NARRATIVE REVIEW

# Intraoperative Adverse Event Reporting in Gastrointestinal Cancer Surgery: A Narrative Review on the Application of ClassIntra

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## Abstract

Intraoperative adverse events are inevitable during complex gastrointestinal cancer surgeries, ranging from minor technical issues to life-threatening complications. Their impact on patient outcomes underscores the need for standardised reporting as no universally accepted system currently exists. The ClassIntra classification system is a five-tier severity scale based on the required interventions, mirroring the Clavien-Dindo Classification for postoperative complications. The current narrative review was planned to explore current intraoperative adverse event reporting practices in gastrointestinal cancer surgery, and to evaluate the effectiveness of ClassIntra in enhancing accuracy and consistency. Validation studies in gastric, colorectal and hepatopancreaticobiliary surgeries demonstrate its predictive value for postoperative complications and surgical outcomes. Although data specific to gastrointestinal oncology remains limited, initial evidence has shown ClassIntra's potential as a standardised tool. A collaborative effort is essential for its widespread adoption, fostering improved safety and outcomes in gastrointestinal cancer surgeries through routine intraoperative adverse event documentation and feedback.

**Keywords:** Intraoperative adverse events, ClassIntra, Adverse event reporting, Gastrointestinal cancer surgery.

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## Introduction

Intraoperative adverse events (iAEs) are unexpected but inevitable components of complex surgical procedures, particularly gastrointestinal (GI) cancer surgery.[1] These events can range from minor technical errors to significant intraoperative crises having a consequential impact on patient outcomes. Despite their critical role in surgical quality assessment and patient safety, the consistent reporting and classification of iAEs remain a challenge in clinical practice and research.[2]

The development of standardised systems for iAE reporting has improved transparency and comparability in surgical outcomes. Among these, the ClassIntra classification system[3] has gained recognition for its structured approach for grading iAEs. ClassIntra provides a five-tier severity scale based on the therapeutic interventions required to manage the complication, making it a practical and reproducible tool for intraoperative reporting. Its use has the potential to improve the quality of surgical audits, facilitate benchmarking, and enhance communication among healthcare teams.

In the context of GI cancer surgery, where patients often undergo extensive and technically demanding procedures, the adoption of such a classification system is particularly pertinent. Accurate reporting of iAEs using ClassIntra can help identify modifiable factors contributing to adverse outcomes, refine surgical techniques, and ultimately improve patient care. However, the literature on application of ClassIntra classification system in GI cancer surgery remains limited,[4] necessitating a comprehensive review to explore its utility and impact.

The current narrative review was planned to explore the current practices iAE reporting in GI cancer surgery, to highlight the utility of the ClassIntra system in enhancing the standardisation and accuracy of iAE documentation, and to discuss its role in improving surgical outcomes and patient safety.

## Materials and Methods

The narrative review was conducted from September to October 2024, and comprised a comprehensive literature search on PubMed, Cochrane, Scopus and Google Scholar databases for studies published between January 2005 and June 2024, focusing on GI cancer surgeries and the application of the ClassIntra classification system.[3] Search terms used were "Intraoperative adverse events", "ClassIntra", "GI cancer surgery", "surgical complications", and "adverse event reporting". Manual search of references from the identified studies was also done.

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Studies addressing iAEs in GI cancer surgery, those discussing the development, validation or application of the ClassIntra classification system, and reviews, original research and clinical guidelines providing insights into IAE reporting were included.

Studies not focussed on GI cancer surgery, those published in languages other than English, conference abstracts lacking full texts, and studies discussing adverse events only in the postoperative period were excluded.

**Definition of iAEs:** iAEs in GI cancer surgeries refer to any deviations from the ideal intraoperative course that lead to unexpected outcomes during surgery.[3] These events are categorised as either surgical or anaesthesia-related, and may include complications, such as bleeding, organ injury, prolonged operative time, and cardiovascular incidents.[5] The definition of iAEs helps clinicians understand the severity and immediate risk to the patient, ensuring better management and postoperative care.

Despite efforts to define iAEs by working groups, no universal definition exists across the surgical community, which has led to variations in reporting systems and classifications.[6] Several notable frameworks have contributed to the conceptualisation of iAE:

• Classic[6] and ClassIntra[3] define iAE as any deviation from the ideal intraoperative course occurring between skin incision and closure.

