.

STRENGTH AND LIMITATIONS

This is one of the largest series reported of laparoscopic gynecologic surgery for benign diseases in women and the first focused on complications in Ukraine. These results add valuable information to the literature regarding the occurrence of postoperative complications after gynecologic procedures.

A limitation our study based on a 10 perinatal centers data is that the results this study may not be generalizable to other hospitals of Ukraine. However, knowledge of centre-specific surgical outcome data can help in providing patients with better preoperative counselling.

CONCLUSIONS

Results this study suggest a high frequency of complications associated laparoscopic gynecologic surgery in Ukraine. Shortened hospital stays have led to the delayed diagnosis of complications in the gynecological department. The most cases of complications were detected after hospital discharge. The level of technical difficulty and existence of prior abdominal surgery, and obesity were associated with a higher risk of complications associated with gynecological laparoscopy procedures. Major operative complications are more likely to occur in complex procedures. Through the comprehensive understanding of the relevant anatomy, surgical instruments, complex maneuvers, and optimal surgical technique, gynecologic laparoscopists can avoid most of the complications described. Surgeons should be diligent in recognizing and managing these events. The accumulation of surgical experience with the aid of preventive maneuvers is helpful to reduce the complication rate significantly. Further research needs to be conducted on this topic to design necessary strategies to decrease the burden on patients facing these complications.

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CONFLICT OF INTEREST

The Authors declare no conflict of interest

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