

## Ethical issues in therapeutic endoscopy – can communication between patient and physician make a difference?

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### Abstract

Therapeutic endoscopy represents a major step in evidence-based medicine with great potential in the evolution of non-invasive surgery. The evolutionary status of endoscopy has reached a level where some of the surgical intervention can be performed in a minimal invasive way, with great benefits for the patient. However, this rises up some ethical issues regarding the patient's comfort zone, possible risks and complications and subjected the physician to possible litigation situations if not well trained. A rather good interaction and communication between patient and endoscopist is mandatory, as the health-care experience might be more satisfying. Unfortunate situations may also be avoided if intensive training and up to date knowledge and skills are acquired before jumping to therapeutic endoscopy. The continuous development and general focus on interventional endoscopy seems to have a key role on current medical standings. Therefore, in the following paper we have tried to underline the potential ethical problems that both the patient and the physician should take into consideration towards a better therapeutic endoscopic result.

**Keywords:** ethical aspects, therapeutic endoscopy, communication, sedation, litigations.

### ☞ Introduction

The path from conventional to minimal invasive surgery is paved with many controversial aspects, starting from the learning curve of young new recruits in performing the procedures and their experience [1], to the legal aspects of potential failure and the need of changing the point of view in treatment. Endoscopy represents a turning point of modern medicine with several innovations so far, which have led to a larger armamentarium of devices and techniques suitable to obviate some traditional surgical techniques. The current tendency promotes gastrointestinal endoscopic intervention as the future of less invasive surgery. Improvements and developments of endoscopic procedures has led to the immergence of national and international screening programs and also has validated several procedures of the gastrointestinal tract, focused on curative and even palliative techniques [2–4]. Jumping from simply visualizing the gastrointestinal tract lesions to stopping bleedings, removing polyps or dilating stenosis has changed the patient's overview and understanding of less invasive treatment.

The ground rules of ethics in gastroenterology, particularly gastrointestinal endoscopy, are centered on the ratio between the patient's well-being and the results following the procedure [5]. While the patient's rate of satisfaction is considered an important factor in judging his healthcare experience [6, 7], endoscopy has brought forward several related issues that may influence patient's emotional status and understanding. Compelling evidence have suggested that endoscopy might be more bearable if the physician would relate more before and after the

procedure, avoid any delays and perform the procedure in a suitable and relax environment [8]. However, the exponential development of therapeutic procedures has promoted endoscopy to more than diagnostic interventions, which should bring even more attention to the patient's comprehension of therapeutic options. This new set-up pointed out that, after a detailed explanation of the following endoscopic procedure and further situations, patients should have a sufficient time to reflect on the severity and potential risks.

In addition to the procedure's walkthrough, an informed consent is definitely necessary as the patient may be under anesthesia and unaware of the development. Since its introduction in modern medicine in the 20<sup>th</sup> century [9], the informed consent is a must obtained before proceeding to endoscopy. This comes in the patient's aid of understanding eventual complicated interventions and provides a direct point of view on the benefits, risks and potential complications [10].

The continuous development and general focus on interventional endoscopy seems to have a key role on current medical standings. With all the advances so far in terms of therapeutic endoscopy, in the following paper we have tried to underline some of the ethical problems that both the patient and the physician may encounter when discussing endoscopic interventions.

### ☞ How endoscopic practitioners are and should be trained in therapeutic endoscopy?

From the first use of the endoscope, in 1853, by

Désormeaux [11] to the current developments of therapeutic endoscopy, patients have surely benefited the most of this evolution. However, with the current tendency of replacing some surgical procedures with an endoscopic perspective, a question should be asked if there is going to be a limit to surgical interventions. Advances in therapeutic endoscopy require a complex setting, a consistent team with important knowledge and skills with the general purpose of improving the patient's condition. Nonetheless for this to be possible, an ongoing process of practice is necessary starting with the basics in special endoscopic facilities to continuous training and competency assessment. Accordingly to the *Organisation Mondiale d'Endoscopie Digestive* (OMED) statements, the trainee should be able to perform routine procedures according to the current standards. From that point on, endoscopy performance should be evaluated regularly according to outcome indicators, quality standard of care as well as number and type of the procedures [12].

