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GENERAL GYNECOLOGY

Evaluating the use of Clavien-Dindo classification and Picker Patient Experience Questionnaire as quality indicators in gynecologic endoscopy

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Abstract

Purpose Over the last few decades, laparoscopy has become a standard procedure within gynecological surgery. Validated quality indicators for the determination of the objective (perioperative complications) and subjective (patient satisfaction) quality of treatment as a surrogate parameter for the success of the treatment have so far found no regular application in the clinical routine. The purpose of this study was to evaluate the use of the Clavien-Dindo (CD) classification for postoperative complications and the Picker Patient Experience Questionnaire (PPE-15) as tools in the evaluation of endoscopic therapies in clinical routine.

Methods Retrospectively, perioperative complications using the CD classification and patient satisfaction utilizing the PPE-15 were reviewed for a total of 212 consecutive patients at a gynecologic endoscopic referral center (Agaplesion Diakonie Kliniken, Kassel, Germany) in September 2018.

Results An overall complication rate of 13.21% (28 out of 138 patients) was observed. Five patients (2.36%) had complications grade III and above according to the CD classification system. 138 patients out of 212 chose to answer the PPE-15 (return rate 65.01%). 112 patients (81.16%) reported about problems during their treatment in our hospital in their PPE-15. "Purpose of medicines not explained" was the most mentioned item (28.99%) by patients during their hospital stay.

Conclusion CD classification and PPE-15 may be helpful instruments to evaluate the quality of care in gynecology. The application of both instruments for the assessment of treatment quality in clinical routine should be further investigated in prospective studies.

Keywords Laparoscopy · Clavien-Dindo-classification · Picker-questionnaire · Quality assessment

Purpose

In recent decades, laparoscopy has become the standard of care for various surgical procedures in gynecology [1]. Advantages of minimally invasive surgery are reduced surgical trauma, resulting in shorter convalescence, less perioperative blood loss and a more favourable cosmetic outcome [2, 3]. Currently, a development in health care, which can be subsumed under the slogan "pay for performance" can be observed. Health insurances are increasingly linking the remuneration paid for medical services to quality indicators such as perioperative complication rates or patients satisfaction [4]. In Germany, the Joint Federal Committee (Gemeinsamer Bundesausschuss, GBA) in its guidelines on planning-relevant quality indicators (clause 17) from 2017 choose iatrogenic organ injury as a decisive quality indicator

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in gynaecological laparoscopy [5]. Another quality indicator is the 30-day readmission rate following inpatient treatment in the context of surgical procedures. It was proposed in Switzerland in 2004 as a quality indicator for the performance of surgical treatment, as most inpatient readmissions due to surgical complications occur within 30-day intervals after patient discharge [6, 7]. To evaluate surgical complication rates, the Clavien-Dindo (CD) classification has been introduced as a validated instrument for the retrospective assessment the morbidity of surgical therapies [8]. In gynaecology, the CD classification has been used as a scientific mean to register surgical complications in minimal-invasive procedures within the last decade [9].

Patient satisfaction with in-patient treatment.

In addition to these objectively ascertainable parameters, the subjective patient evaluation of treatment has become an aspect of scientific interest in the assessment of medical treatments in recent years. The Picker Patient Experience Questionnaire (PPE-15) established at Oxford University in 2002 is a validated and commonly used instrument to evaluate patient's satisfaction [10]. This 15 item questionnaire aims to evaluate various aspects of a hospital treatment from a patient's perspective.

The scope of our study was to evaluate the use of CD classification and PPE-15 as quality indicators for the routine assessment of laparoscopic procedures in gynaecology.

Methods

Study design

The study is a retrospective monocentric cohort study at a gynaecologic endoscopic referral center and academic teaching hospital (Gynecology Department, Agaplesion Diakonie Kliniken Kassel, Germany). With 815 gynecolgocial laparoscopic procedures performed in 2017, the hospital was ranked among the five largest gynaecological endoscopic centers in Germany in a nationwide assessment of the Joint Federal Commission (GBA; executive organ of the joint self-government in the German health service) [5].

