ORIGINAL ARTICLE

Checklist for anesthesiological process: analysis of risks

A. M. GHIRARDINI, E. GUERRA, L. SERIO, M. GIRARDIS, A. PASETTO, S. BUSANI

Cattedra e Servizio di Anestesia e Rianimazione, Policlinico di Modena, Modena, Italia

ABSTRACT

Background. Several methods are reported in the literature to analyze medically undesirable events during hospital care. Each method has several limitations, so no one has been defined as the standard tool to be able to detect failure during a medical process. The aim of this study was to compare an anesthesiological perioperative checklist with traditional Regional Incident Reporting (RIR) form in detecting and describing failures.

Methods. We analyzed RIR number of reports, seriousness and contributing factors. We also analyzed anesthesiological checklist data for: number of reports, seriousness of incident, contributing factors and distribution in macro-phases.

Results. We screened 2681 patients who underwent gynecological and obstetrical surgeries. RIR showed only the most harmful events in 0.4% of surgeries. Conversely, we recorded 135 failures with anesthesiological checklists (3.3%), of which 123 (91.1%) were solved. Categories of incident in checklists were: failures for medical device/equipment (N.=30, 22.2%), for treatment/procedures (N.=25, 18.5%), for clinical assessment (N.=22, 16.2%), for consent/communication (N.=19, 14%), for medication (N.=16, 11.8%) and for documentation (N.=8, 5.9%). Ninety-four failures (69.6%) resulted in no harm for the patient, 41 (30.3%) in reversible damage and there were no cases of permanent damage/death. Contributing factors in checklists were mainly related to team (43.7%), task factors (28.1%) and work environment (22.2%). Failures detected in macro-phases were related to: clinical assessment (31.8%), presurgical re-assessment (23.7%), preparation for anesthesia (30.3%), anesthesia conduction (8.8%) and awakening (5.1%).

Conclusion. An anesthesiological checklist compared with traditional RIR provided a more sensible and complete framework for incident analysis during the perioperative period in patients undergoing gynecological and obstetrical surgeries. *(Minerva Anestesiol 2014;80:913-21)*

Key words: Risk management - Anesthesia - Patient care.

Patients' safety has become a major issue for clinicians and the analysis of risk in medicine is essential to increase the quality of patient care. An incident reporting system for anesthesia has been recommended to measure undesirable events. However, the use of incident reporting systems is under-utilized [1] and ranges from 4% to 85%.[2] Several methods to identify serious events (clinical record review, current data review, interviews, incident reporting and checklist) have been employed in clinical practice as stated by the Working Group of the World Health Organization (http://www.who.int/patientsafety/research/methods_measures/rapid_assessment_methods/en/index.html). Each method has its peculiar limitations and it is difficult to compare data obtained with different methods.

Medical incidents are usually measured per number/frequency of events and frequently described in three domains: categories of incident according to Catchpole *et al.*[3] gravity according to Failure Mode And Effect Analysis (FMEA) Scale [4] and contributing factors as defined by Vincent *et al.*[5] It is also important to frame the problem in the chronological phase of the process in which it occurs.[6] Even though these items

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are part of a defined framework for analysis of medical risk, no papers have been reported about voluntary reporting in anesthesiology, measuring frequency of incident and analyzing together the category of incident, the gravity and the contributing factors. Also there is no universally accepted definition of risks through the term "incident", "accident", "error", "mistake" or "event".

At the beginning of 2009 we tested a first draft of a perioperative checklist to promote incident reporting but we obtained poor data because items listed were scarce (presented in the 7th National Convention of Surgical Graduate School, 20-22 May 2010, Villach, Austria). We decided to implement our first draft with new items according to a checklist suggested for the intraoperative stage by the Italian Society of Anesthesiology and Intensive Care (http://www.siaarti.it/scientifica/pdf_img/checklist.pdf).

