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Education

The Intraoperative Complications Assessment and Reporting with Universal Standards (ICARUS) Global Surgical Collaboration Project: Development of Criteria for Reporting Adverse Events During Surgical Procedures and Evaluating Their Impact on the Postoperative Course

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https://doi.org/10.1016/j.euf.2022.01.018

Article info

Article history:
Accepted January 28, 2022
Available online 15 February 2022
Associate Editor: Christian Gratzke

Keywords:
Intraoperative complications
ICARUS criteria
Intraoperative adverse event
Surgical complications
ICARUS

Abstract

Background: Intraoperative adverse events (iAEs) are surgical and anesthesiologic complications. Despite the availability of grading criteria, iAEs are infrequently reported in the surgical literature and in cases for which iAEs are reported, these events are described with significant heterogeneity.
Objective: To develop Intraoperative Complications Assessment and Reporting with Universal Standards (ICARUS) Global Surgical Collaboration criteria to standardize the assessment, reporting, and grading of iAEs. The ultimate aim is to improve our understanding of the nature and frequency of iAEs and our ability to counsel patients regarding surgical procedures.
Design, setting, and participants: The present study involved the following steps: (1) collecting criteria for assessing, reporting, and grading of iAEs via a comprehensive umbrella review; (2) collecting additional criteria via a survey of a panel of experienced surgeons (first round of a modified Delphi survey); (3) creating a comprehensive list of reporting criteria; (4) combining criteria acquired in the first two steps; and (5) establishing a consensus on clinical and quality assessment utility as determined in the second round of the Delphi survey.
Outcome measurements and statistical analysis: Panel inter-rater agreement and consistency were assessed as the overall percentage agreement and Cronbach's α.
Results and limitations: The umbrella review led to nine common criteria for assessing, grading, and reporting iAEs, and review of iAE grading systems led to two additional criteria. In the first Delphi round, 35 surgeons responded and two criteria were added. In the second Delphi round, 13 common criteria met the threshold for final guideline inclusion. All 13 criteria achieved the consensus minimum of 70%, with agreement on the usefulness of the criteria for clinical and quality improvement ranging from 74% to 100%. The mean inter-rater agreement was 89.0% for clinical improvement and 88.6% for quality improvement.
Conclusions: The ICARUS Global Collaboration criteria might aid in identifying important criteria when reporting iAEs, which will support all those involved in patient care and scientific publishing.
Patient summary: We consulted a panel of experienced surgeons to develop a set of guidelines for academic surgeons to follow when publishing surgical studies. The surgeon panel proposed a list of 13 criteria that may improve global understanding of complications during specific procedures and thus improve the ability to counsel patients on surgical risk.

1. Introduction

Even when skilled operators perform a surgical procedure, intraoperative complications and, more broadly, intraoperative adverse events (iAEs) may occur. Overall, iAEs are not self-limited and may adversely impact both surgeon wellbeing [1] and patients' postoperative course. An iAE is defined as "any unplanned incident related to a surgical intervention that occurs from skin incision to skin closure" [2]. However, with the introduction of endoscopic and minimally invasive approaches, this definition may not appropriately capture all surgeries. For example, several endoscopic procedures that use anatomical orifices (eg, cystoscopy and colonoscopy) do not require skin incisions. Thus, the iAE definition mentioned earlier may warrant clarification.

Efforts have recently been made to standardize iAE grading [2–7]. However, iAE classification systems are rarely used [8,9] and therefore iAE reporting remains heterogeneous, lacking consistency and comparability. There are several theories regarding iAE under-reporting. First and foremost, the lack of universal, standardized criteria and recommendations for iAE grading and reporting means that there are no guidelines for providers and surgeons to follow. Furthermore, the absence of a fully encompassing definition of iAEs combined with a fear of litigation may have contributed to barriers to iAE assessment [10].

In the last few years, recommendations from the European Association Urology (EAU) ad hoc panel for complications grading and reporting [11] have contributed to the standardized collection of postoperative outcomes, with improvement in the accuracy of surgical data [8,12–14] and therefore better global acceptance of the associated surgical techniques. A similar strategy should be applied to the collection of iAEs.

Here we propose a composite list of criteria to standardize the assessment, reporting, and grading of iAEs that occur during surgical procedures. We hope that these resources will improve our understanding of the nature and frequency of iAEs and improve our ability to counsel patients regarding surgical procedures appropriately.

