

# **Errors in Colorectal Surgery**

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"Every surgeon carries about him a little cemetery, in which from time to time he goes to pray, a cemetery of bitterness and regret, of which he seeks the reason for certain of his failures" René Leriche (1879- 1956)

## Introduction

Surgery has five unique characteristics that set it apart from any other medical specialty

- 1. Surgery harms before it heals
- 2. It penetrates the patient's body and thus is highly invasive. According to the judgement of Judge Benjamin Cardozo in Schloendorff v Society of New York Hospitals (1914): "a surgeon who performs an operation without patient's consent commits an assault"
- 3. It is fallible, which means that surgery is predisposed to human error. Increased awareness on this topic has been developed since the Institute of Medicine "To Err is Human" was published (10)
- 4. A surgeon's decision making process is usually performed under circumstances of uncertainty
- 5. It is prone to risks and complications
  The surgeon- patient relationship is built upon
  trust, so it is preferable to speak about it from
  a fiduciary viewpoint, not as a contract. As
  John Gregory stated during the XVIII century,
  the physician (8):

- must be in a position to know reliably the patient's interest
- should be concernid primarily with protecting and promoting the interests of the patient
- should be concernid only secondarily with protecting and promoting his or her own interests

The surgeon-patient relationship is attained and perfected throughout the process of the surgical informed consent, which includes the following elements:

- 1. Preconditions: competence and voluntary attitude of the patient
- 2. Information: disclosure and recommendations by the surgeon and the patient's understanding of the information provided.
- 3. Consent: decision-making (acceptance or refusal), communications, registration, and the patient's authorization to proceed.

Errors in this process due to the lack of truthful and sincere information can result in later claims in the legal system.

## **Vignettes**

The following vignettes serve to illustrate different situations; all of them are based in real cases where surgical expert witness testimony was requested. The legal system in my country, as well as in many others,

comprises both criminal and civil litigation against physicians. In the criminal jurisdiction a mandatory review from the Forensic Advisory Board, dependent of the Supreme Court of Justice, is always requested and most



times, in the civil jurisdiction as well.

### Case I

Female, 68 years old

Diagnosis: sinchronous tumors in caecum and sigmoid colon

Surgery: paramedian right incision. Right hemicolectomy

Postoperative course: postop. bowel obstruction. Referred to another institution due to family request

Surgery: exploratory laparotomy. Colectomy + ileostomy+ closure rectal stump (Hartmann) Postoperative course: sepsis, multiple organ failure, death

#### Case II

Male, 72 years

Rectal bleeding. Negative rectosigmoidoscopy Bleeding persists. Returns for consultation. Piles diagnosed

14 months after: admission due to suboclussion and loss of weight 12 kg Diagnosis: sigmoid cancer 5 cm anal verge + liver mets.+ neoplasic ascitis (T3, N2, M1, stage IV)

#### Case III

Male, 56 years old

Diagnosis: rectal cancer stage III. APR performed

Histopathology: rectal adenocarcinoma, free margins, one node (negative)

Postoperative course: at 4 months, perineal pain. CEA  $\uparrow\uparrow$ , CAT scan: perineal tumor fixed to the sacrum

Referred to another institution. Gets operation, dies due to uncoercible presacral bleeding

#### Case IV

Female, 57 years old

Diagnosis: colon cancer at 40 cm from anal verge (colonoscopy). Ink- marking

Surgery with colon resection. Histopathology: no lesion

New colonoscopy: tumor found at 25 cm from anal verge. New surgery with resection of the tumor

Uneventful postoperative course

#### Case V

Male, 69 years old

Surgery for rectal tumor. The surgeon considers the condition as unresectable and performs a diverting colostomy.

Referred to medical oncologist for neoadyuvancy.

Relaparotomy at another institution (tertiary referral center).

Operation: firm adherences, low anterior resection with termino terminal anastomosis. Uneventful postoperative course.

The analysis of the different clinical scenarios shows the variety of errors, mistakes and breaches to the standard of care throughout the different situations, which always look controversial and debatable.