• The European Association for Endoscopic Surgery (EAES)[7] defines iAE as an event not intended by the surgeon, nor desired by a set of rules or an external observer, or an event that leads the surgical task outside acceptable limits.

• The European Association of Urology Intraoperative Adverse Incident Classification (EAUiaiC)[8] narrows this definition, specifying that iAEs are undesired events due to surgical intervention occurring between skin incision and skin closure.

These frameworks emphasise the need for consistency to enhance the identification, classification and management of iAEs.

**Classification systems of iAEs:** While standardised postoperative complication grading systems, such as the Clavien-Dindo Classification (CDC),[9] have been widely adopted, there is no universally accepted grading system for iAEs. Several classification systems have been developed, each focussing on different aspects of surgical procedures. Early systems, like Shakelton,[10] Modified Satava[11] and the IAE Severity System[5], were limited in scope and did not integrate anaesthesia-related events. The Classic system[6], which includes both surgical and anaesthesia-related iAEs, has been retrospectively validated in various specialties, including GI oncology, and is commonly used to predict postoperative complications. Other systems, such as EAES[7] and EAUiaiC[8], target specific surgical types, like laparoscopic and urological surgeries. ClassIntra, the most recent and prospectively validated system, offers a comprehensive and scalable approach, and is applicable across multiple surgical specialties, including oncology. Despite these developments, a standardised, universally accepted iAE grading system remains lacking, especially in the context of GI cancer surgeries. The available iAE reporting systems have their own key features, strengths and limitations (Table 1).

**Frequency and impact of iAEs in relation to GI cancer surgery:** Intraoperative AEs are a critical challenge in GI cancer surgery, particularly in complex oncological procedures where precision is paramount. The frequency of iAEs varies based on the type and complexity of the surgery. For instance, laparoscopic and robotic radical gastrectomies report iAE rates of 19.9%[4] and 19.7%[15], respectively, highlighting the inherent difficulties of minimally invasive approaches. Similarly, rectal cancer surgeries demonstrate a notable iAE rate of 10.9%, with organ injury emerging as the most common complication.[16] Living donor liver transplant (LDLT) surgeries show even higher rates, with iAEs affecting 50% of donors.[17] In minimally invasive oesophagectomies, procedural complexity often leads to vascular injuries, splenic trauma or recurrent laryngeal nerve damage.[18,19]

Among the various types of iAEs, bleeding is the most frequently reported complication, accounting for 28% of surgical-origin events.[20] Excessive intraoperative blood-loss is not merely a technical challenge, but also a critical factor influencing long-term outcomes. In GI cancer surgeries, blood-loss >400mL[22] has been identified as a significant predictor of hepatic recurrence and mortality. In colorectal cancer surgeries, it correlates with peritoneal recurrence[22] and postoperative complications.[23] Additionally, studies highlight that iAEs, including significant blood-loss, can elevate the risk of local recurrence in rectal cancer[24] and recurrence of hepatocellular carcinoma (HCC),[25] underscoring its impact on oncological outcomes.

Organ injuries represent another major category of iAEs, with bowel and vascular injuries being the most frequently reported in abdominal surgeries.[26] These injuries, alongside cardiovascular complications — responsible for 67%[20] of anaesthesia-related events —

