

Surgical complications in 448 gynecological 3D laparoscopic surgeries adopting the Clavien—Dindo classification

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Abstract The aim of this study is to present and report the perioperative outcomes, intraoperative, and postoperative complications according to the Clavien—Dindo classification. Clinical data of 448 patients who underwent 3D laparoscopy in a single center over 1 year was retrospectively analyzed, and the postoperative complications were stratified adopting the Clavien—Dindo (CD) classification. During the study period, 448 patients underwent gynecological 3 D laparoscopic surgery, TLH (259), laparoscopic myomectomy(104), surgery for endometriosis(20), ovarian cyst(24), and miscellaneous(41). The overall rate of intraoperative complications were 0.9 %. There were two cases of bowel injury (0.4 %), one with intra-operative bladder injury (0.2 %) and one with ureteric injury (0.2 %). In all the above cases, recovery was uneventful and no further intervention was needed. There were no incidences of vascular injury, clinical thromboembolism, ICU admission, or death. The incidence of CD Grade I complications was 1.1 %. There were two cases of postoperative vertigo which was treated with betahistine dihydrochloride. One case each of urinary tract infection and vault infection treated with antibiotics and one case of post-operative dysuria treated with flavoxate hydrochloride. Blood transfusions were required in four patients. The incidence of CD Grade II complications was 2.0 %. Two patients (0.4 %) of TLH underwent vault re-suturing under general anesthesia

(CD Grade IIIb). There were no cases of CD Grade IV and Grade V complications. The complication rate in our study compares favorably with those reported by other large studies. The authors believe that a widespread implementation of a common standardized system for reporting of complications is essential for comparability of clinical data.

Keywords Surgical complications · Gynecology · Laparoscopy · Clavien-Dindo classification

Introduction

The registration of postoperative complications represents an essential component in the evaluation of surgical treatment procedures [1], but there is no consensus on the protocol for reporting and grading postoperative complications.

For a valid assessment, relevant data on outcome must be obtained in a standardized and reproducible manner to allow comparison among different centers, between different therapies and within a center over time [2, 3].

In 1992, Clavien et al. proposed a classification of complications, which was critically reevaluated and modified in 2004 to increase its accuracy and its acceptability in the surgical community [4]. This classification relies on the principle of grading complications based on the therapy used to treat the complication; this prevents the down rating of complications. This is particularly important in retrospective analyses.

The objective of our study is to retrospectively analyze the gynecological cases operated with 3D laparoscopy over 1 year and report the perioperative outcomes, intraoperative complications, and postoperative complications according to the Clavien–Dindo classification.

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Patient and methods

Clinical data of 448 gynecological patients who underwent 3D laparoscopy in a single center over 1 year from 1st of January, 2015 to 31st of December, 2015, was retrospectively analyzed. This included 366 patients from within the same city and 82 patients from outside the city or country. Operations were performed using 3D laparoscopy by an experienced surgical team that always included the same chief endoscopic surgeon. The same evidence-based enhanced recovery protocols were followed in all the patients. Both handwritten and electronic charts were reviewed retrospectively. Patient files were analyzed for complications, including those that affected the bladder, rectum, ureter(s), vessel lesions, and thromboembolism. The evaluation period included all inpatient postoperative days and till 30 days post-surgery.

The Clavien—Dindo (CD) classification of surgical complications was applied for complications that occurred during the postoperative course. Complications were defined as any deviation from the normal postoperative course.

A sequelae is an “after-effect” of surgery that is inherent to the procedure. If the original purpose of surgery has not been achieved, this is not a complication but a “failure to cure”. Sequelae and failure to cure were not included in the complications.

In the Clavien—Dindo classification [4]:-

Grade I was assigned to any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside.

Grade II: Requiring pharmacological treatment with drugs other than such allowed for Grade I complications. Blood transfusions and total parenteral nutrition are also included.

