

Standardised Registration of Surgical Complications in Laparoscopic-Gynaecological Therapeutic Procedures Using the Clavien-Dindo Classification

Standardisierte Erhebung chirurgischer Komplikationen bei laparoskopisch-gynäkologischen Therapieverfahren unter Anwendung der Clavien-Dindo-Klassifikation

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Key words

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- gynaecological surgery
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Abstract

Introduction: The registration of complications represents an important component in the evaluation of surgical therapeutic procedures. The aim of the present study was to examine the frequency of occurrence as well as the severity of surgical complications after laparoscopic-gynaecological operations in a standardised manner using the Clavien-Dindo system.

Material and Methods: Altogether 7438 treatment courses after laparoscopic-gynaecological interventions by 9 working groups were evaluated. Covariates recorded were the technical complexity of the operation, type of study cohort, study size, data acquisition as well as study centre. Target variables recorded were the surgical morbidity rate, subdivided into mild (Clavien-Dindo grade I–II) and severe complications (Clavien-Dindo grade III–V). In addition, a binary logistic regression analysis for the mentioned covariates and the occurrence of surgical complication was carried out.

Results: 946 complications were recorded (overall complication rate: 13%). These included 664 mild complications (8.9%) and 305 severe complications (4.1%). A correlation was found between the covariates technical complexity (relative risk [rR] 1.37; $p < 0.01$), study size (rR: 0.35; $p < 0.01$) and study centre (rR 0.19; $p < 0.01$) and the occurrence of surgical complications.

Conclusion: By means of a standardised registration of complications using the Clavien-Dindo classification it appears to be possible to limit the methodologically caused underestimation of surgical morbidity in the retrospective evaluation of gynaecological-endoscopic therapeutic procedures. Factors decisively influencing the surgical morbidity of gynaecological-laparoscopic therapeutic procedures are the respective operative experience of the treating facility as well as the technical complexity of the intervention.

Zusammenfassung

Einführung: Die Erfassung von Komplikationen stellt einen wichtigen Bestandteil bei der Evaluation operativer Therapieverfahren dar. Ziel der vorliegenden Arbeit war es, die Häufigkeit des Auftretens sowie die Schwere von chirurgischen Komplikationen nach laparoskopisch-gynäkologischen Operationen standardisiert mithilfe des Clavien-Dindo-Systems zu untersuchen.

Material und Methodik: Insgesamt 7438 Behandlungsverläufe nach laparoskopisch-gynäkologischen Eingriffen, erhoben von 9 Arbeitsgruppen, wurden ausgewertet. Als Kovariaten wurden technischer Schwierigkeitsgrad des Eingriffs, Art der Studienkohorte, Studiengröße, Datenakquise sowie Studienzentrum erfasst. Als Zielvariable wurde die chirurgische Morbiditätsrate, unterteilt in leichte (Clavien-Dindo Grad I–II) und schwere Komplikationen (Clavien-Dindo Grad III–V) erhoben. Ferner erfolgte eine binär logistische Regressionsanalyse für die aufgeführten Kovariaten und dem Auftreten von chirurgischen Komplikationen.

Resultate: 946 Komplikationen wurden erfasst (Gesamtkomplikationsrate: 13%). Hierbei handelte es sich um 664 leichte Komplikationen (8,9%) und 305 schwere Komplikationen (4,1%). Es zeigte sich eine Korrelation zwischen den Kovariaten technischer Schwierigkeitsgrad (relatives Risiko [rR] 1,37; $p < 0,01$), Studiengröße (rR: 0,35; $p < 0,01$) und Studienzentrum (rR 0,19; $p < 0,01$) und dem Auftreten chirurgischer Komplikationen.

