How to track and register adverse events and incidents related to gastrointestinal endoscopy

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Abstract

Background and study aims: **Gastrointestinal endoscopic procedures have evolved significantly in the last sixty years revolutionising the approach to the diagnostic and therapeutic spheres of medicine. Despite the advantages of using natural orifices to the bowel, adverse events (AE) may occur following endoscopy. Systematic AE registration is an objective in every realm of quality medicine. Despite the obvious advantage as a quality indicator, tracking endoscopy-related AE is not evident. The current study aimed at tracking all AE of all endoscopic procedures during a 3-month period. The three methods used were voluntary reporting by the endoscopist and by the patient in parallel with retrospective data analysis of patients' electronic medical records to allow capture of all AE and comparison of the three methods.**

Patients and methods: **During a 3-month period endoscopists and patients were requested to report any possible AE. At the end of the period, a systematic review of all patient files was performed to track all AE related to the endoscopic procedure or the endoscopy-related anaesthesia. In total 2668 endoscopic procedures were reviewed.**

Results: **The total AE rate was 1.95%. Only half (51.9%) of all AE were voluntarily reported by endoscopists, the other half were extracted from the electronic medical record. There were no patient-reported AE. Although the majority (66.7%) of unreported AE were mild, these findings illustrate that voluntary AE reporting is unreliable. However, the retrospective tracking process proved to be difficult and time-consuming.**

Conclusions: **The current study highlighted that systematic registration of all endoscopy-related AE is feasible, but challenging because of multiple hurdles. More practical methods are warranted to obtain reliable and long-term data as part of endoscopy quality measures.** (Acta gastroenterol. belg., **2022,** 85, **499-504**).

Keywords: adverse events, endoscopy, anaesthesiology, quality improvement.

Introduction

Endoscopic procedures have evolved significantly in the past sixty years, revolutionising the diagnostic and therapeutic approach in modern medicine (1). Diagnostic gastrointestinal endoscopy by direct visualization of the bowel wall and tissue sampling of abnormal areas has substituted radiographic single and double contrast studies of the gut. The natural portals of access used in endoscopic procedures skilfully bypass perforation of tissue planes, but nevertheless the flexible endoscope is invasive of the human body, and as such burdened by risks and complications.

Large international audits have shown that most risks are preventable and this has led to recommendations and quality guidelines from international endoscopy societies providing procedure specific safety strategies for the prevention, recognition and management of adverse events (AE) (2-4). Quality assurance and improvement in health care presume the ability to compare individual or group performance to an ideal or benchmark, usually formulated as a ratio between the actual procedure/behaviour over a denominator, representing the opportunity to correct it. The parameters used for comparison are termed "quality indicators" or "quality measures / key performances indicators / clinical quality measures" (5). Those measures most relevant to clinical care should be reproducible, have a valid correlation to clinically important objectives and must be based upon evidence demonstrating gaps in performance and amenable to improvement (6). One of these outcome measures is the assessment of AE rates in endoscopy.

Both the European Society of Gastrointestinal Endoscopy (ESGE) and the American Society for Gastrointestinal Endoscopy (ASGE) published performance measures for endoscopy services, including registration of endoscopy-related AE and root cause analysis of serious adverse events (SAE) (7,8). AE have been divided up in two main groups: endoscopic procedure- and anaesthesia-related. Every procedure has its own characteristics and thus can cause specific AE. It is also important to differentiate diagnostic from therapeutic procedures, as AE numbers increase significantly in the latter group and are linked to the complexity of the intervention.

A lot has been written about guidelines on quality indicators and quality health care delivery, with great attention and recommendations on the recording of AE. However, only very few articles actually explain how to go about data collection. Interestingly, studies on AE collection tend to jump the practical aspects and only detailed results and incidence are published. In fact, very few articles published a sample questionnaire for AE data collection (9,10).

