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RESEARCH

The incidence and classification of intraoperative adverse events in urological surgery: a systematic review

Gernot Ortner[1,2,3] · Charalampos Mavridis[4] · Athanasios Bouchalakis[4] · Maria Chrisoula Nakou[4] · Yuhong Yuan[5,6] · Udo Nagele[1,2,3] · Charalampos Mamoulakis[4] · Thomas R.W. Herrmann[2,3,7,8,9] · Chandra Shekhar Biyani[10] · Theodoros Tokas[2,3,4] · Mithun Kailavasan[11,12]

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Abstract

Purpose To perform a systematic review (SR) to examine the application of classification systems (CS) used to report intraoperative adverse events (iAEs) in urological surgery and to evaluate the crude incidence and type of iAEs.

Materials and methods This review was published via PROSPERO (CRD42024549954) and conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA). MEDLINE, Embase, and the Cochrane CENTRAL were searched using a predefined PICO framework: (P) patients with benign and malignant urological diseases, (I) all types of urological surgery, (C) none/any, (O) intraoperative complications classified with grading systems. Retrospective and prospective studies published between January 2019 and June 2024 were included.

Results The search yielded 1,570 abstracts, 1,043 full-text articles were assessed for eligibility, of which 325 studies reported iAEs (54 used iAE-CS, 64 used Clavien-Dindo Classification and 207 used free-text descriptions). Of the 54 studies (15,298 patients) that used an iAE-CS, the three most used systems were the EAUiaiC (54%), SATAVA (26%), and the modified SATAVA (7%). The overall incidence of iAE was 14% (2,153/15,225 patients). On a study level, the crude incidence of iAE was between 0 and 100% (median 7%, IQR: 3-13%). The misapplication of the Clavien-Dindo system to describe iAEs was high ($n = 64$ studies).

Conclusions The use of iAE-CS is scarce, and there is a lack of universal consensus on a CS to describe iAEs. iAE are poorly reported in urological studies. Urologists should report all perioperative complications to improve transparency and surgical and hospital processes.

Keywords Classification · Complications · Intraoperative complications · Perioperative · Risk Management · Urologic Surgical procedures

✉ Mithun Kailavasan
Mithun.kailavasan@doctors.org.uk

1 Department of Urology and Andrology, Hall in Tirol, General Hospital Hall I.T, Hall in Tirol, Austria

2 Hall in Tirol, Training and Research in Urological Surgery and Technology (T.R.U.S.T.)-Group, Hall in Tirol, Austria

3 European Association of Urology Endourology Section, Arnhem, The Netherlands

4 Department of Urology, Medical School, University General Hospital of Heraklion, University of Crete, Heraklion, Crete, Greece

5 Department of Medicine, London Health Science, London, ON, England

6 McMaster University, Hamilton, ON, Canada

7 Department of Urology, Kantonspital Frauenfeld, Spital Thurgau AG, Frauenfeld, Switzerland

8 Division of Urology, Department of Surgical Sciences, Stellenbosch University, Western Cape, South Africa

9 Hannover Medical School, Hannover, Germany

10 St James's University Hospital, Leeds, UK

11 Victoria Hospital, University of Western Ontario, London, ON, Canada

12 Department of Urology, Victoria Hospital, University of Western Ontario, London, ON, Canada

Abbreviations

CDC	Clavien-Dindo classification
CENTRAL	Cochrane Central Register of Controlled Trials
CS	Classification system
EAUiAiC	European Association of Urology (EAU) Intraoperative Adverse Incident Classification (EAUiaiC)
iAE	Intraoperative adverse event
ICARUS	Intraoperative Complication Assessment and Reporting with Universal Standards
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
RARP	Robot-Assisted Radical Prostatectomy
RARC	Robot-Assisted Radical Cystectomy
RAPN	Robot-Assisted Partial nephrectomy
RIRS	Retrograde Intrarenal Surgery
SR	Systematic Review