The aim of this study was to compare an anesthesiological perioperative checklist with the traditional Regional Incident Reporting (RIR) form, routinely used, in detecting and describing failures.

Materials and methods

Local Research Ethic Committee approval was obtained for the study. This study retrospectively analyzed the period between May 2010 and April 2011.

In that period, ward staff (nurses and doctors) and operating room team (surgeons, anesthesiologists and nurses) recorded, as usually, RIR forms. RIR was a form defined as Incident Reporting according to International standard forms. It was a non-specific form for anesthesia, through which all the operators of the wards and operating rooms could report any adverse events and near misses. It consisted of three parts: in the first part operators should provide information about the Unit and the place where the event happened; in the second part operators freely describe the incident, possibly contributing factors, factors that may have reduced the outcome and the need for additional therapies or diagnostic tests; in the third part the head of the Unit defined the severity and the possibility of future occurrence of the event. This instrument, thus completed, in anonymous form, was forwarded to the Regional Agency of Health Authority. We analyzed RIR number of reporting, seriousness and contributing factors as defined above.

In the same period, the checklist was used as a track to be followed by the anesthesiologist and completed if a failure was detected. Anesthesiologist used the checklist in two distinct phases. Phase 1 – upon arrival in the operating room (OR), the anesthesiologist checks the record prior to admission to the OR; and Phase 2 – the patient record from OR arrival until OR discharge. All patients were undergoing gynecologic/obstetric surgery.

Both RIR and checklists were filled in in real time and reviewed at a later date.

According to the organizational model,[5] a report made through a single checklist was defined as an incident, every area completed on the checklist was a failure and an incident could be made of multiple failures. Anesthesiologists reported all failures that happened in the patient's operative process using the checklist and failures solved were reported as well.

We analyzed the following data from the checklists: number of checklists filled, number of failures detected, number of failures solved; temporal distribution of checklist collected. We organized data in the 3 categories described for a system approach: number of failures in some of the categories of incidents according to Catchpole *et al.*[3] gravity of failures according to the FMEA scale [4] and contributing factors according to Vincent *et al.*[5] Severity of failures was defined as follows: level 1 failures (no harm) were considered "near misses", whereas adverse events were divided in two groups: reversible (level 2-7 failures) and permanent, from injury to death (level 8-10 failures).[7] All categories were calculated both for detected and solved failures.

Moreover, we made an analysis of failures in the macro-phases with the checklists of the whole perioperative process: clinical assessment (items related to anesthesia visit as outpatient), presurgical reassessment (items related to re-evaluation by the anesthesiologist the day before surgery), preparation for anesthesia (items related to environment, equipment and patient's check in OR), anesthesia conduction (items related to

TABLE I.—*Checklist adopted.*

Macrophase 1: Clinical assessment	Time and date	Item to check	Operator	Failure detected	Failure solved
Anesthesiological evaluation	__:__ __/__/__	Anesthesiological record		□	□
		Modification of pharmacological therapy		□	□
		Choice of anesthesia		□	□
		Information on pain therapy		□	□
		Informed consent (anesthesia\blood)		□	□
Macrophase 2: Presurgical assessment		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Surgery schedule	__:__ __/__/__	Surgery schedule validation		□	□
Information to\from the patient		Re-information to the patient		□	□
		DVT prophylaxis		□	□
		Check pharmacological therapy		□	□
		Increased LRA risk		□	□
Planning for transfusion		Ask for type and screen		□	□
		Ask for blood\plasma product		□	□
Premedication		Drug prescription		□	□
Macrophase 3: Preparation		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Preoperative check	__:__ __/__/__	**Surgical room and anesthesiological devices** Surgical room: asepsis, temperature		□	□
		Anesthesia devices availability		□	□
		Particular anesthesia devices availability			
		Emergency devices availability		□	□
		Defibrillator		□	□
		Ventilator		□	□
		Ambu bag		□	□
		Suction equipment		□	□
		Rotameters		□	□
		Vaporizer		□	□
		Oxygen cylinder		□	□
		Active warming devices		□	□
		Peculiar equipments for specific anesthesia		□	□
		Vital parameters monitoring systems		□	□
		General anesthesia trolley Anesthesia drugs availability		□	□
		Emergency drugs availability		□	□
		Fluids		□	□
		Tracheal intubation devices		□	□
		Difficult intubation devices		□	□
		Emergency devices		□	□
		Artery\vein catheters		□	□
		Naso-gastric tube		□	□
		Bladder catheter		□	□
		Loco-regional trolley Drugs for anesthesia		□	□
		Dermographic pencil		□	□
		Disinfection and protection equipment			
		Devices for epidural\subarachnoid anesthesia		□	□
		Peripheral nerve blockade devices		□	□
		Blood products availability		□	□
		ICU bed availability		□	□
Patient admission		ID and documentation		□	□
		Persistence of eligibility conditions		□	□
		Nursing: presence of dental prosthesis, nail vanish, jewels, make up, hygiene		□	□