Grade III: requiring surgical, endoscopic, or radiological intervention

Grade III-a: intervention not under general anesthesia

Grade III-b: intervention under general anesthesia

Grade IV: life-threatening complication (including CNS complications) requiring IC/ICU-management

Grade IV-a: single organ dysfunction

Grade IV-b: multi organ dysfunction

Grade V: death of a patient

Microsoft Excel 14.3.7 was used for the descriptive statistical analysis.

Result

During the study period, 448 gynecological patients underwent 3D laparoscopy. Out of the 259 patients of total laparoscopic hysterectomy, in 215 patients, the specimen weight was less than 500 g, including ten cases of malignancy who underwent pelvic lymph node dissection, and in 44 patients the specimen weight was more than 500 g. Laparoscopic myomectomy was done in 104 patients. There were 20 patients of endometriosis, 24 patients of ovarian cyst, and 41 patients who underwent other miscellaneous procedure like Burch colposuspension, sacrocolpopexy, ovarian detortion, rudimentary horn excision, salpingectomy, adenomyoma excision, and diagnostic procedures (Tables 1 and 2).

Intraoperative Two cases of TLH were converted to open surgery. Overall conversion rate was 0.4 %. The reason for conversion in one of the patients was difficult approach to vault due to large 32 week size uterus (specimen weight 2,725 g). In the second patient (specimen weight 1,000 g with components of endometriosis and multiple prior surgeries), dense rectal adhesions were present and the left side ureter was adhered to the tubo-ovarian mass.

There were two cases of bowel injury, one was a superficial serosal injury for which prophylactic stitch was taken. The second case was in a patient with large 26-week size uterus, two prior surgeries for endometriosis, and dense rectal adhesions with distorted anatomy, for which primary repair of sigmoid colon was done. There was a ureteric injury in the same case in which the left ureter was ligated with vascular bundle, identified immediately, ligature was removed, and prophylactic DJ stenting was done.

The incidence of bowel injury was 0.4 % and the incidence of ureteric injury was 0.2 %.

There was one case of bladder injury in a patient of laparoscopic myomectomy with a large 20 × 10 cm anterior wall fibroid, stretching the bladder. The rate of bladder injury was 0.2 %.

The overall rate of intraoperative complications was 0.9 %.

In all the above cases, recovery was uneventful and no further intervention was needed. There were no incidences of vascular injury, clinical thromboembolism, ICU admission, or death (Table 3).

Postoperative There were five cases of non-infectious diarrhea. The incidence of CD Grade I complications was 1.1 %.

There were two cases of postoperative vertigo which was treated with betahistine dihydrochloride.

One case each of urinary tract infection and vault infection treated with antibiotics and one case of postoperative dysuria treated with flavoxate hydrochloride.

Table 1 Patient characteristics

Total cases (<i>N</i> = 448)	Total Laparoscopic hysterectomy (<i>N</i> = 259)	Laparoscopic myomectomy (<i>N</i> = 104)	Laparoscopic surgery for endometriosis (<i>N</i> = 20)	Laparoscopic surgery for ovarian cyst (<i>N</i> = 24)	Miscellaneous (<i>N</i> = 41)
Age <50	168 (64.9 %)	104 (100 %)	20 (100 %)	24 (100 %)	36 (87.8 %)
Age ≥/50	91 (35.1 %)	0 (0 %)	0 (0 %)	0 (0 %)	5 (12.2 %)
BMI < 8.5	0 (0 %)	2 (1.9 %)	3 (15 %)	1 (4.2 %)	0 (0 %)
BMI 18.5–24.99	81 (31.3 %)	56 (53.8 %)	10 (50 %)	16 (58.3 %)	20 (48.8 %)
BMI 25–29.99	102 (39.4 %)	34 (32.7 %)	6 (30 %)	10 (29.2 %)	16 (39.0 %)
BMI ≥/30	76 (29.3 %)	12 (11.6 %)	1 (5 %)	2 (8.3 %)	5 (12.2 %)
Hypertension	41 (15.8 %)	0 (0 %)	1 (5 %)	1 (4.2 %)	2 (4.9 %)
Diabetes mellitus	30 (11.6 %)	2 (1.9 %)	0 (0 %)	2 (8.3 %)	2 (4.9 %)
Asthma	10 (3.9 %)	4 (3.8 %)	1 (5 %)	0 (0 %)	1 (2.4 %)
Hypothyroidism	41 (15.8 %)	17 (16.3 %)	1 (5 %)	3 (12.5 %)	3 (7.3 %)
Anemia with preoperative parenteral iron supplementation	26 (10.0 %)	11 (10.6 %)	2 (10 %)	0 (0 %)	3 (7.3 %)
Previous LSCS	61 (23.6 %)	14 (13.5 %)	2 (10 %)	0 (0 %)	11 (26.8 %)
Previous abdominal surgery	32 (12.4 %)	4 (3.8 %)	0 (0 %)	5 (20.8 %)	4 (9.8 %)
Previous pelvic surgery	64 (24.7 %)	19 (18.3 %)	4 (20 %)	2 (8.3 %)	12 (29.3 %)