The aim of the current study is to track all endoscopy-related AE and incidents during a 3-month period by

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comparing the method of voluntary endoscopist self-reporting with the method of retrospective medical file review by an independent researcher. The comparison of these two methods will help to develop a practical quality system of reporting endoscopy-related AE.

Materials and Methods

The University Hospital Saint-Luc in Brussels is a tertiary medical centre with a total of around 980 beds. Both outpatient and inpatient gastrointestinal endoscopic procedures are performed in the Department of Gastroenterology & Hepatology by regular staff members, trainees, and external consultants. The more complex therapeutic procedures are performed by endoscopists with expertise in particular procedures.

Endoscopy-related AE were defined according to the ASGE guidelines, as shown in Table 1 (11). They state that AE is defined as "an event that prevents completion of the planned procedure and/or results in admission to hospital, prolongation of existing hospital stay, another procedure (needing sedation/anaesthesia), or subsequent medical consultation", whereas an incident is "an unplanned event that does not interfere with completion of the planned procedure or change in the plan of care, (i.e. does not obey to the stated criteria for AE)" (11). For major events, such as cardiac arrest, there is no difficulty in understanding that it cannot be considered as an incident, but the matter becomes more complex when dealing with minor events. For example, an episode of hypotension during the procedure, needing reversal or a vasoconstrictor agent without preventing the completion of the procedure and without sequela on the plan of care, should be considered as an incident when referred to the definitions given above, but in fact it appears in the ASGE AE lexicon list (11). Even though sometimes it can be hassling not to consider an incident as an AE, following the definition of the ASGE classification, we decided to adhere and respect it as a common and standardised system of classification. As suggested in the ASGE guidelines, even minor events qualified as incidents have been reported together with AE in our data collection, because they can contribute to the quality assessment of endoscopic procedures. AE should also be distinguished from negative outcome, defined as a failed but yet uncomplicated procedure (for example inability to cannulate the papilla during ERCP), and from sequela, which is an expected effect resulting from a successful procedure (for example oesophageal ulcer after variceal band ligation) (12). AE severity has been graded into 4 different classes, based mainly on the need for hospitalization: mild (1-3 days), moderate (4-9 days), severe (>10 days) and fatal (death) (11,13). When death is considered a procedure-related consequence, the prerequisites are that it has to occur within 30 days or if it occurred after 30 days it has to be clearly attributable to the procedure and the patient must have been in acute care since the procedure took place.

Table 1. Adverse Events - Definition

Category	Event
Cardiovascular	Hypotension < 90/50 mmHg or down 20% Hypertension > 190/30 mmHg or down 20% Dysrhythmia Arrest Myocardial infarction Cerebrovascular event
Pulmonary	Hypoxia O_2 < 85% Hypopnea Laryngospasm Bronchospasm Pneumonia Pneumonitis
Thromboembolic	Deep venous thrombosis Pulmonary embolus
Instrumental	Perforation = Evidence of air or luminal contents outside the GI tract Penetration = Visual or radiographic evidence of unintended penetration Impaction = Unability to remove instrument or device
Bleeding	Haematemesis and/or melena or haemoglobin dr op >2g/L
Infection	Cholangitis = >38°C > 24 hours with cholestasis Pancreatic Infection = >38°C > 24 hours with collection Fever (UO) = >38°C > 24 hours without obvious sour ce
Drug reaction	Allergy
Pain	Abdominal = Not caused by pancreatits or perforation Non abdominal (*specify site*)
Pancreatitis	Typical pain with amylase/lipase > 3 times normal
Integument	Damage to skin, eyes, bones, muscles
Other	*Specify*

Table 2. Severity Grading

	Mild	Moderate	Severe	Fatal
Procedure aborted or not started because of an AE	x			
Postprocedure medical consultation	x			
Unplanned anaesthesia/ventilation support, ie endotracheal intubation during conscious sedation		x		
Temporary ventilation support by bagging or nasal airway during conscious sedation		x		
Unplanned hospital admission or prolongation of hospital stay for ≤ 3 nights	x			
Unplanned admission or prolongation for 4-10 nights		x		
Unplanned admission or prolongation for > 10 nights			x	
ICU admission for 1 night		x		
ICU admission > 1 night			x	
Transfusion		x		
Repeat endoscopy for an AE		x		
Interventional radiology for an AE		x		
Interventional treatment for integument injuries		x		
Surgery for an AE			x	
Permanent disability (specify)			x	
Death				x