**Table 1 – Consensus Statement of acquiring data of patients satisfaction accepted by voting during the Second European Symposium on Ethics in Gastroenterology and Digestive Endoscopy, held in Greece, 2006**

<ul style="list-style-type: none"> <li>▪ Questions should be short, specific, and easy to understand. Always include general questions as well, such as "Overall, how satisfied were you?"</li> </ul>
<ul style="list-style-type: none"> <li>▪ Questions should be answered using a five-point scale from poor (score 1) to excellent (score 5).</li> </ul>
<ul style="list-style-type: none"> <li>▪ One or two open-ended questions should be included.</li> </ul>
<ul style="list-style-type: none"> <li>▪ A minimum of 200 responses is required to be able to draw significant conclusions. As the expected response rate is about 33%, at least 600 questionnaires should be distributed.</li> </ul>
<ul style="list-style-type: none"> <li>▪ Mailed surveys are preferred over personal-distribution or e-mail surveys.</li> </ul>
<ul style="list-style-type: none"> <li>▪ Inclusion of demographic data in the survey should be very useful.</li> </ul>
<ul style="list-style-type: none"> <li>▪ In general, the questionnaire should be anonymous.</li> </ul>
<ul style="list-style-type: none"> <li>▪ A pan-European endoscopy satisfaction survey should be conducted, based on these indicators, in order to establish a framework for the establishment of a European endoscopy procedure standard.</li> </ul>

So far, the apprenticeship model has been the foundation of hands-on endoscopic training, with each individual developing their skills according to their supervisor. The development of high fidelity endoscopic simulators may have bridged the gap between the potential patient discomfort and risks [13] when directly learning the procedures on patients and the technical requirements prior to clinical practice. While practicing in a safe and controlled situation provides a more relaxed environment for the endoscopist, when passing to patient's procedural setting another factor comes forward. Matharoo *et al.* [8] discussed the non-technical skills for quality assurance of endoscopy with participants consisting of screening endoscopists, which at baseline had over 1000 screening procedures. He pointed out that even the trainers could be trained within some aspects, especially medical attitude. He concluded that after a single day of training patient's safety knowledge and awareness can be improved in screening teams as well as safety attitudes.

Additionally, therapeutic endoscopy requires a learning curve so that the trainees may be considered proficient. For example, endoscopic submucosal dissection (ESD),

a procedure developed in Japan in the 1990s has spread over the last years with good results for early gastric cancer. Whilst this method has its obvious advantages, its complexity requires that trainees are subjected to a long period of training [14]. Two reports on the learning curve on ESD have suggested that 30 cases [15], respectively 40 cases [16] are necessary to be able to reproduce the procedure effectively.

Another therapeutic endoscopic management procedure, which rises ethical issues in training is the peroral endoscopic myotomy (POEM), a rather novel intervention, which requires both endoscopic and surgical knowledge and training. This procedure, which comes to aid of patients with achalasia, has successfully replaced general surgery in hundreds of patients [17] and tends to become the golden standard in this disease. However, this type of procedure requires extensive training while it is only performed in specialized centers [18]. Even so, as it subjects the patients to possible life threatening situation, before performing the intervention, observation of POEM experts and extensive training with animal models has been encouraged.