In August 2018, we incorporated the assessment of complication rates with the CD classification system and the assessment of patient's satisfaction at discharge with PPE-15 in the standard operational procedure course of all gynaecological patients treated in our hospital. In January 2019, we conducted a systematic search in the hospital information system (Orbis, Agfa N.V., The Netherlands) and identified all patients treated laparoscopically in September 2018.

From written and electronic patient's records, the following data were extracted: patient's age, body mass index (BMI) and duration of surgery postoperative length of stay, the perioperative complications according to the CD classification, the 30-day readmission rate and PPE-15 questionnaires results [10]. Type of surgery and classification of surgery were recorded for each patient according to Chi et al. (stage I: diagnostic laparoscopy; stage II: uni- or bilateral adnexectomy, uni- or bilateral cyst ablation on the ovary, hysterectomy, myomectomy, adhesiolysis, resection of superficial endometriosis lesion; stage III: second-look laparoscopy after laparotomy in gynaecological–oncological patients, reconstructive uro-gynaecological surgery, adhesiolysis after oncological, surgical interventions in abdomen or pelvis; stage IV: retroperitoneal lymphadenectomy, extended hysterectomy, resections of intestine, bladder, ureter with or without laparoscopic suture or, respectively, anastomosis) [11]. The collected data were processed anonymously using an electronic database (Microsoft Office Professional, Excel version 2007, Redmond, Washington, USA).

Methods of evaluation

The PPE-15 for the evaluation of patient satisfaction was handed out to the patients with a request for completion on the discharge day. To assess postoperative complication rates, the electronic and written patient data for all patients were evaluated and classified in January 2019 independently by two examiners (SS and MPR) according to CD. To determine patient satisfaction with the treatment that had taken place, all completely filled PPE-15 were evaluated individually.

Patient satisfaction was evaluated using the 15 items standardized PPE-15 (see in "Appendix"). The questionnaires were analyzed dichotomously using the two categories 0 (no complaint) and 1 (reason for complaint). The 30-day readmission rate was determined by a corresponding search query in the hospital information system of Agaplesion Diakonie Hospital, Kassel Germany.

The PPE-15 questionnaire was validated in a prospective multi-center study in 62.925 patients by Jenkinson and colleagues [10]. We used the patients' cohort from this validation study as a reference collective for the PPE analysis of our evaluation.

In 2014, Radosa and colleagues analyzed all minimal-invasive treatment courses in gynecology assessed with the CD classification and published in scientific articles, accessible via the US National Library of Medicine. They included data from 7.438 patients in their systematic review to determine baseline complication rates of endoscopic procedures in gynecology assessed with the CD classification [9]. Data from this analysis were used as a reference cohort for comparisons of surgical complication rates, assessed with the CD classification in the present evaluation.

Statistics

Chi-square test with two-tailored p value and Yates correction was used to examine statistically significant differences between the rate of operative complications and patient satisfaction in our collective versus a reference collective with 7438 patients published by Radosa et al. in 2014 for evaluating complication rates and versus a reference collective including 57,214 patients published by Jenkinson et al. in 2002 for analysing patient satisfaction [9, 10]. The significance level was set at $p < 0.05$.

Ethical approval

For our survey, only existing patient data were retrieved retrospectively from the hospital information system and processed in an anonymous form. The study was reported to the ethics committee of our hospital and it was found that no formal ethics vote had to be requested for this retrospective evaluation of existing patient data.

Results

Descriptive analysis

A total of 212 cases were included in this study. Median age of patients was 43.78 years (minimum 19 years, maximum 73 years, range 54 years). Median BMI was 26.43 (minimum 18.2, maximum 44.8, range 26.6). Median duration of surgery was 90.55 min (minimum 27 min, maximum 405 min, range 378 min) and the postoperative length of hospital stay was 3.23 days (minimum 1 day, maximum 8 days, range 7 days). Patient characteristics of our cohort are summarized in Table 1. Regarding the classification of the technical severity of surgery according to Chi et al. there were 29 stage I operations (21.01%), 98 stage II operations (71.01%), six stage III operations (4.35%) and five stage IV operations (3.62%). 133 out of 138 operations (96.38%) did not experience a complication at all.