Schlussfolgerungen: Durch eine standardisierte Komplikationserfassung mithilfe der Clavien-Dindo-Klassifikation erscheint es möglich, die methodisch bedingte Unterschätzung der chirurgischen Morbidität bei der retrospektiven Auswertung von gynäkologisch-endoskopischen Therapieverfahren zu begrenzen. Als die chirurgische Morbidität gynäkologisch-laparoskopischer The-

Introduction

The registration of postoperative complications represents an essential component in the evaluation of surgical treatment procedures [1]. Currently the registration of surgical morbidity in clinical case series is, however, difficult due to the lack of a widely accepted definition of the term “complication” [2]. Standardised classification systems for recording the surgical morbidity of surgical interventions provide uniform definitions for the existence of a complication as well as for its degree of severity. They are thus helpful in the recording of the surgical morbidity of a surgical technique, in the categorisation of the severity of the observed event and thus improve the comparability of individual studies on surgical procedures [3]. In the daily clinical routine, standardised systems for recording complications contribute to a structured quality assurance in gynaecological endoscopy and thus to a higher quality of care [4,5]. The Clavien-Dindo classification is one such standardised system for the registration of surgical complications. It defines the occurrence of a complication as any deviation from the ideal postoperative course that is not inherent to the operation and that cannot be considered as a therapeutic failure of the operation. In concept, the classification is made according to the degree of severity on the basis of the respective therapeutic intervention that led to treatment of the observed deviation (Table 1) [6]. In its current revised form, the Clavien-Dindo classification has experienced an exponential use in visceral and urological clinical research in the course of the past two decades; its use to record surgical complications in the course of scientific evaluations is recommended in the two specialties [7,8]. In contrast, the use of standardised systems to

rapieverfahren maßgeblich beeinflussende Faktoren wurden die jeweilige operative Erfahrung der durchführenden Behandlungseinrichtung sowie der technische Schwierigkeitsgrad des Eingriffs identifiziert.

register surgical complications in general and the use of the Clavien-Dindo classification in particular has yet not found regular usage in the published gynaecological research literature. The current evaluation of our own laparoscopic-gynaecological therapeutic interventions as well as those of treatment courses from other institutions identified in a selective search of the literature in which the occurrence and degree of severity of surgical complications were primarily recorded with the help of the Clavien-Dindo classification was carried out with the objective to examine the frequency of occurrence as well as the degree of severity of surgical complications after endoscopic gynaecological procedures by means of a standardised registration method.

Materials and Methods

Study design

In the present analysis we included 1050 laparoscopic-gynaecological treatment courses from our own groups that were evaluated in a standardised manner using the Clavien-Dindo classification as well as 6388 published treatment course from other working groups.

The Clavien-Dindo classification as a tool for the standardised registration of surgical morbidity has been in use in the framework of clinical research projects in our working group at the Department of Gynaecology and Obstetrics, Jena University Hospital since 2009 and since 2011 at the Department of Gynaecology and Obstetrics, University Hospital of the Saarland. For the present analysis all standardised treatment courses after laparoscopic interventions that were recorded in the course of scientific clinical evaluations by our group in both treatment centres up to July 2013 were collected in anonymised form in a complication register by means of an electronic data base (SPSS Statistics, Version 22, IBM, Armonk, USA).

For the identification of previously published treatment courses evaluated by means of the Clavien-Dindo classification after laparoscopic-gynaecological interventions, we performed a literature search in July 2013 with the help of the databank *ISI Web of Science*. All original papers and meta-analyses from the field of gynaecology which contained references to the Clavien-Dindo classification among the citations were selected [6,9]. 57 publications were primarily identified and, in a subsequent step, subjected to abstract text analysis in order to select articles concerning laparoscopic-gynaecological treatment procedures. Ten contributions published by nine working groups were finally chosen (Table 2) [10–19] and the described treatment courses were entered into our complication register for further analysis.

Methods of evaluation

For the included treatment courses consisting of study cohorts from our own group as well as study cohorts identified by means of a literature search the covariates *degree of technical difficulty of the laparoscopic intervention*, *study size*, *data acquisition* as well as *study centre* were recorded. For those treatment courses identified by means of the literature search, registration of these covariates was achieved by a full text analysis of the respective pub-

Table 1 Classification for recording postoperative complications in its revised version according to Clavien and Dindo [6].