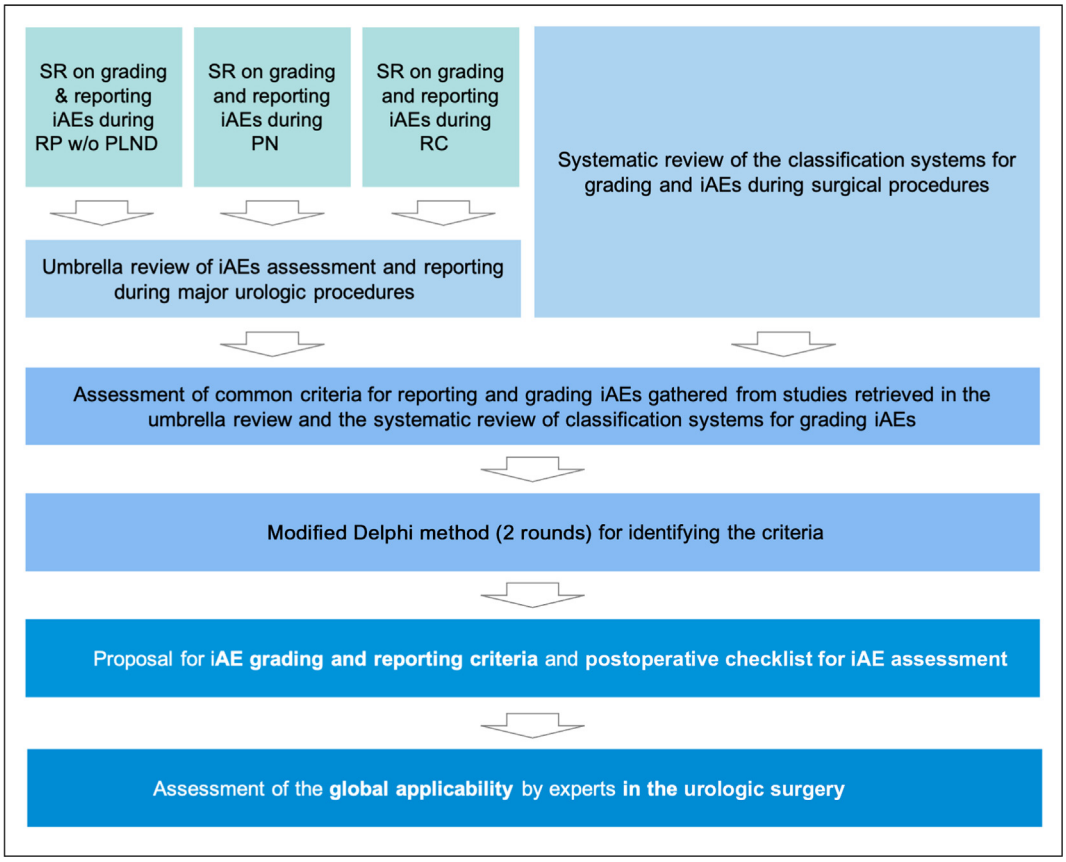

Fig. 1 – Study flowchart. SR = systematic review; iAEs = intraoperative adverse events; RP = radical prostatectomy; w/o = without or without; PLND = pelvic lymph node dissection; PN = partial nephrectomy; RC = radical cystectomy.

2. Materials and method

2.1. Study design for iAE reporting criteria

The multistep approach used for the present study, summarized in Figure 1, involved the following steps: (1) collecting criteria for assessing, reporting, and grading iAEs via a comprehensive umbrella review of the literature; (2) collecting additional criteria via a survey of experienced panelists, defined as having at least 10 yr of surgical practice (included in the first round of a Delphi survey); (3) creating a comprehensive list of reporting criteria; (4) combining the criteria acquired in the first two steps; and (5) establishing a consensus of clinical and quality assessment utility as determined via a second round of the Delphi survey. Lastly, a validity assessment of the global applicability of the final iAE reporting criteria to urologic surgery is planned for a follow-up study. This protocol and study design have previously been published [15] and the present guideline is registered as a guideline under development in the EQUATOR network [16].

2.2. Evidence acquisition

First we carried out an umbrella review [17] of systematic reviews (SRs) and meta-analyses assessing perioperative adverse events for the three most common urologic oncology surgeries, namely radical prostatectomy (RP) with/without pelvic lymph node dissection (PLND) [8], radical cystectomy (RC) and urinary diversion, and partial nephrectomy (PN) [9,12,18–20]. In these reviews, adverse events were collected and defined as follows: intraoperative complications; overall, minor (Clavien I–II), and major (Clavien III–V) events; postoperative sequelae (>90 d); and readmissions. Each SR was conducted according to the PRISMA guidelines [21] and each systematic review was registered in PROSPERO (CRD42020192048, CRD42021231699, and CRD42017062712). From each SR and meta-analysis, we selected the studies that reported iAEs as an outcome of interest. The number and percentage of patients presenting one or more iAEs, the number of patients presenting each iAE, and the methodology for reporting, grading, and managing the iAEs were recorded in a database. For each SR, two paired investigators independently screened all articles, focusing the research on papers reporting any of the outcomes of interest. Any disagreement about eligibility was resolved via discussion with senior authors until consensus was reached.

Second, an SR of iAE reporting and grading was carried out as previously reported [2]. All surgical series that reference a classification systems for grading iAEs were screened, and all the criteria for assessing and grading iAEs were collected in a database.

2.3. Consensus via a modified Delphi approach

The measures for assessing, collecting, grading, and reporting the iAEs collected in the evidence acquisition steps were merged into a comprehensive list of criteria. A modified Delphi consensus approach [22] among experienced urologic surgeons was used to evaluate the usefulness of the combined criteria for assessment, reporting, and grading iAEs. The surgeons who designed the study (G.E.C., I.G., W.A., R. Sotelo, and M.D.) did not participate in the survey to avoid potential bias. Multiple iterations with feedback were used to achieve consensus ($\geq$70% agreement) as previously reported [2,23,24]. A total of 37 experienced urologic surgeons affiliated to the AGILE consortium (Italian Group for

Advanced Laparo-Endoscopic Surgery; www.agilegroup.it) were enrolled in the modified Delphi consensus survey. The survey was administered in April 2021 using Google Forms (https://docs.google.com/forms/).