Introduction

Perioperative morbidity, which includes both intraoperative adverse events (iAE) and postoperative complications, is often used as a surrogate marker of surgical quality [1]. An iAE is "any unplanned incident related to a surgical intervention occurring between skin incision and skin closure" [2]. It has significant negative implications for patients regarding prolonged recovery and increased hospital costs [3–5]. Like the widely used Clavien-Dindo classification (CDC) to assess postoperative complications, iAE classification systems (CS) are based on a tier system with higher grades representing more severe injuries with potential long-term adverse outcomes for the patient [2, 6–9]. However, iAEs seem to be frequently underreported. Several factors have been suggested for inadequate reporting. These include a lack of clear iAE definitions, the absence of validated CS, concerns over "negative outcomes" and legal liability, and poor generalizability across surgical specialities with different techniques (e.g., open, endoscopic, minimally invasive) [2, 10, 11]. This gap in knowledge of iAE can hinder surgeons and hospitals from effectively evaluating and enhancing surgical processes to improve patient care. Among various initiatives, the European Association of Urology's intraoperative adverse incident classification (EAUiaiC) was developed in 2019 via a multi-step Delphi consensus to categorize iAE [2]. This systematic review (SR) aimed to examine the application of CS for reporting intraoperative complications and their incidence in urologic procedures.

Materials and methods

The SR was performed per the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (PRISMA) 2020 [12]. The protocol was registered in the International Prospective Register of Systematic Reviews database (http://www.crd.york.ac.uk/PROSPERO; CRD42024549954).

Search strategy

An experienced librarian (YY) systematically searched databases, including MEDLINE, Embase, and Cochrane Central Register of Controlled Trials (a detailed summary can be found in Supplementary Fig. 1). Due to the conception of the EAUiaiC classification in 2019, the search was limited to English-language articles published between January 1, 2019, and June 19, 2024 [2].

Study selection and outcomes

The primary outcome was to evaluate the proportion of studies that used an iAE-CS to describe intraoperative complications in urology. The secondary outcome was to evaluate the crude incidence and type of iAEs using CS and assess the CDC misapplication of describing iAEs [9].

Studies were included if they fulfilled the following criteria: (P) patients with benign and malignant urological diseases, (I) all types of urological surgery, (C) none/any, (O) intraoperative complications classified with grading systems. Case reports, conference abstracts, reviews, letters, commentaries, and editorials were excluded. Initial title-abstract screening was performed by four reviewers (GO, MK, CMav, AB). Full-text screening and data extraction was performed by eight reviewers independently (GO, MK, CMav, AB, MCN, UN, CSB, TT). Reference lists of included manuscripts were also screened for eligibility. Any disagreement was resolved by consensus by reference to the senior authors. The assessment of the risk of bias (ROB) was not conducted, as this SR is solely focused on summarizing the reporting of iAE, and therefore, evaluating ROB was beyond the scope of our study.

Data extraction

Study data included the publication year, type of iAE-CS, journal name, country of derived patient data, study type, surgical domain, patients (number, subgroups), gradings, and types of complications (overall iAEs for each study, grades for the applied iAE if available, detailed assessment of complications).

Statistical analyses and subgroup analyses

Continuous variables were either reported with mean and standard deviation (SD) or median and interquartile range (IQR) depending on the distribution (graphical analysis). Dichotomous and categorical data were reported with n (%). Due to the heterogeneity of study data (surgical domains, different modifications for surgeries, selection of patients), no meta-analyses were performed. Descriptive analyses were performed using R Version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria. http://www.R-project.org).

Results

The PRISMA flow diagram (Fig. 1) details the study selection process. The initial search yielded 1,570 abstracts for screening. We assessed 1,043 full-text articles for eligibility, of which 325 studies reported iAEs (54 used iAE-CS, 64 used CDC and 207 used free-text descriptions without CS to report iAEs). Therefore, 54 studies ($n=15,298$ patients, range: 5−1,891) met the inclusion criteria for the primary outcome analysis. Supplementary Table 1 provides an overview of the included studies, including the number of patients and iAEs with gradings, if assigned. Further information regarding the type of iAEs and management (if available) is provided in Supplementary Table 2. The number of studies using iAE-CS published for each year during the search period was: 3/54 (6%) in 2019, 2/54 (4%) in 2020, 10/54 (19%) in 2021, 15/54 (28%) in 2022, 13/54 (24%) in 2023, and 11/54 (20%) till June 2024, respectively (Fig. 2). The study design was retrospective, prospective non-randomized, or a randomized-controlled trial for 48/54 (89%), 4/57 (7%) and 2/54 (4%), respectively. Additionally, 64 studies were included for the secondary outcome (misapplication of the CDC to describe iAEs) (Supplementary Table 3).

