Complications in laparoscopic and robotic-assisted surgery: definitions, classifications, incidence and risk factors – an up-to-date review

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Abstract

Almost all gynecological and general-surgical operations are — or can be — performed laparoscopically. In comparison to an abdominal approach, the minimally invasive access offers several advantages; however, laparoscopy (both conventional and robotic-assisted) can be associated with a number of approach-specific complications. Although the majority of them are related to the laparoscopic entry, adverse events may also occur due to the presence of pneumoperitoneum or the use of laparoscopic instruments. Unfortunately, a high proportion of complications (especially affecting the bowel and ureter) remain unrecognized during surgery. This narrative review provides comprehensive up-to-date information about definitions, classifications, risk factors and incidence of surgical complications in conventional and robotic-assisted laparoscopy, with a special focus on gynecology. The topic is discussed from various perspectives, e.g. in the context of stage of surgery, injured organs, involved instruments, and in relation to malpractice claims.

Key words: complications, risk factors, incidence, classification, gynecological laparoscopy, robotic-assisted surgery.

Introduction

Since its beginnings in the 1970s, laparoscopy has gradually become the standard surgical approach to the abdominal cavity in all surgical specialties including gynecology [1]. The benefits of modern laparoscopy are: decreased blood loss, less postoperative pain, fewer wound complications, reduced risk of adhesion formation, shorter hospital stay, faster return to daily activities, excellent cosmetic results [2–5], and lower treatment costs in comparison to open abdominal procedures [3–5]. The implementation of robotic-assisted laparoscopic surgery (RALS) – fol-

lowing the USA Food and Drug Administration approval for the first DaVinci system in 2005 – allowed for further minimizing intraoperative blood loss and acceleration of patient recovery [6–8]. Despite the undoubted advantages, the minimally invasive approach does not rule out the possibility of adverse events [9–15]. Depending on definitions and classifications used, 0.2–18% of conventional and 3–15% of robotic-assisted gynecological laparoscopies are associated with (either intra- or postoperative) adverse events (AEs). Fatalities resulting from a laparoscopic approach occur in 0.02% (0.01–0.03%) of cases and are most often related to injuries of large

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retroperitoneal vessels, and – less frequently – to bowel injuries [14–27]. Compared to open surgery, laparoscopy for benign indications is associated with similar rates of severe complications (1.4%) but a significantly lower incidence of "minor" complications (15.2% vs. 4.3–8.9%) [10, 11, 15].

In turn, in comparison to conventional laparoscopic surgery (CLS), RALS is associated with further benefits, such as decreased intraoperative bleeding, reduced need for transfusions, lower level of postoperative pain, shorter hospital stay and faster convalescence, while showing similar rates of intraoperative, and roughly comparable rates of postoperative complications [6, 7, 12, 13, 28].

Although complication rates increase with the complexity of the procedure, a considerable proportion of severe incidents still occur during diagnostic or minor procedures (e.g. sterilization). This is because half of the complications occur during laparoscopic entry [9, 10, 15–17, 21, 25–27]. For some exclusively laparoscopy-related incidents, e.g. postlaparoscopic shoulder pain, subcutaneous emphysema or morcellation of occult malignancy, minimally invasive access is a prerequisite.

Unique limitations of the conventional laparoscopic approach are:

- (Usually) blind entry into the peritoneal cavity,
- Restricted vision (fixed angle of view; limitations resulting from smoke, fog or bleeding; dependence of camera assistant),
- Often two-dimensional field of view,
- Fixed trocar positions with limited degrees of freedom,
- Limited tactile feedback,
- Effects of intra-abdominal pressure (overstretching of nerves, impaired ventilation),
- Physical and chemical effects of the insufflation gas (CO₂),
- Necessity of specimen fragmentation (morcellation) prior to evacuation.

The aforementioned limitations can be attenuated, but not eliminated, by technical improvements (3D optical systems, 4K display resolution, integrated smoke evacuation systems).

The RALS differs from CLS in terms of:

- Improved visibility due to angulated optical instruments with 3D optics,
- Variable use of optics in all four trocars,
- Integrated fluorescence imaging near-infrared technology (FireFly mode),

- Motion dampening sensors (tremor filtration),
- Wristed instrumentation with up to 7° of freedom,
- Larger trocars compared to CLS (Da Vinci Si System),
- Absence of tactile feedback,
- Longer setup of the robotic equipment,
- Longer total operating time (conflicting data),
- Higher costs,
- Longer learning curve which has to be traversed even by experienced laparoscopists [6–8, 28].

Aim

This review aims to provide essential knowledge about definitions, classifications, incidence rates and risk factors of procedure-related complications of CLS and RALS, with special focus on gynecology. Complication management and non-approach-specific AEs (e.g. anaesthesia-related problems or hospital-acquired infections) are not topics of the present work.

Material and methods

We chose the form of a narrative review as the most appropriate for discussing a broad range of questions from different perspectives, e.g. according to the time of occurrence, affected organs, and involved instruments. We adhered to the quality standards for narrative reviews, as defined by experts [29] and quantified by "SANRA - a scale for the quality assessment of narrative review articles" [30]. The relevant publications were identified after systematic query of the following sources: PubMed, Google Scholar, Cochrane Library, SciELO, and publishers' databases (Elsevier/ScienceDirect, Wiley, Taylor & Francis, Springer, Sage, Mary Ann Liebert, Wolters Klouwer/Lippincott, Hindawi, Termedia, and Via Medica), complemented by cross-check of the reference lists. We used a combination of the search terms "complication", "adverse event", "injury", "intraoperative" and "iatrogenic" with terms relevant to the topic of each paragraph (e.g. "vessel", "vascular", "aorta"), with and without restriction to "gynecology/gynecologic". With singular exceptions ("classical" publications in the field and unique case reports), only papers published in the 21st century were included. The final selection of references was made after full-text reading. We examined all types of publications (original research, systematic reviews, meta-analyses, narrative reviews, and case reports). When multiple studies reported similar results, we selected those that were the most up to date and represented the highest methodological quality. Publications related to non-procedure-specific complications were excluded. No language restrictions were applied.

Definitions of surgical adverse events

The U.S. National Institutes of Health (NIH) and the National Cancer Institute (NCI) recommend the definition of an adverse event (AE) as "any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure" [31]. The NIC provides "Common Terminology Criteria for Adverse Events (CTCAE)" reporting, a freely accessible and regularly updated catalogue (in the current version 145 pages), including definitions and grading for each type of AEs [31]. The NCI five-level grading of AEs is presented in Table I. The newest version of the CTCAE (6.0) is announced for the fall of 2022. The CTCAE is recommended for reporting of AEs by health services and used in clinical trials, e.g. the LACC (Laparoscopic Approach to Carcinoma of the Cervix) trial [32].

Some authors interpret the meaning of "complications" more broadly than that of AEs, that is (besides "events") as any kind of undesirable treatment course, e.g. prolonged hospitalization resulting from healthcare system or institutional policies [33]. However, commonly the terms "AEs" and "complications" are used interchangeably [32, 34–36]. Clavien

et al. [35, 36] distinguished between three types of negative postoperative outcomes: "complications", "sequelae", and "failure to cure". A complication was defined as any deviation from the normal postoperative course, inclusive "asymptomatic complications such as arrhythmia or atelectasis". A sequela was proposed for any "after-effect" of surgery that was inherent to the procedure (e.g., inability to walk after amputation of the leg). Failure to cure would occur, when - despite an uncomplicated surgical course the intended result of surgery, e.g., complete oncological cytoreduction, could not be achieved. In fact, "sequelae" and "failure to cure" should be assessed separately from complications [35, 36]. For this purpose, Sokol and Wilson [37] established the following, widely accepted definition of surgical complication – which we also use in the present review (synonymously to AE): "any undesirable, unintended, and direct result of an operation affecting the patient, which would not have occurred had the operation gone as well as could reasonably be hoped" [37]. They argued that, although in high-risk procedures complications can be "expected", two conditions define a surgical complication: it is always unintentional and occurs although an uncomplicated surgical course was realistic [37].

Classifications of surgical complications

Surgical complications can be classified according to:

- a) their severity: from "mild/minor" through "severe/major" to "lethal";
- b) time period: preoperative, intraoperative, early postoperative, late postoperative;

Table I. Common Terminology Criteria for Adverse Events (CTCAE) v5.0 – guideline for severity description of adverse events

Grade		Description		
1	Mild	Asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated		
2	Moderate	Minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*		
3	Severe	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**		
4	Life-threatening	Life-threatening consequences; urgent intervention indicated		
5	Death	Death related to an adverse event		

ADL – Activities of Daily Living. *Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.; **Self care ADL refer to bathing, dressing and undressing, feeding oneself, using the toilet, taking medications, and not bedridden.