In the first round, we asked the urologic surgeons to report their annual case volume, whether or not they regularly collected iAE data in their daily practice, and, if so, which classification system they use. For those who do not typically record iAEs, we requested the reason. We intentionally left this as a broad statement since the method of recording varies depending on practice (eg, prospective trials may record data on case report forms, while some surgeons record the data in an institutional database or the operation notes, depending on standard practice). Lastly, the respondents were encouraged to list essential aspects for assessing, grading, and reporting iAEs, as previously recommended [25]. These responses were screened to identify additional iAE reporting criteria.

In the second round, the panelists were asked to separately evaluate the composite criteria obtained from the umbrella review and additional iAEs from the first round of the Delphi survey in terms of their usefulness from a clinical and a quality assessment and improvement perspective using a Likert scale from 1 to 5. Survey questions were phrased as follows. (1) How clinically useful is this criterion? (on a scale from 1 to 5, where 1 indicates that the criterion is not clinically useful and 5 is the highest level of clinical utility). (2) How useful do you think such a criterion is from a quality assessment and improvement perspective? (on a scale from 1 to 5, where 1 indicates that the criterion is not useful for this purpose and 5 is the highest level of utility for quality assessment and improvement). After reaching consensus on each item for the iAE reporting criteria, we developed a representative iAE reporting template.

2.4. Statistical analysis

The inter-rater reliability (IRR) and consistency of the panelist responses were analyzed to ensure panel consensus. For determination of the percentage agreement, the Likert scores were dichotomized, with a score of 4 (useful) and 5 (very useful) representing agreement and scores of 1 (not useful), 2 (less useful), and 3 (neutral) representing disagreement. Screening for outliers was performed using absolute agreements for individual questions and the distribution of responses. IRR was assessed using Cronbach's α [26]. Continuous and categorical variables are reported as the mean and standard deviation and the percentage, respectively. The statistical analysis was performed using R with the *psych* package [27,28].

3. Results

3.1. Umbrella review of SRs assessing the grading and reporting of iAEs

Individually, the three SRs identified 176 [8], 203 [29], and 356 [9,12] studies reporting complications as an outcome of interest for RP, RC and PN, respectively. Collectively, 340/735 studies (46.3%) reported iAEs as an outcome of interest. The rates of studies reporting 0 and $\geq$1 iAEs were 19 (22.6%) and 65 (77.4%) for RP ± PLND [8], 20 (29.5%) and 47 (70.5%) for RC, and 59 (35.3%) and 108 (64.7%) for PN [9,12], respectively. iAEs affected 1393/55 508 patients (2.5%) in total, of whom 534/22 428 (1.8%) underwent RP [8], 98/3853 (2.5%) underwent RC [29], and 761/29 227 (2.6%) underwent PN [9,12]. Our screening of the methodology for each study reporting iAEs as an outcome of interest identified nine common criteria for assessing, grading, and reporting iAEs.

3.2. iAE classification and grading systems

Our systematic review identified four classification systems for grading iAEs (Table 1) [2–6]. To evaluate their applicability, we systematically screened the case series and surgical studies that cited each classification system. In terms of total citations since classification publication, ClassIntra (formerly CLASSIC) was the most cited, followed by the Modified Satava scheme, the iAE severity classification scheme, and EAUiaiC, with 43, 35, 35, and six citations, respectively. Of note, a number of the subsequent citations were self-citations by one or more of the primary authors of each classification system. The Modified Satava system was the most used for classifying urologic surgery iAEs, followed by EAUiaiC, ClassIntra, and the iAE severity classification scheme, with four, two, one, and zero citations, respectively. When delineated by year of citation, there was no clear trend in usage for urologic papers. Of note, only the ClassIntra scheme has been validated [6]. After reviewing the four grading systems, two criteria were added to the list of iAE reporting criteria (Table 2).

3.3. Reliability of criteria for assessing, grading, and reporting iAEs

In the first round of our consensus approach for development of recommendations, we distributed the survey to 37 urologic surgeons and received 35 responses (95%). The median estimated procedural caseload was 200 cases/yr. Overall, 62.9% (22/35) of surgeons endorsed reporting of iAEs. Regarding the importance of correct and standardized criteria for assessing, rating, and grading of iAEs, 91.4% (32/35) of surgeons judged this as either important or very important; the remaining three were neutral. Of the surgeons who endorsed iAE reporting, EAUiaiC is the system most often used (45.5%, 10/22), followed by ClassIntra (13.6%) and Modified Satava (4.5%), while 36.4% reported that they use another system. Of those who do not regularly report iAEs, 76.9% (10/13) stated that they do not report because they would like to have guidance and 7.7% reported that they do not have iAEs. Lastly, the surgeons were asked to identify aspects and criteria that should be included in a checklist for reporting and grading of iAEs. Nearly all of their suggestions overlapped with criteria captured by the four previously discussed iAE classification systems. The most common recommendation for checklist characteristics was ease of use. After reviewing all the suggestions, we added two criteria to the list and implemented the other criteria accordingly (Table 2).