As stated above, AE essentially change the plan of care, and most of the times they lengthen the hospitalisation stay, but there are some others circumstances, which do not fulfil this criterion, but still represent an AE. Table 2 describes these other situations and states the severity. AE can occur before (pre-procedure), during (intra-procedure) and after (post-procedure) the endoscopic procedure. The post-procedure AE were defined as immediately after, late AE (within 14 days) and delayed AE (within 30 days). Delayed AE are the most challenging to track.

During a 3-month period, all endoscopy-related AE were recorded using a voluntary reporting by the endoscopist and the patient. For this purpose, two different formats were selected. A one-page questionnaire was addressed and given out to every endoscopist and to the medical staff of the gastroenterology and hepatology hospitalisation wards, requiring completion only in the case of a suspected procedure-related AE. This questionnaire included items on the type of endoscopic procedure and therapeutic intervention, the type of AE, and its management. A second questionnaire was in letter form and addressed to every outpatient undergoing an endoscopic procedure, with explanations regarding post-procedure complications and recommendations to contact the endoscopy unit if that had been the case. All endoscopists were informed about the AE registry during multiple staff meetings, to increase their awareness for the study. At the end of the 3-month registry, a retrospective analysis of all endoscopic procedures performed during the registration period was carried out, and results were compared with the results obtained through the voluntary reporting.

By using the electronic agenda software (UltraGenda, DXC Technology, Virginia, USA), all patients undergoing an endoscopic procedure were identified. The endoscopy reports were created in Endobase (Olympus, Tokyo, Japan) and the patients' medical files were available through the electronic medical record software (Medical Explorer, Cliniques universitaires Saint-Luc, Brussels, Belgium), in order to track endoscopy-related AE, especially in the post-procedure (late and delayed) period. In case of anaesthesia care (light and deep sedation or general anaesthesia), all relevant details concerning cardiopulmonary measurements, as well as information on the time and dose of every drug administered were recorded. The local ethical committee of the University Hospital Saint-Luc gave approval to the research project.

Statistical analysis was performed using Excel (Microsoft for Windows, Washington, USA). Descriptive statistics were used to calculate the AE incidence and endoscopist compliance in reporting AE. Data were expressed as percentages as the variables were normally distributed, using 95% confidence intervals (CI) when appropriate. Comparative analysis was done using Fisher's exact test. P values <0,05 were considered significant.

Results

A total of 2668 endoscopic procedures were performed during the 3-month period, including both outpatient and inpatient procedures, and all were included for analysis. According to the previously described definitions, there were a total of 52 AE, 551 incidents, 10 failed procedures (negative outcome) and 138 technical errors, representing a prevalence rate of 1.95±0,53%, 20.65±1,54%, 0.37± 0,23% and 5.17±0,46% respectively of the overall procedures (IC 95%). The mean age of the patients

COMPARISON WITH ASGE-REPORTED AE RATES

	ASGE AE rates	CUSL
Perforation rate of colonoscopy*	0.1%-0.3%	0.3%
Post-ERCP pancreatitis	3.5% (1.6%-15.7%)	3.2%
Post-polypectomy bleeding (Colo)**	0.9%	0.7%
Post-ESD perforation (Gastro)***	6.0%	3.5%

*All procedures
**Procedures with polypectomy
***Procedures with ESD

Figure 1. — Endoscopy-related AE and their incidence during the 3-month study period in the University Hospital Saint-Luc (CUSL) in comparison with the ASGE-reported AE rates.