Utilization-rate of iAE-CS to describe iAEs

When focusing on studies that aimed to report iAEs for the selected study period, 325 studies ($n=54$ using iAE-CS, $n=64$ misusing the CDC, and $n=207$ using free-text descriptions for complications) (Fig. 1) could be identified. The relative utilization rate of iAE-CS was 16.6% (54/325).

iAEs classification systems

Approximately 5% of studies (54/1,043) used a CS to report iAEs. Out of 54 included studies, 29 (54%) [13–41] used the EAUiaiC classification (5/29−17% with adherence to the ICARUS framework [37–41]), fourteen [42–55] used the SATAVA classification (7), four studies [56–59] utilized the modified SATAVA classification (8), and three [60–62] used the CTCAE (Common Terminology Criteria for Adverse Events) system. The PostUreteroscopic Lesion scale (PULS) [63], Kaafarani classification [64], DEpth of Endoscopic Perforation (DEEP) scale [65], and ClassIntra-system (formerly CLASSIC) [5, 66] were only used in 1/54 (2%) each [65, 67–69] (Fig. 2). Detailed information regarding the definition of gradings for the main iAE-CS used can be found in Table 1.

The overall incidence of iAEs

One out of fifty-four studies [61] did not report overall iAEs. A total of 2,153 iAEs occurred, involving 15,225 patients (overall incidence of iAEs = 14%). On a study level, the crude incidence of iAE ranged between 0% and 100% (median 7%, IQR: 3- 13%).

Surgical domains

The three most studied urological procedures were cystectomy (12/54), radical prostatectomy (7/54), and retrograde intrarenal surgery (RIRS) (6/54).

Regarding surgical modalities, robot-assisted surgical studies constituted the majority of included studies (26/54 (48%)). Seven out of 54 studies (13%) focused on stone surgery (RIRS $n=6$, mini-percutaneous nephrolithotomy ($n=1$). Further, 5/54 (9%) of studies concentrated on open radical cystectomy with various diversion methods, and 2/54 (4%) on Holmium laser enucleation of the prostate. There were 3/54 (6%) studies each focusing on (cytoreductive) surgery for advanced renal cell carcinoma, minimal-invasive kidney transplantation, and open kidney surgery approaches. There were 1/54 (2%) studies each for transurethral resection of bladder tumor, retroperitoneal lymphadenectomy, penile prosthesis implantation, female incontinence surgery, and inguinal lymphadenectomy for penile carcinoma.

Subgroup analysis – complication incidence and complication grade for each iAE-CS

To avoid bias, nine studies [25, 27, 28, 35, 36, 39, 60–62] that did not report on either grade or overall iAEs were excluded from this analysis. Furthermore, Branger et al. were excluded from the subgroup analysis because the study focused on reasons for conversions to open surgery only (rate of iAE = 100%) [16]. Hence, a total of 44 studies were further analyzed. Due to the small study number for ClassIntra ($n=1$), DEEP ($n=1$), Kaafarani ($n=1$), and

