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SCIENTIFIC REVIEW

Adverse Events in the Operating Room: Definitions, Prevalence, and Characteristics. A Systematic Review

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Abstract

Background Adverse events occur commonly in the operating room (OR) and often contribute to morbidity, mortality, and increased healthcare spending. Validated frameworks to measure and report postoperative outcomes have long existed to facilitate exchanges of structured information pertaining to postoperative complication rates in order to improve patient safety. However, systematic evidence regarding measurement and reporting of intraoperative adverse events (iAE) is still lacking.

Methods We searched Ovid Medline, Embase, and Cochrane databases for articles published up to June 2016 that measured and reported iAE. We presented the terms and definitions used to describe iAE. We identified the types of reported iAE and summarized them into discrete categories. We reported frequencies of iAE by detection methods.

Results Of the 47 included studies, 30 were cross-sectional, 14 were case-series, and 3 were cohort studies. The studies used 16 different terms and 22 unique definitions to describe 74 types of iAE. Frequencies of iAE appeared to vary depending on the detection methods, with higher numbers reported when direct observation in the OR was used to detect iAE. Twenty studies assessed severity of iAE, which were mostly based on whether they resulted in postoperative outcomes.

Conclusions This study systematically reviewed the current evidence on prevalence and characteristics of iAE that were detected by direct observation, reviews of patient charts, administrative data and incident reports, and surveys and interviews of healthcare providers. Our findings suggest that direct observation method has the most potential to identify and characterize iAE in detail.

Introduction

Adverse events occur not uncommonly among hospitalized patients [1–3] and can lead to significant morbidity [4, 5], mortality [1, 6], and increased healthcare expenditure

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[7, 8]. Several studies demonstrated that a large number of adverse events take place in the operating room (OR) [5, 9]. Further, about half of these events were deemed preventable [4, 6]. Thus, significant improvement in patient safety may be achieved by better understanding the patterns, nature, risks, and effects of intraoperative adverse events (iAE).

Frameworks to measure postoperative outcomes, such as the one developed by Clavien and colleagues [10], have been validated and adopted by several surgical communities. They provide the uniform language for clinicians and healthcare researchers to discuss the prevalence and characteristics of postoperative outcomes. Such exchange of structured information provides insights into how to reduce rates of postoperative complications and allow developments of educational and quality initiatives. On the other hand, although the need to systematically identify and characterize iAE has been advocated in the past, it has rarely been done [11]. This knowledge gap on iAE may be due to several factors. Several terms were used in place of iAE in the literature, and various methods were utilized to detect them, including patient charts, self-reported incident reports, and direct field observations in the OR. The heterogeneous nature of reporting in the literature has hindered any attempt to systematically synthesize evidence on the characteristics and incidence rates of iAE.

This systematic review summarizes published data on iAE in adult and pediatric patients undergoing elective or emergent surgery. The objectives of the present study are to (1) present the terms used in the literature to describe iAE, as well as their definitions, (2) identify types of reported iAE and summarize them into discrete categories, and (3) describe reported frequencies and severity assessments of iAE.

Materials and methods

We performed a systematic review according to the guidelines outlined in the Cochrane Collaboration handbook [12] and reported the findings following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statements [13]. Research ethics approval and informed consent were not required.

Data sources and search strategy

Ovid Medline, Embase, and Cochrane Central Register of Controlled Trials were searched from inception to June 2016. We used database-specific combinations of key index terms and text words related to medical errors, iatrogenic disease, patient harm, never event, and near miss, and combined these with terms related to surgical procedures and operating rooms, and terms related to risk management and reporting. We limited our search to studies reported in English. Detailed search strategies for each database are presented in Supplemental text. In addition, references of the included studies were manually searched for eligibility. EndNote X7 (Reuters, New York) was used to organize references.

Inclusion and exclusion criteria

We included original research studies that reported iAE from elective or non-elective operations on adult or pediatric populations in academic or non-academic and urban or rural hospitals around the world. Specifically, we included studies that reported types and incidence rates of iAE. We included randomized/quasi-randomized trials and cohort, case–control, cross-sectional, and case-series studies. We excluded abstracts, dissertation/thesis work, unpublished reports or data, reviews, commentaries, protocols, and letters to editors. Additionally, we excluded studies that took place in endoscopy or procedure rooms.

Study selection and data extraction

Two reviewers evaluated the titles and abstracts of all eligible articles and created a subset for full-text review. The same two reviewers independently applied the inclusion and exclusion criteria in the full-text review to select studies for data abstraction. A data abstraction form was created based on the protocol using Excel sheet (Microsoft, WA). It was pilot-tested on five studies for feasibility and acceptability by both reviewers. Then, the two reviewers independently abstracted data. When disagreement in selection or data abstraction occurred, it was resolved through discussions or by a third reviewer if no consensus was reached. We did not contact study authors to obtain additional data.