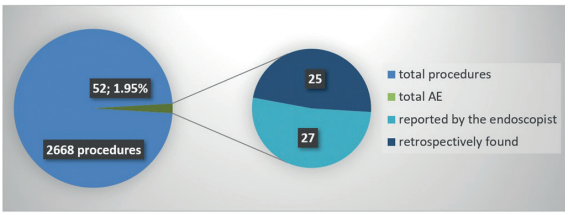

Figure 2. — AE rate related to endoscopy and endoscopy-related anaesthesia during a 3-month period, subdivided by tracking method.

was 58,3±17,2 (SD) years for AE and 59,4±16,0 years for incidents. In the AE group, 33 patients were female and 19 were male (sex ratio 1,8:1,0), whereas in the incidents group 147 were female and 248 were male (sex ratio 1,0:1,7) with multiple incidents in some patients. The main AE were perforation, bleeding and post-ERCP pancreatitis. Figure 1 shows the overall incidence of these AE during the 3-month study period, compared to the ASGE-reported AE rates.

The main objective was to compare the results of the voluntary AE reporting of the endoscopist to those of the retrospective evaluation of the electronic patient files, in order to define the reliability of voluntary reporting as a tracking tool. As for "endoscopist compliance" in AE reporting, the feedback returned during the initial three months amounted to 50% for the first month, 65% for the second and it declined to 37% for the third month of the registry. The voluntary reporting system recorded by the endoscopist yielded 27 AE (51,9% of all AE) (Figure 2). Table 3 shows the distribution of AE related to the type of endoscopic procedure and related to the reporting system. When classified according to severity, 8 of the reported AE were mild (over a total of 24 mild AE, representing 33,3%), 11 were moderate (over a total of 16 moderate AE, representing 68,8%), and 8 were severe (over a total of 12 severe AE, representing 66,7%). There was no mortality related to endoscopic procedures during the 3-month registration period. The retrospective analysis of all medical files of patients undergoing endoscopy during the 3- month period tracked back 25 extra AE (46,2%), divided into 16 mild AE (66,7%), 5 moderate

Table 3. Over all AE incidence and reporting system

	EGD (n=1326)	ERCP (n=156)	Colono-scopy (n=1013)	upper EUS (n=141)	ano-rectal EUS (n=52)	Gastro-stomy (n=32)	Upper Entero-scopy (n=17)	Lower Entero-scopy (n=8)	All procedures (n =2668)
Over all AE	13 **0,98±0,86%**	21 **13,46±5,35%**	12 **1,18±0,67%**	4 **2,84±2,74%**	0	2 **6,25±8,38%**	0*	0	52 **1,95±0,53%**
• Reported by the **endoscopist**	9 **69,23%**	7 **33,33%**	7 **58,33%**	2 **50,00%**		2 **100,00%**			27 **51,92%**
• Reported by the **patient**									0
• Retrospectively **found**	4 **30,77%**	14 **66,67%**	5 **41,67%**	2 **50,00%**					25 **48,08%**

*Two cases of Enteroscopy - ERCP developed complications but were included into the ERCP group

Table 4. Overall AE incidence and severity grading

	EGD (n=1326)	ERCP (n=156)	Colono-scopy (n=1013)	upper EUS (n=141)	ano-rectal EUS (n=52)	Gastro-stomy (n=32)	Upper Entero-scopy (n=17)	Lower Entero-scopy (n=8)	All procedures (n =2668)
Over all AE	13 **0,98±0,86%**	21 **13,46±5,35%**	12 **1,18±0,67%**	4 **2,84±2,74%**	0	2 **6,25±8,38%**	0*	0	52 **1,95±0,53%**
Diagnostic	4 **30,77%**	0	4 **33,33%**	1 **33,33%**					9 **17,31%**
Therapeutic	9 **69,23%**	21 **100,00%**	8 **66,67%**	3 **66,67%**		2 **100,00%**			43 **84,61%**
• **Mild**	6 **46,15%**	8 **38,10%**	9 **75,00%**			1 **50,00%**			24 **46,15%**
• **Moderate**	5 **38,46%**	7 **33,33%**	1 **8,33%**	2 **50,00%**		1 **50,00%**			16 **30,77%**
• **Severe**	2 **15,38%**	6 **28,57%**	2 **16,67%**	2 **50,00%**					12 **23,08%**
• **Fatal**									0