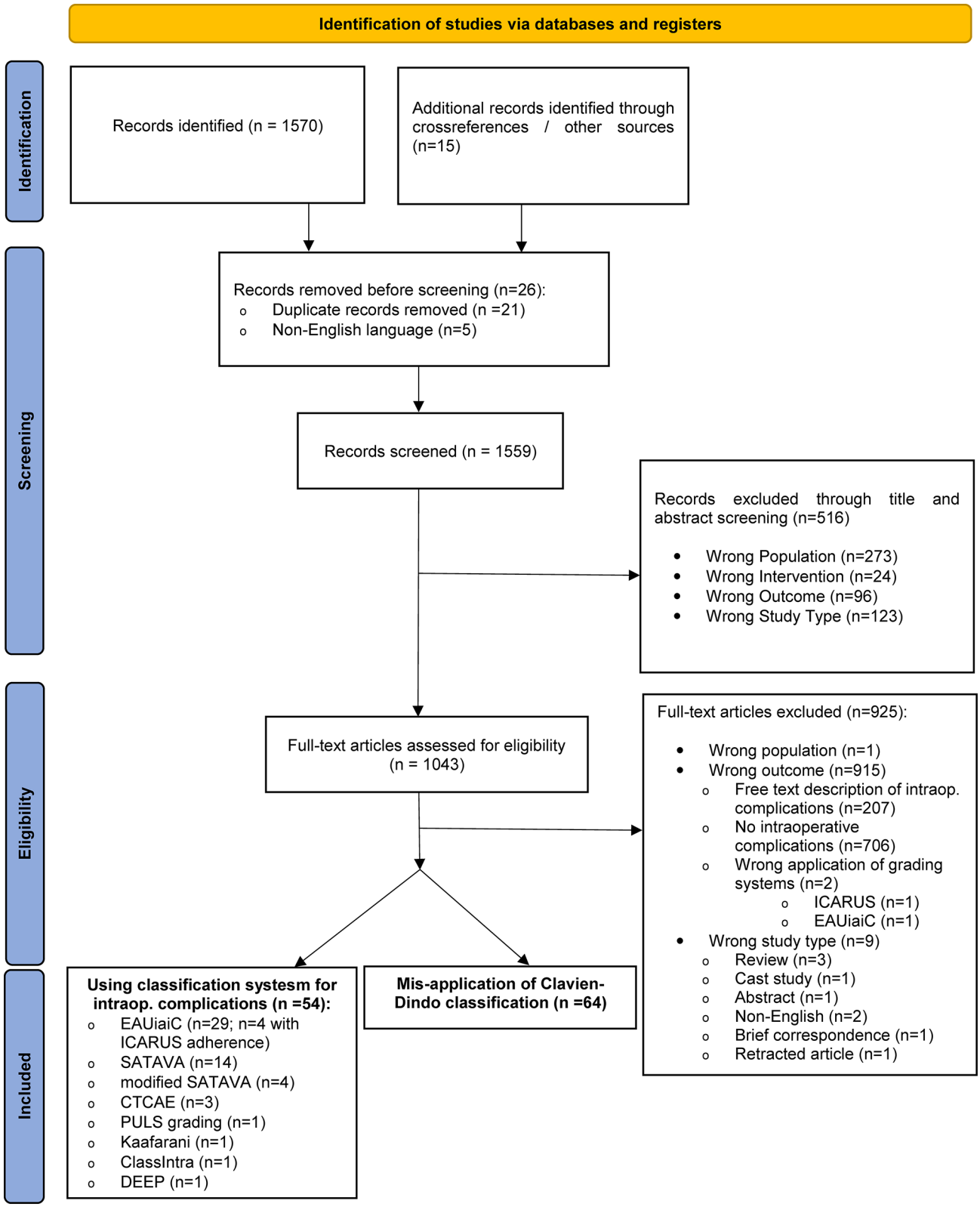

Fig. 1 PRISMA 2020 flow chart for the systematic review

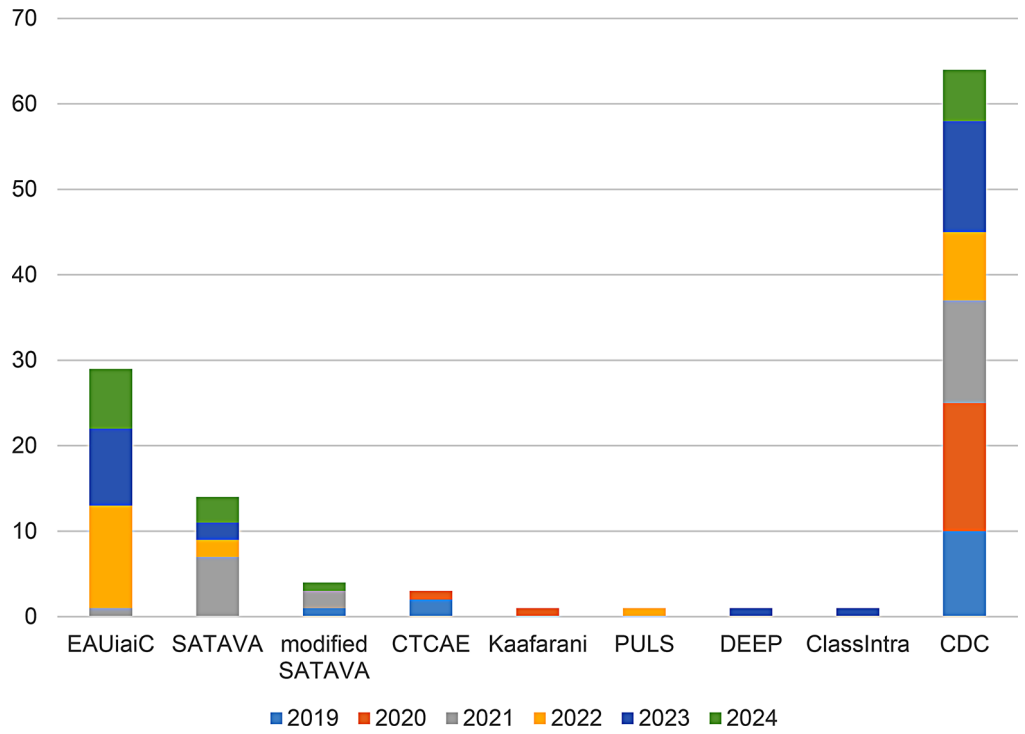

Fig. 2 Overview of included studies according to the iAE-CS used for each publication year stratified by publication year. The y-axis represents the cumulative number of publications per iAE-CS. CTCAE = Common Terminology Criteria for Adverse Events system. PULS = PostUreteroscopic Lesion Scale. DEEP = DEpth of Endoscopic Perforation (DEEP) scale

PULS ($n=1$), only a subgroup analysis for the EAUiaiC ($n=22$), the SATAVA classification ($n=14$), and the modified SATAVA classification ($n=4$) was performed.

EAUiaiC

Twenty-two studies were included for subgroup analysis [13–15, 17–24, 26, 29–34, 37, 38, 40, 41]. We registered 558 iAEs for 6,884 patients (overall incidence of 8% for all grades). The crude incidence of iAEs was 0-93% (median 4%, IQR: 3-7%). 15/558 (3%) were grade 0 iAEs, 305/558 (55%) grade 1, 117/558 grade 2 (21%), 61/558 (11%) grade 3, 58/558 (10%) grade 4 (grade 4a: 22/558 (4%), grade 4b: $n=29$/558 (5%), and 2/558 (< 1%) grade 5 iAEs.

The three main procedures using the EAUiAiC were robot-assisted radical prostatectomy (RARP) ($n=5$), robot-assisted radical cystectomy (RARC) ($n=3$), and robot-assisted partial nephrectomy (RAPN) ($n=3$), which were further analyzed.

EAUiaiC – RARP

In five studies, 67 iAEs were registered for 2,456 RARP (overall incidence = 3%) [13, 21, 23, 31, 33]. The crude incidence of iAEs was 2–14% (median 4%, IQR: 3-5%). A detailed overview of specific iAEs is presented in Supplementary Table 4.

EAUiaiC – RARC

In three studies [34, 37, 38], 35 iAEs were registered for 941 RARCs (overall incidence = 4%). The crude incidence was 1–7% (median 3%, IQR: 2-5%). A detailed overview of specific iAEs is presented in Supplementary Table 5.

EAUiaiC – RAPN

In three studies, 4/91 patients developed an iAE (overall incidence = 4.4%) [15, 17, 40]. The crude incidence of iAE amongst the included studies was 0-5% (median 5%, IQR: 3-5%). A detailed overview of specific iAEs is presented in Supplementary Table 6.