Assessment of bias

We used the National Institute of Health (NIH) Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies to assess the quality of studies included in the review [14]. We used four items in the tool that specifically assessed internal validity of the included studies (Table S1, supplemental material). Two items assessed risk of sampling bias, and the other two items assessed risk of measurement bias. All items were rated as yes, no, cannot determine, not reported, or not applicable. The overall quality rating per included study was provided. A rating of "good" was given if all four items were rated as yes. A rating of "poor" was assigned for studies that contained more than 3 items rated as no or not reported.

The rest of the combinations of item ratings were given "fair" overall assessment. Two authors independently performed assessments of bias. Differences in the assessments were discussed, and consensus was reached.

Data synthesis

The primary objectives of the present review study were to characterize iAE and to assess frequencies of their occurrences. First, several terms were used in place of iAE in the literature. We summarized these terms and their respective definitions. Second, we presented the types of iAE that were reported in the included studies. Further, we summarized the iAE types into seven discrete categories. Third, we attempted to estimate frequency of iAE occurrences; however, a statistical meta-analysis was not possible due to the wide heterogeneity in patient samples, procedure types, data sources, and outcome definitions and measurement techniques. Therefore, we performed descriptive synthesis of the reported frequencies from individual studies that were deemed to have fair to good methodological quality. We presented these findings by the methods used to detect iAE. Specifically, the detection methods of iAE included direct observation (i.e., human observers in the OR), patient charts, administrative data, incident reports, and surveys. Additionally, we summarized the studies that measured severity of iAE and reported corrective processes taken to rectify the events.

Results

We identified 3346 articles through database search and additional 16 titles by hand for a total of 3362 articles. After 340 duplicates were removed, 3022 titles and abstracts were screened and 2691 articles were excluded as they did not fit our inclusion criteria. We reviewed the full texts of the remaining 331 articles and excluded 284 of them. Thus, 47 articles were included in the final cohort. A flowchart of study selection process is illustrated in Fig. 1.

Study characteristics

Table 1 demonstrates characteristics of the 47 included studies. The studies were published in years 1999 to 2016 with a steady increase in the number of publications per year with time (Figure S1, supplemental material). Nine surgical specialties were represented, and neurosurgery had the most number of included studies (17%). All included articles were observational studies. Thirty articles were cross-sectional (64%), 3 were cohort (6%), and 14 were case-series studies (30%). Various data sources were used to identify iAE. Thirteen studies (28%) examined incident reports, 8 studies (17%) administered surveys to healthcare providers, and 5 studies (11%) used patient charts. Eight studies (17%) deployed human observers in the clinical settings to identify iAE. The methodological quality assessment of the included studies is presented in Table S1 (supplemental material). Eight of 47 studies [15–22] were deemed to be of poor methodological quality. Ten studies [6, 23–31] were deemed to have good methodological quality, and the rest were rated as fair.

Definitions and types of intraoperative adverse events

Several terms were used to describe iAE as demonstrated in Table 1. Nine of 47 studies (19%) [21, 32–39] identified wrong-site or wrong-patient operations specifically. The rest of the studies (81%) reported various types of iAE and adopted sixteen different terms to describe them. Adverse events (30%) was the most frequently used term, followed by error (11%) [22, 40–43] and incident (6%) [25, 44, 45]. Twenty-four studies explicitly stated definitions of the terms used to describe intraoperative events. Two [42, 46] of them used the same definitions as other studies, leaving 22 unique definitions. While several definitions were found, there was a pattern of recurrent concepts. Nine definitions [31, 43, 45, 47–52] included the notion that an iAE was unintended or unanticipated. Eight definitions [6, 27, 31, 48, 50–53] stated that an iAE was caused by medical teams and was not due to patients' underlying conditions. Further, an iAE resulted in increased potential harm in 7 definitions [20, 45, 47, 49, 54–56] and in actual physical harm in 13 definitions [6, 16, 27, 45, 48–53, 55–57]. The included studies characterized a total of 74 unique iAE types as demonstrated in Table S2 (supplemental material). Equipment (identified in 13 studies), communication (12), wrong site/wrong patient surgery (12), diagnosis (11), tissue injury (11), technical (10), and medication (9) were the iAE types most frequently identified in the studies.