**Table-1:** Classification systems of intraoperative adverse event (iAE) reporting.

| Classification system | Year | Grades | Scope/ Targeted Specialty | Validation | Strengths | Limitations |
|---|---|---|---|---|---|---|
| Shakelton (Shakelton et al)[10] | 2005 | Not graded | Living donor liver transplant (LDLT) | Not validated | Comprehensive for complex surgeries | Limited to LDLT; high complexity |
| Satava (Satava et al)[14] | 2005 | 3 grades | Minimally invasive surgeries | Not validated | Focused on minimally invasive surgeries | Lack of generalised applicability; does not include anaesthesia related side effects |
| Oslo/Modified Satava (Kazaryan et al)[11] | 2013 | 3 grades | Various surgical procedures | Limited formal validation | Broad applicability across different specialties | Does not include anaesthesia-related complications; limited validation across settings |
| IAEs Severity system (Kaafrani et al)[5] | 2014 | 6 grades | General surgery | Retrospectively validated | Broader applicability | Lacks integration with other systems;does not include anaesthesia related events |
| Classic (Rosenthal et al)[6] | 2015 | 4 grades | Multiple specialties including GI, oncology, orthopaedics, etc. | Retrospectively validated | Broader applicability;Includes anaesthesia related complications | Lacks granular detail in some cases; limited to retrospective data |
| EAES Classification European Association of Endoscopic Surgeons(Francis et al)[7] | 2018 | 5 grades | Laparoscopic / endoscopic Surgery | Retrospectively validated | Tailored to laparoscopic procedures | Limited to minimally invasive surgeries not widely generalizable to open surgeries |
| SEVERE Severity of Intraoperative events and rectification system(Jung et al)[12] | 2020 | Scoring system based on 5 types of iAEs (bleeding, thermal injury, mechanical injury, ischemic Injury and insufficient closure) | Elective laparoscopic gastrointestinal surgeries | Prospectively validated only in laparoscopic roux-en-y gastric bypass | Well-defined iAEs, detailed scoring system | Not applicable to open surgeries; based on video data rendering biased results |
| EAUiaiC classification system (Biyani et al)8 | 2020 | 8 grades | Urology | Retrospectively validated | Relevant for specific urological procedures | Subjectivity in application; based on literature and expert opinion |
| ClassIntra (Dull Kuster et al)[13] | 2020 | 5 Grades | Multiple specialties including oncological surgeries | Prospectively validated | Scalability, granularity, global use | Needs broader application studies in oncology |

Abbreviations: LDLT: Living donor liver transplant; IAE: Intraoperative adverse event; GI: gastrointestinal; EAES: European Association of Endoscopic Surgeons; SEVERE: Severity of intraoperative events and rectification system; EAUiaic: The European Association of Urology Intraoperative Adverse Event Classification.

contribute significantly to postoperative morbidity and mortality.

The consequences of iAEs are far-reaching, affecting both surgical outcomes and recovery. Patients experiencing iAEs are more likely to face prolonged operating time, greater blood-loss and extended length of hospital stay (LOS). Moreover, severe iAEs, such as bleeding or organ damage, increase the likelihood of postoperative infections, slower recovery and heightened morbidity.[4,15] The cumulative impact of iAEs highlights their role in worsening surgical and oncological outcomes. Patients with severe iAEs face higher risks of prolonged recovery, increased healthcare resource use, and poorer survival rates. Given these findings, a standardised system like ClassIntra is vital for systematically identifying, reporting and addressing iAEs to enhance surgical quality and to improve patient care.

**Challenges in reporting iAEs:** Despite the critical importance of iAE reporting in improving surgical quality, significant challenges persist. Preliminary findings from a study[27] highlighted that very few surgeons consistently report iAEs, primarily due to concerns about potential litigation, and the absence of a robust reporting framework. Underreporting of iAEs, particularly those of low severity, has also been observed in operative documentation. A study[28] found that iAEs were omitted

**Table-2:** ClassIntra classification system.

| | |
|---|---|
| Grade 1 | Any deviation from the ideal intraoperative course without the need for any additional treatment or intervention |
| Grade 2 | Any deviation from the ideal intraoperative course with the need for any additional treatment or intervention that is not life threatening and not leading to permanent disability |
| Grade 3 | Any deviation from the ideal intraoperative course with the need for any additional treatment or intervention which is life-threatening and/or leading to permanent disability |
| Grade 4 | Any deviation from the ideal intraoperative course with the need for any additional major and urgent treatment or intervention. Patient with life threatening symptoms or leading to permanent disability |
| Grade 5 | Any deviation from the ideal intraoperative course with death of the patient |

in 24.3% of operative notes even though surgeons expressed the willingness to report such events. This discrepancy underscores the reluctance to document minor iAEs, likely due to time constraints, perceived insignificance, or medico-legal fears.