SATAVA

Fourteen studies were included in this subgroup analysis [42–55]. We registered 193 iAEs for 1,662 patients (overall incidence = 12%). The crude incidence of iAE was between 0 and 29% (median 6%, IQR: 3-9%). 136/193 (71%) were grade 1, 55/193 (29%) grade 2, and 2/193 (1%) grade 3. The

Table 1 Overview of definitions for gradings for the major iAE-CS included in the study

	Modified Satava Classification (for endoscopic surgery)	Satava Classification (for open surgery)	EAUiaiC	Common Terminology Criteria for Adverse Events v5.0 (CTCAE)
Studies (N)	**4**	**14**	**17**	**3**
Grade 0			Event requiring no intervention or change in operative approach, no deviation from planned intraoperative steps, no consequence for the patient	
Grade 1	Incidents managed without change in operative approach and without consequences for the patient	Incidents managed without change of operative approach and without further consequences for the patient. It includes perforations of adherent or adjacent organs, minor change in intraoperative tactics, and cases with blood loss exceeding the normal range	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	Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
Grade 2	Incidents treated with endoscopic surgery A. treated intraoperatively with endoscopic surgery) B. incidents requiring endoscopic re-treatment)	Incidents with further consequences for the patient. It includes cases requiring limited resection of intraoperatively injured organs cases with blood loss appreciably more than the normal range	Event requiring major additional/alternative procedure in operative approach but NOT immediately life-threatening. The event was addressed in a controlled manner, however may have short- or long-term side effects	Moderate; minimal, local or non-invasive intervention indicated; limiting age-appropriate instrumental ADL*.
Grade 3	incidents requiring open or laparoscopic surgery (e.g. ureteral intussusception / avulsion)	Incident leading to significant consequences for the patient	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	Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**.
Grade 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)	Life-threatening consequences; urgent intervention indicated.
Grade 5			A. Wrong site or side for ablative surgery or removal of an organ or wrong patient or no consent B. Intraoperative death	Death related to AE.

Intra-operative Classification systems reported more than once in the included studies

main procedure for utilizing SATAVA was RARC ($n=4$), which was analyzed further.

In four studies, 47 iAEs occurred in 539 RARCs (overall incidence = 8.7%) [46, 51, 53, 54]. A detailed overview of specific iAEs for RARCs is presented in Supplementary Table 7.

Modified SATAVA

Four studies were included for subgroup analysis [56–59]. We registered 485 iAEs for 1,833 patients (11%). The crude incidence of iAEs was between 7% and 100% (median 26%, IQR: 14-51%). Three out of four studies utilized the modified SATAVA in retrograde intrarenal surgery (RIRS), which was further analyzed.

Modified SATAVA - RIRS

Four hundred and seventy-three iAEs were registered in 1,671 RIRS (overall incidence = 28%, $n=3$) [56, 57, 59]. The crude incidence of iAEs was between 16 and 100% (median 35%, IQR: 26-67%). A detailed overview of specific iAEs is presented in Supplementary Table 8.

Use of clavien-dindo classification to describe iAEs

We found 64 studies using the CDC to assess iAEs (Supplementary Table 3). There were 33,705 patients in these studies. The range of included patients in these studies was 6–9,858. Most commonly, the CDC was not specified to report the type of iAE (27/64).

Discussion

Principal findings

Reporting iAEs in surgical studies is essential for several reasons, including enhancing patient safety, promoting transparency, and enabling benchmarking across institutions and surgeons [11, 70]. To our knowledge, this is the first study to assess the use of CS in reporting iAEs and their incidence in urological surgery. Our principal finding was that the relative utilisation rate of iAE-CS was low at 16.6% (54/325). Second, the crude incidence of iAEs was 14% (2153/15225). However, this value excludes studies that used a free-text description to describe these events and those that did not report on any iAEs. Given that perioperative complications are generally considered "negative" outcomes, this highlights a well-documented bias in surgical literature [11]. Thus, the lack of reporting does not necessarily indicate the absence of these events.