Five (2.36%) major complications of grade III according to the CD classification (re-laparoscopy under general anesthesia) were observed. Four of the five complications occurred in the technical difficulty degree II and one complication in the difficulty degree I according to the classification of Chi et al. We recorded 23 (10.85%) minor complications according to CD. The statistical analysis did not show significant differences of the complication rate between our cohort and the reference collective published by Radosa et al. [9] neither for total complications nor for minor complications (CD I/II) nor for major complications (CD III–V) (Tables 2, 3). We did observe one surgical complication according to the definition of the Joint Federal Commission in our patient cohort (0.47%). An accidental cystostomy was perceived during a laparoscopic hysterectomy. The injury was endoscopically sutured, postoperative a transurethral urinary diversion was conducted for 36 h. In the independent survey of CD complication rates by both investigators, there were no differences in both the number and the classification of the severity of the surgical complication.

The 30-day readmission rate was 3/138 (2.17%).

From a total patients cohort of 212, we obtained and consecutively evaluated 138 PPE-15 questionnaires (response rate: 65.01%).

In the evaluation of patient satisfaction with PPE-15 112 patients (81.16%) had at least one complaint regarding their hospital stay. An average of 3.28 items per patient was rated as non-satisfactory (minimum 0/15, maximum 13/15, range 13/15). “Doctors didn’t discuss anxieties or fears” was the best rated item in the PPE-15 in our cohort (marked as non-satisfactory by four patients, 2.90%). “Purpose of medicine not explained” was the item with the highest complaints, marked by 40 patients (28.99%) as non-satisfactory (Table 4).

Compared with the reference collective in the validation study of the PPE-15 published by Jenkinson et al. [10], we found no significant difference with regards to the return rate of PPE-15 (between 46 and 74% in validation cohorts). Compared to an average of 3.28 out of a total of 15 items in PPE-15 marked as non-satisfactory in our cohort no significant differences were noted in the reference cohort (3.6 items).

In comparison with the reference collective the items (1) doctors answers to question not clear (8.7% vs. 20.8%, $p < 0.01$) (4) doctor didn’t discuss anxieties or fears (2.9% vs. 11.2%, $p < 0.01$) and (15) not told about danger signals to look for at home (13.8% vs. 43.3%, $p < 0.01$) were evaluated significantly better in our collective as compared to the reference cohort. In contrast, the items (2) nurses` answers to questions not clear (28.3% vs. 18.4%, $p = 0.02$) (3) staff gave conflicting information (28.3% vs. 17.8%, $p < 0.01$) (10) staff did not do enough to control pain (13.0% vs. 6.0%, $p < 0.01$) and (13) purpose of medicines not explained (29.0% vs. 16.2%, $p < 0.01$) were evaluated significantly more often as non-satisfactory in our cohort.

Table 1 Patient characteristics ($n = 212$)

Parameter	Mean	Standard deviation
Age (years)	43.78	8.21
BMI (kg/m^2)	26.43	5.76
Duration of surgery (minutes)	90.55	22.23
Length of postoperative stay (days)	3.2	1.31

Table 2 Surgical complications in the study cohort ($n=212$)

Technical classification of surgery according to Chi et al.	*N*	%
I	38	17.92
II	156	73.59
III	11	5.19
IV	7	3.3
Complications classified according to Clavien-Dindo		
I	14	6.6
II	9	4.24
III	5	2.36
IV	0	0
V	0	0
Overall	28	13.21
Minor (I/II)	23	10.85
Major (III/IV/V)	5	2.36
Minor complications		
Urinary tract infections	4	
Prolonged postoperative pain	13	
Cutanous hematoma	5	
Prolonged (> 24 h) transurethral urinary diversion	1	
Major complications		
Hemorrhage with laparoscopic revision	4	
Vaginal vault dehiscence, laparoscopic revision	1	
30-days readmission rate	3	1.42
Vaginal vault dehiscence	1	
Intraabdominal hematoma	1	
Urinary tract infection	1	
Complication rate according to Joint Federal Commission (iatrogenic injury of neighbouring organs)-incidental cystotomy during laparoscopic hysterectomy, intraoperatively laparoscopic suture, postoperatively urinary diversion for 36 h	1	0.47