The different vignettes offer a wide range of situations:

- Case I illustrates a wrong site surgery, the surgeon directed his attention to the right lesion, forgetting the left side tumor
- Case II a lack of thorough physical examination, with a lack of precise diagnosis and thus, loss of chance. We must remember the dictum from William J Mayo (1861- 1939): "The examining physician often hesitates to make the necessary examination because it involves soiling the finger"
- Case III and IV involve technical errors, which are probably the most difficult to define, prove and discard.
- Case V shows evidence of an error in surgical judgement.

## **Background**

Attention is better paid to errors in surgical care since the publication of "To Err is Human" by the Institute of Medicine (10), but there were very important historical landmarks.

Hammurabi's code, the oldest legal codification, states in its law 218: "If a physician performed a serious operation with the bronce scalpel and made the person die, or if he operated on the eye cataract and

destroyed the eye of this man, his hands should be cut".

The Edwin papyrus records in case XIV (injury to the nostrils) "...If the set bone festers, and the slave suffers, the conclave of elders will convene and deliberate lest the healer know not of his error"

Ernest Codman, surgeon from Harvard and one of the founders of the American College of



Surgeons, considered four different types of medical errors in surgical care (4):

- a. Due to lack of diagnostic accuracy
- b. Due to lack of surgical sound judgement
- c. Due to lack of knowledge or technical abilities
- d. Due to lack of care or of a resourceful team

Richard Cabot investigated errors in clinical diagnosis based on the analysis of 1000 autopsies and later on, on other additional 2000 autopsies and he described huge mistakes in the surgical practice (3)

Max Thorek, an American surgeon in Chicago born in Hungary stated in 1935 the following principles (17)

"The first great error in Surgery is unnecessary operation, and the next is the undertaking of a major operation which the surgeon is not technically fitted to perform"

"No surgeon, no matter how skillful or proficient he may be, should ever consider himself beyond the possibility of error or accident"

"It is seldom that they tell us what not to do, how to avoid complications and technical errors or how to at when face to face with some of the abnormal circumstances which constantly present themselves during the course of a surgical operation"

"While it is human to err, it is inhuman not to try, if possible, to protect those who entrust their lives into our hands from avoidable failures and danger"

McIntyre and Popper, physician the first and philosopher the latter, published their research in 1983: "Mistakes occur in medicine as in other walks of life. Their consequences may be trivial, but often they are serious, and they may be catastrophic. Some errors cannot be helped; others are avoidable, even culpable. Steps may be taken to correct errors but in many instances the mistake is irrevocable; the only benefit is the prevention of similar errors in the future. To learn only from one's own mistakes would be a slow and painful process and unnecesarily costly to one's patients" (15).

James Reason, a british cognitive psychologist, introduced the "swiss cheese model" including latent errors and barriers to their production (16).

Leape published in 1994 a seminal work with the application of Reason's research in the medical field, arising the awareness about the topic (13) and in 1999, the Institute of Medicine published its report (10).

According to recent statistics, aroung 234 million of surgical interventions are performed annually (18). The incidence of complications is between 3 to 25% and the operative mortality is 0.4 to 8% (7, 9)

Some figures will illustrate the magnitude of colorectal surgery: in the US about 600.000 surgeries are performed annually with a 30 days readmission rate of 11.4%, climbing to 23.3% at 90 days, with a median length of stay of 8 days and a cost of 300 million U\$S (19).

A recent expert consensus warned on discharge signs and action plans for patients with complications after colorectal surgery. These symptoms should be watched by patients and request an inmediate contact with the surgeon in case of their appearance (14):

- Wound drainage, opening or redness
- No bowel movement or lack of gas/stool from ostomy for more than 24 hours
- High ostomy output and/or dark urine or no urine
- Increasing abdominal pain
- Vomiting
- Abdominal swelling
- Fever higher than 101.5 F
- Not being able to take liquids for more than 24 hours
- Chest pain
- Shortness of breath

This overview is coincident in the sense that errors in colorectal surgery represent a hot topic for patients, their surgeons, health care institutions and the health care system as a whole due to their economic, ethical and legal implications.