- c) stage of surgery: laparoscopic entry, main part of surgery including dissection of anatomical structures, trocar removal and leaving the abdominal cavity;
- d) injured organs, e.g. vascular, intestinal, urological, or neurological injuries;
- e) causality: instrument-related, pneumoperitoneum-related, surgeon-related etc.;
- f) specificity: "surgical and approach-specific", e.g. morcellator related complications or pneumoperitoneum-related incidents; "surgical and approach-independent", e.g. organ injury due to severe adhesions; and "non-surgical", e.g. anesthesiologic complications or hospital infections.

Unfortunately, several important reports did not strictly differentiate between intra- and postoperative complications [9–11, 15]. Additionally, the surgical literature contains a variety of occasional and hybrid terminologies, making even important results hard to generalize. For instance, in their seminal work Wechter *et al.* [12] propose an eclectic distinction between "benign simple", "benign complex", "urogynecological" and "oncological" RALS procedures, wherein "adhesiolysis" is classified concurrently as a "simple complex" or "oncological" procedure, and "urogynecological" procedures are handled separately from "benign complex".

Classifications according to severity, complexity and time of occurrence

The severity is often the first and main criterion used for classification of surgical AEs. Unfortunately, the reporting of AEs in surgical studies is commonly unsatisfactory. For instance, intra- and postoperative complications are defined in only 13% and 50% of trials, respectively, and classification systems are

used in 9% for intraoperative and in 54% for postoperative AEs, respectively [34]. A systematic review of 179 trials from the area of oesophago-gastric and gynecologic-oncological surgery revealed that definitions of AEs (e.g. according to the CTCAE) and their grading (e.g. the Clavien-Dindo classification) were provided in only 27.3% and 16.8% of studies, respectively [38]. Classification grading systems allow for reliable and comparable reporting of AEs. They rely on additional interventions, necessary medications, affected organs, and duration of a patient's impairment or eventually life-long disability resulting from a complication.

Intraoperative complications

A practical classification of intraoperative complications has been proposed by Satava [39] and improved by Kazaryan *et al.* [40] (Table II). This three-grade classification of intraoperative incidents attempts to combine general (e.g. necessity of changing the operative approach) with subjective or adjustable (e.g. "normal" or expected blood loss) criteria [40]. The latter can, however, be a point of criticism because of possibly imprecise and incomparable results (e.g. the proposed use of "values typical for own institution").

A sufficient combination of universality and practicability has been obtained by the European Association of Urology (EAU) grading of intraoperative incidents (Table III) [41]. The EAU classification of *intraoperative* incidents could be a useful aid, being applicable for all surgical specialties.

Postoperative complications

In regard to the postoperative period, two classification systems have gained broad recognition: the Accordion Severity Classification of Postoperative

Table II. Satava-Kazaryan classification of unfavorable intraoperative incidents

Grade	Definition of intraoperative incidents
1	Incidents managed without change of operative approach and without further consequences for the patient. This includes minor injury of adherent or adjacent organs and minimal change of intraoperative tactics and cases with blood loss over normal range*
2	Incidents with further consequences for the patient. This includes cases requiring limited resection of intraoperatively injured organs or cases with blood loss which is appreciably over the normal range*. For laparoscopic/thoracoscopic/endoscopic surgery it includes intraoperative incidents requiring conversion
3	Incident leading to significant consequences for patient
*	*"A normal range of blood loss for each particular procedure is subjective in a certain degree, but one can quantify it in regard to different procedures based both on contemporary scientific literature and values typical for own institution." [40]

Table III. European Association of Urology intraoperative adverse incidents grading [41]

Grade	Description
0	Event requiring no intervention or change in operative approach, no deviation from planned intraoperative steps, no consequence for the patient
1	Event requiring additional/alternative procedure in planned intraoperative steps, not life-threatening or involving part or full organ removal. The event was addressed in a controlled manner with no long-term side effects
2	Event requiring major additional/alternative procedure in operative approach but NOT immediately life-threat- ening. The event was addressed in a controlled manner, but may have short- or long-term side effects
3	Event requiring major additional/alternative procedure in addition to planned intraoperative steps and incident becoming immediately life-threatening but NOT requiring part or full organ removal; may have short- or long-term side effects
4	Event requiring major additional/alternative procedure in addition to planned intraoperative steps becoming immediately life-threatening and with short- or long-term consequences to patient: A. Requiring part or full organ removal B. Unable to complete planned procedure as planned due to a technical issue or surgical event and/or required unplanned stoma (change in body image, e.g. stoma, major skin flap)
5	A. Wrong site or side for ablative surgery or removal of an organ or wrong patient or no consent B. Intraoperative death

Complications [42] and the Clavien-Dindo Classification of Surgical Complications (Table IV) [35, 36]. The first of them outlines four severity grades – "mild", "moderate", severe" and "death" – whereas the latter uses a 5-point Likert scale. The Clavien-Dindo classification was initially devised for general surgery and transplantology [43] but is suitable for CLS and RALS [12, 13, 28, 44].

Surgical complexity

Finally, it is crucial to distinguish between "complicated" and "complex" procedures, since thousands of patients undergo "complex" surgery without AEs, and, on the other hand, "major" complications also occur during "minor" procedures [15]. Nevertheless, the complication rates statistically decrease with the surgeon's experience and increase with the complexity of the surgical procedure [10, 12, 13, 15]. In terms of defining sustainable training and certification goals, international (e.g. the European Society for Gynaecological Endoscopy (ESGE) [45]) and national (e.g. the German Society for Gynaecological Endoscopy (AGE) [46]) laparoscopic boards proposed their own classifications of surgical complexity, based on the four-level grading proposed (more than two decades ago) by Chapron et al. [15]. Table V provides examples of these three classification systems of surgical laparoscopical complexity.

Of note, the difficulty level of myomectomy or hysterectomy is rated differently by these popular grading systems. The category "ectopic pregnancy" is not listed in the ESGE classification. While the "treatment of pelvic floor disorders" is assigned to the highest difficulty level by the ESGE [45], urogyne-cological procedures are divided into "cervical- and colposacrocopoplexy" (level 3) and "complex pelvic reconstruction" (level 4) by the AGE [46]. Procedures for "endometrial and cervical cancer" – despite their different extent and type – were confusingly placed together by Chapron *et al.* [15].

Incidence of laparoscopic complications

The awareness of frequency ranges of typical laparoscopic complications is indispensable for the consideration of treatment options and informed consent prior to surgery. However, the incidence of reported perioperative AEs varies depending on definitions, proportion of minor to major procedures in the analyzed sample, inter-institutional variability, or differences between individual surgeons. These facts explain the broad range of complication rates which can be found in the literature: the overall incidence of 0.2% to 18% for CLS, and 3.2% to 14.6% for RALS; "major" complications observed after 0.6% to 14.6% of CLS, and 4.1% to 6.4% of RALS, and intraoperative AEs noted in 2.7 to 7.5% of CLS and in 1.6% to 3.5% of RALS [12, 13, 44].

Chapron *et al.* describe undesirable surgical events in 0.08%, 0.4% and 1.7% of "minor", "major" and "advanced" gynecologic laparoscopies, respectively

Table IV. Accordion severity classification of postoperative complications and Clavien-Dindo classification of postoperative surgical complications

Severity	Accordion Severity Classification of Postoperative Complications (Contracted Classification) [42]	Clavien-Dindo Classification of Surgical Complications [35, 36]	Grade
1. Mild complication	Requires only minor invasive procedures that can be done at the bedside such as insertion of intravenous lines, urinary catheters, and nasogastric tubes, and drainage of wound infections. Physiotherapy and the following drugs are allowed: antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Allowed therapeutic regimens are: antiemetic, antipyretic, analgesic, or diuretic drugs, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside	Grade 1
2. Moderate complication	Requires pharmacologic treatment with drugs other than those allowed for minor complications, for instance antibiotics. Blood transfusions and total parenteral nutrition are also included	Requiring pharmacological treatment with drugs other than those allowed for grade 1 complications. Blood transfusions and total parenteral nutrition are also included	Grade 2
3. Severe complication	All complications requiring endoscopic or interventional radiologic procedures or re-operation as well as complications resulting in failure of one or more organ	Requiring surgical, endoscopic or radiological intervention: Grade 3a. Intervention not under general anesthesia Grade 3b. Intervention under general anesthesia	Grade 3
	systems.	Grade 4 Life-threatening complication (including central nervous system)* requiring intensive-care unit management Grade 4a. Single organ dysfunction (including dialysis) Grade 4b. Multiorgan dysfunction	Grade 4
4. Death	Complications resulting in death	Patient's death	Grade 5
		Suffix "d" If the patient suffers from a complication at the time of discharge, the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication *Brain hemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks	

[15]. In contrast, studies applying the Clavien-Dindo classification report markedly higher incidences, e.g. 13.1% (Grade \geq 3: 4.1%) for gynecological CLS [44], 18.4% (Grade \geq 3: 5.2%) for gynecological RALS [12], and 12.5% (Grade \geq 3: 7.5%) for general-surgical laparoscopies [43].