TABLE I.—*Continues from previous page.*

Macrophase 3: Preparation		Item to check	Operator	Failure detected	Failure solved
Patient preparation		Positioning on surgical bed		□	□
		Artery\vein catheter positioning		□	□
		Bladder catheter positioning		□	□
		Monitoring of vital parameters		□	□
Pre-surgical prophylaxis		Antibiotic prophylaxis (short term)		□	□
		PONV prophylaxis		□	□
		Aspiration prophylaxis		□	□
		Stress ulcer prophylaxis		□	□
Macrophase 4a: General anesthesia		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Induction	__:__ __/__/__	Choice of induction technique\drugs		□	□
		Pre-oxygenation		□	□
		Neuromuscular blockade		□	□
Airways		Tracheal intubation (technique)		□	□
		Alternative devices for intubation use		□	□
		Difficult intubation		□	□
		Fixing		□	□
Connection to the machine		Check connection and working of ventilator		□	□
Maintenance of anesthesia		Choice of maintenance drugs		□	□
		Intraoperative monitoring (Neurological, RS, CVS, T°)		□	□
		Active warming		□	□
		Fluids administration		□	□
		Blood products transfusion		□	□
		Adjunctive drugs and procedures		□	□
		Malignant hyperthermia		□	□
		Confirm ICU bed		□	□
First anesthesia recovery		Start pain therapy		□	□
		Decurarization		□	□
		Awakening		□	□
		Extubation		□	□
		Surgical bed\hospital bed transfer		□	□
		Anesthesia record		□	□
Macrophase 4b: Loco-regional anesthesia		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Preparation to LRA	__:__ __/__/__	Choice of drug		□	□
		Choice of level\extension of blockade		□	□
Execution of anesthesia		Sterile preparation of trolley		□	□
		Skin disinfection and sterile field		□	□
		Loco-regional anesthesia execution		□	□
		Loco-regional anesthesia effectiveness		□	□
		Patient repositioning for surgery		□	□
Maintenance of anesthesia		Choice of maintenance drugs		□	□
		Intraoperative monitoring (Neurological, RS, CVS, T°)		□	□
		Treatment of complications		□	□
		Active warming		□	□
		Fluids administration		□	□
		Blood products transfusion		□	□
		Adjunctive drugs and procedures		□	□
		Malignant hyperthermia		□	□
		Confirm ICU bed		□	□

Table I.—*Continues from previous page.*

Macrophase 4b: Loco-regional anesthesia		Item to check	Operator	Failure detected	Failure solved
First anesthesia recovery		Start pain therapy		□	□
		Surgical bed\hospital bed transfer		□	□
		Anesthesia record		□	□
Macrophase 5: Awakening		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Recovery room	__:__ __/__/__	Active warming ongoing		□	□
		Pharmacological therapy ongoing		□	□
		Monitoring ongoing		□	□
		Emergency equipments and devices		□	□
		Emergency drugs		□	□
		Prevention and treatment of postoperative complications		□	□
Macrophase 6: Discharge		**Item to check**	**Operator**	**Failure detected**	**Failure solved**
Discharge from the operating room	__:__ __/__/__	Patient discharge and transfer plan		□	□
		Planning of post-operative pain therapy		□	□