The lack of a standardised approach to reporting further complicates the issue. A critical analysis of 46 randomised controlled trials (RCTs) revealed that 41% of trials did not report iAEs at all, only 13% of the studies provided a clear definition of iAEs, and a mere 9% utilised a classification system to describe severity or impact.[29]

Without standardised reporting tools, meaningful comparisons among studies become difficult, limiting the ability to draw evidence-based conclusions related to surgical quality and outcomes. To address this gap, tools like ClassIntra have been introduced to promote consistent data collection and classification of iAEs. Implementing such a system is essential for improving transparency, benchmarking surgical performance, and ultimately enhancing patient safety.

**An overview of ClassIntra:** Introduced in 2020,[3,13] ClassIntra is a standardised system for grading iAEs based on severity and the interventions required to address them (Table 2). It was developed as an extension of the earlier Classic system,[6] which originally had four grades. The addition of a fifth grade in ClassIntra aligns it with the widely adopted CDC[9] for postoperative complications, ensuring consistency in reporting across the surgical timeline.

The system addresses a critical gap in iAE reporting by providing clear and objective criteria for grading deviations during surgery.[13] ClassIntra's development marks a significant step forward in surgical quality control, offering a systematic approach to identifying, documenting and evaluating iAEs. By addressing both severity and necessary interventions, the system allows for better comparison across studies and helps identify areas for improvement in surgical practice.

**Application of ClassIntra in GI cancer surgeries:** Although ClassIntra has shown promise in various surgical disciplines, its application in surgical oncology remains limited. Only a few studies have validated its use in predicting iAEs and postoperative complications, with higher ClassIntra grades linked to increased complication rates, longer LOS, and poorer survival outcomes. To provide a clearer overview, key findings from recent research on the use of ClassIntra in GI cancer surgeries carry a lot of value (Table 3).

Additionally, Krielen et al.[31] validated ClassIntra in elective abdominal surgery patients, showing near-perfect inter-rater agreement for grading iAEs. The study further highlighted that higher ClassIntra grades were directly associated with a higher incidence of postoperative complications, emphasising its predictive value. These findings reinforce the potential of ClassIntra as a tool for surgical quality control and patient outcome prediction, particularly in GI cancer surgeries, and underscore the system's potential to improve the management of GI cancer surgeries by accurately identifying intraoperative complications, allowing for better monitoring, adjustment of surgical strategies, and anticipation of postoperative challenges.

**Comparison with other classification systems:** Several studies have compared ClassIntra with other intraoperative adverse event classification systems, highlighting its comprehensive approach and superior reliability. L. Gravia et al. conducted a comparative analysis of various systems for reporting iAEs in abdominal surgeries, and found that ClassIntra was the most comprehensive and consistent tool for classifying iAEs, offering a more uniform reporting structure compared to the other systems.[32] This makes ClassIntra particularly beneficial in a variety of surgical contexts, including complex GI and oncological surgeries.

**Strengths and limitations:** ClassIntra is a comprehensive and patient-centred system for reporting iAEs in GI cancer surgery, capturing both surgery and anaesthesia-related