Nevertheless, when using similar criteria, the complication rates of CLS and RALS seem to be comparable [6, 8, 13, 28]. Most publications report identical [7, 13, 28] or lower [8] frequencies of intraoperative complications in favor of RALS, no difference [7, 8, 28] or reduction of minor postoperative complications (13.9% vs. 22.8% [13]) with the aid of the robot, but similar [8, 28] or increased incidence of major postoperative complications [7], e.g. 5.2% vs. 2.2% in the robotic arm of Ref. [13]. A comparison

of intra- and postoperative complication rates of CLS and RALS is presented in Table VI.

Mortality

Operative mortality from any minimally invasive gynecological surgery (laparoscopy and RALS) is extremely low (1 of 6456 procedures) [15, 23]. The procedure-associated mortality of CLS is quoted at 0.02% (0.01–0.03%), which can be translated into an estimated risk of death of 1 in 6512 (1:3971–1:10680) laparoscopies [23]. Major vascular injuries (MVI) are responsible for 74–82% of all laparoscopy-associated fatalities, followed by (not recognized) intestinal injuries [14–27]. The mortality rate of RALS is 1 out of 5430 procedures, although

Table V. Complexity grading systems of gynecologic laparoscopic procedures. The original nomenclature of surgical procedures remained unchanged

Chapron <i>et al</i> . 1998 [15]		ESGE [45]		German Association of Gynecologic Endoscopy [46]	
LEVEL	Procedures	LEVEL	Procedures	LEVEL	Procedures
Diagnostic Minor	Diagnostic laparoscopy Minimal adhesiolysis (as assessed by the surgeon), destruction of minimal endometriosis, ovarian biopsies, ovarian punctures, tubal sterilization, assisted conception procedures	Basic	Diagnostic laparoscopy, tubal sterilization, cyst aspiration, biopsy	Type I	Diagnostic laparoscopy, tubal sterilization, chromopertubation, simple adhesiolysis, destruction of endometri- osis rAFS I, or comparable procedure
Major	Ectopic pregnancy, pelvic inflammatory disease, polycystic ovaries, benign ovarian cysts, distal tubal plasty, uterine suspension, extended adhesiolysis, moderate or severe endo- metriosis	Intermedi- ate	Salpingotomy, salpingectomy, oophorectomy, ovarian cystectomy, adhesiolysis, treatment of mild-moder- ate endometriosis	Type II	Ectopic pregnancy, salpingectomy, oophorectomy, adnexectomy ovarian cystectomy, myomectomy for pedunculated or subserous myomas (without uterine reconstruction), hysterectomy, extended adhesiolysis, destruction of endometriosis rAFS I/II, Enzian A1/B1, or comparable procedure
Advanced	Hysterectomy, myomectomy, lymphadenectomy, colposuspension, tubal sterilization reversal, genital prolapse, endometrial and cervical cancer, retroperitoneal endome- triosis	Advanced	Hysterectomy, myomectomy, extensive adhesiolysis, treatment of severe endo- metriosis, treatment of urinary incontinence, treatment of bladder or bowel injuries	Type III	Type II procedures performed in presence of distorted anatomy, intramural or intraligamentary myomectomy, destruction of endometriosis rAFS III/Enzian A2/B2/C1, microsurgical distal tubal reconstruction, cervico- or colposacropexy, or comparable procedure
		Special procedures	Treatment of pelvic floor disorders, oncology (lymphadenectomy, radical hysterectomy, axilloscopy), treatment of recto-vaginal nodules procedures not yet described	Type IV	Radical hysterectomy, lymphadenectomy, destruction of endometriosis rAFS IV/ Enzian A3/B3/ C2-3/FB/FU/FI, complex pelvic floor reconstruction, microsurgical proximal tubal reconstruction, reconstructive surgery for congenital malformations, or comparable procedure

Table VI. Average incidence rates of intra- and postoperative complications in gynecological laparoscopica
procedures (in percent)

Variable	Conventional laparoscopical surgery	Robotic-assisted laparoscopical surgery		
Overall (intra- and postoperative period)	0.5–13%	3.2–18.4%		
Intraoperative	1.9%	3.2%		
Vascular injury	0–1.7%	0-1.7%		
Intestinal injury	0.13-0.5%	0.6–2.8%		
Urinary tract	0.5–1.7%	1.2–3.5%		
Postoperative	13–34%	18.4%		
Clavien-Dindo grade 0–2	9%	13.2%		
Clavien-Dindo grade 3–4	4%	5.2%		
Vaginal cuff dehiscence	0.6–1.3%	1.6%		
Port-site metastasis	1.0–1.2%	1.4–1.9%		

the available data are less robust [23]. The mortality of conventional laparoscopic hysterectomy (LH) is 0.01% (0.01–0.02%), corresponding to 1:6799 (1:4109-1:11249) procedures. The highest mortality amongst non-oncological laparoscopic procedures is associated with sacrocolpopexy, reaching 0.07% (0–5.65%), that is 1:1343 (1:18-1:107855) interventions [23].

The odds of death from any laparoscopic or robotic gynecologic oncology surgery is 1 in 381 (95% CI: 1:306–1:474), with odds at 1:289 (1:175–1:476) and 1:476 (1:365-1:619) for CLS and RALS, respectively [24]. The operative mortality rate of any type of minimally invasive hysterectomy performed for oncologic indications is 1 in 379 (95% CI: 1: 304–1: 472), with the lowest incidence of procedure-related death reported for radical hysterectomy (1: 2049; 95% CI: 1:356–1:11 832), and the highest one for hysterectomy with lymph node dissection for endometrial cancer - 1: 195 (95% CI: 1: 109-1: 349). However, these numbers should be interpreted with caution, given that patients with cervical cancer are usually younger and healthier as compared to patients with endometrial cancer, who are more often affected by multiple comorbidities and obesity [24].

The mortality data, pooled from [23, 24] and stratified by procedure and indication, are presented in Table VII.

Incidence of complications according to the stage of surgery

In the following paragraph we examine the incidence of complications related to: entering and leav-

ing the abdominal cavity, and presence of the pneumoperitoneum. AEs occurring during the surgery itself will be presented in the sections "organ-related" and "instrument-related" complications.

Entry-related complications

The insufflation of CO₂ using a Veress needle (VN) usually precedes the placement of trocars. The VN is typically inserted via the umbilicus, but in case of suspected adhesions or very large uteri, the abdomen can be more safely accessed via left upper quadrant (Palmer's) and supraumbilical (Lee-Huang') entry points, respectively [47-49]. Direct trocar entry (DTE) and open laparoscopic access (Hasson technique) offer non-inferior but less popular alternatives [47-49]. VN is chosen by 80% of general surgeons and 96% of gynecological laparoscopists as a standard method [16, 49]. Transuterine and trans-cul-de-sac access (both proposed for extremely obese patients) or VN insertion through the ninth or tenth intercostal space (as an alternative to Palmer's point) is reserved for rare situations and for very experienced surgeons [48, 50]. About 50% (35-57%) of all laparoscopic complications, especially 50-83% of serious vascular complications, 41–50% of intestinal complications, and 36% of urological injuries, occur during the initial set up: creation of the pneumoperitoneum and trocar insertion [9, 14, 15, 17, 19, 49]. Entry-related complications are significantly less common in gynecological than in general surgery (4-fold and 3-fold for bowel and combined bowel/vascular injuries, respectively [17]). Similarly, the entry-related

Table VII. Mortality of minimally invasive surgical procedures in gynecology (data pooled from [23, 24])

