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NO PERFORMANCE IS BETTER THAN IMPROPER PERFORMANCE. MALPRACTICE AND LIABILITY IMPLICATIONS OF CONTRAINDICATING A GASTROINTESTINAL ENDOSCOPY PROCEDURE

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Abstract: Digestive endoscopy procedures are performed in millions of cases worldwide each year, and the appropriateness of indications is relatively well defined by guidelines or professional societies' recommendations. Nevertheless, endoscopists are facing situations when performance of a procedure should be refused due to either inability to achieve proper quality indicators or lack of reasonable risk/benefit ratio. Such circumstances may trigger patient insatisfaction, and furthermore may lead to malpractice and medical litigation. The aim of our study is to assess the medico-legal implications of procedural refusal in digestive endoscopy and to find proper solutions and indications for endoscopists. Google Scholar was searched for reported keywords and a review of the relevant publications was performed. Despite the multitude of guidelines and recommendations, the indications for digestive endoscopy procedures are still not clearly defined. Contraindications are inconsistently reported. Quality indicators and timing of procedures vaguely defined. Therefore, even if refusing to perform a procedure may seem a feasible alternative in particular situations, it may trigger legal liability consequences. Endoscopists should be aware of such consequences and local position statements are encouraged.

Keywords: upper digestive tract bleeding, gastroscopy, colonoscopy, surveillance, colon preparation.

INTRODUCTION

Upper and lower gastrointestinal (GI) endoscopy procedures are minimally invasive techniques for investigating and treating various lesions of the GI tract. As reported by iData Research International, over 51 million GI endoscopies are performed each year worldwide, with a growth rate of approximately 2.6% per year, a majority of which are screening procedures [1]. The delivery of healthcare in this field is therefore in constant change, with a great emphasis placed on quality assurance and patient safety and satisfaction. Thus, the demand for quality control has lead to the issue of international societies' position papers and guidelines on performance measures and quality indicators [2, 3]. According to the American Society for Gastrointestinal Endoscopy (ASGE) guideline paper, a GI endoscopy procedure is generally indicated (i) if it brings a change in patient management based on the results of endoscopy, (ii) in non-responsive patients after an empirical trial of therapy for a suspected benign disease, (iii) as the initial method of evaluation for the upper and lower GI tracts, or (iv) when a primary therapeutic procedure is planned [3]. The same guideline recommends against performing a GI endoscopy when (i) it's results will not alter management or (ii) as a periodic follow-up of healed benign, and contraindicates such procedures (i) if the risks to patient health or life exceed the most favorable benefits of the procedure, (ii) when adequate patient cooperation or consent cannot be obtained in non-emergent procedures, or (iii) when perforation is suspected [3]. Moreover, lower GI endoscopy is generally contraindicated in acute fulminate colitis or in documented acute diverticulitis [3].

Assuring quality of care demands both proper recognition of procedure indications and exclusion of a documented contraindication if the decision to undergo a GI endoscopy has been taken, as a quality measurement tool [4, 5]. An area of debate has risen over the extent of specific situations when the endoscopist should refrain from performing the endoscopic procedure based

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on the altered risk/benefit ratio of a specific clinical scenario. Thus, refusing or refraining from a procedure may lead to engaging professional responsibility as it could be perceived by the patient as non-compliance, and therefore generate professional litigation and malpractice claims [6, 7]. Contraindicating a procedure is under such circumstances an equally responsible professional act of conduct as performing that specific procedure. Hence, the aim of our research paper is to assess if endoscopists are at risk for medical litigation when refraining from a GI endoscopy procedure, and to define specific situations where the procedures should likely be not performed rather than improperly performed.

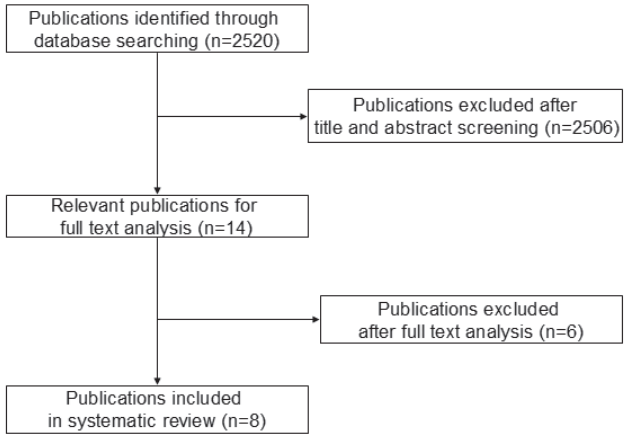

Figure 1. Review of the literature and study selection algorithm.