Degree	Definition
I	Every deviation from normal postoperative course without the necessity for drug treatment or a surgical, endoscopic or radiological intervention. Permissible therapeutic measures: drugs from the substance classes antiemetics, antipyretics, analgesics, diuretics; electrolyte substitution and physiotherapy. Surgical treatment of wound infections at the bedside.
II	Drug treatment in excess of the pharmacological measures listed under degree I. Blood transfusions and parenteral nutrition.
III	Necessity for surgical, endoscopic or radiological intervention.
III a	Intervention without general anaesthesia.
III b	Intervention with general anaesthesia.
IV	Life-threatening complications leading to transfer to an intermediate care or intensive care unit.
IV a	Dysfunction of an organ system (including the necessity for temporary dialysis).
IV b	Multiorgan dysfunction.
V	Death of the patient.
Suffix d	The complication degree is given the suffix “d” if the complication needs further treatment after release of the patient from hospital.

Table 2 Selected publications.

Study	Publication type	Therapeutic procedures	n	Degree of difficulty	Study cohort	Data acquisition
Chi D et al., 2004 [10]	original paper	various surgical procedures	1 451	I/II/III/IV	oncological	prospective
Siedhoff MT et al., 2012 [11]	original paper	hysterectomy	834	II	mixed	retrospective
Alperin M et al., 2012 [12]	original paper	hysterectomy	446	II	mixed	retrospective
Fagotti A et al., 2012 [13]	original paper	radical hysterectomy with retroperitoneal lymphadenectomy	75	IV	oncological	retrospective
Soudaka A et al., 2012 [14]	original paper	retroperitoneal lymphadenectomy	98	IV	oncological	retrospective
Palomba S et al., 2012 [15]	original paper	retroperitoneal lymphadenectomy	403	IV	oncological	retrospective
Kondo W et al., 2011 [16]	original paper	hysterectomy	2 092	II	mixed	retrospective
Kondo W et al., 2011 [17]	original paper	resection of deeply infiltrating endometriosis	568	IV	mixed	retrospective
Gendy R et al., 2011 [18]	meta-analysis	hysterectomy	332	II	mixed	prospective
Hong JH et al., 2010 [19]	original paper	retroperitoneal lymphadenectomy	89	IV	oncological	retrospective

Study: included publications; **Therapeutic procedures:** investigated laparoscopic therapeutic procedure; **n:** number of included treatment courses; **Degree of difficulty:** technical degree of difficulty of the analysed therapeutic procedure according to Barakat (Chi et al., 2004); **Study cohort:** type of investigated study collective; **Data acquisition:** type of data acquisition.

lication. For an assignment according to *degree of technical difficulty* of the respective laparoscopic procedure, we used the classification suggestion by the group of Barakat and Abu-Rustum into interventions with low or medium degrees of technical difficulty (Levels I–II) and those with enhanced or higher degrees of difficulty (Levels III–IV) (Table 3) [10]. For the *type of study cohort* we distinguished between mixed study cohorts and study cohorts in which exclusively the treatment courses of gynaecological-oncological patients were assessed. For the covariate *study size* treatment courses from research projects with patient cohorts containing less than 500 patients and analyses with cohorts of 500 or more patients were compared. For the covariate *data acquisition* a distinction was made as to whether the postoperative complications arising in the included treatment courses were recorded retrospectively or prospectively. With regard to the covariate *study centre*, a comparison was made between treatment courses evaluated by our own group and the treatment courses from other working groups. For the included treatment courses the postoperative complications recorded as target variables by means of the Clavien-Dindo classification

were subdivided into *mild* (Clavien-Dindo grade I–II) and *severe complications* (grade III–V). Complications of severity degree V according to Clavien-Dindo were used for calculation of the mortality rate in the evaluated treatment courses.

Statistics

After a descriptive analysis of the data, further investigations with regard to a relationship between the above-mentioned covariates and the occurrence of postoperative complications were undertaken. For this we performed a binary logistic regression analysis for the covariates *degree of technical difficulty*, *cohort size*, *data acquisition*, *study cohort* and *study centre* and the occurrence of *postoperative complications overall*, the occurrence of *mild postoperative complications* and the occurrence of *severe postoperative complications*. For each covariate we also calculated the Wald statistics, the relative risk, the significance level *p*, and the 95% confidence interval.