**Table-3:** Application of ClassIntra in gastrointestinal (GI) cancer surgeries.

| Study Details | Gastrointestinal cancer | IAE according to grades | Main outcomes | Oncological outcomes |
|---|---|---|---|---|
| Kinaci et al.[30]2016 n=58 | The study included patients undergoing hepatobiliary and pancreatic surgeries of which 81.03% were oncological procedures | 31% patients had an iAE<br>Grade I= 12 (21%)<br>Grade II= 4 (7%)<br>Grade III= 2 (3%)<br>Grade IV= 0 | Higher grade of iAEs was significantly related to higher grade of postoperative complications<br>Common iAEs: hepatic parenchymal bleeding (Pringle manoeuvre), right hepatic artery transection, haemorrhage requiring vascular repair. | Not specified |
| Dell Kuster et al.[13]2020 n=2530 | 18% patients underwent major plus procedures including right and left hemicolectomies and distal pancreatectomy<br>26% patients underwent complex major procedures including whipple pancreatoduodenectomy, hepatectomy, two stage esophagectomy, anterior resection and abdominoperineal resection | 26.92% patients who underwent major plus procedures had an iAE while 33.49% had iAE in complex major<br>Grade I= 198 (25%)<br>Grade II= 417 (54%)<br>Grade III= 142 (18%)<br>Grade IV= 21 (3%)<br>Grade V= 0 | Higher ClassIntra grades linked to increased postoperative complications, longer surgeries (+16% per grade), and longer hospital stays (+6.1% per grade).<br>iAE risk increased with surgical complexity (major procedures: OR 1.20, 95%CI:0.74-1.94; complex procedures: OR 1.27, 95%CI: 0.79-2.04). | Risk of iAEs significantly increased with complex procedures but oncological outcomes were not specifically addressed. |
| Zhi-Yu Liu et al.[4]2023 n=528 | Patients undergoing laparoscopic radical gastrectomy for gastric cancer | 19.9% patients had an iAE<br>Grade I= 28 (26.7%)<br>Grade II= 57 (54.3%)<br>Grade III= 17 (16.2%)<br>Grade IV= 3 (2.9%)<br>Grade V= 0 | iAE group: significantly longer surgeries, hospital stays, higher blood loss, delayed liquid diet, and increased postoperative complications ($p<0.001$).<br>- Independent risk factors: age ≥65, BMI ≥25, total gastrectomy, and pTNM stages II-III. | - Worse OS, DFS, and RFS for iAE group ($p<0.001$).<br>- Higher ClassIntra grades (≥II) significantly correlated with worse prognosis. |
| Zhi-Yu Liu et al.[15]2024 n=366 | Patients undergoing robotic radical gastrectomy for gastric cancer | 19.7% patients had an intraoperative adverse event<br>Grade I= 17 (23.6)<br>Grade II= 39 (54.2)<br>Grade III=14 (19.4)<br>Grade IV= 2 (2.8)<br>Grade V= 0 | iAE group: significantly worse surgical outcomes, including longer operative time ($p=0.001$), higher blood loss ($p=0.009$), delayed liquid diet ($p=0.042$), longer hospital stays ($p=0.022$), and higher unplanned readmissions ($p=0.015$).<br>- Lower textbook outcome achievement ($p=0.001$).<br>Independent risk factors: BMI ≥28 and clinical N+. | ClassIntra grade ≥II: worse OS and DFS.<br>- iAE group: fewer total lymph nodes retrieved and higher number of metastatic nodes |

Abbreviations: n=number of patients; IAE: Intraoperative adverse event; OR: Odds Ratio; IC: Confidence Interval; OS: Overall survival; DFS: Disease-free survival; RFS: Recurrence-free survival; BMI: Body mass index.

complications. It is aligned with CDC[9], facilitating cross-centre comparisons and aiding quality improvement efforts.[12] The system is practical and easy to use, with strong inter-rater reliability across diverse specialties, including GI cancer surgery[3-4,13,15] However, its effectiveness may be limited owing to interpretation variability, underreporting, and cultural differences in surgical teams. Additionally, the system focusses on events occurring before hospital discharge, potentially missing later complications, and independent reporting can be challenging in clinical settings.[3,13] Despite these limitations, ClassIntra remains a valuable tool for improving surgical safety and outcomes in GI cancer surgeries.[3,13,32]

**Future directions:** The future of iAE reporting in GI

cancer surgeries lies in the continued refinement and adoption of standardised systems that improve accuracy, consistency and global applicability. As surgical techniques evolve, including the rise of robotic and minimally invasive approaches, iAE reporting systems will need to adapt to capture new types of complications. Additionally, integrating advanced technologies, such as real-time intraoperative monitoring and predictive tools driven by artificial intelligence (AI), can enhance the ability to anticipate and mitigate iAEs, further improving patient outcomes. A collaborative effort across institutions, with ongoing validation and feedback, will be essential in ensuring that iAE reporting becomes a routine part of surgical practice, contributing to safer and more effective GI cancer surgeries.

## Conclusion

In conclusion, intraoperative adverse event reporting is a critical component in enhancing the safety and quality of gastrointestinal cancer surgeries. By systematically identifying and classifying iAEs, healthcare providers can better understand the complexities of surgical complications and implement strategies to reduce their occurrence in future procedures. While systems like ClassIntra provide a structured approach to reporting, the overall goal remains the improvement of surgical outcomes through accurate, comprehensive, and standardized adverse event documentation. Continued efforts to standardize reporting, integrating technological advancements, and foster a culture of transparency will play a pivotal role in optimizing patient care in gastrointestinal oncology surgeries.

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