The second round of the survey involved rating the clinical usefulness and quality improvement utility of the 13 criteria developed on the basis of the iAE classification systems and comments from the first round (Table 2). Thirty-five of the 37 urologic surgeons (95%) responded in the second round. All 13 criteria achieved the consensus minimum of 70%, with agreement (assessed as useful or very useful) for clinical and quality improvement utility ranging from 74% to 100% (Fig. 2) and mean inter-rater agreement of 89.0% and 88.6% for clinical and quality improvement, respectively. The criterion with the highest agreement on

clinical usefulness (100%) is criterion 1: studies reporting perioperative outcomes should include iAEs as one of the outcomes of interest. The criterion with the highest average score for clinical usefulness (4.74) was criterion 11: endorsement of reporting management of iAEs. The lowest agreement on clinical utility (80%) was for criterion 6 (reporting the number of iAEs and patients experiencing iAEs) and criterion 7 (reporting conditions associated with iAEs). The criterion with the highest agreement on usefulness for quality assessment and improvement (100%) and the highest average score for quality improvement utility (4.71) was criterion 8: iAEs that necessitate surgical conversion should

Table 1 – Classification systems for intraoperative adverse events and citation counts for 2014–2021

EAUiaiC		iAE severity classification scheme		Modified Satava		ClassIntra (formerly CLASSIC)	
Grade	Description	Class	Description	Grade	Description	Grade	Description [c]
0	Event requiring no intervention or change in operative approach, no deviation from planned intraoperative steps	I	Injury requiring no repair within the same procedure (eg, cauterization, use of prothrombotic material, small vessel ligation)	I	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 [b]	0	No deviation from the ideal intraoperative course
1	Events requiring change in planned intraoperative steps, not life-threatening, no tissue or organ removal. Event addressed in a controlled manner with no long-term side effects	II	Injury requiring surgical repair, without organ removal or a change in the originally planned procedure (eg, any suture repair, patch repair)			I	Any deviation from the ideal intraoperative course without the need for any additional treatment or intervention. Patient asymptomatic or with mild symptoms
2	Event requiring change in operative approach but NOT life-threatening. The event was addressed in a controlled manner, but may have short-/long-term side effects			II	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 above the normal range. [b] For laparoscopic/ thoracoscopic/ endoscopic surgery this includes intraoperative incidents requiring conversion	II	Any deviation from the ideal intraoperative course with the need for any additional minor treatment or intervention that is not life-threatening and not leading to permanent disability. Patient with moderate symptoms
3	Event requiring deviation from planned intraoperative steps, event becoming life-threatening but NOT requiring tissue or organ removal					III	Any deviation from the ideal intraoperative course with the need for any additional moderate or treatment or intervention which is potentially life-threatening and/or potentially leading to permanent disability. Patient with severe symptoms
4	Event requiring deviation from planned intraoperative steps and with short-/long-term consequences for the patient	III	Injury requiring tissue or organ removal with completion of the originally planned procedure	III	Incident leading to significant consequences for the patient	IV	Any deviation from the ideal intraoperative course with the need for any additional major or urgent treatment or intervention which is life-threatening and/or leads to permanent disability

(*continued on next page*)

Table 1 – continued

	EAUiaiC		iAE severity classification scheme		Modified Satava		ClassIntra (formerly CLASSIC)	
	Grade	Description	Class	Description	Grade	Description	Grade	Description [c]
	4A	Requiring tissue or organ removal						
	4B	Unable to complete procedure as planned owing to a surgical event or technical issue or unplanned stoma	IV	Injury requiring a significant change [a] and/or noncompletion of the originally planned procedure				
	5A	Wrong site or side for open surgery or wrong patient or no consent	V	Missed intraoperative injury requiring reoperation within 7 d				
	5B	Death	VI	Intraoperative death			V	Any deviation from the ideal intraoperative course with death of the patient
			Suffix T	Add if injury requires transfusion of ≥2 U of blood				
Citation count		6		35		35		43
2021		2		1		3		1
2020		4		10		8		21
2019				5		3		5
2018				4		4		6
2017				5		4		1
2016				3		6		6
2015				5		5		3
2014				2		2		
USS using classification		2		0		4		1

USS = urologic surgical studies.
a Excludes conversion from minimally invasive to open surgery.
[b] A normal range for blood loss for each particular procedure is subjective to a certain degree, but can be quantified for different procedures using both contemporary scientific literature and values typical for a specific institution.
[c] Including surgery-related and anesthesia-related events.

be recorded alongside action undertaken. The lowest agreement on quality improvement utility (74%) was for criterion 9: iAEs should be reported with specification of the associated surgical step. Cronbach's α for the second round of the Delphi process was 0.87 (indicating good IRR agreement [26]). Specifically, Cronbach's α was 0.73 for the clinical usefulness of the criteria (indicating acceptable IRR agreement [26]) and 0.8 for quality improvement utility (indicating good IRR agreement [26]).

4. Discussion

The present study reports 13 criteria (Table 2) to ensure more accurate assessment and reporting of iAEs during and after surgical procedures. The primary goal of the ICARUS project is to provide guidance and guidelines for reporting of intraoperative complications in surgical research papers. The ICARUS guideline is not a competing system for grading of intraoperative complications, but is a list of criteria that should be met when researchers or clinicians report intraoperative complications as an outcome of interest.

