

UNIVERSITY OF MEDICINE AND PHARMACY OF CRAIOVA

Doctoral School



PhD Thesis

(abstract)

**ETHICAL ASPECTS IN GASTROENTEROLOGY AND
DIGESTIVE ENDOSCOPY**

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Craiova

2015

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Key Words: medical ethics, gastroenterology, digestive endoscopy, informed consent, quality indicators, medical research

Current State of Knowledge

Continuous developments of science and technologies has a major impact and a large contribution on human civilization, especially in the medical field. Changing the way healthcare assistance is provided imposes new challenges for every member of the medical staff, either doctors or auxiliary personnel. Thus, medical evolution has facilitated technology to join the medical professions, process which allowed the appearance of ethical issues involving both the physician and patient. The need to reflect over a moral dimension of continuous medical progress in providing new services, of new breakthroughs and technologies has compelled the development of new medical ethic codes for that justice and equality of medical act and responsibilities of the medical staff are in order.

What is ethics?

Medical ethics represent the constant reflection of the medical staff over the patient's behavior and morality, especially over a medical intervention. Several principles of medical ethics have been defined as they are considered the basis for a proper medical practice such as autonomy, beneficence, non-maleficence and respect for human rights. Even so, some of these principles may interact and be connected when applying them to a medical case. Medical ethics allows the possibility to adapt every case to a certain situation, while taking difficult decisions and providing specific medical decisions becomes much more easier.

Ethical Aspect in Endoscopy

Over the years, Gastroenterology and Endoscopy have known an important development, due to the large armamentarium of medical equipment, techniques and new diagnostic and therapeutic guidelines. With this evolution they gained an imperative role in patient's satisfaction, while providing an environment which allows a certain medical protection against litigation.

One of the endoscopist's duties is to provide attentive care for the necessary decisions when providing diagnostic and therapeutic services. This aspect is influenced by the fact that patients desire the liberty to have a point of view over the procedures they are going to be subjected and have the possibility to choose over their treatment options.

Even more they expect that the endoscopic interventions will not cause any discomfort or pain, which raises the standards for endoscopic health services.

When analyzing endoscopic ethical aspect we have to take into account the following:

- Patient's satisfaction
- Elder patient's safety
- Endoscopic paliative options
- Industry related interractions
- Emergency endoscopic procedures

Ethical aspects of gastroenterologic research

Medical studies which involve human subjects are of great importance for the gastroenterological field. This is mostly due the industry influence over the research developments and it's results, to the potential conflicts of interest, unidentified plagiarism, or medical research of questionable quality and bad conduct of studies.

Contemporary behaviour ethical aspects while doing research are derived from the basic principles and ethical values which have their roots in the ancient practice of medicine.

Ethical aspect on live demonstrations in endoscopy

Extensive development and wide spreading of telecommunication under several forms, allows using the internet and satelite connection to explore new ways of expanding current sciences horizons, experience sharing and information exchange and building more effective teaching programs. This technology allowed the connection of scientists and relationship strenghtening between distant medical centres in a new interactiv and more productive way, which provides a great advantage for the education and training programmes in gastrointestinal endoscopy. In recent years a rise of the of live endoscopic procedures has been encountered during national and international meetings. These types of live demonstration attract a large number of participants, both fellows in training and experienced endoscopists. Live sessions cover wide areas of interest throught their programs, starting with elementary notions of endoscopy to high fidelity endoscopic procedures using new technologies.

Personal Contribution

Objectives

This study proposes an evaluation of ethical issues in general medicine and gastroenterology in particular. Along with the development of practical medicine new aspects are required to fulfill a correct, beneficial and transparent medical act which will provide the necessary safety for the patient.

Ist Objective – to assess the informed consent in patients which underwent a therapeutic colonoscopy. To assess the factors that influence the way that the informed consent is perceived and the aspects which may improve its use.

IInd Objective - to assess the examination process of the colon using quality indicators accepted in international guidelines, with the purpose to enhance the procedure quality as well as the patients perception over the colonoscopy.

IIIrd Objective – to assess the results obtained in research projects on human subjects by correlating the results of published articles, books and patents

Understanding and Acceptance of the Informed Consent in Gastroenterology

Materials and Methods

Between January 2013 and September 2015, 72 patients of the Gastroenterology Unit of the Emergency County Clinic Hospital of Craiova, which were subjected to therapeutic endoscopic procedures were asked to complete a structured and self-administered questionnaire based on the procedure of obtaining the informed consent for endoscopic polypectomy.

Results

Leading factors in understanding the risks of endoscopic procedures were age, education level and previous endoscopic experiences. The t student test within IBM SPSS (IBM, New York, USA) was used to assess the results. A p value less than 0.005 was considered statistically significant. Of all the age groups, the ones under 40 years old were more aware of the bleeding risks the ones between 40 and 60 years old ($p=0.008$). When discussing the infection risk, patients with an age between 40 and 60 years old

were more aware than the group under 40 years old ($p=0.03$). The level of education had a key role in risk understanding. Along with a college diploma, better knowledge on possible side effects of the endoscopic procedures became available in comparison with middle school graduates ($p=0.1$), as well as high school graduates ($p=0.0007$). Previous experience on colonoscopies was also considered important in understanding possible complications, as well as the benefits of colonoscopies. Thus, patients subjected to 2 colonoscopies were significantly better informed than the others with no previous experiences. ($p=0.1$).

Quality Indicators in Digestive Endoscopy

Materials and Methods

This was a retrospective study and consisted of non-anesthesia colonoscopy review which were performed within the Gastroenterology Unit of Emergency County Clinic Hospital of Craiova between January 2013 and September 2015.