METHODOLOGY

In order to identify specific situations related to higher incidences of medical litigation, we performed a systematic analysis of the Google Scholar database between the 1st and the 31st of October 2019. The matched keywords included: "malpractice", "litigation", "contraindication", "GI endoscopy", and "performance". 2520 articles matched the keyword search. Relevance of articles was assessed primarily by the abstract content. 14 relevant articles were selected. Within the relevant articles, full text analysis searched to determine specific situations when contraindications of GI endoscopy led to malpractice claims and litigation. Only full text papers were included in the systematic analysis. 8 such articles were identified and systematically reviewed. The excluded studies did not make any reference to contraindications of GI endoscopy procedures. The type of study, number of cases, contraindications, claims, and authors' personal point of view were searched and analyzed. The algorithm of study selection is summarized in Figure 1. The relevant articles selected for systematic review and analysis are presented in Table 1.

Table 1. Selected publications that were included in the systematic review

Author, year of publication	Title	Type of study	Source	Date of access	Number of malpractice cases
Gerstenberger, *et al.*, 1993 [12]	Malpractice claims in gastrointestinal endoscopy: analysis of an insurance industry data base	Case series (database review)	Gastrointest Endosc. 1993; 39(2): 132-138.	09.10.2019	20
Conklin *et al.*, 2008 [13]	Medical Malpractice in Gastroenterology	Case series (database review)	Clin Gastroenterol Hepatol. 2008; 6(6): 677-581.	09.10.2019	46
Hernandez *et al.*, 2017 [14]	556 Contributing Factors in Malpractice Claims Against Gastroenterologists.	Systematic review	Gastrointest Endosc. 2017; 85(5): AB85-AB86.	09.10.2019	43
Bruguera *et al.*, 2011 [15]	Alleged malpractice claims related to gastrointestinal endoscopy. Analysis of casuistics over 22 years	Case series (judicial review)	Gastroenterol Hepatol. 2011;34(4): 248-253.	09.10.2019	6
Nagpal N., 2017 [16]	Legal hurdles for gastroenterologists in India	Review of literature	Indian J Gastroenterol. 2017;36(3):174-178.	09.10.2019	2
Hiyama *et al.*, 2006 [7]	Medical malpractice litigation related to gastrointestinal endoscopy in Japan: a two-decade review of civil court cases	Systematic review of database	World J Gastroenterol. 2006;12(42): 6857-6860.	13.10.2019	2
Neale G., 1998 [17]	Reducing risks in gastroenterological practice	Case series	Gut. 1998;42(1): 139-142.	13.10.2019	6
Hernandez *et al.*, 2013 [6]	Malpractice claims for endoscopy	Systematic review of database	World J Gastrointest Endosc. 2013;5(4): 169-173.	27.10.2019	4

RESULTS AND DISCUSSIONS

Malpractice claims related to GI endoscopy occur relatively frequent worldwide. In most cases they are related to diagnostic errors and improper performance linked to incidence of complications [8, 9]. Nevertheless, as reported death rates among cases linked to malpractice claims occurred in over 34%, one of the most important issues to be addressed is whether the procedure is really indicated and then, whether the patient is fully prepared for it [10]. Moreover, in one of his well known judicial case-reviews, Peter Cotton shows a clear link between litigation and improper qualification of procedural indication as opposed to non-indication of an otherwise indicated procedure [11].

The frequency of claims related to non-indicating and not performing an otherwise indicated procedure is constantly among the first 5 to 10 GI endoscopy-related lawsuit claims in the reviewed literature. All publications included in the systematic review were either case reports or database reviews. Hence, it is to be expected that the published cases represent only a minority of the total claims. 129 malpractice cases where procedures were either delayed or not-indicated and thus led to misdiagnosis affecting case management have been identified in the systematically reviewed literature. Even if the claims referred to both diagnostic and therapeutic procedures, more than two thirds of the total claims involved therapeutic GI procedures. Furthermore, the majority of malpractice allegations were against gastroenterology endoscopists.