Table 3 Comparison of surgical complications between the study cohort and the reference cohort, reference cohort derived from [9]

Degree of complication	Study cohort ($n=212$)		Reference cohort ($n=7438$)		*p* value Chi-square with Yates correction, two-tailored
	N	%	*N*	%	
CD I	14	6.6	350	4.7	
CD II	9	4.24	317	4.26	
CD III	5	2.36	248	3.33	
CD IV	0	0	48	0.65	
CD V	0	0	2	0.003	
Overall	28	13.21	965	12.97	n.s
CD I/II (minor)	23	10.85	667	8.97	n.s
CD III/IV/V (major)	5	2.36	298	4	n.s

Discussion

In this retrospective cohort study we evaluated the use of CD classification to assess surgical complications and the PPE-15 to assess patients' satisfaction in the context of gynecologic endoscopy.

The CD classification system is a standardized, validated measuring instrument to assess surgical complications, especially in a retrospective study setting. In contrast to other classifications, the complication`s degree of severity in relation to the postoperative course is co-involved [12]. In the CD classification system, the severity of a complication is defined by the therapeutic measures needed to treat the complication (e.g. antibiosis, operative revision, intensive care [9]. Nowadays the CD classification is used in many surgical disciplines including gynecology to evaluated surgical complications [9, 13–16].

Another possibility to assess surgical morbidity may be the detection of iatrogenic organ lesions during laparoscopic intervention. This assessment method has been introduced by the GBA for quality assessment of inpatient treatment in

Table 4 Comparison of patient satisfaction between the study cohort and the reference cohort, reference cohort derived from [10]

PPE-15 assessment ($n=138$)	Own cohort ($n=138$)		Reference cohort ($n=57{,}214$)	p value Chi-square with Yates correction, two-tailored
	N	%	%	
Doctors' answers to questions not clear	12	8.7	20.76	<0.01
Nurses' answers to questions not clear	39	28.26	18.4	0.02
Staff gave conflicting information	39	28.26	17.78	<0.01
Doctors did not discuss anxieties or fears	4	2.9	11.2	<0.01
Doctors sometimes talked as if I was not here	38	27.53	26.98	n.s
Not sufficiently involved in decisions about treatment and care	38	27.53	28.2	n.s
Not always treated with respect and dignity	29	21	27.58	n.s
Nurses did not discuss anxieties and fears	17	12.32	15.44	n.s
Not easy to find someone to talk to about concerns	52	37.68	46.18	n.s
Staff did not do enough to control pain	18	13.04	6.04	<0.01
Family did not get opportunity to talk to doctor	37	26.81	21.4	n.s
Family not given information needed to help recovery	28	20.29	26.06	n.s
Purpose of medicine not explained	40	28.99	16.2	<0.01
Not told about medication side effects	39	28.26	34.46	n.s
Not told about danger signals to look for at home	19	13.77	43.3	<0.01
Overall		21.86	23.99	n.s

endoscopic gynecological procedures in Germany [5]. The Rationale for this *modus operandi* is derived from reports ranking organ injuries as the second leading cause of death in endoscopic procedures after anaesthesia incidents in laparoscopy [17]. In principle, these injuries can be subdivided into intestinal and stomach injuries, vascular injuries and injuries of the urinary tract (ureter and urinary bladder). Due to the importance of such complications with regards to morbidity and mortality in endoscopic procedures, it appears reasonable to record these data as part of quality assurance. However, the sole detection of neighboring organ injuries during endoscopic operations without further classification and evaluation of the course of the disease (for example, by the qualitative assessment of the severity of the complication by CD), as currently practiced, appears to be of limited use in the assessment of surgical quality. Intraoperatively detected and treated injuries of neighbouring organs usually have a different implication for patients than delayed diagnosed organ injuries in the later post-operative course. For example, laparoscopic suturing of a gastrointestinal or urinary tract lesion detected promptly intraoperatively will usually not compromise the postoperative course substantially. A late-detected bowel injury with postoperative peritonitis on the other hand will be of considerable concern to the patient and the surgeon involved with regard to the postoperative course as peritonitis often requires an open-surgical revision followed by intensive care unit stay. Di Saverio et al. reported in a monocentric retrospective cohort study that 75% of cases of bowel injuries occurring during laparoscopic intestinal adhesiolysis were followed by an open bowel surgery with consecutive increased morbidity. They emphasized the importance of an intraoperative assessment of intestinal injuries [18]. For this reason, in our understanding, the sole detection of adjacent organ injuries in laparoscopic surgeries as a surrogate parameter of perioperative morbidity as a sole quality measure might be of limited clinical use.