Before developing the ICARUS list of criteria, we performed an umbrella review of studies reporting intraoperative complications as one of the outcomes of interest. We found that only a small fraction of surgical publications mention intraoperative complications and an even smaller proportion appropriately report these events, with substantial heterogeneity among studies [8,9,12,18–20,29]. Interestingly, in a preliminary survey we received feedback that many surgeons do not publish intraoperative complications because they do not have the tools to do so at an individual level. Thus, our goal in developing these reporting guidelines was prospective improvement of research and publications on surgical outcomes.

First, the panel highlighted the importance of iAE reporting, suggesting that iAEs should be reported as an outcome of interest in studies assessing perioperative outcomes (criterion 1). This is crucial for proper assessment of surgical performance and for appropriate patient counseling before surgery. The umbrella review of the three studies assessing iAE reporting after RC [29], RP [8], and PN [9,12,18–20] showed that only ~50% of papers reporting perioperative outcomes assessed iAEs as an outcome of interest. There could be many reasons for this deficiency in iAE reporting, ranging from a lack of clear iAE definitions to a fear of litigation [10]. iAEs are negative outcomes, which broadly epitomize a paradoxically well-documented bias in the literature. More importantly, this gap in documentation could limit the ability of surgeons and the medical community to assess and improve surgical quality. The panel highlighted that not reporting iAEs as an outcome of interest is not equivalent to not having any iAEs. In cases in which no iAEs occur, authors (surgeons and anesthesiologists) should explicitly state "no iAE occurred". Moreover, the definition of each iAE collected should be provided or refer-

Table 2 – ICARUS criteria and explanation: recommended items to address in a clinical trial reporting iAEs as an outcome of interest

No.	Criterion	Description
1	In a study reporting perioperative outcomes, iAEs should be reported as one of the outcomes of interest	Our umbrella review of studies assessing iAE complication reporting after RC, RP, and PN showed that only ~50% of papers reporting perioperative outcomes assessed iAEs as an outcome of interest. The panel feels that NOT reporting iAEs as an outcome of interest is not equivalent to not having any iAEs. In cases in which no iAEs occur, surgeons and authors should state "no iAE has been reported"
2	iAEs and the definition of each specific iAE should be reported or referenced	According to the new EAU guidelines, an iAE is defined as an undesired event due to the surgical intervention occurring between skin incision and skin closure. Moreover, the definition of each iAE collected should be provided or referenced in the methods in order to reduce heterogeneity between studies
3	Each iAE should be reported using one of the proposed classification systems (ClassIntra, EAU, iAE severity classification scheme, or modified Satava), with a preference for schemes that are validated	Intraoperative complication classifications are rarely reported. The panel encourages the use of one of the following classification schemes: ClassIntra, EAUiaiC, iAE severity classification scheme, or modified Satava, with a preference for schemes that are validated
4	Each iAE should be reported separately by grade	When adverse events are reported, it is important to grade them according to the preferred iAE classification system outlined for the previous criterion
5	iAEs related to anesthesiology, surgery, and equipment malfunction should be reported separately	Complications related to anesthesiology, surgery, and equipment malfunction have different causes and treatment. Separate reports are recommended
6	The number of iAEs and the number of patients with iAEs should be reported separately	The number of patients that report an adverse event may differ from the total number of events. For example, in a cohort of 100 patients 20 patients (20%) reported a total of 34 events
7	When appropriate, pre-existing medical conditions, atypical anatomical variants, and malfunctioning surgical instruments associated with iAEs should be reported	Not all iAEs are related to the surgery. Examples include some pre-existing conditions (eg, history of pelvic radiation would lead to a difficult posterior prostate detachment leading to a rectal perforation), atypical anatomy (eg, atypical vessel variants causing intraoperative bleeding requiring prolonged cauterization or vessel suturing), or malfunctioning surgical instruments (eg, electrocautery malfunction or malpositioning of the protective sheath of robotic scissors leading to vessel injury)
8	If an iAE requires conversion during surgery, both the iAE that caused the conversion and the action undertaken should be reported	Conversion because of iAEs could dramatically impact the postoperative course and management, with appropriate reporting required (eg, switching from one approach to an alternative, from one technique to an alternative, or aborting the procedure)
9	iAEs should be reported, specifying the surgical step that was associated with or affected by the iAEs	Reporting the surgical steps during which iAEs occur is important and can help surgeons and trainees in becoming aware of specific surgical step–dependent complications
10	The timing of iAE assessment should be reported as follows: • If an iAE is recognized during the surgical procedure, hold a debriefing after the surgical procedure • If an iAE if not recognized during the surgical procedure, report the point at which the iAE became apparent in the postoperative course	Reporting the surgical steps during which iAEs occur is important and can help surgeons and trainees raise awareness of specific surgical step-dependent complications
11	The management of iAEs should be reported	Information on the management if an iAE is important and could provide important insight for colleagues who may find themselves dealing with the same iAEs.
12	Report the clinical consequences of a given iAE in the postoperative course as follow: a) Without postoperative sequelae b) With nonpermanent postoperative sequelae c) With a permanent postoperative sequela d) Requiring reoperation e) Postoperative death	An iAE may impact the postoperative course. It could be related to postoperative complications and to postoperative consequence that will be permanent, impacting patient quality of life (eg, obturator neuropathies resulting of physical nerve damage intraoperatively, which will present clinically with motor and sensory deficits to the lower limb.) NB: new adjunctive classification is compatible with all the previously reported classification schemes for iAEs and is not in conflict with the Clavien-Dindo classification system. It will add clarity in the assessment of each iAEs and its impact on the postoperative course
13	Report changes to the clinical course that were associated with any iAEs	In addition to reporting patient-centric sequelae, it is important to report changes to the clinical course that resulted from the iAEs, such as operative time (either increase for management or decrease due to abortion of operation), extension in hospitalization duration, additional procedures, ICU stay, or unplanned specialty consults.