Damage for the patient:

maneuvers during anesthesia), awakening (items related to the recovery room) and OR discharge (items related to transfer plan and postoperative pain management) (Table I). Distribution of the severity grades was also analyzed according to its distribution in macro-phases and months (Table I).

Anesthesiologists received a preliminary training on the checklist use in April 2010. In October 2010, December 2010 and February 2011 retraining meetings were performed.

To analyze the data, descriptive statistics were used reporting the observations as the number of observations (N.) and percentages (%).

Results

We analyzed 2681 gynecological and obstetrical surgical operations, the total number of operations carried out by our department of anesthesia in a year. RIR collected 12 reports (0.4% of 2681) with 27 failures. All failures were recorded among levels of gravity from 4 to 7. Contributing factors were: team (55.5%), task factors (29.6%), individual (7.4%) and patient (7.4%).

Ninety checklists reported incidents (3.3% of 2681) with 135 failures; of those 123 (91.1%) have been solved. All failures in the RIR were detected also using checklists. We recorded an average of 7.5 checklists completed per month. From July to September 34 checklists were completed (37.7% of the 90 checklists reporting incidents). There was an increase in reporting until August, a progressive drop in October, a smaller peak in November and then a progressive drop until February (Figure 1).

Failures detected and solved are shown in Table II. In terms of frequency, failures were categorized as to: medical device/equipment (N.=30, 22.2%), treatment/procedures (N.=25, 18.5%), clinical assessment (N.=22, 16.2%), consent/communication (N.=19, 14%), medication (N.=16, 11.8%) and documentation (N.=8, 5.9%). Some failures (11.1%) did not match with the categories described. It was more difficult to solve problems in consent/communication, treatment/procedures and in documentation.

Ninety-four failures (69.6%) were considered to be level 1 in severity; 41 failures (30.3%) in level 2-7 (with levels 4 and 5 being the most common), while no events were recorded in level 8-10 gravity. Contributing factors were more frequently related to team (N.=59, 43.7%), task factors (N.=38, 28.1%) and work environment (N.=30, 22.2%). Individual (N.=4, 2.9%) and