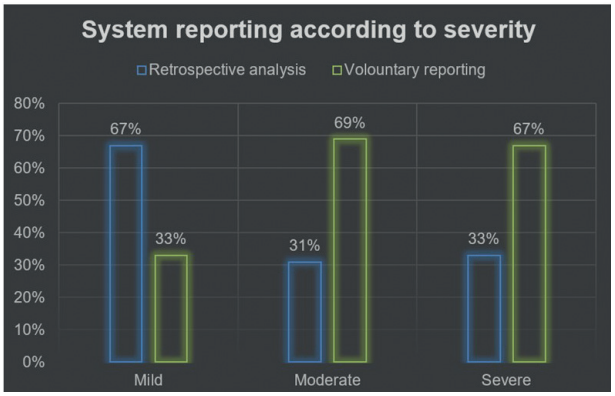

Figure 3. — Severity of AE according to the reporting system, expressed in % per degree of severity.

(31,3%) and 4 severe (33,3%). Statistical analysis of AE rates showed that endoscopists reported only 1,01% AE (over a total of 2668 endoscopies) whereas retrospective analysis of electronic patient files revealed an AE prevalence of 1,95% ($p<0,01$ Fisher's exact test) (Figure 2). However, Figure 3 shows that endoscopists mainly neglected reporting mild AE (64,0% of all missing AE were mild), whereas they missed to report only 33,3% of severe AE.

In total 6 patients called back to report an incident, thus representing only 1,1% of the total number of incidents. No patient-reported AE were recorded (Table 3). Compared to diagnostic procedures, AE occurred more frequently during or after therapeutic procedures (n=9 (17,3%) vs n=43 (84,6%) respectively).

Most of the incidents were found in the anaesthesia protocols, and in most cases they were of cardio-pulmonary origin, such as transient hypotension and/or tachycardia, hypertension, desaturation (where SpO_2 was decreased but not <85%), bronchospasm or laryngospasm. Other frequent incidents were abdominal pain, nausea and vomiting and headache. All of them resolved easily within a short delay of time, with or without specific drug administration.

In 10 cases the procedure failed. All of them were ERCP procedures and in 2 with surgically altered anatomy. In 4 cases, bleeding during the procedure was considered an incident and therefore not an AE, because it was easily managed during the same endoscopic procedure, not leading to a change of the initial plan of care. Poor bowel preparation prevented complete colonoscopy in 1 case, and in 26 cases poor bowel preparation made the result of the colonoscopy inconclusive. A total of 138 technical errors were recorded, including Endobase errors not allowing endoscopic image capturing during the endoscopy. During the 3-month period 14 endoscopes needed technical revision or repair.

Discussion

Keeping track of all endoscopy-related AE is not as easy as it might seem. The current study revealed several hurdles in the process of AE registration. A key point to this problem concerned the definition of an AE, which despite the ASGE guidelines, was not a minor aspect because the right item could not always be inserted into

the right box (11). Incidents, failed procedures with negative outcome, sequelae and technical errors are sometimes difficult to differentiate from AE, representing a grey watershed area with undefined limits (14). For example, biliary stent migration is considered an AE in the ASGE guidelines, but in our research we did not follow that line of action because it appeared counter-intuitive. Stent migration can and should be considered a sequela rather than an AE.