EAU = European Association of Urology; iAE = intraoperative adverse event; PN = partial nephrectomy; RALP = robot-assisted laparoscopic prostatectomy; RC = radical cystectomy; RP = radical prostatectomy.

enced in the methods to reduce the heterogeneity between studies (criterion 2).

For proper iAE grading, the panel encourages the use of one of the aforementioned standardized classification schemes [2–5] for intraoperative complications (criteria 3 and 4), with a preference for validated schemes. As part of our review of the literature on iAE reporting, we determined their usage in urologic surgical studies and identified differences among the iAE classification systems. We found that only a few studies have used these grading systems (Table 1). Interestingly, we noted that some studies rated iAEs using the Clavien-Dindo classification, which was

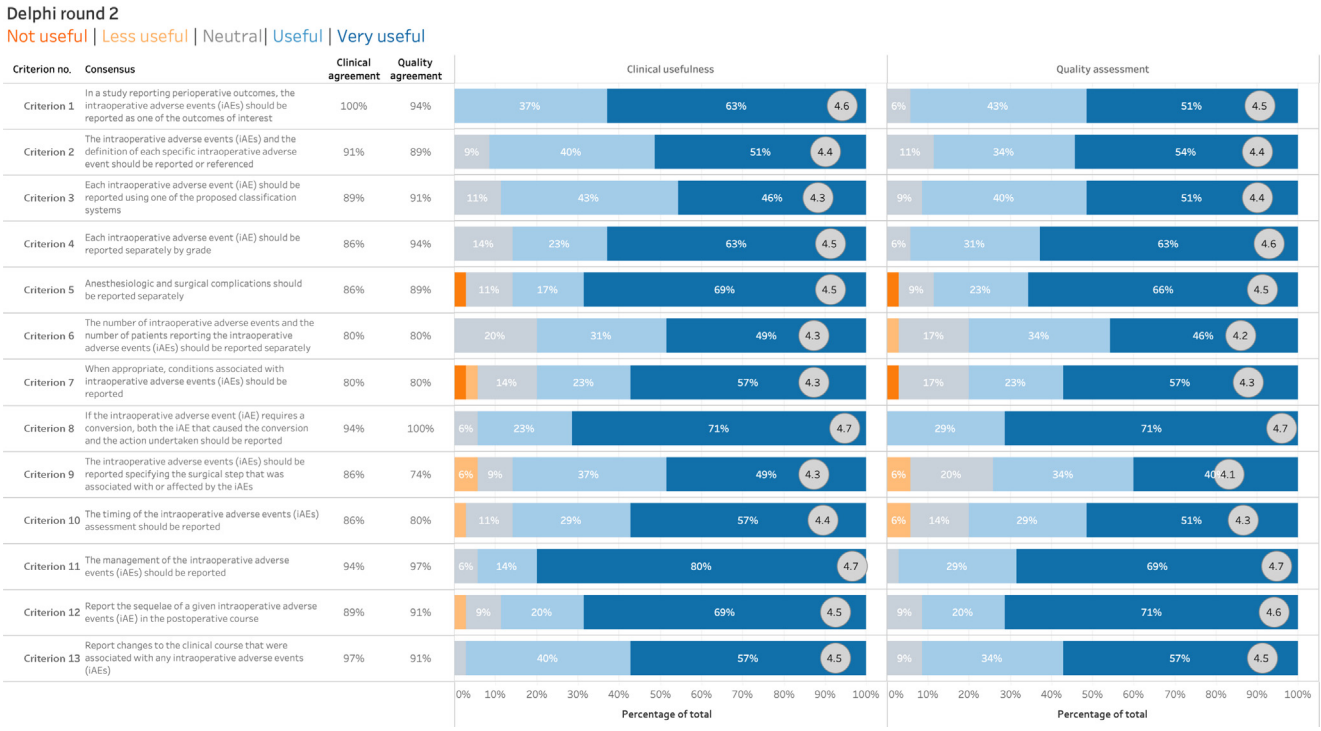

Fig. 2 – Agreement in the second Delphi round on the ICARUS criteria for intraoperative complication assessment and reporting with universal standards. Bar charts denote percentage agreement on the clinical usefulness and quality assessment according to a Likert scale from 1 to 5. Circles contain the mean Likert score for each criterion.

designed only for postoperative complications [30]. The iAE classification schemes vary in several domains [31], some of which are apparent on visualization of the overlap for the systems [2–5]. The Modified Satava scheme has the fewest severity levels at three and has relatively broad grades and descriptions. The EAUiaiC system has the most detailed descriptions and eight iAE grades. It also includes a grade for surgical errors due to incorrect site or lack of patient consent, which is not part of any of the other classification systems. The iAE severity classification scheme includes delineation of missed intraoperative injuries that necessitated reoperation. While all the systems reviewed are intended for surgical adverse events, only the Modified Satava and ClassIntra schemes also include anesthesiologic iAEs. Of note, only ClassIntra has recently been validated [6].