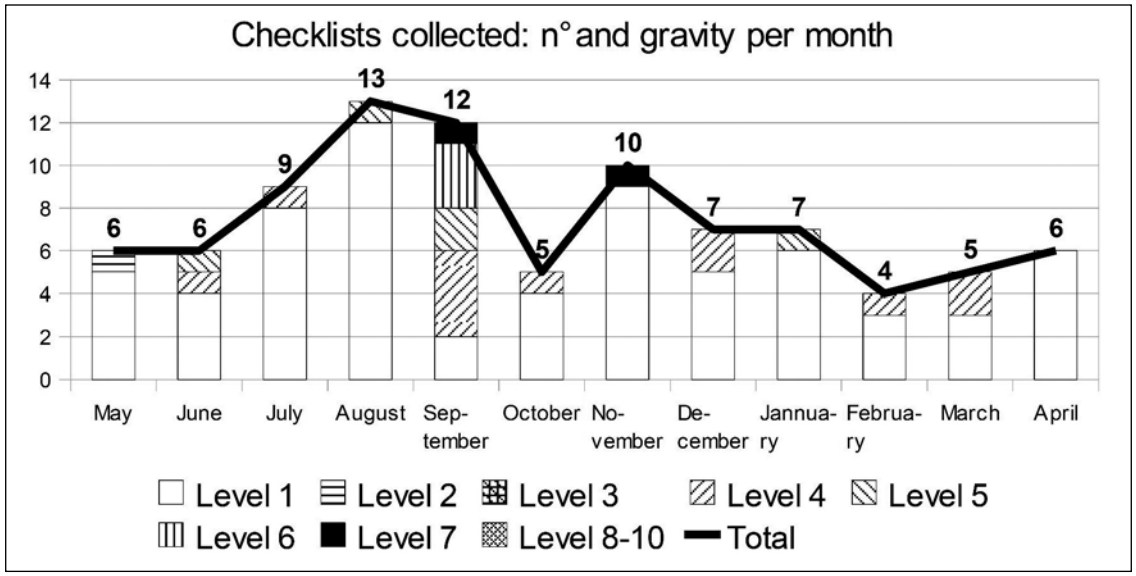

Figure 1.—Checklists collected: N. and gravity per month.

patient (N.=4, 2.9%) factors were less frequent. No report about institutional or management was found as a contributing factor (Table II).

Individual or patient factors, as defined by Vincent *et al.*[5] were the most common causes of failed resolutions (Table II).

Of the total of 135 failures, failures were detected in macro-phases: 43 for clinical assessment (31.8%), 32 for presurgical reassessment (23.7%), 41 for preparation to anesthesia (30.3%), 12 for anesthesia conduction (8.8%) and 7 for awakening (5.1%). No failures were recorded at OR discharge phase. The percentage of failures solved in the macro-phases was high for clinical assessment, presurgical reassessment, preparation for anesthesia and awakening. During the conduct of anesthesia only 66.6% of failures were solved and therefore the highest levels of harm were recorded.

In detail, the percentage of near misses/failures detected in macro-phases was higher in the clinical assessment (84.4%), presurgical reassessment (66.6%), preparation for anesthesia (67.5%) and awakening (85.7%). During anesthesia near misses were only 23% of failures while adverse events were at the higher percentage of 76.9% (all in levels 4-7). Gravity by months was variable (Figure 1), even though September had been more heterogeneous, showing 5 different levels of gravity, including 100% of failures in level 6 and 50% of level 7.

Discussion

The main finding of our retrospective analysis of the use of a checklist was that it was more sensitive than the standard RIR reporting for the detection of process failures. Moreover, there was better definition of the severity of failures and their remediation. Regional System of Incident Reporting achieved lower percentage of report (0.4% *vs.* 3.3%), and its system registered only adverse events (level 4-7) whilst the checklist gave a more complete map of failures: our data shows that RIR is less worthwhile than checklist in pointing out perioperative anesthesiological risk. Moreover, the checklist allowed us also to detect and calculate the percentage of solving for each failure.

Criticisms of the RIR in our view are as follows: it is not a specific tool for the reality of anesthesia and also in reporting the event a free text description may not always provide an accurate timing. As regards the checklist, the value of the identified failure would probably have been greater if the checklist had been used in a proactive manner and not only as a guide for identifying the events. Moreover, the checklist reflects

Table II.—*Comparison between failures detected and solved.*

Macrophases	Failures detected	Failures solved	Percentage (solved/ detected)
Clinical assessment	43	40	93.02%
Presurgical reassesment	32	29	90.62%
Preparation to anesthesia	41	39	95.12%
Anesthesia	12	8	66.67%
Awakening	7	7	100%
Discharge	0	0	0%
Total	135	123	91.11%
Categories of incident	**Failures detected**	**Failures solved**	**Percentage (solved/ detected)**
Clinical assessment	22	21	95.45%
Consent/communication	19	15	78.95%
Documentation	8	7	87.50%
Medical device/equipment	30	30	100%
Medication	16	15	93.75%
Treatment/procedures	25	21	84%
Others	15	14	93.33%
Total	135	123	91.11%
Gravity	**Failures detected**	**Failures solved**	**Percentage (solved/ detected)**
Level 1	94	92	97.87%
Level 2	1	1	100%
Level 3	0	0	0%
Level 4	21	21	100%
Level 5	12	6	50%
Level 6	3	3	100%
Level 7	4	0	0%
Level 8	0	0	0%
Level 9	0	0	0%
Level 10	0	0	0%
Total	135	123	91.11%
Near misses	94	92	97.87%
Levels 2-7	41	31	75.61%
Levels 8-10	0	0	0%
Contributing factors	**Failures detected**	**Failures solved**	**Percentage (solved/ detected)**
Institutional context	0	0	0%
Organisational	0	0	0%
Work environment	30	30	100%
Team factors	59	53	89.83%
Individual factors	4	1	25%
Task factors	38	36	94.74%
Patient characteristics	4	3	75%
Total	135	123	91.11%