Blood transfusions were required in four patients. In one patient of laparoscopic myomectomy with specimen weight of 1240 g and 1700 cm³ blood loss; and in three patients of TLH with previous multiple surgeries and dense adhesions with 1000, 1000, and 1600 cm³ blood loss. These included the patient converted to open surgery and the patient with bowel and ureteric injury. The incidence of CD Grade II complications was 2.0 %.

Two patients of TLH were readmitted 25 and 30 days after surgery with complains of bleeding per vaginum and underwent examination under general anesthesia and vault re-suturing. These were classified under the CD Grade IIb classification. The incidence of CD Grade III complications was 0.4 %. There were no cases of CD Grade IV and Grade V complications (Table 4).

Table 2 Operative time, blood loss and specimen weight

	Duration of surgery	Blood loss	Weight of specimen
TLH (uterus <500 g) (<i>N</i> = 215)	Mean 55.8 min	Mean 52.5 cm ³	Mean 222.1 g
	Median 50 min	Median 30 cm ³	Median 195 g
	Range 26–130 min	Range 5–650 cm ³	Range 44–498 g
TLH (uterus >500 g) (<i>N</i> = 44)	Mean 83.8 min	Mean 229.1 cm ³	Mean 864.8 g
	Median 75 cm ³	Median 100 cm ³	Median 672 g
	Range 45–210 min	Range 10–1600 cm ³	Range 511–2725 g
Laparoscopic myomectomy	Mean 65.1 min	Mean 120.5 cm ³	Mean 241.6 g
	Median 55.5 min	Median 50 cm ³	Median 138 g
	Range 19–210 min	Range 5–1700 cm ³	Range 10–1243 g
Laparoscopic surgery for endometriosis	Mean 55.6 min	Mean 78 cm ³	
	Median 44.5	Median 50 cm ³	
	Range 30–165 min	Range 10–250 cm ³	
Laparoscopic surgery for ovarian cyst	Mean 39.4 min	Mean 18.6 cm ³	
	Median 34 min	Median 10 cm ³	
	Range 10–110 min	Range 2–100 cm ³	
Miscellaneous	Mean 41.8 min	Mean 21.6 cm ³	
	Median 35 min	Median 5 cm ³	
	Range 12–116 min	Range 0–300 cm ³	

Table 3 Intra-operative complications

Total cases (<i>N</i> = 448)	Total laparoscopic hysterectomy (<i>N</i> = 259)	Laparoscopic myomectomy (<i>N</i> = 104)	Laparoscopic surgery for endometriosis (<i>N</i> = 20)	Laparoscopic surgery for ovarian cyst (<i>N</i> = 24)	Miscellaneous (<i>N</i> = 41)
Vascular injury	–	–	–	–	–
Bowel injury	2	–	–	–	–
Bladder injury	–	1	–	–	–
Ureteric injury	1	–	–	–	–
DVT/PE	–	–	–	–	–

Discussion

Gynecological-laparoscopic interventions are in general associated with a low surgical morbidity [5, 6] and the use of 3D laparoscopy leads to a further reduction in patient morbidity and operating time [7].