Results



Descriptive analysis

Altogether 7438 treatment courses were included in the analysis. Of these 1050 treatment courses from our own working groups within the framework of four clinical evaluations on laparoscopic-gynaecological treatment procedures were assessed. At the Department of Gynaecology and Obstetrics, Jena University Hospital the surgical morbidity of 553 interventions was recorded retrospectively, of these 451 interventions were of degree of technical difficulty II and 102 interventions were of technical difficulty degree III [20, 21]. 497 treatment courses from the Department of Gynaecology and Obstetrics at the University of the Saarland were evaluated, of these 202 treatment courses were of difficulty degree II in the framework of a retrospective evaluation on quality of life after laparoscopic hysterectomy and 295 were of difficulty degree II in a prospective clinical investigation on pain reduction after laparoscopic total or subtotal hysterectomy [22]. The 6388 treatment courses identified by means of the literature search were reported by a total of nine working groups. In three original papers and one meta-analysis the perioperative morbidity after laparoscopic hysterectomy was recorded, three contributions reported surgical complications after laparoscopic, retro-

Table 3 Classification laparoscopic interventions according to degree of technical severity after Chi et al. [10].

Degree of difficulty	Type of intervention
Stage I	diagnostic laparoscopy
Stage II	<ul style="list-style-type: none"> uni- or bilateral adnexectomy uni- or bilateral cyst ablation on the ovary hysterectomy (laparoscopic, supracervical, laparoscopy-assisted vaginal) myomectomy adhesiolysis/resection of superficial endometriosis lesion
Stage III	<ul style="list-style-type: none"> second-look laparoscopy after laparotomy in gynaecological-oncological patients reconstructive uro-gynaecological surgery adhesiolysis after oncological, surgical interventions in abdomen or pelvis
Stage IV	<ul style="list-style-type: none"> retroperitoneal lymphadenectomy extended hysterectomy resections of intestine/bladder/ureter with or without laparoscopic suture or, respectively, anastomosis

Table 4 Survey – evaluated study collectives.

Study cohort	Cohort size (n)	Degree of technical difficulty after Barakat	Complications according to Clavien-Dindo degree of severity (n)					Complications overall	
			n	I	II	III	IV	V	(n) (%)
Our own working group	1 050								65 6.19
		II	948	26	13	14	0	0	53
		III	102	6	5	1	0	0	12
Chi et al.	1 451								129 8.89
		I	146	14	1	4	0	3	22
		II	1 002	42	24	20	0	0	86
		III	224	5	5	6	1	0	17
Siedhoff et al.	834	IV	79	1	1	2	0	0	4
									130 15.59
		II	834	10	78	38	4	0	
Alperin et al.	446								82 18.39
		II	446	30	27	23	2	0	
Fagotti et al.	75								3 4
		IV	75	0	2	1	0	0	
Soudaka et al.	98								8 8.16
Palomba et al.	403	IV	98	0	0	7	1	0	
									166 41.21
Kondo et al.	2 660	IV	403	44	28	52	40	2	
									264 9.92
		II	2 092	100	55	31	0	0	186
Gendy et al.	332	IV	568	38	12	28	0	0	78
									113 34.04
Hong et al.	89	II	332	30	64	19	0	0	
		IV	89	4	2	2	0	0	8 8.98

peritoneal lymphadenectomy and in one study each the surgical morbidity after laparoscopic resection of deeply infiltrating endometriosis and after laparoscopic radical hysterectomy with retroperitoneal lymphadenectomy was evaluated. One last publication reported a standardised investigation of the complication rates in oncological patients after laparoscopic gynaecological interventions of various types (► **Table 4**).

Altogether 146 laparoscopic interventions of difficulty degree I, 5654 interventions of difficulty degree II, 326 interventions of difficulty degree III and 1312 interventions of difficulty degree IV were evaluated.

The registration of the occurring postoperative complications was retrospective in 5360 treatment courses and in the framework of prospective clinical evaluations in 2078 treatment courses.

5220 treatment courses were recorded in investigations in which exclusively patients with a malignant underlying disease were included; 2218 treatment courses were from mixed patient collectives.

2493 of all included treatment courses were from clinical investigations involving cohorts of 500 or fewer patients, 4945 treatment courses were recorded in studies on cohorts of 500 or more patients.