The aim of the ICARUS Global Collaboration guidelines is to guide surgeons and anesthesiologists in correctly reporting iAEs. We used the macro-level guidelines to determine what to include in a micro, patient-level template for surgeons. Of note, we did not create, expand, or validate any patient-level classification systems; rather, we provide these in a comprehensive format for appropriate reporting of intraoperative complications.

Comprehensive evaluation of iAEs necessitates recording of events within multiple domains. Surgical and anesthesiologic iAEs have different causes and treatments, and the panel recommends reporting them separately (criterion 5). Complications related to anesthesiology or surgical equipment can have an equally significant impact on morbidity and mortality [32,33]. Furthermore, anesthesiologic complications can represent direct consequences of the surgical intervention (ie, complex or prolonged surgical procedures may impact intraoperative anesthesiologic management) [34].

The panel recommends reporting the number of iAEs and the number of patients experiencing iAEs separately (criterion 6). The number of patients who experience an iAE may differ from the total number of events. For example, in a cohort of 100 patients of whom 20 (20%) experience a total of 35 iAEs, separate reporting provide more clarity for the results.

Not all iAEs are related to the surgical procedure [35]. Examples include some pre-existing conditions [35] (eg, body mass index [14,36]), medical history (eg, pelvic radiation potentially leading to a difficult posterior prostate detachment with the possibility of rectal perforation [37]), anatomical variations not recognized preoperatively [38] (eg, atypical vessels variants causing intraoperative bleeding requiring prolonged cauterization or vessel suturing), and malfunctioning surgical instruments [39,40] (eg, malfunction of the electrocautery device or malpositioning of the protective sheath of the robotic scissors, leading to a vessel injury). While equipment malfunctions are typically considered a subcategory of surgical complications, they warrant explicit inclusion in these guidelines as they are commonplace, infrequently reported, and often preventable [40,41]. Thus, the panel recommends reporting of all past medical conditions, atypical anatomical variants discovered during the surgical procedure, and any malfunctioning of the surgical instruments that could be associated with iAEs (criterion 7).

Conversion to open surgery because of iAEs has been associated with worse postoperative morbidity [2,42,43]. Conversion may negatively impact the postoperative course, potentially exposing patients to severe complications and surgical reintervention [42,44], inevitably leading to an increase in length of stay. Emergency conversion differs from elective conversion for a lack of progress or unsuitability for minimally invasive approaches. Therefore, the panel agrees that if an iAE requires surgical conversion, both the iAE responsible for the conversion [45,46] and the action needed [41,46] should be reported (criterion 8). For example, conversion might be required in the case of a vascular injury during robotic PLND after (several) unsuccessful attempt to identify and close the bleeding source with rolled gauze sponges/clips and definitive suturing. The instrument set required for conversion should be promptly opened; the bedside assistant should compress the vessel injury, remove the robotic instruments, and disconnect the robotic camera from the robot and hold it with a fixed view on the lesion; the surgical staff should undock the robot; and the console surgeon should scrub in and open the abdominal wall to control the injury [41]. Vascular surgeon evaluation might be useful. Structured training programs involving emergency scenario simulations are available [47,48] and might assist all operating room staff during critical conditions, ensuring safe minimally invasive surgery. Surgical support staff should receive structured training in nontechnical skills to guarantee appropriate communication with confirmatory feedback during emergency situations [49]. Console surgeons should receive preclinical simulation-based training on living animal models (ie, porcine models) for safe management of emergency situations such as vascular injuries [50–52].

Documentation of intraoperative complications and of surgical step–specific complications is crucial to increase awareness and gain an understanding of the etiology and the actions necessary to avoid and deal with these events [41,53–58]. With the advent of minimally invasive surgery [59], particularly robotic surgery [60], routine collection of intraoperative videos allows surgeons to accurately inspect the actions responsible for iAEs to analyze surgical step–specific complications in more depth, which can aid surgeons in appropriate operative planning, highlight precautionary measures to prevent iAEs, and facilitate the learning process for addressing emergency situations [41,53–55]. For this reason, the panel agreed that iAEs and their management should be reported with specification of the surgical step that was associated with or affected by each iAE (criteria 9 and 11). In this specific setting, application of proficiency-based progression in simulation training [61,62] might be crucial to reduce procedural errors [63], with an additional potential effect on shortening the learning curve for a specific procedure that is often longer and more complex than expected [64,65]. Validated objective performance metrics for each surgical procedure are imperative [66] and lay a foundation for implementation of structured simulation-based training programs [50] to guarantee effective and quality-assured surgical training, improve patient safety and outcomes, and help surgeon awareness of specific surgical step–dependent complications. The latter led to implementation of changes in surgical steps/techniques that significantly reduce the risk of complications [67].