Frequency of intraoperative adverse events by detection method

Five studies [23, 29, 47, 58, 59] used direct observation in the OR by human observers during surgical procedures to identify iAE (Table 2). Two studies [47, 58] reported major and minor events in pediatric cardiac surgery. Catchpole et al. [58] reported 7 major events and 366 minor events in a sample of 24 patients and Barach et al. [47] found 90 major events and 991 minor events in a sample of 102 patients. Another study [59] reported a mean of 10 minor problems and a mean of 6 operating problems per case in 24 pediatric cardiac operations and means of 13

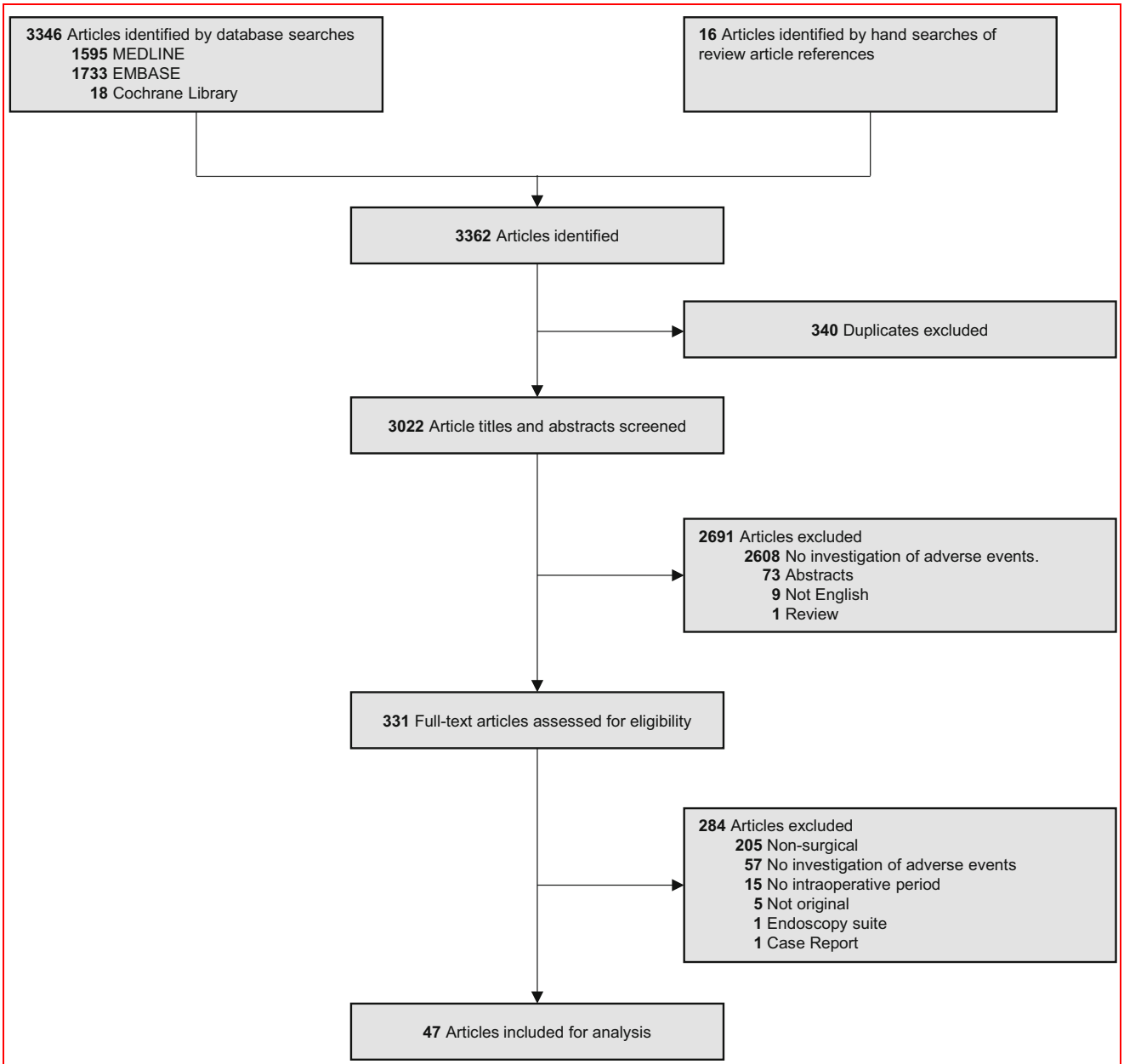

Fig. 1 PRISMA flow diagram

minor and 5 operating problems per case in 18 adult orthopedic procedures. Two studies [23, 29] observed consecutive adult complex arterial surgical cases. Albayati et al. [23] observed 66 cases during a 9-month period and identified 1145 failures. Mason et al. [29] developed a structured tool based on the work by Albayati et al. to identify 256 intraoperative error events in 21 consecutive cases.