Procedure type	Procedures (n)	Deaths (n)	Deaths, % (95% CI)	Deaths, odds (95% CI)
All MIS procedures	39 183	77	0.26 (0.21–0.33)	1 : 381 (1 : 306–1 : 474)
Any hysterectomy	38 619	77	0.26 (0.21–0.33)	1:379 (1:304–1:472)
Radical hysterectomy	3369	0	0.05 (0.01–0.28)	1 : 2049 (1 : 356–1 : 11 832)
Hysterectomy + lymph nodes	3501	11	0.51 (0.29–0.91)	1:195 (1:109–1:349)
Ovarian cancer	418	0	0.15 (0.01–2.29)	1 : 685 (1 : 44–1 : 10 971)
Conventional laparoscopy:				
All laparoscopic procedures	9365	13	0.35 (0.21–0.57)	1 : 289 (1 : 175–1 : 476)
Any hysterectomy	8842	13	0.36 (0.21–0.59)	1 : 281 (1 : 169–1 : 469)
Radical hysterectomy	2442	0	0.05 (0.01–0.4)	1 : 1842 (1 : 247–1 : 13 771)
Hysterectomy + lymph nodes	1334	0	0.05 (0–1.59)	1 : 2217 (1 : 63–1 : 79 448)
RALS:				
All robotic procedures	27 971	54	0.21 (0.16–0.27)	1 : 476 (1 : 365–1 : 619)
Robotic hysterectomy	27 930	54	0.21 (0.16-0.27)	1:476 (1:365–1:620)
Radical hysterectomy	927	0	0.07 (0-1.06)	1 : 1496 (1 : 94–1 : 23 933)
Surgery (CLS + RALS) for benign indi	cations:			
All MIS procedures	124 216	15	0.02 (0.01–0.03)	1:6456 (1:3946–1:10562)
MIS hysterectomy	119 721	15	0.01 (0.01–0.02)	1 : 6814 (1 : 4119–1 : 11275)
Laparoscopic hysterectomy	114 750	15	0.01 (0.01–0.02)	1 : 6799 (1 : 4109–1 : 11249)
All robot procedures	5458	0	0.02 (0-1.45)	1 : 5430 (1 : 69–1 : 435 052)
All laparoscopy procedures	118 758	15	0.02 (0.01–0.03)	1 : 6512 (1 : 3971–1 : 10 680)
Sacrocolpopexy (MIS)	864	0	0.08 (0-2.8)	1 : 1246 (1 : 36–1 : 44700)
Sacrocolpopexy (laparoscopy)	757	0	0.07 (0–5.65)	1:1343 (1:18–1:107855)
Adnexal surgery	1960	0	0.04 (0-2.2)	1 : 2245 (1 : 45–1 : 113 372)

CI – confidence interval, MIS – minimally invasive surgery.

mortality following general-surgical laparoscopies has been reported as high as 0.05% to 0.2% [49]. Earlier studies comparing open (Hasson technique) vs. closed (VN, DTE) entry modes indicated a higher number of vascular injuries with closed techniques as compared to open entry (0.8% vs. 0%), but no significant differences in relation to bowel injuries, gas embolism or perioperative death [9]. Surprisingly, the introduction of optical trocars did not increase the safety of abdominal entry in regard to bowel or vascular injuries [48, 49]. The latest Cochrane Review (as of 2019) did not find any differences between laparoscopic entry techniques with regard to vascular injury, visceral injury or solid organ injury and identified no evidence supporting the use of one laparoscopic entry technique over another [51]. Failed entry was less frequent with DTE as compared to VN, and no

difference was observed when comparing direct VN with open-entry technique [51]. For similar reasons, the general-surgical and gynecological societies across the world do not recommend any single entry technique [52]. Nevertheless, VN-related (as compared to trocar) injuries are usually smaller (2 mm vs. 5-10 mm), are associated with less dramatic morbidity and mortality, and result less often in malpractice claims [26]. Baggish considers "trocar or needle deviation from the midline during entry", and "insertion of trocars and needles at angles approaching 90°" as the major risk factors for entry-related complications [3]. The risks associated with blind insertion of the primary trocar cannot be fully eliminated. In contrast, injuries related to secondary trocar insertion are almost always preventable, and yet every third trocar-related complication occurs during secondary trocar placement [9, 53].

One of the main risk factors at the step of laparoscopic entry is periumbilical adhesions. They are rarely present (0.7%) in never-operated-on patients; however after laparoscopy, Pfannenstiel laparotomy, and midline laparotomy they can be expected in 1.6%, 20%, and 52% of cases, respectively [54, 55]. In this context, the widespread trend towards non-closure of the peritoneum during caesarean section should by questioned. The accumulating long-term data have demonstrated that – in contrast to the slightly improved short-term outcomes – the abandoning of peritoneal closure during caesarean section results in a significantly increased likelihood of adhesion formation [56, 57], which is a known risk factor for a variety of surgical AEs, including entry-related complications.

Failed entry

The real incidence of failed laparoscopic entry depends on individual surgical experience and, eventually, the patient collective. For entry of the peritoneal cavity one, two, three or more attempts are necessary in 85–87%, 8.5–11.6%, 2.6–3.0%, and 0.3–1.6%, respectively [48, 58]. Any additional attempt increases the probability of complications or conversion to laparotomy. Pre-peritoneal insufflation is reported in 2.7%, 15%, 44.4%, and 100% of cases, after, respectively, one, two, three, and more than three entry failed attempts [58]. The overall complication rates reported in relation to the number of unsuccessful attempts are: 0.8% to 16.3% after one attempt; 16.31% to 37.5% after two attempts; 44.4% to 64% after three attempts; and 84.6% to 100% after more than three attempts [48, 58].

Consequences of failed entry are preperitoneal insufflation (79%), omental emphysema (21%), bowel injury [10, 48, 58], and failed laparoscopy (up to 3.6% in [10]).

Approach-specific complications at or after completion of surgery

Intraabdominal spillage of adnexal tumors

Intraoperative spillage occurs in 55–65% (15–100%) of laparoscopic removals of presumably benign ovarian cysts [59–61]. The relative risk for this event – compared to mini-laparotomy – is 5.5-fold higher [61]. The spillage probability is independent of ovarian cyst diameter [62]. Intraoperative cyst rupture is not a risk factor for reoperation, infertility, transient fever, or readmission [62]. In the case

of a dermoid cyst, the risk for chemical peritonitis caused by leaked fat, sebum, hair and other tissues is statistically (up to 10-fold) increased by spillage [62], but – fortunately – this complication is extremely rare (0–0.2%) [59, 60, 62, 63].

With respect to malignant ovarian tumors, capsule rupture and intraperitoneal spillage are noted in 22-23% of minimally invasive surgery (MIS) procedures (including CLS and RALS) [64]. Unlike for benign ovarian cysts, the larger size is a strong predictor for iatrogenic rupture of a malignant ovarian tumor in MIS [64]. The histological type of the tumor seems to impact the probability of its iatrogenic spillage, with the majority of ruptures observed in clear cell (57%), followed by endometrioid (49%), serous (42%), and mucinous (32%) carcinomas [65]. The consequence of rupture is seeding of tumor cells within the abdominal cavity and disease upstaging to FIGO Ic1 (provided the tumor was occult and confined to the ovary). This fact determines the need for chemotherapy and probably worsens the prognosis, although the latter consequence is still under debate [64]. On the one hand, the comparison of long-term outcomes in 8850 women with stage I ovarian cancer confirmed the negative impact of capsule rupture on the overall survival, both for open and MIS. Moreover, the minimally invasive approach has been independently associated with tumor rupture (adjusted relative risk, 1.17; 95% CI: 1.06-1.29) [64]. In contrast, recent meta-analyses showed that: a) the upstaging and cyst rupture rates are comparable in MIS and laparotomy [66], b) the negative prognostic impact of iatrogenic tumor rupture is not proven [67], and c) neither the 3-year nor 5-year disease-free survival nor overall survival differs between patients undergoing MIS and those operated on by an open approach [67–69].

Given these conflicting data, every effort to improve the preoperative diagnosis of adnexal tumors [70, 71] and to minimize the incidence and consequences of intraoperative tumor rupture (e.g. peritoneal washings and careful intraoperative assessment prior to oophorectomy, early conversion to laparotomy in presence of suspected ovarian tumor in a technically demanding field, use of endoscopic retrieval bags) should be taken to minimize the risk of ovarian capsule rupture during MIS [64, 65].

Trocar-site hernias

Trocar-site hernias (TSHs) following gynecological laparoscopies are observed after 0.1% to 1.8%

of procedures, which is significantly lower than the frequency of incisional hernias following gynecological (2–6%) or general-surgical laparotomy (5–20%) [72–74]. Within these incidence rates, only 3% of TSHs are diagnosed at incision sites < 8 mm; 11% of them at incision sites 8–10 mm, and the majority (86%) at sites > 10 mm [75]. The most dangerous complication of incisional hernia is bowel or omental incarceration. Cases of both types of complications, 5 mm- and 8 mm-trocar site hernias (including omental and small bowel incarceration), following RALS have been repeatedly reported [76–78].

Risk factors for developing a trocar-site hernia are: trocar diameter > 10 mm, use of bladed (pyramidal) trocars, prolonged operative times, as well as high parity, older age and high body mass index (BMI) of the patient [74, 79, 80]. The risk for developing an incisional hernia is three to four times higher following single-incision laparoscopic surgery [81, 82].