Quality indicators consisted of caecal intubation rate (CIR), polyp detection rate (PDR) and also the detection rate of colorectal carcinoma (CRC) was taken into consideration with its colon distribution.

Results

The study consisted of 3147 colonoscopies performed by gastroenterologists, both specialists or fellow in training within the Gastroenterology Unit of the Emergency County Clinic Hospital of Craiova. Patients which underwent the colonoscopy procedure were admitted in different Hospital Clinics, with most of them in the Gastroenterology Unit. 91 colonoscopies did not allow the visualization of the caecal valve due to the low level of bowel preparation, 173 were interrupted because of patients level status, while in 44 patients technical problems were presented. From the 550 colonoscopies which did not reach CIR, 37,45% were because a stenosis was found either malignant or benign, due to external compressions, and 6.54% were due to a previous intervention on CRC.

From all examined patients 955 presented polyps in different parts of the colon, of which 760 (24.14%) were categorized with the diagnosis of "colonic polyp". Thus, the

difference between these two parameters was because patients presented more than one polyp in different areas of the colon.

Regarding the polyp distribution, a considerable prevalence was observed on the left colon (59,68%), followed by approximately equal values between the right colon (20,20%) and the transvers colon (20,10%).

While using the p Chi square test, a statistically significant difference was identified on gender distribution of polyps (p Chi square = 0.032 < 0.05).

The p test Z showed high statistically significant difference compared to the general population, in Romania there are 51,4 % women and 48.6% men (p test Z < 0.001).

255 (8,10%) of cases presented tumors which benefited of pathological assessment which guided the diagnosis to CRC. When discussing tumor localization it was observed that more than half of the cases were diagnosed on the left colon (65.09%). A smaller rate was encountered on the right (18.03) and the transvers colon (16.86%). As for gender distribution there was a higher CRC rate in men (70.19%), than in women (29.81%).

Significant statistical difference was observed when discussing presumptive diagnosis and CRC localization. While analyzing the differences between the three locations, the result of the p Chi square test was $p=6,82 \times 10^{-7}$, which is lower than <0,001, thus, observing that the most encountered colonoscopy indication was based on the symptomatology on the transvers and left colon, and as for the right colon, anaemia was the primary indication.

Also significant statistical differences were presented when analyzing the presumptive diagnosis to the patients gender, with the symptomatology indications being more frequent in men, while the laboratory results indication being more frequent in men p Chi square=0,021 < 0,05.

Scientific Research on Human Subjects in Gastroenterology and Dissemination of Results

Materials and Methods

According to the Ethics Commission of the University of Medicine and Pharmacy of Craiova between 2005 and 2015, 47 statements for research studies in Gastroenterology on human subjects were approved, of which 16 were after grant proposal winnings by the Romanian Government, and 18 as a partner. Using the website <http://www.umfcv.ro/granturi>, we selected the national grants won through national competition by the Gastroenterology Department members. Consecutively, by studying the final reports of the projects we followed the completion and quantified the criteria of research results. For the scientific articles, we searched the international databases Pubmed, and Pubmed Central using the names of researchers which were approved by the Ethics Commission.

Results

Between 2005 and 2015 the members of the Gastro Unit won through competition, 16 projects financed by the Romanian Government which involved human subjects. From these, 2 were infrastructure projects which allowed an increase in the workspace, the purchase of new medical equipment and enrolling new human resources.

Over this period, 68 ISI articles followed by acknowledgment according to each project, 36 BDI articles and 73 international congresses presentations were accomplished.

When comparing the number of ISI articles published during the research grants before 2010 and after 2010 a statistically significant difference was observed using the t Student=0,0011<0,05, with more recent grants enrolling better results.

According to the final reports, the human subjects were aware and well informed of study inclusion. Also, all studies received Ethics approval, opinion which was obtained prior the study.

General Conclusions

- Gastroenterology and digestive endoscopy represent an area which is in a continuously under development, both because of the large number of diseases recorded worldwide as well as increased focus on medical research. Thus, the gastroenterologist must be able to provide a high quality medical services, with the obligation to choose what is best for the patient;
- Most of the endoscopic procedures are invasive, require a considerably time to perform and expose the patient to certain complication risks, which is why the process itself should not only have the desired effect but also provide a bearable experience for the patient;
- In an environment where commitment to patient comes first and where the patient may be considered as „consumer”, his satisfaction during the endoscopic procedure became one of the medical objectives of day-by-day practice. Patient’s feedback may lead to a better quality of endoscopy, to improve endoscopy practitioners skills and performances and also to diminishing the complication risks;
- Obtaining the informed consent is a legal medical process encountered in every medical procedure. For the consent to be informed, patients require to be aware of the procedure and accept it;
- Patients have different perceptions, concerns, mentalities and that for medical information must be delivered to the patient’s level of understanding. With these studies it was emphasized the way that age, education, previous endoscopic experiences influence the medical and legal process of obtaining the informed consent;
- Availability of quality indicators for procedures are important for assessing the performance and quality of endoscopy and the continued development of the medical staff;
- The use of quality indicators in a screening program can bring important benefits to potentiate the medical act;
- Research in Gastroenterology is a process in continuous development, which is directly dependent of the funding process. This aspect was confirmed by the doctoral study, showing that research with self-funding, may not have results as valuable as the ones from external funding.

➤ Progress in Medicine and Gastroenterology is based on the desire for knowledge and investigations made in the prevention and treatment of various diseases. The continuous funding of the research process will result in an enhanced human capital through individual development, which in the future will have effects on the economy.

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