Tracking AE is not just an intellectual task, but it also represents a practical hurdle. Voluntary reporting by the endoscopist was shown to be quite unreliable as it relies on human error and compliance. The current project showed that underreporting occurred in nearly 50% of all AE, even though all endoscopists were informed about the AE registry on multiple occasions. However, they tended to miss out preferably on mild AE. The retrospective tracking back of all endoscopic procedures in our study design entailed patience and was a very time-consuming activity and, as such, cannot be used as a practical method for registering AE on a systematic base. A third hurdle is the risk of missing out late (up to 14 days post-procedure) and delayed (up to 30 days post-procedure) AE, since they are not mentioned in the original endoscopy report. Our study revealed that two thirds of all AE occurred in the post-procedure period, rendering their inclusion in the AE registry more challenging. Furthermore, patients from other wards form another subset of difficult to record AE, in association with the frequent problems of sharing the same definition of AE amongst clinicians. Compared to internationally accepted AE rates, the results of our AE registry were within the acceptable limits suggested by ASGE as shown in Figure 1 (11).

The rapid technical evolution of gastrointestinal endoscopy contributes further to the difficulty in extracting crucial information from pre-existing studies. The dramatic increase in endoscopic volume demand together with the widely varying baseline health conditions (ranging from screening of a healthy population to assisting patients with multiple comorbidities), made the task of capturing AE quite an ordeal. Most studies in this field concluded that only large prospective cohort studies, although costly and cumbersome to perform, are the solution (15). Multidisciplinary single site and multiple site meetings could provide an answer to achieve competence, compliance, coordination, and mainly specific interest in measuring and improving patient outcome, as we performed in the beginning of this registry. However, despite these efforts, voluntary reporting of endoscopy-related AE by the endoscopist only revealed half (51,9%) of all AE.

Despite the internationally approved guidelines to define AE in endoscopy, there is little coherence in the available literature regarding the definition of what should be regarded as an AE and how AE are recorded. It largely depends on the endoscopic procedure under study and the selection of specific AE, in contrast to our study trying to encompass all AE and incidents related to all endoscopy procedures or anaesthesia in endoscopy (16-18). These differences in recording (all vs specific endoscopic procedures / retrospective vs prospective / voluntary vs systematic review of medical files / early vs late AE) may lead to a wide variation in reported AE rates, as encountered in the literature (19,20). The current study clearly highlights all these difficulties. Automated nationwide prospective registration of endoscopic procedures and outcomes may be the only reliable solution, as already successfully implemented in some countries (21-24). This also accounts for the registration of anaesthesiology-related AE (25,26). Mandatory nationwide registration, which is currently not at the seams in Belgium, will also allow reliable analysis of high-volume data and subsequent publication.

Regarding the severity classification of endoscopy-related AE, a recent publication suggested to use the 5-degree AGREE classification, which is based on the well-known Clavien-Dindo classification of severity of surgical AE (27,28). The only difference is within grade III. A grade III severity of AE means that an endoscopic, radiological or surgical intervention is necessary. Grade III is divided into grade IIIa (endoscopic or radiological intervention) and grade IIIb (surgical intervention) in the AGREE classification (27). In the original Clavien-Dindo classification, grade III severity also means that an endoscopic, radiological or surgical intervention is necessary, but grade IIIa is an intervention without general anaesthesia, whereas grade IIIb is with general anaesthesia (28). The Clavien-Dindo classification has been shown to be very useful, and is therefore nowadays also adopted as the AGREE classification to describe severity of endoscopy-related AE.

Conclusions

The ultimate objective of tracking AE is to identify the association of endoscopic procedures and their respective risks, and to take measures to reduce the AE rate and to improve quality of endoscopy.

The current study highlights the difficulties and challenges to systematically register AE related to endoscopy and endoscopy-related anaesthesiology. Voluntary reporting of AE by the endoscopist remains problematic despite multiple awareness campaigns. Systematic review of all medical files of all patients who underwent an endoscopic procedure up to 30 days after the procedure is very effective but too time-consuming to implement. Automated nationwide registries of all endoscopic procedures and patient outcomes (early and late) seem the only reliable solution, as shown and implemented in other countries.

Conflict of interest

The authors declare no conflict of interest.

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