Mirhashemi determined the surgical morbidity rates after gynecological-laparoscopic interventions in an academic teaching hospital; the overall complication rate in this study amounted to 19.6 % and the rate of severe complications with an indication for surgical revision to 4.7 % [8]. Saidi reported a similar complication rate (10.4 % overall; 5.1 % severe complications) after gynecological-laparoscopic interventions of various degrees of difficulty [9]. A French report evaluated 1033 gynecological-laparoscopic procedures of moderate and enhanced degrees of difficulty at a single treatment center and stated a complication rate of 3 % [10].

Definitive assessment of therapeutic procedures is limited by the lack of consensus on how to report and grade surgical complications. Subjective terms such as ‘major’ or minor should be discarded.

By means of a standardized registration system such as the Clavien—Dindo classification it appears to be possible to limit the methodologically caused underestimation of surgical morbidity in the retrospective evaluation of gynecological-endoscopic therapeutic procedures [11].

The registration of surgical morbidity in clinical case series is also difficult due to the lack of a widely accepted definition of the term “complication” [12]. Standardized classification systems provide uniform definitions for the existence of a complication as well as for its degree of severity thus improving the comparability of individual studies on surgical procedures [13] and leading to a higher quality of care [14, 15]. Since its introduction the Clavien—Dindo classification has experienced an exponential use in the visceral and urological clinical research [16, 17, 18, 19]. A standardized system for reporting and grading surgical complications has yet to find regular use in gynecological research, with only a few studies reporting surgical complications according to the CD classification [11, 20, 21, 22]. The classification was found to be simple, reproducible, logical, and comprehensive and may present a compelling tool for quality assessment in surgery in all parts of the world. It had a significant correlation with the complexity of surgery as well as with the length of the hospital stay [4].

Disadvantages of the Clavien—Dindo classification include the fact that complications with different morbidity may be classified similarly. Also, the choice to use general vs regional anesthesia as in vault re-suturing and the criteria for ICU admission may vary from hospital to hospital. This diminishes the validity when comparing different series [23]. Another disadvantage of the CD classification is that it is only to be used for postoperative complications. Myatt et al.

Table 4 Postoperative complications classified adopting the Clavien—Dindo classification

Total cases (<i>N</i> = 448)	Total laparoscopic hysterectomy (<i>N</i> = 259)	Laparoscopic myomectomy (<i>N</i> = 104)	Laparoscopic surgery for endometriosis (<i>N</i> = 20)	Laparoscopic surgery for ovarian cyst (<i>N</i> = 24)	Miscellaneous (<i>N</i> = 41)
Grade I	2	2	1	–	–
Grade II	8	1	–	–	–
Grade III a	–	–	–	–	–
Grade III b	2	–	–	–	–
Grade IV	–	–	–	–	–
Grade V	–	–	–	–	–

suggested a modification of the Clavien—Dindo system for urological procedures to include intraoperative complications [24].

The complication rate in our study compares favorably with other large studies [[8–10]], and the authors believe that the widespread use of a simple, easy to use standardized system such as Clavien—Dindo classification would help in comparison of surgical outcomes leading to improvement of surgical care.

Author's contribution R Sinha: project development, manuscript writing, manuscript editing

I Jalote: data collection, data analysis, manuscript writing

M Sinha: project development, manuscript writing, manuscript editing

S Raje: project development, manuscript editing

G Rao; data analysis, manuscript editing

Compliance with ethical standards

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Ethical standards All procedures performed in the study involving human participants were in accordance with the ethical standards of the institute and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all the patients for being included in the study.

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