# Framing the issue

Though everybody seem to understand the meaning of error, it represents different things to different people. As L Carroll put in Humpty Dumpty's words "when I use a word, it means

just what I want it to mean" ("Through the looking glass").

But the situation is different when we use the term surgical error, or error in the surgical care



process, which may seem more appropiate. According to Donabedian's model, the quality of care is derived from the analysis of three categories: structure, process and outcomes. Structure describes the context in which care is delivered and includes hospital buildings, staff, equipment and infraestructure. Process denotes the interactions between patients and providers (physicians and others) through the delivery of healthcare. Finally, outcomes refers to the effects of healthcare on the health status of patients and populations. Errors will be committed during the process of care and their occurrence cannot be judged just by the presence of unfavourable outcomes, otherwise our analysis would be partial. Harm may be even achieved in the absence of error. This sequence applies also to technical errors. Many times there will be data to judge the quality of performance of an operation (e.g., number of resected nodes) but many times the only way to define the presence of an error during the surgical care process is just by being present during the process and with the previous knowlledge of the definition of what an error consists of (1).

The IOM based its definition on Reason's theories and in that sense, distinguishes (10):

- Error of execution or skills: the failure of a planned action to be completed as intended
- Error of planning or knowledge: the use of a wrong paln to achieve an aim

The consequence of a medical error (the use of the term "error in the process of health care delivery" is preferred) constitutes a preventable adverse event. A medical error can cause injury or not, if there is no harm it is not an adverse event. If it is interrupted or its occurrence is prevented, it is a near-miss.

To make things worse the non preventable adverse event is the injury or complication not due to an error or system failure and which can not be prevented with the present scientific knowledge or evidence.

The preventable adverse event is the injury or harm attributable to a system error or to an individual failure, and according to the American Society of Healthcare Risk Management can be of three categories:

- Type I: physician's error
- Type II: error of another member of the health team
- Type III: system error but not individual

Besides, you must bear in mind that "Good practice does not guarantee a good result"

The taxonomy of errors in the surgical care process is useful since it can provide a deeper and more detailed analysis of their characteristics:

Leape distinguishes (13):

- a) Individual errors, incurred by those working in the interface with patients. Correspond to active errors, at the operators' level and have immediate effects.
- b) Systemic errors, where all the step and processes are involved. They represent latent errors and are usually out of individual control. They include inadequate designs, poorly structured organizations, inefficient maintenance, bad managerial decisions and others.

For Reason (16), the human error in the surgical domain occurs in three cognitive levels:

- Knowledge: related to inadequate or incorrect information
- 2. Rules: the information is correct but the applied methodology is incorrect
- 3. Skills or abilities: the execution is imperfect

Cushieri proposes two categories (5):

- Proximal errors: those imposed by the system operated by the organization and the process used by the practitioners, resulting in defects relating to:
- Coherence and goal conflicts
- Poor leadership
- Inadequate team work
- Inadequate training
- Inadequate resource allocation
- nclear protocols and procedures
- Non transparent culture
- Overwork
- Lack of quality assurance measures
- Inadequate detection of poor performers
- Distal errors: also known as coal face, front line, sharp end, related to the interface and interaction between patient and the health care team (physician, nurses, others)
  - Input error (knowledge and perception)
  - Intention (mind- set) error
  - Execution (psychomotor) error due to either omission or commission

Charles Bosk in his seminal work "Forgive and remember, managing medical failure" define the following errors in surgical care with an special emphasis on the time of training in a surgical residence (2):



- Judgement: due to lack of knowledge or expertise
- Technical: related to surgical skills and tolerated while in training
- Normative: related to personal behaviour and increased responsibility in the management of surgical patients
- Quasi- normative: related to the interaction betweeen surgical residents and attending staff and faculty

Krizek defined the following types of surgical errors (11):

- Judgemental
- Technical
- Expectations
- System
- Mechanical

Besides, errors in colorectal surgery may be attained during the different stages of the surgical care of a patient:

- Preoperative period: related to knowledge, rules and expertise
- Intraoperative period: usually related to the skills and abilities, but also to judgemental issues. Errors originated

- in the preoperative period can even manifest themselves now
- Postoperative period: related to the knowledge, the rules and the skills.