Logistic regression analysis

In the entire investigated collective, 969 complications occurred (overall complication rate: 13%). Of these 664 were mild complications (Clavien-Dindo grade I–II; 8.9%) and 305 were severe complications (grade III–V; 4.1%). The mortality rate in the observed collective amounted to 0.1% (► **Table 4**).

The binary logistic regression analysis revealed a significant dependence between the covariates *degree of technical difficulty*, *study size*, and *study centre* and the occurrence of surgical complications overall. The covariates *data acquisition* and *study collective* did not have a significant influence on the overall rate of observed complications.

After interventions with enhanced and higher degrees of difficulty complications occurred significantly more frequently (rR: 1.37; $p < 0.01$). The reason for the increased rate of surgical morbidity was the increased occurrence of severe complications after interventions with enhanced and higher degrees of difficulty (grade III–V; rR: 2.37; $p < 0.01$). In contrast, for the occurrence of mild complications (grade I–II) there was no significant difference between interventions with enhanced and higher degrees of difficulty and those with low or moderate degrees of difficulty. In clinical investigations of cohorts with 500 and more patients a significantly lower rate of complications was observed compared to those with less than 500 patients (rR: 0.35; $p < 0.01$). This applied not only to the frequency of occurrence of mild complications (rR: 0.33; $p < 0.01$) but also to the occurrence of severe complications (rR: 0.41; $p < 0.01$).

Furthermore in treatment courses from the studies of our own working group a significantly lower rate of complications was observed (rR: 0.19; $p < 0.01$). This lower risk could be observed not only for the occurrence of mild complications (rR: 0.2; $p < 0.01$) but also for the occurrence of severe complications (rR: 0.23; $p < 0.01$) (► **Table 5**).

Table 5 Binary logistic regression analysis, risk factors for the occurrence of complications.

Covariate	Wald	Relative risk	p	95% Confidence interval	
				lower value	upper value
Complications overall					
Enhanced technical difficulty	16.32	2.04	< 0.01	1.44	2.89
Large study cohort (≥ 500)	59.98	0.35	< 0.01	0.26	0.45
Own working group	34.87	0.19	< 0.01	0.11	0.34
Oncological study cohort	0.84	1.18	0.36	0.82	1.69
Retrospective data acquisition	2.81	0.74	0.09	0.52	1.05
Mild complications (Clavien-Dindo I–II)					
Enhanced technical difficulty	7.45	0.75	0.06	0.62	1.02
Large study cohort (≥ 500)	91.41	0.41	< 0.01	0.34	0.49
Own working group	76.51	0.23	< 0.01	0.17	0.32
Severe complications (Clavien-Dindo III–V)					
Enhanced technical difficulty	46.47	2.37	< 0.01	1.85	3.03
Large study cohort (≥ 500)	75.38	0.33	< 0.01	0.26	0.42
Own working group	37.15	0.19	< 0.01	0.11	0.32

Enhanced technical difficulty: laparoscopic intervention with degrees of difficulty stages III and IV according to Barakat; **large study cohort (≥ 500):** analysed treatment courses from study collectives of 500 and more patients; **own working group:** analysed treatment courses from our own working group; **oncological study cohort:** analysed treatment courses from oncological study collectives; **retrospective data acquisition:** retrospective analysis of treatment courses.

Discussion

Gynaecological-laparoscopic interventions are in general associated with a low surgical morbidity [23–25]. This estimation has been decisively influenced by two investigations on the postoperative morbidity after minimally invasive gynaecological interventions from the last decade of the last century. Chapron and coworkers retrospectively determined the surgical complication rate after gynaecological-laparoscopic operations in seven university endoscopic centres in the period from 1985 to 1995, with inclusion of altogether 29 966 patients. The overall complication rate in the investigated collective was given as 0.46%. According to a free-text analysis of the complications listed in the publication there were 96 adverse events that could be assigned to Clavien-Dindo severity stage III and higher. This corresponds to a rate of severe complications of 0.32% [26]. In a second study in 1997 Hakki-Siren evaluated the data of the Finnish statutory health insurance with regard to claims for reimbursement due to surgical complications after gynaecological-laparoscopic interventions. In the observation period, the statutory insurance funds reimbursed the costs for 70 607 gynaecological-laparoscopic operations whereby 0.36% reimbursement claims due to surgical complications were recorded; in the total of 10 processed claims, the responsible health insurance authorities reported just one case due to a “severe complication”. The definition of the term “severe complication” used here essentially corresponds to the severity degree III–V according to Clavien-Dindo [27].