Although the need for performing a procedure is frequently emphasized by the referring medical teams, family of patients or even concurring clinicians involved in patient management, the responsibility for indication or detection of a procedural contraindication lies with the endoscopists. In this respect, delaying a procedure in order to achieve enough information and prepare proper staff for patient management seems a better option than to perform a procedure in a possibly contraindicated setting or clinical status. Proper antibiotic prophylaxis, anesthesia consult, coagulopathy management, or fluid imbalance correction are key pre-procedural steps that could delay and temporary contraindicate an otherwise indicated GI endoscopy procedure [8,10]. In such cases, reasons involving procedure delay or contraindication should be thoroughly documented. Given the multidisciplinary approach to such cases, shared responsibility should be addressed in resolving most of the claims.

On the other hand, when compared to improper performance (over 25% reported litigation risk), the overall litigation risk related to absent or delayed performance is constantly lower in most of the reviewed publications (reported rates under 10%) [12-17]. Therefore, whenever one of the above mentioned causes that may contribute to improper performance occurs, a logic conduct would be to rather not indicate the procedure than to commit non-performance.

The ethical approach to such issue relies on the respecting values of medical professional status when debating alternative options that the endoscopist faces in order to achieve standard professional performance targets. In GI endoscopy procedures are concerned, rational decisions of an overly implicated endoscopist can be altered by the excessive willingness to perform. Thus, there could be a bilateral influence between professional decisions and the personal values of the endoscopist. In what the improper performance issues are concerned, the ethical approach searches for a balance between achieving therapeutic goals and proving performance measures. Hence, we emphasize the need for promoting reciprocity between professional decision standards on the first hand, and institutional responsibility and support on the other hand.

One of the main responsibility issues identified in such circumstances is that the endoscopist performing the procedure takes all responsibility related to both indication and performance despite the possible lack of concurring quality indicators (such as anesthesia, monitoring, proper medication, etc.) independent to the GI team. In all cases, lack of proper competence, indication, preparation, available logistics and follow-up should lead to procedure contraindication or delay until proper quality indicators are assured [4, 5].

Documenting such situations within the patient records or informed consent sheets is an essential step for the justification of specific conducts [7]. Secondly, proper training to detect vulnerable situations that may affect patient outcome is mandatory for quality assurance [18, 19]. Lack of proper training is consequently a good reason for not indicating a specific procedure. Thirdly, both practice guidelines and expert opinions should be established for such situations where litigation risks are high, thus contributing to proper definition for the standard of care [7, 20, 21]. Moreover, endoscopists should be aware of the implications of non-performance versus

under-performance especially in what the delay in diagnosis is concerned. Proper documentation and use of alternative resources for both diagnostics and therapy should be always emphasized in situations where endoscopy may be delayed [22, 23].

Not the least, as reassuring fact for endoscopists, when compared to other interventional or surgical specialties, despite the assumptions, both the malpractice claims and litigation rates related to GI endoscopy are lower [13]. One of the most valuable data sources in the field was the insurance claim resource published by the Physician Insurers Association of America (PIAA). Despite such resources, there generally there is a paucity of data within the literature regarding the medical and legal claims and outcomes of malpractice cases.

In conclusion, quality assurance in endoscopy is an essential step that augments the benefits and reduces procedural risks thus contributing to the beneficence of such invasive procedures. Delaying or not performing a GI diagnostic or therapeutic endoscopic procedure may lead to judicial claims, litigation and malpractice. Nevertheless, abstinence from such a procedure seems preferable when compared to under-performance especially in cases when quality indicators such as periprocedural medication management, proper monitoring and sedation, or correct scope and devices cannot be efficiently assured. The importance of proper auditing of such situations should be recognized and the need to prioritize research in the field of medical malpractice and litigation should be strengthen uniformly in academic centers.

Conflict of interest

The authors declare that they have no conflict of interest.

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