The 30-day readmission rate has been introduced as a medium to long-term indicator for surgical treatment quality [7]. Unplanned hospital readmissions affect patients' quality of life and constitute a considerable source of additional financial burden to the health care systems. An estimated 10–20 billion dollar is spent annually in the US for medical treatment after readmitting patients after stationary care at an average 30-day readmission rate of 13–18% [19]. A variety of factors influencing the 30-day readmission rate have been described, including the severity of the inpatient procedure, the general condition of the patient, patient's comorbidities or the interlocking between the inpatient treatment facility and the outpatient care [20, 21]. The rate of readmission of patients is certainly one important part of quality assurance for surgical procedures. However, in our opinion it falls short as a sole quality parameter: In our cohort only two out of five major complications were recorded by the 30-day readmission rate. In addition, in our study we observed a low number of complications which consecutively lead to a low 30-day readmission rate. Hence the potential use of the 30-day readmission rate as a surrogate parameter for quality was limited by this overall low complication rate in our study. In such a clinical setting, where a low complication

rate is anticipated, the 30-day readmission rate might be of limited value to evaluate the morbidity of surgical procedures. We assessed the readmission rate for our cohort based on the readmissions of patients within 30 days in our hospital. This is a possible bias of our study since readmissions in other hospitals within our study cohort could not be validly assessed resulting in a potential under-reporting of the 30-day readmission rate in our study. We feel that this is a general conceptional limitation of the use of the 30-day readmission rate as a quality indicator in the clinical routine. Due to patients' privacy rights, the sharing of the information that a patient has been readmitted between two different hospitals is routinely not possible. In our views, this factor substantially limits the use of the 30-day readmission rate as a quality indicator for individual hospitals.

In our study cohort, the complication rate, evaluated with the CD system was consistent with the complication rate described in previous studies using a comparable methodological approach [9]. This finding indicates in our view a constant complication rate in endoscopic gynecology during standard procedures over the course of the last decade.

Recording of complication rates, length of hospital stay or readmission rates after surgical treatment are important parameters in the quality assessment of surgical treatments. To depict surgical treatments in an integrated manner, these parameters may be supplemented with subjective patient evaluations of the assessed treatments [22]. Validated questionnaires can be useful in assessing patient outcome measures.

Recently different assessment systems have been introduced into clinical routine such as the IRES-24 patient questionnaire, a common questionnaire for the evaluation of patient satisfaction during rehabilitation or the visual analogue scale for the quantification of pain in the context of the assessment of analgesia`s effectiveness [23, 24]. The PPE-15 was developed and validated by Harvey Picker and colleagues to assess the patient's perspective on medical treatments. The National Coordination and Information Office for Quality Improvement in Switzerland incorporated the use of PPE-15 into their annual nationwide survey of patients to assess treatment quality [10, 25].

We introduced the PPE-15 in clinical routine, to separately record and evaluate individual aspects of the medical treatment [26].

A previously described limitation when using the PPE-15 is a reduced return rate [10, 27, 28]. Similar in our own study cohort the observed return-rate of PPE-15 was at 66%. Especially older patients and patients with special needs in our service reported about difficulties in completing the PPE-15, which constitutes a possible bias.