#### ▣ What is the general perception of patients on interventional endoscopic procedures?

No doubt that most of the patients perceive endoscopy as a rather stressful experience, starting from the appointment decision to the receipt of diagnosis. During this period, the patient may pass through various moods, which can be facilitated by the endoscopy team. The feeling of personal invasion and possible anxiety could enhance the emotional and physical discomfort. Studies so far on evaluating patient's experience in endoscopy emphasize that there is strong relation between the general perception and patients' imagination and the effective communication of the medical staff. Toomey *et al.* [19] found out that almost 85% of the patients were considered very satisfied with the information received in the outpatient clinic, even though 71% of them did not understand the indication. This backs up the idea that patients might be reluctant to asking questions or there is a bigger need of additional information before endoscopy. A Korean study [20] proposed a 10 to 15 minutes preparatory education program based on information, behavioral intervention and cognitive intervention. General information included the purpose of endoscopy, diagnostic value, internal organs examined, average inspection time, possible interventions during the procedure, as well as the standard position of the examinee. The behavioral intervention was based on a breathing exercise, while the cognitive situation made use of an audio tape of music and narration for self-encouragement. This preparatory education program revealed that self-confidence was statistically significant in patients aged 60 and over, and also reduced the anxiety situation. Also, the group following the program, showed less retching during endoscopy. Additional benefits may be added after allowing the patient to watch a video a week before the scheduled colonoscopy [21]. Apparently, watching a recording of a general colonoscopy increases the short-term knowledge and significantly decreases

the degree of fear on the day of the procedure. However, there was no influence on patient satisfaction. Pontone *et al.* [22] tried to find a connection between the waiting time before endoscopy and the patient's tolerance of endoscopy. According to their results, an average time to the procedure of 172 minutes does not influence the patient's tolerance and general perception of the endoscopic experience.

### ☞ Is sedation mandatory?

The physical discomfort, which in some situations might even be evaluated as a painful experience caused by endoscopy, it has been countered by several decisions, in order influence the patient's status. The most effective option so far is considered the use of pharmacological sedation during the procedure. Since the first use of pentobarbital with transtracheal injection xylocaine injection in the in 1960's, to the currently available guidelines in using midazolam and propofol, things have facilitate the patients tolerance of endoscopic procedure [23].

Sedation *versus* non-sedation study [24], confirmed that using sedation in an endoscopic procedure might improve patient satisfaction as well as willingness to repeat the procedure. Four hundred nineteen patients underwent endoscopy with 209 without sedation. Despite the fact that the recovery increasing time was prolonged, the endoscopic experience was very well tolerated.

Therapeutic endoscopy adds additional risks to endoscopy due to its invasiveness and time consuming status. These aspects have influenced the use of sedation during endoscopy, trying to focus more attention on patient's comfort and safety profile. Even though complications may occur, especially in elder patients [25], a good collaboration and communication between patients, endoscopists and anesthesiologists could avoid these types of situations. For example, the use of propofol with a slower rate of infusion and small cumulative doses, might fend complications such as desaturation, hypotension or bradycardia. ERCP (Endoscopic Retrograde Cholangio-Pancreatography) procedures also require the use of anesthetics. A recent survey [26] on patients completing a questionnaire on their experience after ketamine-induced anesthesia after ERCP, focusing on vivid dreaming has rated patient's satisfaction as 3.5 on a scale ranging from 1 to 4. No dysphoric events or vivid dreaming were present emphasizing that other options might be as useful as conventional propofol or midazolam during endoscopic interventions.

### ☞ Litigations in endoscopy

Medical malpractice and litigations are increasing all over the world, however in terms of gastrointestinal endoscopy and according to the literature data, things might still be considered in the beginning. With a continuous increasing number of therapeutic endoscopies, the iatrogenic injuries will rise as well. Apparently, most of the claims against endoscopist are related to improper performance, diagnosis error, failure to monitor the patient and to recognize possible complications, time-delay performance [27]. For all that, since endoscopies may be

performed by several specialties, it seemed that most of the negligence errors were described at non-gastroenterologist physicians, especially internists. This highlights the fact that adequate training, as well as error management is required at a large volume for preventing patient injuries [28].

A Japan survey [29] on medical litigations in endoscopy procedures, revealed only 18 cases and 30 allegations related to gastrointestinal endoscopy over a 21 years period, from 1985 to 2005. Only 6% were found to be related to misdiagnosis, as for the rest were pertained to complications. Until now, gastroenterology has been viewed as a low risk specialty with most of the literature data on litigation in endoscopy being mostly limited to editorials, case presentations and discussions in conferences. However, due to the continuous development of medical armamentarium of devices and techniques that may obviate surgery, it has been recently ranked as six out of 25, in malpractice claims. This strengthens the theory that more attention should be accorded to medical communication between patient and physician, as well as the fact that greater experience in performing therapeutic procedures translates into better quality performance.