In gynecology, umbilical defects are more common than lateral port-site defects [73, 79, 83] and remain in 16–56% of cases asymptomatic [79]. Traditionally, closing the fascia at incision sites ≥ 10 mm (or > 7 mm) has been recommended [9, 80]. On the other hand, 90% of reported trocar site hernias develop despite declared fascial closure [75, 83]. Moreover, the mounting evidence has failed to prove any benefit of the routine fascial closure of incisions under 10 mm [74, 84]. This observation is of importance, since fascial closure, like any surgical maneuver, can itself induce complications, e.g. broken needle, breakage of fascial closure device or aorta puncture [74, 85, 86].

Port-site metastases

Port-site metastases (PSMs) are observed, respectively, in 1.0–1.2% and 1.4–1.9% of patients undergoing CLS [87, 88] or RALS [89–91] for any abdominal malignancy. Non-carcinomatous implants at previous trocar sites, e.g. parasitic myomas [92, 93] or ectopic trophoblast tissue [94], have also been reported.

After (predominantly therapeutic) conventional or robotic-assisted laparoscopic procedures for cervical and endometrial cancer, PSMs were diagnosed after a median time of 5 (range: 1.5–19) months, and 13.5 (range: 6–21) months, respectively [87, 91]. In the event of isolated PSM, local excision, radio-, chemo- or combined radiochemotherapy were cura-

tive and no further recurrences were reported (however, the data are limited) [91].

With respect to ovarian cancer, PSMs are observed very often (in 47-49% of patients) and very early (median: 17 days) after initial MIS (usually performed as a diagnostic procedure) [95-97]. The risk factors for developing PSM in ovarian cancer are: higher tumor stage, positive lymph node status, ascites > 500 ml, and laparoscopy performed in a non-oncological center [96]. Wound healing disorders and postoperative morbidity are significantly higher in patients with PSM (Clavien-Dindo Classification grade ≥ 3: 41.0 vs. 14.9%) [96]. However, the overall survival of ovarian cancer patients classified as FIGO IV stage solely due to isolated PSM is significantly longer (58 months) as compared to FIGO IV due to other distant metastases (25 months), and (although not reaching statistical significance) longer as compared to FIGO IIIC (37 months) [98]. Ataseven et al. failed to identify PSM as an independent prognostic factor in ovarian cancer [96]. In contrast, in the study of Nunez et al. PSMs were independently associated with a worse prognosis [99]. Despite these unresolved questions, resection of previous laparoscopy port sites in patients with otherwise complete cytoreduction is advocated by most authors [96, 99].

The following factors can contribute to the development of PSM: physical impact of pneumoperitoneum (aerosolization of tumor cells), chemical properties of CO₂, wound contamination with malignant cells (e.g. in presence of ascites or during specimen removal), "chimney effect" (leakage of gas along the trocars), local immune reactions, or improper surgical technique (frequent trocar removal and reintroduction, rapid desufflation) [88]. The fact that (both in CLS and RALS) the PSMs develop predominantly (> 70%) at the position of the tissue-manipulating (specimen-retrieval) port [89, 95, 100] indicates that measures for preventing PSM should focus on minimizing the risk of tumor cell implantation into and minimizing tissue trauma at the trocar site, e.g. avoidance of laparoscopy in presence of massive ascites, atraumatic tissue handling, clean resection margins, use of plastic retrieval bags, reduced instrument transfers, closure of all abdominal layers including the peritoneum, removal of entire intraabdominal fluid before trocar removal, irrigation of the port site with chemotherapeutic agents or povidone-iodine solutions [88, 100]. Unfortunately, the application of the preventive measures is underreported in studies and therefore their effectiveness can hardly be assessed [91]. In contrast, they have been shown to be highly effective in an animal model. Schneider et al. [100] performed a prospective randomized study for studying the impact of several protective measures on the occurrence of PSM after intraoperative injection of tumor cells into the peritoneal cavity of pigs. In the experimental arm, trocar fixation, prevention of gas leaks, rinsing of instruments with povidone-iodine, minilaparotomy protection, rinsing of trocars before removal, peritoneal closure, and rinsing of all wounds with povidone-iodine were applied. After 4 weeks, histologically confirmed PSM were found in 14% of port sites in the study group but in 64% of port sites in the control group [100].

Vaginal cuff dehiscence

The poor standing of LH in regard to vaginal cuff dehiscence (VCD), which was reported by earlier studies after 4.9% of laparoscopic, 3.0-4.1% of robotic-assisted, 0.29% of vaginal, and 0.12% of abdominal hysterectomies [101, 102], has been revised by the recent evidence. Contemporarily, VCD is noted after 0.11-1.27% of laparoscopic, 0.45-1.64% of robotic-assisted, 0.05-0.13% of vaginal, and 0.02-0.38% of open hysterectomies [103-107]. As of 2021, the occurrence of VCD following total LH (TLH) can be expected in 0.64-1.35% of cases, and after robotic hysterectomy in approximately 1.6% of cases [108, 109]. The manifestations of VCD are: pelvic pain, abnormal vaginal discharge and bleeding, peritonitis, and – in 30–68% of cases – omentum or bowel protruding from the vagina [101-103, 107]. Sexual intercourse earlier than 8 weeks after LH is the main risk factor for VCD, regardless of how (CLS or RALS) and why (benign or oncologic indications) the hysterectomy was performed [101-104, 108, 109]. In oncological patients, vaginal brachytherapy and chemotherapy have been identified as further risk factors for VCD [103, 109, 110].

Surgical risks include extensive or inadequate application of electrosurgical technique (e.g. coagulation instead of cutting mode for vaginal incision [111]), transvaginal closure of the vault, use of single instead of continuous stiches, postoperative infection and supravaginal hematoma [106, 108]. Patient-related risks for developing VCD are: premenopausal status, smoking habit, and preexistent endometrio-

sis [103, 105–113]. No differences in the frequency of VCD were noted in relation to the use of barbed versus non-barbed suture (polyglactin 910) [114] or single-layer versus double-layer barbed suture [108, 115], with the exception of RALS, where the use of barbed sutures was associated with better healing and fewer separations of the vaginal cuff [108, 116].

Pneumoperitoneum-related complications

Subcutaneous emphysema, pneumothorax and hypercarbia

Using computed tomography, residual pneumoperitoneum can be detected in 70% and subcutaneous emphysema in 56% of patients 24 h after laparoscopy [117]. Grossly detectable subcutaneous emphysema occurs in 2.3%, pneumothorax/pneumomediastinum in 1.9%, and hypercarbia in 5.5% of patients [118]; however, all conditions resolve spontaneously within 2–3 days. Operative times > 200 min elevate the chance for hypercarbia (2-fold), subcutaneous emphysema (5-fold) and pneumothorax/pneumomediastinum (20-fold) [118].

Gas embolism

Gas embolism following damage of large retroperitoneal vessels or high-pressure insufflation into the hepatic venous system is exceptionally rare but usually fatal [17, 19]. Otherwise, minimal amounts of $\rm CO_2$ diffuse into capillary vessels during every laparoscopy and are – due to good solubility of $\rm CO_2$ – clinically irrelevant. Kim *et al.* observed detectable gas within venous blood samples in 100% of patients undergoing TLH, and bubbles filling more than half of the right side of the heart at transesophageal echocardiography in 37.5% of patients. However, no patient in this study developed hemodynamic instability or electrocardiogram changes despite confirmed venous air embolism [119].

Postlaparoscopic shoulder pain

Postlaparoscopic shoulder pain (PLSP) is reported by 50–80% of patients undergoing laparoscopic interventions. PLSP is a referred pain caused by chemical irritation of the phrenic nerve by CO_2 and by mechanical distention of the parietal peritoneum and liver capsule. PLSP usually lasts 1–3 (occasionally up to 7) days [120, 121]. The main risk factor for developing PLSP is residual intraabdominal CO_2 ;

therefore maneuvers improving its elimination at the end of surgery, such as gas suction and saline instillation before leaving the abdomen as well as the pulmonary recruitment maneuver, reduce the incidence and severity of PLSP [121–125].

Complications related to laparoscopic instruments

Morcellator-associated complications

Laparoscopic evacuation of a bulky specimen presumes its fragmentation. Morcellation is an essential part of myomectomy, supracervical LH, TLH for large uteri, or non-suspicious ovarian fibroids [126–128]. For cutting or peeling the specimen, morcellators use mechanical forces (rotating blade) or, occasionally, an integrated electrosurgical device [126, 129]. The use of morcellators harbors three types of risks: direct injury to adjacent organs, intraperitoneal spread of a benign disease, and inadvertent morcellation of a malignant tumor [128–132].

Direct injury

The morcellator's blade rotates with 500–1000 revolutions per minute. The diameters of the blades vary between 12 and 13, and 15 mm [126]. Devised for quick removal of large tissue portions, morcellators can cause severe injuries, which affect in 47% of cases the intestine, in 41% the vascular system, in 20% multiple organs, and in 10% result in the patient's death [126, 129–131]. In every third case, the complication remains undetected during surgery. "Lack of experience", "lack of training", and "lack of control", followed by poor visualization or device malfunction, were identified as risk factors for morcellator-related injuries [129].