In this SR, seven different CS were utilized to describe iAEs, reflecting that no single tool has been universally implemented, unlike the CDC, for postoperative complications. The EAUiAiC was the most frequently used grading system (29/54) to describe iAEs. The EAUiAiC comprises five grades and includes a category for surgical errors related to incorrect site procedures (a "never event") and lack of patient consent, which other CS do not address [2]. A weakness of the EAUiAiC is that it is based solely on surgical interventions alone, which, in some cases, can result in misleading gradings. For example, the same iAE grade (EAUiAiC grade 3) can be applied to a small bleed in the inferior vena cava addressed with a few sutures by an experienced surgeon or prolonged suturing by an inexperienced surgeon, which may result in hemodynamic instability [30]. From an outcome perspective, these scenarios differ significantly regarding patient recovery and surgical quality [30]. In contrast, the modified SATAVA classification has a three-tier system with broad categories designed explicitly for endourological surgery, which limits its generalizability. While all the iAE-CS focus on surgical adverse events, only the ClassIntra classification includes anaesthesiologic iAEs. Not all iAEs are related to the surgical procedure; some may arise from anaesthetic complications, which can have an equally significant impact on morbidity and mortality [72, 73]. One drawback of the ClassIntra is that the grading system requires considerable judgment for interpretation. Of all the iAE-CS, only ClassIntra and EAUiAiC have been prospectively validated, highlighting a lack of suitable tools in the existing literature [5, 71].

The CDC was the most commonly used method for describing iAEs in this SR; however, most cases either did not provide a specific grade or left it unclear. Various authors have reported the limitations with CDC, including the severity of grade related to the type of anaesthesia (where most patients will have a general anaesthetic for iAE); the most severe grade of complication is often reported without considering cumulative morbidity and high inter-rater variability [71].

A significant challenge in understanding the true nature of iAEs is the variability in how they are reported. For instance, data on open conversions during minimally invasive surgeries are reported in several studies included in this SR, but there are no detailed explanations for the reasons behind these conversions. Some procedures may necessitate a planned open conversion due to significant abdominal adhesions or for optimal oncological control. It is essential to distinguish these from unplanned conversions (e.g. substantial bleeding or organ perforation), which are associated with worse postoperative outcomes [74, 75].

Transparency about complications during the perioperative period is crucial, as delays in recognizing and managing

iAEs may lead to life-threatening or fatal consequences [11, 70]. Hence, recent efforts have been made recently to improve education and awareness. For example, the Intraoperative Complications Assessment and Reporting with Universal Standards (ICARUS) Global Surgical Collaboration criteria was developed in 2022 to standardize the assessment, reporting, and grading of iAEs, however, only 4/54 of this SR utilized ICARUS, perhaps demonstrating a lack of awareness or utility [11]. In 2023, Soliman et al. conducted a SR assessing the quality and utility of classification systems for intraoperative and postoperative complications [71]. They found that only 6 out of 13 CS were clinically validated and that reporting adverse events was inconsistent [71].

Strengths and limitations

One of the main strengths of this SR is that over 1000 full-text articles were screened by eight reviewers for study eligibility (Fig. 1). This was necessary because many abstracts mentioned "peri-operative" complications, and we did not want to exclude them prematurely. However, there are several limitations to consider. First, studies that intended to use a CS for iAEs but did not report on their incidence were placed in the "no intraoperative complications" category, introducing potential bias in the 11% iAE-CS application rate. Second, our review focused on studies published since the 2019 introduction of EAUiAiC, meaning studies before this date may have used different CSs. Third, reporting bias is likely, as iAEs are considered negative outcomes, leading to an underestimation of their true incidence. Lastly, caution is needed when interpreting the overall and subgroup crude incidence rate. While the crude incidence rate of iAEs described in this study lacks the precision of more refined data, it provides an important starting point for understanding risk in urological studies and highlights the significant underreporting and/or inconsistency, reflected by the wide range in incidence (0–100%, median 7%).

Conclusion

The urological literature reports iAEs poorly. Studies utilizing CS significantly misuse the CDC, which was developed in the postoperative setting but has never been designed for classifying iAEs. Urologists should report all perioperative complications to improve transparency in surgical and hospital processes.

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Data availability No datasets were generated or analysed during the current study.

Declarations

Ethical approval of studies and informed consent Due to the study design, no ethical approval was required.

Competing interests The authors declare no competing interests.

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