From a gastroenterologist point of view, some of these litigations might be countered with some general prevention strategies. Most important is the effective communication with patients. Possible complications may occur even when performing diagnosis endoscopy and certainly may occur during therapeutic endoscopy, therefore the patient should be very well informed. The foundation of endoscopic patient-physician relation is the informed consent. Advance signing of a document that contains all possible risks and complications to which the patient might be submitted is of high importance. Consecutively, therapeutic endoscopy should be performed only by the specialized staff with continuous training and knowledge enhancement through medical debates and conferences. On the other hand, there is a general need of setting out specific guidelines in order to randomize in a controlled manner the litigations errors.

### ☞ Is the consent informed enough?

The informed consent is considered the turning point of legal recognition for every individual, which takes health care decisions on his own being [10]. When subjecting a patient to an endoscopic procedure, not only he should receive precise and sufficient data, but also he should acknowledge and have the capability to understand what are the benefits and potential complications. Moreover, the process of patient's actual understanding is of great importance, as this operation rarely occurs [30, 31]. Yeoman *et al.* [32] evaluated the understanding rate of the informed consent after interviewing 100 patients, with the age ranging from 19 to 82 years. A mini state mental examination was performed after the informed consent process was realized showing that the understanding assessment might be suboptimal. Thirty-six percent of the subjects had a low level of understanding, with a higher level in women than men and as expected the understanding progress regressed with age. Concerning this, a question should be address: Is the consent informed

enough? Well, there are many methods that should be taken into consideration when delivering the consent to the patient. Starting from the general idea of informing the patient about what is following, a variety of methods may be used. Either Power Point based presentations, web information materials, or a simple sheet may provide the general information required so that data might be embedded. However, the methods should be adapted to the patient's education and capability of understanding. A Korean study [33] strengthens this theory after submitting 209 patients to a survey. The results also suggested that understanding is decreased in elder patients as well as in less educated population. Voiosu *et al.* [34] also concluded after a multicenter study that information provided before the procedure may increase the patient's acceptance and bearing of colonoscopy while increasing the satisfaction and providing a more comfortable situation.

In other scenarios, informed consent may even reach a new approach in patients with work related time constraints, by supplying procedural data through e-mail, and to be read at the desired time. Also, several other questions may appear as in some situations the endoscopic intervention may need to be redone due to various reasons, either because the patient would require sedation to avoid discomfort or some additional measures need to be done as in follow-up. Patients need to take into account this idea from the beginning, as well as the physicians should fulfill their duty and communicate the results of the examination and future management.

The evolutionary steps in medicine will also require adapting their new therapeutic endoscopy to the patient's understanding. All new non-invasive procedure may require additional information than diagnostic interventions, facts that should be taken into consideration within the informed consent.

On the other hand, all of this information provided through various methods may protect the physician from various issues that may arise during endoscopic procedures. Litigations in which patients may not recall some aspects of the presentations or discussions may be tackled if a situation reaches court accusations.

## ☐ Conclusions

Due to evidence-based medicine, gastrointestinal endoscopy had a fulminant evolution in the last 20 years, with a wide range development of several new therapeutic techniques. The patient's expectation of therapeutic procedures is that they will be performed according to available guidelines, by skillful practitioners in a comfortable environment and with maximum liability. For this to be possible, a good communicative relation should be grounded and adequate training is required so the patient's safety is secured. No doubt that specific and conclusive information are a turning point for physician-patient connection and may surely provide an auspicious environment so the procedure has a positive impact on the patient's mental perception. These ideas should be embedded in general practice because it may lead to avoidance of possible medico-legal cases and can provide a rather assurance status for both doctor and patient.

## Conflict of interests

The authors declare that they have no conflict of interests.

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