Complications following morcellation of benign specimen

After LH or myomectomy, which includes the process of morcellation, iatrogenic endometriosis develops in 1.4%, adenomyosis in 0.57%, isolated parasitic myoma in 0.9%, and disseminated peritoneal leiomyomatosis in 0.1% of cases [128]. Parasitic myomas and adenomyomas can develop at distant localizations, e.g. the colon, diaphragm, omentum or umbilicus, and can reach a diameter > 10 cm [130], predominantly in premenopausal women. The median time to presentation is 5 years [128].

Inadvertent morcellation of a malignant tumor

The rates of any occult malignancy encountered in morcellated uterine specimens are reported between 0.25% (1 in 400) and 0.43% (1 in 230) [131, 132]. When limited to uterine leiomyosarcoma (LMS), the numbers range from 0.05% (1 in 2000) [133] to 0.14% (1 in 700) [127]. Unexpected LMS morcellation complicates 0.15% (1 out of 650) of hysterectomies and 0.08% (1 out of 1306) of myomectomies [127]. In uterine leiomyosarcoma (LMS), morcellation increases the overall recurrence rate (62% vs. 39%; OR = 3.16; 95% CI: 1.38-7.26) and the intra-abdominal relapse (39% vs. 9%; OR = 4.11; 95% CI: 1.92–8.81), as well as the mortality rate (48% vs. 29%; OR = 2.42; 95% CI: 1.19-4.92) [134], whilst no survival differences were observed for patients with morcellated low-grade endometrial stromal sarcoma [135] or occult endometrial carcinoma [136]. The risk of occult LMS is elevated in black women, patients aged > 40 years, patients with a history of retinoblastoma, women presenting with a rapidly growing, large (≥ 8 cm), solitary, highly vascularized (peripheral and central), heterogeneous myometrial tumor with central necrosis or degenerative cystic changes [127, 137]. In case of uncertainty, magnetic resonance imaging with contrast enhancement, determination of lactate dehydrogenase and its isoenzyme type 3 in serum, as well as endometrial sampling prior to surgery, may help to better distinguish between LMS and fibroid [138, 139].

In 1995 the American Food and Drug Administration (FDA) approved the first power morcellator for the US market to be used for gynecological laparoscopic procedures, with special indication for the removal or morcellation of uterine myomas [140]. However, in 2014, after the globally discussed case of iatrogenic LMS morcellation in the patient Amy Reed, the FDA released a warning, followed by a recommendation for limiting the use of laparoscopic power morcellation [140, 141]. When morcellation is appropriate, power morcellators should be used only with compatible containment systems [141]. Additionally, on 29 December 2020 the FDA issued a final guidance for "Product Labeling for Laparoscopic Power Morcellators", maintaining the warning that "laparoscopic power morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are: post-menopausal or over 50 years of age, or candidates for en bloc tissue

removal through the vagina or via a mini-laparotomy incision" [141].

Nevertheless, contained tissue extraction techniques, which are recommended to reduce the risk of specimen spillage [141, 142], have not been proven satisfactory to date. The spillage of dye or tissue is noted in 9% of cases with a macroscopically intact bag [143], and bag perforations are reported in 13% of contained morcellations [144]. Therefore, according to the Cochrane review of 2020 the benefit of "in-bag" morcellation remains unproven [145].

Instrument-related complications: energy

Energy-based surgical devices (ESDs) comprise electrosurgical, ultrasonic, hybrid (electrosurgical and ultrasonic), and laser-based instruments [146]. All types of ESDs produce thermal effects. The ranges of working temperatures of ESDs are (depending on instrument model, power setting and application time): 100-400°C for monopolar instruments, 80-120°C for bipolar instruments, 60-100°C for advanced bipolar systems, 60-200°C for ultrasonic devices, and 100-220°C for the hybrid device Thunderbeat [146-148]. The lateral thermal spread reaches 2-22 mm for monopolar instruments and 2-6 mm for conventional bipolar instruments. The lateral thermal spread of advanced bipolar systems is reported at 2-5 mm for Ligasure, 1-1.7 mm for Enseal and 1.5-6 mm for PK PlasmaKinetics. Among ultrasonic devices, the Harmonic Scalpel produces 1–4 mm lateral spread, and the hybrid device Thunderbeat 2-3 mm [146-148]. The thermal effects of the main ESD types are summarized in Table VIII.

ESD-related complications are reported after 0.2–0.5% of laparoscopic procedures [22, 53, 146], being in 70% recognized post-operatively [22, 53, 149, 150]. Every fourth laparoscopic AE – including 26–29% of all bowel injuries and 33–50% of ureter

injuries – [22, 53, 149, 150] is created by ESD. The majority of ESD-related complications are preventable [151]. They happen usually due to inappropriate use and can cause harm at sites distant from the surgeon's field of view [146, 149–153]. The most common scenarios are inadvertent ESD activation, instrument defects (e.g. insulation failure), or ignorance of physics laws (e.g. lateral temperature spread, direct coupling, capacitive coupling) [146, 152-154]. Monopolar - as compared to bipolar and ultrasonic - instruments usually cause more extensive injuries [146-148, 150]. Insulation failure and capacitive coupling are the most common reasons for ESD-related injuries in laparoscopy: 18% of insulation defects are located in the critical parts of the instrument most likely to create a catastrophic electrosurgical injury [152, 154].

Instrument-related complications: skin burns

Skin burns (SB) during laparoscopy are rare, but almost always related to improper ESD use, reduced attention of the surgeon or, less frequently, to device malfunction [151]. As in the case of other ESD-associated complications, the use of monopolar energy is associated with the highest risk of injury. However, all devices producing thermal effects can cause harm following unprotected and uncontrolled contact with skin. Saaiq *et al.* grouped iatrogenic intraoperative SB according to their mechanism:

- a) direct contact burns from the active electrode resting on the patient's skin or contacting the operating staff,
- b) burns at the site of the grounding electrode,
- c) burns resulting from electrode heating of pooled solutions such as spirit,
- d) burns occurring outside the operative field as a result of circuits generated between the active electrode and an alternate grounding source [155].

Table VIII. Thermal effects depending on ESD type

Energy modality (ESD type)	Working temperature range [°C]	Thermal spread within tissue [mm]	
Monopolar	100–400	2–22	
Bipolar (conventional)	80–120	2–6	
Bipolar (advanced)	60–100	1–7	
Ultrasonic	60–200	1–4	
Hybrid (bipolar-ultrasonic)	100–220	2–3	

ESD - energy-based surgical device.

Alternative site burns occur when the patient's skin is in contact with conductive materials (e.g. metallic OP-table elements or metallic i.v. pole) and the electric currents return to the ground [156]. Severe SB can result from direct or capacitive coupling to metal cannulas or capacitive coupling to the skin edge across plastic cannulas [157]. The "active electrode monitoring" technology reduces the chance for alternate site burns resulting from e.g. faulty application or detachment of the return pad, but it does not fully eliminate the possibility of SB. Apart from monopolar technology, accidental severe SB have been reported as a result of inadvertent activation of bipolar instruments resting on the patient's skin or wet surgical drapes [158]. The use of alcoholand spirit-based skin preparation solutions can further increase the risk of fires and burn injuries [151, 155]. In addition, fiberoptic cables represent another source of serious iatrogenic SB: their tips heat to 120-267°C, the minimal distance between skin and light source required for producing skin necrosis is 3 mm, and surgical drapes char after 3-6 s exposure to the tip of the cable [159].

Instrument-related complications: equipment failure

About 40% of CLS procedures are complicated by at least one equipment failure [152, 160]. The bipolar cable and forceps account for 31-42% of instrument malfunctions [152, 160]. Insulation failure (IF) affects 19-37% of ESDs, reaching 39% in monopolar instruments [161, 162]. IF is localized in 40-54% of cases at the distal third of the instrument and is more frequent in reusable instruments [154, 162]. Intense exploitation of reusable instruments, predominant use of high voltage modes, multiple passages through trocars and frequent mechanized sterilization facilitate the development of IF [154]. Fluid, gas, and light transmission complicates 36.2% of laparoscopies, while imaging defects are noted in 12% [160]. In every fifth case equipment failures can potentially cause severe harm to the patient [160]. Time wasted due to the malfunctions in laparoscopy accounts for 1.4-7% of the overall surgical time [152, 160]. Causes of malfunctions are in 45% of cases limited to the instrument and in 43-47% were the result of erroneous combination of elements. Human decisions contribute to 43-50% of instrument failures [152, 160]. The ignorance about function and safety principles of ESD among laparoscopic surgeons is at a similar level [148, 163].