Early detection and quick resolution of iAEs are the basic principles to decrease late morbidity and secondary mortality. Delay in iAE recognition may complicate the treatment of intraoperative complications and, in the worst-case scenario, end in life-threatening or fatal events [54,68]. Thus, the panel recommends reporting the timing of iAEs (criterion 10). (1) If an iAE is recognized during the surgical procedure, a debriefing should be held when the surgery is completed in order to learn from the procedural errors and prevent similar iAEs. (2) If an iAE is not recognized during the surgical procedure, the point at which the iAE became apparent in the postoperative course should be reported. This might happen, for example, in the case of a bowel injury. Some 69% of bowel injuries are not recognized intraoperatively [69] and most patients show no symptoms on the first postoperative day. Therefore, if there is any concern regarding a possible unrecognized intraoperative injury, surgical and ancillary staff should remain vigilant and, in select cases, consider prolonging hospitalization for further surveillance.

It should be noted that the panel proposed that the clinical consequences of a given iAE should be reported [70] (criterion 12). For cases in which no consequences occur, the surgeon should report: iAE without postoperative clinical consequence. Conversely, for cases with associated sequelae, the surgeon should report one of the following: iAE with nonpermanent postoperative clinical consequence; iAE with permanent postoperative clinical consequence; iAE requiring reoperation; iAE leading to postoperative death. For example, an obturator nerve injury during PLND might be related to nonpermanent postoperative sequelae (eg, stretching or direct thermal injury [71]) or permanent clinical sequelae (eg, complete transection [55,72,73]). The latter example, if not intraoperatively aligned and sutured, is associated with gait disturbance, anesthesia along the nerve distribution, inability to adduct the inferior limb, and, in progressive cases, atrophy of the adductor muscle. Other iAEs, might lead to sequelae that require reoperation. For example, an unrecognized intraoperative rectal injury may lead to a rectourinary fistula that requires delayed fistula repair after primary diversion [74] or, in rare cases, septic peritonitis and death.

Finally, changes to the standard clinical course that were associated with any iAEs, such as longer operative time (either an increase for management or a decrease if the operation was aborted), higher rate of blood transfusion, longer intensive care unit and postoperative stay, higher readmission rate, additional procedures, or unplanned specialty consultation [46,75], should be reported (criterion 13). Preoperative identification of patients who have a higher risk of iAEs [42,43,76] can help in improving care before surgery, optimizing and individualizing therapeutic decisions (eg, open surgery as the first choice), and foreseeing a need for surgical instruments and multidisciplinary experts that might be crucial during the surgery. This could significantly prevent iAEs, avoid changes in the clinical course, and thus reduce costs related to intraoperative and perioperative complications [76,77].

This consensus project should be interpreted bearing in mind its limitations. First, although we had a broad spectrum of experience, we invited surgeons experienced in open, endoscopic, and minimally invasive oncologic and non-oncologic surgical procedures. Their views and experi-

ence do not represent those of the broader urology community. In addition, we have not yet performed a global validation assessment involving other surgical specialties, anesthesiologists, and OR nurses, which is planned as a follow-up study (ClinicalTrials.gov NCT04994392). This further project will also provide information about facilitators and potential barriers to the adoption of these criteria.

5. Conclusions

There is an imperative need for standardized assessment and reporting of iAEs that occur during surgical procedures and their impact on postoperative outcomes. Overall, the standardized ICARUS iAE reporting system is of considerable interest and practical use and has important implications for academic and clinical practice. Specifically, it will allow: (1) proper interpretation of surgical outcomes to avoid missing critical information and subsequent underestimation of iAE rates and inaccurate quality-of-care measurements; (2) improvements in patient counseling regarding iAEs related to specific procedures; and (3) follow-up of the real-world and theoretical impact of iAEs on the postoperative course for patients.

The ICARUS Global Collaboration guidelines might aid in identifying important criteria when reporting iAEs as an outcome of interest, which will support all those involved in patient care and scientific publishing.

Author contributions: Giovanni E. Cacciamani had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Acquisition of data: Cacciamani, Sholklapper.

Analysis and interpretation of data: Cacciamani, Sholklapper, Sotelo, Desai, Artibani, Gill.

Drafting of the manuscript: Cacciamani, Sholklapper, Dell'Oglio, Artibani, Biyani.

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Statistical analysis: Sholklapper, Cacciamani.

Obtaining funding: None.

Administrative, technical, or material support: None.

Supervision: Cacciamani, Artibani, Gill.

Other (survey responders): Rocco, Annino, Antonelli, Amenta, Borghesi, Bove, Bozzini, Cafarelli, Celia, Leonardo, Ceruti, Cindolo, Crivellaro, Dalpiaz, Falabella, Falsaperla, Galfano, Gallo, Greco, Minervini, Parma, Sighinolfi, Pastore, Pini, Porreca, Pucci, Sciorio, Schiavina, Umari, Varca, Veneziano, Verze, Volpe, Zaramella.

Financial disclosures: Giovanni E. Cacciamani certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

***Funding/Support and role of the sponsor*:** None.

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