the patient's medical record, if an event was not reported in the medical record it could not be clearly identified with the checklist. Both systems have the limitation of being voluntary.

It is difficult to compare results with other reports of the use of reporting instruments [8, 9] due to the lack of a common denominator (number and type of surgery) in most of them.

Categories of incident in Table II were useful to underline the specific causes of failure; catego-

ries represented more were medical device/equipment and treatment/procedures. This analysis resulted in a complete description of failures not limited to their timing, because our instrument covered the perioperative spectrum. Near misses were more common than adverse events and no events in level 8-10 or sentinel events (as defined by the Italian Ministry of Health - Protocollo per il monitoraggio degli eventi sentinella. Ministero della salute, Roma 2009) were reported. Therefore, our study outlined more near misses then adverse events: an adequate incident reporting system should point out "no harm" events also, because they are useful to show latent failures in the system.[6]

The absence of higher levels of adverse events in our study may be due to the number and the type of surgery scheduled (since number of death in anesthesia is likely to be 1:100,000-1:500,000).[10] The contributing factors confirmed that the most critical point of the perioperative anesthesiological assistance was the organization of teams and tasks. Individual or patient factors were not easily managed in spite of the use of the checklist.

Our study has identified that macro-phases before induction of anesthesia were the more critical, indeed many failures occurred in the days before surgery. Even though failures detected were more common in macro-phases before the induction (116/135), most harmful ones were intra-operative (76.9% of adverse events). The use of checklists had the advantage to gather information about the correct timing of risks during the perioperative process of the patient. The picture which emerged from this study warns the anesthesiologist about two different phases of the perioperative process: the preoperative phase to the high number of incidents that can happen and during surgery for their extreme gravity.

Temporal trend of incidents and their gravity suggested that months with high rotations of anesthesiologists due to holidays (July-September) were more critical and it was a high factor affecting the team performance, according to the fact that team function is the greatest contributor in failure. Other authors demonstrated that there is a strong correlation between team rotation and patient safety.[11] The rise in reports observed after the 2/3 retraining meetings (November and March) seemed to confirm that sharing the knowledge about safety measures enhances voluntary reporting. According to the World Health Organization guidelines checklists and incident reporting forms have to be used by a trained team.[12]

Conclusions

The introduction of the checklist allowed us to obtain a better framework for the analysis of risk in medical perioperative anesthesiological care in our Unit, compared to the RIR use. To best minimize negative outcomes, our results suggest that improvements should be made in what precedes and follows surgery and not only in the operating room.

Key messages

— Use of a checklist has proven to be more sensitive in identifying failures compared with traditional incident reporting form; it provided a better quantitative and qualitative description of the failures and identified the time frame of their occurrence in the perioperative period.

— Causes of failure represented more were medical device/equipment and treatment/procedures.

— Failures detected were more common in macro-phases before the induction of anesthesia, but the most harmful ones were intra-operative.

— Temporal trend of incidents and their gravity suggested that months with high rotation of anesthesiologists due to holidays (July-September) were more critical and it was a high factor affecting the team performance.

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Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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Corresponding author: A. M. Ghirardini, Policlinico di Modena, via Del Pozzo 71, Modena, Italia. E-mail: ghirap@hotmail.com