Despite technical developments, equipment malfunctions are not infrequent in RALS [164, 165]. Event logs of the da Vinci (Si) systems registered robotic malfunctions in 5% of operations, e.g. errors of pressure sensors in the robotic arms, unrecoverable electronic communication, illuminator- or battery-related errors [165]. An analysis of FDA data revealed the following distribution of instrument malfunctions – impacting patient safety through injuries or procedure interruptions – in RALS: falling of burnt/broken pieces of instruments into the patient (14.7%), electrical arcing of instruments (10.5%), unintended operation of instruments (8.6%), system errors (5%), and video/imaging problems (2.6%) [164].

Instrument-related complications: lost or broken surgical items

The occurrence of intraoperatively retained instruments is reported after 0.06-0.11% of minimally invasive procedures [166]. The most often retained surgical instrument is the surgical needle - lost (or broken up) either in the surgical field or within the patient's abdominal wall, arrested within the trocar valve or sucked away via the suction device [166-170]. Broken tips of laparoscopic stitch devices or disintegrated laparoscopic instruments have also been reported [167, 168]. A survey performed among minimally invasive surgeons in the United States revealed that 64% of them experienced a needle loss (NL). Most respondents (90%) reported 1 to 5 NL incidents during their careers, and the remaining 10% reported 6 to 20 incidents or more. Typically, needle removal through a trocar and laparoscopic suturing were the common situations resulting in NL [170]. Risk factors for NL during MIS are: high BMI, concurrent use of more than one needle, equipment malfunction, and emergency [166]. RALS and single-site surgery are associated with a higher likelihood of NL than CLS [166]. An overseen NL can have devastating long-term consequences for the patient (bowel and vessel perforations, development of fistulas, chronic pain, subsequent surgery) and for the surgeon (medical and legal consequences) [166]. Fortunately, NL is usually noticed immediately. However, due to limited vision and restricted instrument flexibility in laparoscopy, finding the needle (or a part of it) can be more

demanding than in open surgery [170]. When inspection of the surgical field and abdominal incisions, revision of trocars and suction devices, and application of a laparoscopic magnet (provided its availability) fail, additional patient burdens can result from X-ray exposure and laparotomy [166, 167].

Complications in relation to affected organs Vascular injuries

The perforation of abdominal wall vessels (inferior and superficial epigastric arteries and muscular perforating vessels) by secondary trocars is reported in 0.3% to 2.5% of procedures [9, 21, 171]. The inferior contact is a secondary trocars and the secondary trocars are secondary trocars.

in 0.3% to 2.5% of procedures [9, 21, 171]. The inferior epigastric vessels are the most affected, comprising 48% (95% CI: 40–55) of all vascular injuries [21]. The use of sharp pyramidal trocars elevates this risk of abdominal wall vessel injury [9].

Injuries to large retroperitoneal (aorta, vena cava and the iliac) vessels (usually summarized as "MVI") occur in 0.2% to 1.0% of procedures, with the most quoted rate of 0.5% [9, 14, 19, 172]. Amongst large retroperitoneal vessels, the right iliac arteries are affected in 41-48% of cases, followed by the right iliac veins (38%), left iliac veins (29%), aorta (13-25%), inferior vena cava (6-11%) and mesenteric vessels (6-17%) [18-21, 173]. In 50-83% of cases, MVI occur during laparoscopic entry [14-21]. VN is causative for MVI in 6-46%, trocars in 54-83% [9, 14, 16-18, 26, 27], and scalpel (skin incision) in up to 6% of cases [174]. Higher frequency and severity of MVI were reported by disposable (as compared to reusable) trocars [9, 18]. Secondary trocar insertion accounts for 6-37% of MVI [9, 18]. Very low BMI and periumbilical adhesions elevate the risk for MVI at the entry stage [173]. In 10-20% of cases, MVI is caused by ESDs, followed by dissecting instruments or stapling devices [18-21]. Every fourth MVI occurs during diagnostic procedures [15, 18], whereas lymphadenectomy and hysterectomy are associated with the highest risk for MVI [18–21]. While injuries to the abdominal vessels can be commonly managed laparoscopically, the repair of the great retroperitoneal vessels usually requires (in at least 88% of cases [21]) an immediate laparotomy [3, 19, 172].

Major vascular injuries (MVI) are associated with a 6–31% mortality rate [16, 19, 20, 172] and responsible for 74–82% of all laparoscopy-related deaths [23, 27, 52]. Venous injuries are more frequently lethal than the arterial ones [18]. Collateral damage

to adjacent structures (small bowel, ureters, nerves, suturing the wrong vessel, etc.) happens concurrently or sequentially in every second case of MVI [20, 26]. The most recent systematic review of King et al. [21] reported a surprisingly low MVI-related mortality rate of 1.1% (2 deaths from 179 MVI in 197 062 laparoscopies), most likely due to applied reporting criteria: injuries to the inferior epigastric vessels (85/179) and "not otherwise specified" vessels (64/179) were considered as MVI, so laparoscopic-oncological procedures were excluded from the study [21].

Intestinal injuries

The incidence of gastrointestinal injuries (GI-I) following gynecological CLS is estimated at 1:769 (0.13%; 95% CI: 0.12–0.14%), with an incidence range of 0.06–0.5% [9, 22, 53, 149, 175]. The incidence of GI-I in connection with RALS is 1:160 (0.62%; 95% CI: 0.50–0.76%), with an incidence range of 0.7% to 2.8% [12]. The robotic hysterectomy for benign and malignant is associated with GI-I rates of 1 in 262 and 1 in 156, respectively [176].

In CLS, the small intestine is involved in 34–62% of GI-I, followed by large bowel (39–48%), and stomach (1.6–6%) [22, 53, 149, 175]. Ileum (accounting alone for 48% of GI-I) is the predominantly affected part of the small intestine, whereas the sigmoid (with 22–29%) is the most affected part of the large bowel [53, 175]. The distribution of GI-I in RALS is more equal, with the rectum and large bowel being affected in 37.5% each, followed by small intestine injuries reported in 24% of cases [176].

Similarly to MVI, 55% (32-77%) of all GI-I in CLS and 67% of GI-I in RALS occur at the start of the surgery (VN or trocar insertion, creation of pneumoperitoneum) [14, 17, 22, 53, 149, 175, 176], with 77% of small bowel and 41% of large bowel injuries complicating the initial set up of CLS [53]. Disposable trocars are associated with more frequent injuries (47%) as compared to reusable or other trocar types [53]. A further 45% (23–57%) of GI-I occur during the main part of surgery, with - unlike entry-related complications – the large bowel being significantly more frequently involved as compared to the small bowel (60% vs. 25%, respectively) [22, 53, 175]. The causative factor for 26-34% of bowel lesions is ESD, whereas mechanical - dissecting, grasping or morcellating - instruments are involved in 15-20% of GI-I [22, 53, 149]. Among ESD, monopolar instru-

ments are responsible for 43% of bowel injuries [53]. ESD are typically causative for late-presenting complications. The main risk factors for bowel injury are adhesions and/or previous laparotomy, noted in 70% of GI-I [53, 149]. The risk of laparoscopic bowel injury increases with surgical complexity and is estimated at 0.07% (0.05-0.1%) for diagnostic and minor procedures, 0.2% (0.17–0.24%) for major procedures such as endometriosis surgery, 0.39% (0.34-0.45%) for any form of LH, and 1-1.3% (0.43-2.3%) for laparoscopic sacrocolpopexy [22, 177]. The overall mortality rate associated with bowel injury at CLS is 0.8% (0.36-3.6%), almost exclusively resulting from delayed diagnosis [22, 53, 149]. Delayed detection of bowel injury increases the mortality rate to 3.2–3.6% [22, 149]. Unfortunately, more than half (41–84%) of GI-I following CLS are diagnosed postoperatively [22, 53, 149, 175]. The median time to diagnosis is 3 (1–13) days [22], with 70% of small bowel and 50% of large bowel perforations being diagnosed > 48 h after surgery [53, 149]. A fortunate reversal trend has been reported for RALS, where 87% of reported GI-I were recognized at the time of surgery and in the majority of cases (58%) could also be managed laparoscopically. As a consequence, a very low mortality – 0.02% (95% CI: 0.01-0.07%) - has been reported for GI-Is associated gynecological RALS [176].

Urinary tract injuries

Gynecological procedures are responsible for the majority (52–82%) of all iatrogenic urinary tract injuries (UTIs) [178–180]. In separate analyses, UTIs are reported in 0.5% (0.03% to 1.7%) of gynecological laparoscopies [9, 178, 181, 182] and 2.1% (1.2% to 3.5%) of gynecological RALS [12], respectively. A recent systematic review did not confirm significant differences between the two approaches [180].