Three studies reported frequency of iAE by reviewing patient charts [28, 50] or administrative data [36] (Table 2). Kaafarani et al. [28] identified 181 patients with at least one iAE out of 9292 patients who underwent general surgery procedures by reviewing the validated and risk-adjusted database based on patient charts. Proctor et al. [50] performed a chart review of 64 pediatric general surgery patients and found 18 intraoperative errors, five of which led to adverse outcomes. The Veteran Health Administration (VHA) database of more than 2 million surgical procedures performed in the USA during 54 months was assessed to identify 108 intraoperative wrong site or wrong patient operations [36].

Table 1 Characteristics of the included studies

Author	Year	Geography	Surgery type	Study design	Detection method	IAE term	Definition of iAE	Rectification identified?
Albayati et al.	2011	Europe	Vascular	Cross-sectional	Direct observation	Failure	Error of execution and error of planning	No
Anderson et al.	2012	USA	Multiple	Case-series	M&M	Adverse event	None	No
Barach et al.	2008	USA	Cardiac	Cross-sectional	Direct observation	Adverse event	Unintended incidents in care that may result in adverse outcomes or may require additional care efforts to prevent adverse outcomes	Yes
Bilimoria et al.	2009	USA	Multiple	Cross-sectional	Incident reports	Adverse event	None	No
Catchpole et al.	2006	Europe	Cardiac	Case-series	Direct observation	Failure	None	No
Catchpole et al.	2007	Europe	Multiple	Case-series	Direct observation	Event	None	No
Christian et al.	2006	USA	General	Case-series	Direct observation	Safety-compromising event	Action or inaction that significantly increased the vulnerability of the system and had potential to lead to an adverse event	Yes
de Vries et al.	2011	Europe	Multiple	Case-series	Malpractice claims	Incident	None	No
Dea et al.	2014	Canada	Multiple	Cohort	Incident reports	Adverse event	None	No
Fabri and Zayas-Castro	2008	USA	Multiple	Cross-sectional	Incident reports	Error	None	No
Ferroli et al.	2012	Europe	Neuro	Case-series	Incident reports	Incident	None	No
Gawande et al.	1999	USA	Multiple	Cross-sectional	Patient charts	Adverse event	An injury caused by medical management (rather than the disease process) that resulted in a prolonged hospital stay, disability at discharge, or death	No
Gawande et al.	2003	USA	Multiple	Case-series	Interview	Adverse event	An injury involving disability (temporary or permanent) or death that resulted from medical management, as opposed to disease.	No
Griffin and Classen	2008	USA	Multiple	Cross-sectional	Patient charts	Adverse event	Unintended physical injury from medical care	No
Heideveld-Chevalking et al.	2014	Europe	Multiple	Case-series	Incident reports	Adverse event	Any unintended or unexpected event which could have led or did lead to harm of one or more patients receiving hospital care	No

Table 1 continued

Author	Year	Geography	Surgery type	Study design	Detection method	IAE term	Definition of iAE	Rectification identified?
Houkin et al.	2009	Asia	Neuro	Cross-sectional	M&M	Adverse event	1) Resulted in a greater length of hospital stay than expected; 2) required additional treatment to be performed; 3) resulted in deficits or deterioration (transient or permanent) in patients that appeared after the procedure, even if these were inevitable because of the original disease	No
James et al.	2012	USA	Ortho	Cross-sectional	Incident reports	Wrong-site surgery	None	No
Jhawar et al.	2007	Canada	Neuro	Cross-sectional	Survey	Wrong-sided, wrong-level spine surgery	Craniotomy = "cut skin on the wrong side" wrong spine = "removed disk at the wrong level"	No
Kaafarani et al.	2014	USA	General	Cohort	Patient charts	Adverse event	None	Yes
Kantelhardt et al.	2011	Europe	Neuro	Case-series	Incident reports	Critical incident	None	No
Mandal et al.	2005	Europe	Ophthal	Case-series	Direct observation	Adverse healthcare event	An event or omission during clinical care causing physical or psychological injury to a patient	No
Mason et al.	2013	Europe	Vascular	Cross-sectional	Direct observation	Event	Events in which a sequence of actions initially failed to achieve their intended outcome	No
Mattioli et al.	2012	Europe	Multiple	Case-series	Incident reports	Adverse event	Any action or omission that affected or could have affected safety of the patient	No
McElroy et al.	2014	USA	Transplant	Cross-sectional	Debrief	Patient safety issues	Harmful incident that results in harm to a patient, resulting from a medical intervention and not due to the underlying condition of the patient	No
McElroy et al.	2016	USA	Transplant	Cross-sectional	Debrief	Patient safety issues	Same as McElroy et al. (2014)	No
Meinberg and Stern	2003	USA	Ortho	Cross-sectional	Survey	Wrong-site surgery	None	No
Michalak et al.	2016	USA	Neuro	Cross-sectional	Debrief	Error	Any deviation from an optimal course	No
Mody et al.	2008	USA	Neuro	Cross-sectional	Survey	Wrong-level/part surgery	A surgical procedure that is performed at the wrong level or part of the operative field	No