Thereafter appreciably higher complication rates for gynaecological-laparoscopic interventions were reported in prospectively collected monocentric studies. Mirhashemi determined the surgical morbidity rates after gynaecological-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% [28]. Saidi reported on a similar complication rate (10.4% overall; 5.1% severe complications) after gynaecological-laparoscopic interventions of various degrees of difficulty [29]. A French report evaluated 1033 gynaecological-laparoscopic procedures of moderate and enhanced degrees of difficulty (stages III and IV accord-

ing to Barakat) at a single treatment centre and stated a complication rate of 3%, the complications mentioned in the publication can be assigned to severity stages III to V according to Clavien-Dindo [30].

In our own analysis of the data from 10 treatment centres on gynaecological-laparoscopic interventions the determined complication rate was in a comparable order of magnitude with the results of the prospective monocentric studies mentioned above. In comparison with the retrospective evaluations of Chapron and Hakki-Siren, not only the overall complication rate but also the rate of severe complications were, in contrast, about 10-fold higher. The reason for such a widely different evaluation of the postoperative morbidity risk of gynaecological-laparoscopic operations seems to be inherent to the methodology: Hakki-Siren did not determine the complication rate by evaluation of individual treatment courses but rather from the ratio of reimbursement claims due to surgical complications to the number of all gynaecological-laparoscopic operations reimbursed by the Finnish statutory health insurances in the observation period. The use of such a surrogate parameter for surgical morbidity after operative interventions could represent a bias in the sense of an underestimation of the actually occurring complication rates. In the investigation of Chapron it is not clear which definition of the term “complication” was used in the evaluation of the study collective; a standardised procedure for the registration of the complications occurring in the investigated patient collective was not described in the publication. A free-text analysis of the complications listed by the authors could place them in the severity grades III and higher according to the Clavien-Dindo classification. The occurrence of complications of the severity grades I and II was not reported, this could be indicative of a systematic underestimation in the registration of complications.

On the whole, the differing evaluations of the morbidity of gynaecological-laparoscopic operations by the individual working groups suggests that the use of a laparoscopic approach as such should not a priori be set as being equal to a low complication rate. Instead, it seems that the risks for complications in gynaecological-laparoscopic operations is influenced to an appreciable extent by covariates.

Among the as yet identified factors responsible for the increased complication risks of gynaecological endoscopy are the degree of technical difficulty of the respective surgical procedure [4], the surgical experience of the operator as well as the question [31] as to whether the respective surgical method is a new or a well established process at the corresponding treatment centre [32, 33]. The influence of accompanying malignant diseases on the surgical morbidity is not evaluated uniformly. Whereas some authors described a significantly higher rate of complications for gynaecological-laparoscopic operations for patient collectives with malignant underlying diseases, other working groups could not detect such a correlation [34, 35]. Last but not least, some authors view a retrospective non-standardised registration of the surgical morbidity in the evaluation of surgical treatment procedures as a methodologically intrinsic reason for a systematic underestimation of the actually occurring complication rates [36].

An association of, on the one hand, the degree of technical difficulty of a laparoscopic intervention and, on the other hand, surgical complications was also observed in our studies: interventions with the degrees of difficulty of III and IV according to Barakat exhibit a significantly higher number of severe complications and, in turn, a significantly higher rate of overall morbidity for this intervention group. If we compare the complication rates of gynaecological-laparoscopic treatment procedures with enhanced and higher degrees of difficulty in our own analysis with published data from the last decade of the last century we could get the impression that nowadays such operative interventions paradoxically have a higher rate of morbidity. The averaged complication rate from 10 studies in the years 2004 to 2013 in our own analysis amounts to 18.07%; in contrast Chapron in 1998 reported a complication rate of merely 8.9% for laparoscopic interventions with an advanced degree of difficulty [26]. A reason for this observed increase of surgical complications in gynaecological-laparoscopic interventions with enhanced and advanced degrees of difficulty could be the ongoing development of endoscopic techniques and the thus associated extension of the field of application of these therapeutic procedures: Chapron used a classification according to Querleu to subdivide the investigated endoscopic treatment procedures according to the respective degree of difficulty [37]. According to Querleu the performance of a laparoscopic hysterectomy is assigned as an intervention of category IV, the highest degree of severity in this classification. More recent classification systems such as the division according to Chi et al. used in our investigations, in contrast, assign laparoscopic hysterectomy as an intervention of the category II (medium degree of difficulty) [10]. On the other hand, surgical techniques, such as laparoscopic retroperitoneal lymphadenectomy, which have expanded the spectrum of endoscopic surgery in gynaecology in the past decades, are considered as interventions of a higher degree of difficulty (category IV). The results of our own investigations suggest that these interventions differ markedly with regard to their postoperative morbidity from the diagnostic and therapeutic interventions of difficulty stages I and II according to Chi.