We noted no difference regarding the overall satisfaction with the treatment in terms of PPE-15 assessments between our cohort and the reference cohort from the validation study of PPE-15 two decades ago [10]. Similarly, recently published PPE-15 assessments of surgical treatments reported comparable results for patient satisfaction [29, 30]. From a patient's perspective, this finding could be regarded as a challenge towards the efforts undertaken in our health care system to improve inpatient treatment quality over the course of the last decade.

Although the total PPE-15 score of our cohort did not differ significantly compared with the reference collective from the validation study of the PPE-15, we observed significant differences for single items: patients in our cohort were less satisfied with the treatment of pain postoperatively. This finding underlines the requirement of stringent pain management also after endoscopic procedures. Clinically significant pain levels have been previously described even for less extensive endoscopic procedures in gynecology such as oophorectomies [31]. In the last few years, the perioperative pain therapy has come into focus in the scientific evaluation of endoscopic therapy in gynecology and measures such as port-site infiltration or assisted ventilation with an open umbilical trocar valve have been introduced to address postoperative pain treatment [32].

Communication between nursing staff and patients as well as between medical and nursing stuff were also addressed by patients in our study cohort. Reasons for a compromised communication between care-givers and patients as well as between different health-care professions have been linked to an increasing condensation of medical inpatient treatment and increasing requirements on medical documentation [33]. Tan et al. specifically addressed problems of communication between different medical professions in a systematic review of the literature. They conclude that communication between doctor and nurses is often ineffective, due to different communication styles and suggested an inter-professional education for improving communication [34].

The low number of complications analyzed in this study constitutes a possible limitation of our evaluation: as outlined in the methods section of our manuscript, we implemented the use of PPE-15 and CD as part of a quality assessment in the clinical routine of our department in August 2018. In September 2018 we systematically recorded results from the PPE-15 and CD survey to create a baseline value for both methods at our department. We only opted for a relatively short period of time of one-month for this baseline assessment of both methods, since PPE-15 and CD both are already validated instruments and the primary goal of their implementation into the clinical routine of our department was to create data in a prompt manner to improve quality of treatment in our service. With the beginning of October 2018, we started to alter our inpatient management based on the PPE-15 and CD survey, e.g. we introduced a new SOP on post-operative pain management based on the results of PPE-15 questionnaires in November 2018 in our department.

We acknowledge that the study's statement could have been further sustained by a longer duration of the baseline assessment of PPE-15 and CD in our study with more complications to analyze.

Conclusions

We assessed the implementation of CD classification and PPE-15 as two means to evaluate quality for endoscopic gynecological procedures in clinical routine. CD classification and PPE-15 may be helpful instruments to evaluate the quality of care in gynecology. The application of both instruments for the assessment of treatment quality in the clinical routine should be further investigated in prospective studies.

Compliance with ethical standards

Conflict of interest We declare that we have no conflict of interest.

Ethical approval The study was conducted in concordance to the ethical standards of the institution.

Informed consent Only retrospective data from patient records were analyzed without any intervention. All patients gave their agreement in analyzing and publishing data anonymously before treatment.

Appendix

PPE-15 items

1. If you asked important questions to a doctor, did you get clear answers?
2. If you asked important questions to nurses, did you get clear answers?
3. Sometimes it happens that a doctor or nurse says something, and another doctor or nurse tells you something else. Did that happen to you?
4. If you were worried or worried about your condition or treatment, did a doctor discuss it with you?
5. Did it happen that doctors in your presence talked about you as if you were not there?
6. Could you participate in your treatment?
7. Did you have the feeling of being treated with care and attention during your stay in hospital?
8. If you were worried or worried about your condition or treatment, did the nurses discuss it with you?
9. Was it easy to find someone from the hospital staff who talked to you about your concerns and concerns?
10. Did you have pain during this hospital stay?
11. Did your family or other people close to you have ample opportunity to talk to your doctor?
12. Has anyone informed your family or other people who are close to you how recovery can help you?
13. Did someone explain the purpose of the medication that you should take at home understandably?
14. Has anyone told you what side effects of these medicines you should look at home?
15. Has anyone told you what symptoms you should be aware of at home with regard to your illness or surgery?

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