Table 1 continued

Author	Year	Geography	Surgery type	Study design	Detection method	IAE term	Definition of iAE	Rectification identified?
Neily et al.	2011	USA	Multiple	Case-series	Administrative data	Wrong site, wrong patient surgery	None	No
Panesar et al.	2012	Europe	Multiple	Cross-sectional	Incident reports	Incident	Unintended or unexpected incident that could have or did lead to harm for one or more patients receiving care	No
Papaspyros et al.	2010	Europe	Cardiac	Cross-sectional	Debrief	Problem	None	No
Pollock and Hayward	2001	Europe	Neuro	Cohort	Patient charts	Adverse operative event	Perioperative complication occurring within 36 h of the operation	Yes
Proctor et al.	2003	Canada	General	Cross-sectional	Patient charts	Adverse event	Unintended substantial harm to a patient resulting from medical treatment and not directly attributable to the patient's underlying disease.	No
Shah et al.	2004	USA	ENT	Cross-sectional	Survey	Error	Anything that has happened anywhere in your practice that was not anticipated, should not have happened and makes you say I don't want this to happen again	No
Shah et al.	2010	USA	ENT	Cross-sectional	Survey	Wrong-site surgery	None	No
Shah et al.	2014	USA	ENT	Cross-sectional	Survey	Error	Same as Shah et al. (2004)	No
Shen et al.	2013	USA	Ophthal	Cross-sectional	Survey	Wrong site, wrong procedure	Operating on the wrong eye or muscle or performing the wrong procedure	No
Simon et al.	2013	USA	Ophthal	Case-series	Incident reports, malpractice claims	Surgical confusion	None	No
Singh et al.	2003	Europe	Urology	Cross-sectional	Direct observation	Near miss	Any event that could have led to harm	No
Stahel et al.	2010	USA	Multiple	Cross-sectional	Incident reports	Wrong site, wrong patient surgery	None	No
Steeples et al.	2016	Europe	Ophthal	Case-series	Administrative data	Wrong intraocular lens event	None	No
Street et al.	2012	Canada	Neuro	Cross-sectional	Incident reports	Adverse event	None	No

Table 1 continued

Author	Year	Geography	Surgery type	Study design	Detection method	IAE term	Definition of iAE	Rectification identified?
Thiels et al.	2015	USA	Multiple	Cross-sectional	Incident reports	Never event	Any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness.	No
Ugur et al.	2016	Europe	Multiple	Cross-sectional	Survey	Error	None	No
Unbeck et al.	2008	Europe	Ortho	Cross-sectional	Patient charts	Adverse event	Untoward or unintended patient event caused by healthcare management	No
Wanzel et al.	2000	Canada	General	Cross-sectional	Patient charts, direct observation, and interview	Complication	Unintended adverse outcome that occurred after medical management or a surgical procedure and not caused by the underlying disease and resulted in impaired health.	No
Zingg et al.	2008	Europe	Multiple	Cross-sectional	Incident reports	Critical incident	Any event that actually or potentially resulted in an adverse outcome for the patient	No

iAE intraoperative adverse events, *M&M* mortality and morbidity round, *Neuro* neurosurgery, *Ortho* orthopedic surgery, *Opthal* ophthalmology, *ENT* ear, nose, and throat

Seven studies [24, 26, 30, 32, 39, 45, 51] identified iAE through reviews of incident reports (Table 2). Of these, two studies [26, 30] utilized a tool dedicated to prospectively report adverse events in spine surgery called the Spine AdVerse Events Severity system, version 2 (SAVES V2). Street et al. [30] found 113 intraoperative events in 942 patients admitted to a referral spine center during 12 months. In the same center, Dea et al. [26] also used SAVES V2 to identify 32 patients with at least one intraoperative event out of 101 patients who underwent emergency operations with a diagnosis of metastatic oncologic spine disease during 48 months. Another incident reporting tool called the Northwestern Online Surgical Quality Improvement (NOSQI) system was used to allow healthcare providers to disclose intraoperative events [24]. The authors reported 957 adverse events from 15,524 operations, and 43 events were detected in the intraoperative phase out of the 340 events in which timing of the occurrence was known. Further, four studies reported low frequencies of wrong site surgery [32, 39], intraoperative death [45], and never events [51].