Previous reports have demonstrated a dependence of the surgical morbidity not only on the surgeon's degree of experience with the respective laparoscopic operation but also on the amount of experience with endoscopic procedures of the entire treating centre [29, 38]. Here there are differing opinions about the required number of completed surgical interventions in order to ensure the secure mastery of a gynaecological laparoscopic treat-

ment. While in some investigations a learning curve of about 30 operations is considered to be sufficient for an experienced surgeon to learn even technically demanding gynaecological-laparoscopic interventions (degree of difficulty IV according to Chi) [19], in a study collective comprising surgeons with different levels of training, other authors have observed an increase in experience as reflected in a decline in the rate of surgical complications even after the performance of 500 laparoscopic interventions [39]. In our own analysis we oriented ourselves on the second estimation of the endoscopic learning curve on the basis of a reference value of 500 performed operations. In such an evaluation there are hints towards a relationship between the experience with laparoscopic methods in the respective treatment centre and the occurrence of surgical complications: in the involved study collectives of more than 500 treatment courses a significantly lower rate of complications was observed. This result can be objectively related to the fact that, in each of the six publications with study collectives of less than 500 patients included in this analysis, experience in the establishment of an up to now new operation technique for the respective study centre was evaluated.

Regarding the question if and to what extent an underlying malignant disease increases the risk for developing complications after gynaecological-laparoscopic interventions, only few studies are available yet: Erikson referred to a case series that analysed predominantly vaginal-operative and gynaecological-surgical interventions performed per laparotomy which revealed a high morbidity risk for patients with an underlying malignant disease [40]. It is not clear to what extent these results may be transferred to gynaecological-laparoscopic procedures. In our own analysis the presence of an underlying malignant disease was not an independent risk factor for the occurrence of surgical complications. Instead, in the numerically largest included cohort of oncological treatment courses, an assessment by a group at Memorial Sloan-Kettering Cancer Center, an even lower complication rate was seen in comparison to the averaged overall morbidity of our investigation (9% compared to 13%). The low complication rate of the study cohort at this specialist centre emphasises the significance of an expertise in gynaecological-laparoscopic therapy procedures that is not limited to just technical aspects for the avoidance of surgical complications [10].

In our own analysis, no significant differences were found in complication rates for retrospectively and prospectively evaluated treatment courses. This observation might suggest that the registration of surgical complication rates in retrospective cohort studies could be improved with the help of the Clavien-Dindo system so as to approach the validity of complication rates determined in prospective studies. Beside the terminologically preformulated definition of the term "surgical complication", the conceptual structure of the Clavien-Dindo classification could also be of importance: the division of the degree of severity of a complication is oriented to the respective therapeutic intervention, which would be necessary for the correction of deviations (e.g., antibiotics, operative revision). Since these therapeutic measures are regularly documented in the patient records, such a classification facilitates a valid retrospective registration of complications in surgical case series.

Conclusions for Clinical Practice

With the use of of Clavien-Dindo classification it appears to be possible to limit the methodologically derived underestimation of surgical morbidity in the retrospective evaluation of gynaecological-endoscopic therapeutic procedures. Our own analysis has identified the respective surgical experience of the treating centre as well as the degree of difficulty of the respective intervention to be factors decisively influencing the surgical morbidity of gynaecological-laparoscopic therapeutic procedures.

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Conflict of Interest

None.

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