The etiology of human error in colorectal surgery includes the following factors:

- 1. The patient: mostly due to issues of health literacy
- 2. The surgeon: some of the factors are life style, poor satisfaction, overconfidence, impairment and fatigue
- 3. The operating room and the institution Some examples of errors in Colorectal Surgery include the following, some examples have been achieved with the introductory vignettes (6):
  - Unnecessary surgery
  - Wrong side surgery
  - Technical errors
  - Thermal injuries
  - Retained foreign bodies
  - Surgical pathology reports
  - Medication
  - Hospital falls
  - Clinical documentation

Informed consent process.

### Recommendations

If the surgical team or the institution are interested to start a systematic approach to prevente errors in the surgical practice, it is very important to have a knowledge of them. In that way, their prevention will be enhanced as well as their legal implications. That may be the path to lead a strong and successful patient safety program.

Once an error has been discovered, its knowledge and notification keeps an essential role in the communication and dissemination, this process includes the following steps:

- Disclosure to the patient and relatives.
   Different positions arise in this sense with a clear predominance of a policy of transparency and tending to express the regret of the surgical team ("We are sorry").
- Report to the institution and ad-hoc organizations or boards. The reporting system, similar to the one in the aviation industry, should be (12):
- Non punitive
- Confidential and anonymous
- Independent

- Expert analysis
- Timely
- Systems- oriented
- Responsive
- The implementation of surgical patient safety programs which must be:
- Safe
- Effective
- Efficient
- Timely
- Patient centered
- Just and equitative

The three main targets of this Program should be:

- The institutional culture towards medical error, which most probabely should be modified
- The surveillance detection of errors in clinical practice
- The prevention and the education of the medical team/s

The following methods are recommended for the prevention of error in the operating room and all of them show the influence of aviation in the surgical field



- a. Briefing and debriefing: including preoperative informative discussion and postoperative update
- Time out: for mutual knowledge of all the team members, procedure and side confirmation, and

discussion of critical situations or hazards

Check list: before anaesthetic induction (entrance), before skin incision (time out) and before operating room discharge (exit), as recommended by the World Health Organization.

## **Conclusions**

- Surgery is characterized by fallibility, the paradigm which resembles surgeons to gods must be modified
- Error, by definition, is involuntary and non intentional; nobody intends to perpetrate one
- A surgical error impacts on two victims: the patient as well as his or her surgeon
- The analysis of surgical errors must not pursue blame or punishment, but the improvement of the surgical care
- Prevention is based not only on an individual struggle but also in the organization of institutional systems protecting patients from individual mistakes
- Errors must be reexamined in the context of a surgeon performing an operative procedure on a patient, many times instructing a younger colleague or resident and with lack of adequate and sufficient resources.
- The analysis of error concentrates in the weaknesses of a system ("the holes of the swiss cheese") and of its members. It must research: active failures like slips, near-misses and mistakes (technical, judgement, diagnostic, etc) and latent conditions

- (structural systemic weaknesses) as well. This understanding is of paramount importance for the design of prevention systems to achieve a safer surgical care
- In order to know errors and their incidence, we must promote the report of adverse events, asserting: confidentiality, no punishment, analysis, recommendations to prevent relapsing
- Analysis of human factors engineering overwies the the interrelation of the surgeon with his/her environment, other physicians and professionals and the organization
- Communication breakdowns are one of the most important factors in error production: special attention must be given to hand-overs, medical records and the surgical informed consent
- Quality and safety of surgical care are 2 sides of the same coin. To lower the incidence of adverse events and increase patient safety means better quality and outcomesEthical principles (beneficence, non maleficence, respect for patient autonomy and justica) must characterize the analysis of human errors

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