Seven studies [33–35, 37, 38, 42, 43] administered surveys to healthcare providers to identify iAE. Of these, five studies reported proportions of the surveyed surgeons who had any wrong-site or wrong-patient operations in neurologic [33, 35], hand [34], head and neck [37], and eye [38] surgery. Nine to fifty percent of the respondents admitted to having performed at least one wrong-site or wrong-patient operation in their careers. In the two other studies, surveys to identify iAE that occurred within the last 6 months of practice were administered to Head and Neck physicians in years 2003 [43] and 2012 [42]. These studies reported 91 and 101 iAE from 466 to 681 respondents, respectively.

Severity of intraoperative adverse events

Twenty studies rated iAE by their severity (Table 3). In 18 studies, the severity was classified based on patients'

Table 2 Frequency of iAE by data source types

Author	Year	Data source	Duration	Consecutive sample	Sample size	Number of events
Albayati et al.	2011	Direct observation	9 months	Yes	66 patients	1145 failures
Barach et al.	2008	Direct observation	17 months	No	102 patients	90 major events and 991 minor events during intraoperative phase
Catchpole et al.	2006	Direct observation	10 months	No	24 patients	7 major failures, 366 minor failures
Catchpole et al.	2007	Direct observation	NR	No	42 patients	8 major problems (total); mean 10 minor problems (cardiac); mean 13 minor (ortho); mean 6 operating problems (cardiac); mean 5 operating (ortho)
Mason et al.	2013	Direct observation	1 month	Yes	21 patients	256 intraoperative error events
Kaafarani et al.	2014	Patient charts	70 months	Yes	9292 patients	181 patients had at least one intraoperative event
Proctor et al.	2003	Patient charts	1 month	Yes	64 patients	43 patients had 18 intraoperative errors and 5 errors led to adverse outcome
Neily et al.	2011	Administrative data	54 months	Yes	2,028,233 cases	108 wrong site, wrong patient surgery in the OR
Bilimoria et al.	2009	Incident reports	24 months	Yes	15,524 cases	43 of 340 complications are intraoperative (timing available for only 340/957 complications)
Dea et al.	2014	Incident reports	48 months	Yes	101 patients	32 patients (32%) had at least one intraoperative event
James et al.	2012	Incident reports	144 months	No	1,291,396 cases	61 surgeons performed 76 wrong site surgery
Panesar et al.	2012	Incident reports	60 months	Yes	NR	28 deaths during intraoperative phase out of 191 incidents of death
Stahel et al.	2010	Incident reports	78 months	Yes	27,370 cases	132 wrong site or wrong patient procedures
Street et al.	2012	Incident reports	12 months	Yes	942 patients	113 intraoperative events
Thiels et al.	2015	Incident reports	60 months	Yes	>1.5 million cases	40 never events in OR
Jhawar et al.	2007	Survey	NA	NA	126 surgeons	25% of surgeons had at least one incorrect site surgery in career
Meinberg and Stern	2003	Survey	NA	NA	1050 surgeons	217 surgeons (21%) had at least one wrong site surgery in career
Mody et al.	2008	Survey	NA	NA	415 surgeons	207 surgeons (50%) had at least one wrong site event in career
Shah et al.	2004	Survey	NA	NA	466 physicians	91 errors in intraoperative phase
Shah et al.	2010	Survey	NA	NA	455 physicians	42 physicians (9%) had or heard of at least one wrong site surgery in career
Shah et al.	2014	Survey	NA	NA	681 physicians	101 errors in intraoperative phase
Shen et al.	2013	Survey	NA	NA	517 surgeons	173 surgeons (33%) reported at least one wrong site/patient surgery in career
Gawande et al.	2003	Interview	5 months	NA	38 surgeons	96 incidents occurred due to intraoperative management
Michalak et al.	2016	Debrief	NR	CD	31 cases	66 intraoperative errors

iAE intraoperative adverse events, *NR* not reported, *NA* not applicable, *CD* cannot determine