After exclusion of oncological and urogynecological procedures, the overall incidence of UTI following CLS for benign indication is about 0.3% (0.03–5.8%) [182]. Wechter *et al.* analyzed RALS-associated UTIs with regard to type and complexity of the procedure, and observed the following frequencies: 0.5% in benign simple, 2.7% in benign complex, 3.2% in oncological, and 5.8% in urogynecological RALS [12].

Amongst UTIs, the bladder is three times more often affected than the ureter (in 0.24% vs. 0.08%, respectively). Separating the bladder from the uterus at hysterectomy or during adhesiolysis accounted for 42% of all bladder injuries, followed by primary (30%),

and secondary trocar insertion (6%) [150]; therefore every third bladder injury is related to laparoscopic entry [150]. ESDs are responsible for 45% and 33–48% of bladder and ureteral injuries, respectively [150, 182]. The mechanism of ureteral injury involves laceration, partial or complete transection, ligation or kinking with a suture, crushing from a clamp, thermal injury and ischemia from devascularization [180].

With regard to CLS procedures, LH and laparoscopically assisted vaginal hysterectomy (LAVH) represent, with 1.8% and 1.0%, respectively, the highest rates of UTI [182]. If restricted to publications from 2003-2013, the overall incidence of UTI after LH was estimated at 0.73-0.84%. The bladder injury rates range from 0.05% to 0.66%, and the ureteral injury rate ranged from 0.02% to 0.4% across procedure types [181]. The TLH and laparoscopic-assisted vaginal hysterectomy (LAVH) are associated with a higher proportion of bladder compared to ureteral injuries, whereas the laparoscopic supracervical hysterectomy (LASH) is complicated more frequent by ureteral injury [181]. Laparoscopic radical hysterectomy is associated with significantly higher risk of urological complications at 3.8%, with injuries to the bladder occurring in 2.5%, and to the ureter in 1.3–1.8% of surgeries [183]. Vesicovaginal fistulas and ureterovaginal fistulas accounts for 3.44% and 2.35% of UTI after LH [181].

Bladder injuries are diagnosed in 45–85% during surgery, whereas ureteral injuries in only 3–12% (0–40%) of cases [150, 181, 182]. Injuries to other parts of the urinary tract (urethra, kidney) are casuistic, e.g., accidental kidney morcellation [129] or renal calyx rupture following ureter injury were reported [184].

Peritoneal (e.g. post-cesarean) adhesions are the main risk factor for bladder injury. Endometriosis increases the risk of ureteral complications. The overall frequency of UTI is increased in patients with pelvic malignancy, broad ligament myomas, or being operated on by low-volume surgeons [150, 181, 182].

Neurological complications

Central nervous complications after laparoscopic surgery are usually secondary to anesthesiological or catastrophic surgical complications, e.g. cerebral ischemia following exsanguination [26] or gas embolism [19]. In contrast, laparoscopic surgeons are quite often – in 1–5% of cases – faced with postoperative peripheral neuropathies [185–187]. Predominantly, they are caused by patient mal-positioning of

the patient, insertion of trocars or closure of lower lateral trocar sites, intraoperative nerve entrapment, transection or thermal damage, or nerve compression following hematoma formation [185, 186, 188, 189]. Pre-existing risk factors for postoperative nerve malfunctions include previous peripheral neuropathies, diabetes mellitus, peripheral vascular disease, and extreme BMI [185, 190–192].

The overall incidence of intraoperative peripheral nerve injury in urological, gynecological and colorectal RALS is 0.16-10.0%. Usually, the symptoms appear immediately after surgery [189]. In the retrospective study of Shin et al., the occurrence of abdominal wall nerve injury during laparoscopic gynecological surgery was observed in 4.9% of procedures [190]. In CLS, nerves of the lower limbs (1.5-1.8%) are more frequently affected than those of the upper limbs (0.02-0.16%) [186]. In RALS, upper and lower extremity nerve injury is observed after 0.25-1.8% and 0.3-2% of procedures, respectively [187]. Inappropriate patient positioning in the Trendelenburg position is the most common cause of nerve injuries of the upper extremity: abduction of arms > 90°, bean bag use and improper placement of shoulder restraints (resulting in excess pressure over the acromioclavicular joint) are the main risk factors for upper limb neuropathies [187, 189, 191]. Inaccurate lithotomy positioning is the most common cause of lower extremity injuries [189-192]. The common peroneal, sciatic, and femoral nerves are affected in 81%, 15%, and 4% of cases, respectively [192]. The common peroneal nerve, which runs very close laterally to the head of the fibula, can be injured following inappropriate placement of the patient's legs in the stirrups, while extreme flexion of the hip may cause femoral nerve injury [191]. The use of candy cane stirrups is associated with a threefold increased risk of lower extremity postoperative neuropathy compared with boot stirrups [193]. Low patient's BMI, prolonged time spent in the lithotomy position, and insufficient padding of leg supports are additional risk factors for perioperative lower limb neuropathies [187]. Injury to the ilioinguinal and iliohypogastric nerves typically occurs during lateral trocar insertion or following nerve entrapment during fascial closure of the lateral ports [190]. Hypogastric nerves, the sciatic nerve, the obturator nerve, and the posterior hypogastric plexus may be at risk during deep endometriosis surgery or pelvic lymphadenectomy [194].

Vaginal lacerations

Vaginal lacerations in CLS or RALS occur due to forced removal or intravaginal morcellation of a large uterus [195], the use of an oversized uterine manipulator cup [196] or vigorous instrumental manipulation within a narrow or atrophic vagina [197]. The incidence of vaginal lacerations has been reported as high as 0.8% for RALS [198], and 0.7–1% for CLS (e.g. 1% for TLH [199] and 0.7% for radical LH in the LACC trial [32]).

Malpractice claims

Gynecological surgery accounts for a high proportion of malpractice claims, independently of health and legal systems [200–203]. In a high proportion of cases, non-adherence to fundamental safety principles is responsible for the surgical mishap and its legal consequences [151, 204].

The majority of claims (82%) result from visceral and/or vascular injuries, especially to the bowel (39-40%) and ureters (20%) [202, 203]. Whilst intestinal injuries are usually not related to a specific procedure, the vast majority (92%) of ureter injuries occur during LH or adnexal surgery. Entry-related complications account for 38% of claimed injuries [26, 175, 202, 204]. Among them, trocar-related injuries are by far the most common (78%), as compared to VN (16%) or blunt cannula (6%) [26, 203]. In a Dutch evaluation, a surprisingly high proportion (77%) of the claims were filed after non-advanced procedures: adnexal surgery was responsible for the highest proportion of claims (34%), followed by LH (20%), diagnostic laparoscopy (19%), and laparoscopic sterilization (16%). In the same study, only 20% of complications were identified intra-operatively, whereas 30% were diagnosed in the early postoperative phase, and 50% after discharge [202]. Therefore, it is not surprising that delayed diagnosis was the most frequently (33%) reported reason for financial compensation, followed by negligence during surgery (26%), consequences of the event itself (20%), and incomplete informed consent (9%) [26, 202].

Complication prevention – chances and opportunities

The majority of complications are of a surgical nature and every second is potentially preventable [205]. Although these facts have been recognized for several years, the situation still remains the same.

Especially the safety of laparoscopic entry and that of ESD use could be reduced through the sufficient knowledge of anatomy and surgical instruments and adherence to basic laparoscopic principles [146, 204]. Given that these two areas are responsible for the vast majority of complications and catastrophes, it is confusing why some surgeons simply ignore these facts [3, 9, 151, 162, 163, 204]. Nevertheless, several ways to improve patients' security and surgical proficiency have been noted during the last two decades, especially multi-level certifications programs offered by national and international societies [45, 46] as well as modern, scientifically sound concepts of laparoscopic training. Sufficient knowledge of anatomy and surgical instruments, ability to anticipate the risks and to manage unexpected difficulties, paralleled by training on body donors, pelvitrainers or virtual simulators, seem to be the right way to optimize the surgical outcome and to minimize patients' suffering caused by AEs [206, 207].

Conclusions

The majority of severe laparoscopic complications occur during laparoscopic entry. Amongst surgical instruments, ESDs are involved in every fourth complication. In a very high proportion of cases, complications (especially those affecting the bowel and ureter) are detected postoperatively. Delayed diagnosis increases the mortality and the risk for malpractice claims. However, every second complication is preventable: the adherence to basic surgical principles as well as awareness of potential hazards of MIS could protect the patients from inadvertent harm. The ability to define surgical complications and the knowledge about their incidence and risk factors are necessary for consideration of treatment options, patient counseling and to obtain informed consent.

Conflict of interest

The authors declare no conflict of interest.

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