Table 3 Severity of intraoperative adverse event classifications

Study	Basis of severity classification	Severity of iAE classification
Albayati et al.	Clinical outcome, disruption	Danger and delay score: 0—insignificant effect on procedure or patient safety; 3—moderate effect; 5—severe effect
Barach et al.	Clinical outcome	Major and minor. Major—may have serious consequences; minor—not expected to cause serious consequences
Bilimoria et al.	Clinical outcome, postoperative intervention	Not life-threatening noninvasive treatment; potentially life-threatening noninvasive treatment; invasive treatment; permanent disability; death
Catchpole et al. (2006)	Clinical outcome, disruption, postoperative intervention	Major—events that came close to an incident or accident; minor—judged to have had small negative effects on the duration or difficulty of the operation, the risk to the patient or the demand for resources.
Catchpole et al. (2007)	Clinical outcome, disruption	Major—potentially dangerous; minor—seemingly inconsequential; operating—disruptive but not dangerous
Ferroli et al.	Clinical outcome	Outcome: 0—none; 1—low; 2—medium; 3—significant; 4—high and duration: 0—none; 1—quick recovery; 2—recovery at the end of operation; 3—recovery within post-op day 1; 4—late or no recovery
Gawande et al.	Clinical outcome	Temporary disability; permanent disability; death
Griffin and Classen	Clinical outcome, postoperative intervention	Temporary harm and required intervention; temporary harm and required initial or prolonged hospitalization; permanent harm; intervention required to sustain life; death
Heideveld-Chevalking et al.	Clinical outcome, probability of occurrence	Probability: almost inevitable; probable; possible; small; very small, consequence: catastrophe; very serious; serious; marginally serious; none
Kaafarani et al.	Intraoperative intervention	1—injury requiring no repair; 2—Injury requiring surgical repair, without organ removal or change in original procedure; 3—injury requiring tissue or organ removal with completion of the planned procedure; 4—injury requiring a significant change and or incompletion of the planned procedure; 5—missed injury requiring reoperation in 7 days; 6—intraoperative death
Mason et al.	Disruption	0—insignificant impact on flow or required no resolution; 3—moderate impact; 5—severe impact, almost impossible to resolve
Neily et al.	Clinical outcome, probability of occurrence	Harm: catastrophic to minor and probability: frequent to remote combined for a score from 1—lowest priority to 3—highest priority
Shah et al. (2004, 2010, 2014)	Clinical outcome, postoperative intervention	No error; no harm; temporary harm and required intervention; temporary harm and required initial/prolonged hospitalization; permanent harm; required intervention to sustain life; death
Simon et al.	Clinical outcome	Temporary or insignificant; temporary or minor; mild but permanent; severe permanent
Stahel et al.	Clinical outcome	No harm; minimal harm; significant harm; death; equivocal/undetermined
Steeples et al.	Clinical outcome	Severe; moderate; low; no harm
Unbeck et al.	Clinical outcome	0—minor; 1—minor temporary; 2—minor permanent; 3—major temporary; 4—major permanent; 5—potential major or major contributing; 6—death
Wanzel et al.	Clinical outcome	Serious consequence; fatal or life-threatening consequence

iAE intraoperative adverse events

postoperative outcomes. It ranged from resulting in no harm to transient harm to permanent harm or death. In six studies [24, 37, 42, 43, 48, 58], the severity was categorized based on whether the patients required additional postoperative interventions including noninvasive and invasive treatments, as well as initial or prolonged hospitalization. In four studies [23, 29, 58, 59], the severity was classified by the degree of disruption in flow of operations caused by the iAE. Kaafarani et al. [28] determined the severity based on the level of intraoperative interventions required to rectify the iAE ranging from no intervention to intervention not requiring organ removal to intervention requiring tissue or organ removal and to missed injury.

Characteristics of intraoperative rectification of adverse events

Four studies [18, 28, 47, 54] characterized how iAE were rectified during the same procedure. In two studies [47, 54] where human observers were deployed in the OR, rectification processes were classified as cognitive, system, monitoring, collaboration/compromise, adaptation/

Table 4 Proposed framework of intraoperative adverse event types and their examples

Intraoperative adverse event type	Examples
Cognitive	Inappropriate/missed decision, judgment, planning, diagnosis, or treatment. Missed injuries, retained instruments/gauze, and wrong site or wrong patient operations
Behavioral	Communication or coordination failure, and team conflicts
Expertise and technical skills	Suboptimal expertise or technical/psychomotor skills and poor visualization during operations
Tissue injury	Bleeding, tissue tear, organ injury and inappropriate anastomosis
Equipment and medication	Absent or malfunctioning equipment such as cardiopulmonary bypass devices, mechanical ventilators, and implants. Wrong medications or blood products and adverse or allergic drug/transfusion reaction
Environmental and organizational	Distractions, workspace/ergonomic issues, fatigue, absence of team members, unnecessary delays, and transport issues
Patient-related	Events related to patient disease state and difficult operations due to patient anatomy or physiology

innovation, leadership/authority, verification, luck, and surgical technical types. Kaafarani et al. [28] categorized rectification processes by the invasiveness of surgical interventions needed in response to tissue injuries. Pollock and Hayward [18] characterized rectifications of events by providing brief descriptions, such as revision for blocked ventriculoperitoneal shunt and repair for dural laceration during lumbosacral discectomy.

Discussion

In this systematic review, we found that intraoperative adverse events were reported under various terms and definitions and by using different detection methods, including direct observation in the OR, patient charts, administrative data, incident reports, and surveys. Frequencies of iAE appeared to vary depending on the detection methods, with higher numbers reported when direct observations took place in the OR. Collectively, the included studies identified 74 types of iAE. When severity of iAE was measured, most studies stratified it based on the seriousness of postoperative outcomes or the invasiveness of additional interventions required. Corrective processes to rectify intraoperative events were rarely assessed.

Various terms and definitions have been used in the literature to describe iAE. The World Health Organization (WHO) adopted the definition of an adverse event as "an injury related to medical management, in contrast to a complication of disease," originally published in the Harvard medical practice study [2, 60]. The WHO also stated that other terms such as incidents, mishaps, unanticipated events, or accidents were sometimes used in place of adverse events. In our review, the included studies used various terms including problems, surgical confusion, patient safety issues, and errors to describe iAE. This variability in the chosen terms can hinder anyone wanting to synthesize evidence on and discuss with others about iAE. Errors, in particular, carry a distinct definition from adverse events. Errors are defined as "the failure of a planned action to be completed as intended or the use of wrong plan to achieve an aim" and may occur in the absence of adverse events [61]. However, in four of the five included studies that used the term errors, in fact, described iAE, such as tissue injuries and wrong site surgery [22, 41–43]. Based on our summary of the definitions used by several studies, we propose that an iAE to be defined as any unintended event caused by medical teams during surgical procedure and unrelated to patients' underlying conditions that led to potential or actual physical harm. Our review identified a total of 74 iAE types, several of which shared similarity and could be classified in the same broader category. Therefore, we summarized the iAE types to 7 categories based on similarity while achieving maximum mutual exclusivity possible between the categories. In our proposed framework, our iAE types included cognitive, behavioral, expertise/technical skill, tissue injury, equipment/medication, environmental/organizational, and patient-related events (Table 4).

Frequency of reported iAE varied widely depending on the detection method chosen. Due to the heterogeneous nature of included data, a statistical meta-analysis was not possible. However, some observations could readily be made. Direct observation method yielded a higher number of iAE than reviews of patient charts, incident reports, and surveys. Retrospective analysis using patient charts to recreate chain of adverse events is often done without first-hand knowledge of the situation and results in suboptimal data collection. Incident reports require consistent and complete inputs from healthcare providers, who often fail to comply due to time constraints and fear of punishment, litigation, and lessened reputation [62]. Survey studies are

often limited by respondents' recall bias and lack of detail in their input. In a highly complex system like the OR, a prospective direct observation is a more sensitive technique to detect iAE that either lead to or have potential to result in harm [63].

Assessment of iAE severity allows identification of the most pertinent events from a patient safety perspective. Most of the studies in our review measured severity based on patient outcomes or requirement for additional therapeutic interventions in the postoperative phase and this method has limitations. It is often unclear whether the postoperative outcomes can be attributed to the identified iAE. Instead, frameworks that measure severity based on the characteristics of iAE may be more elucidating. Kaafarani et al. [28] classified the iAE severity based on the level of intraoperative therapeutic treatments performed and demonstrated construct validity evidence by predicting 30-day postoperative morbidity. Similarly, a Delphi study from Rosenthal et al. [64] constructed an iAE severity classification tool based on the level of intraoperative therapeutic interventions required and postoperative outcomes. Both tools were designed to be applied when assessing iAE using patient charts. Using direct observation methods, more frequent identification and detailed characterization of iAE are possible. Therefore, a severity measurement tool that can be implemented in direct observation methods may help better understand the relationship between the severity of iAE and postoperative outcomes.

Our study has limitations. Our review relied mainly on search of articles in a wide range of academic journals indexed in major databases and may have missed evidence published in non-indexed journals and in the gray literature. Individual studies adopted various definitions of iAE using different detection methods, and thus, our review was restricted to a synthesis of the results as reported in these studies. Assessment of bias in the included studies was performed using a modified version of NIH Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies [14], a relatively new tool still awaiting full validation. However, the four items we chose from this tool to assess the quality of methodology represented key components of internal validity.

This study systematically reviewed the current evidence in prevalence and characteristics of iAE that were detected by direct observation, surveys and interviews of healthcare providers, and reviews of patient charts, incident reports, and administrative data. There is a lack of general agreement on how iAE should be measured and reported. Our findings suggest that direct observation method has the most potential to identify and characterize iAE in detail. Further, a framework to measure severity and corrective processes to rectify iAE needs to be developed and validated. Structured framework (Table S3) for reporting may facilitate discussions among clinicians and healthcare researchers to discover ways to prevent iAE from recurring and help foster more responsible attitudes and heightened awareness toward surgical safety.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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