

SURGICAL MALPRACTICE – A SERIOUS PROBLEM FOR THE MEDICAL SYSTEM

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Abstract: Although medical malpractice recordings date even from 2030 BC, nowadays, medical malpractice litigation has gained an overwhelming dimension. As general surgery conveys a higher risk of complications and medical errors than other specialties, surgeons receive more than twice malpractice claims than other specialty doctors. In fact, it is estimated that each surgeon will face a malpractice claim at least once in his/her career. The reported medical errors associated to abdominal surgery complications and malpractice claims are numerous, being human- or system-related and can appear intra-, pre-, postoperatively or at multiple care-phases. Therefore, understanding the timing and causes of the medical errors becomes a requisite for future prevention strategies in order to limit preventable surgical complications and patient death. Several hospitals have already reported the beneficial effects of various preventive strategies, such as: standardized team briefings and checklists, strategies to reduce communication breakdown, standardized transfer of protocols and responsibility, as well as others. Therefore, a worldwide implementation of such strategies should be promptly considered to improve the current standard of care and prevent future surgical errors.

Keywords: surgical malpractice, medical errors, negligence, surgical complications, general surgery, abdominal surgery, preventive strategies.

INTRODUCTION

A historical view over medical malpractice across times

Medical malpractice recordings date even from 2030 BC, when surgical mistakes associated liability, as described in the Code of Hammurabi [1]. This code appears to be one of the first ever written, documented records of medical malpractice cases, where a surgical mistake leading to patient death or harm was drastically punished by cutting off the surgeon's hands. Since then, the legal background of medical malpractice has been expanded, although initially relatively slowly, first by the Roman law and then by being introduced to Europe around 1200 AD. However, the first continuous written record of the medical malpractice cases and decisions appears to date back from the 12th century under the reign of Richard Coeur de Lion. Currently, medical malpractice cases often require the opinion of an expert witness that has to judge whether there was a breach in a patient care (medical negligence) based on the generally acknowledged standard of care [2]. However,

this modern concept of medical malpractice law is also quite old, as even from 1532 the opinion of a doctor was required when judging cases of violent deaths. Despite such evidences of a continuum of medical malpractice claims across history, the cases of medical error claims were rare until the 1960s, holding a limited impact on medical practice [1]. However, since the 1960s, along with the progress in the medical technology and scientific knowledge, the expectations of the patients greatly increased, leading to a burst in the medical malpractice legal claims number, with significant consequences (both positive and negative) on the medical system.

Current medicolegal definitions and types of malpractice, negligence and adverse events

According to the international and Romanian law (Law number 95/2006 regarding the reform in the health system), medical malpractice is described as an inadequate, negligent or incompetent professional medical act, below the generally accepted standard of care, which determines a significant injury/harm to the patient (such as death, permanent or temporary disability,

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financial costs or negative psychological effects) and that associates civil liability of the medical personnel [1, 3]. Medical malpractice definition must therefore meet three essential criteria: a sub-standard, deviated, wrong medical care; the generation of significant patient harm; and a cause-effect relationship between the medical error and the patient injury. In judging medical malpractice cases, an expert witness is required, to evaluate which standard of care should have been considered in the given case and whether the deviation from it might have resulted in the patient's injury [2]. That is, medical malpractice is a medical error that holds medical liability (disciplinary- from the hospital and College of Doctors; civil and criminal) and legal consequences [4]. The medical mistakes that are at the base of the malpractice claims can be of several types: commisive, "in agendo- when a wrong action is taken ; omissive, „in omitendo" - when the right action is not taken; technical, „in eligendo"- when the medical mistake is generated by an inadequate choice or use of medical techniques; of communication, correlative or „in vigilando"- when the error is generated by poor, insufficient or even lack of communication between various healthcare partners [5-8].

Although medical malpractice involves medical professional negligence, not all the cases of negligence lead to malpractice cases if the negligent behavior does not arrive to patient harm. Medical negligence is defined as an inadequate treatment that falls below the generally accepted standard of care that would have been applied by other healthcare professionals in the same given conditions [9, 10]. Medical malpractice or negligence must be differentiated of adverse events. Many medical adverse events are commonly acknowledged complications that can arise from a medical act/surgery and can be preventable or not, active or latent. Only the preventable adverse events can be regarded as medical negligence/malpractice. However, some adverse events are clearly classified as never-events (should never happen if a correct, standard of care is administered to the patient) and therefore always represent medical negligence. Other events are „near-misses", that is they almost happened but another factor intervened and rescued the situation. "Near-misses are therefore an example of medical negligence that does not become malpractice [6].

The current dimension of surgical malpractice in the world and its consequences

Nowadays, medical malpractice litigation is a frequent phenomenon, being estimated that each

surgeon will encounter it at least once in his/her career [1]. In fact, compared to other medical specialty doctors, surgeons are the most frequent category faced with malpractice claims. From the surgeons' category, the most frequent malpractice claims affect general surgeons (abdominal/visceral), orthopedics doctors, gynecologists/obstetricians and, less frequently, plastic surgeons [11-14]. In fact, surgeons appear to receive more than twice malpractice claims than other specialty doctors, male surgeons being at the highest risk as they concentrate in the most complex surgery areas. One explanation behind this phenomenon is that surgeons deliver the highest-risk type of treatment to their patients that usually associates a high risk of severe complications, as they face with the most severe cases that were not treatable by medical therapies [11, 15, 16]. Another explanation could come from the surgeons' culture and behavior, different from other specialties, with specific traits acquired during their education and practice that is characterized by poor, short communication with the patients [11]. This aspect is of importance, as poor communication between the doctor and the patient is at the base of many malpractice lawsuits, as the high expectancies of the patient in terms of treatment are not balanced by a doctor's detailed explanation of the potential side effects/complications that can normally occur during surgery [9, 14, 15, 17]. That is, the patients are not informed sufficiently in regards to the difference between preventable (medical negligence) and non-preventable medical adverse events that are commonly described as a consequence of a surgical procedure [6]. The correct communication between the physician and the patient is even more important as otherwise there is a significant disagreement between the patient's perspective of the complications and that of the surgeon [18].

Understanding the types of surgical errors: timing and causes

The medical errors that are at the basis of abdominal (visceral) surgery malpractice claims can occur: intraoperatively, preoperatively and postoperatively. There are also medical errors that extend at multiple stages, from the preoperative to the postoperative period and involve multiple care personnel. Although intraoperative medical mistakes are considered as being the most frequent type of errors, there are also studies that report an almost equal distribution of the errors among the three mentioned types. In a retrospective review of the surgical malpractice claims in Belgium between 1996 and 2006, the most frequent

errors were found to occur intraoperatively (48% to 60% of the cases), followed by postoperative (37% of the cases) and lastly by preoperative mistakes (15% of the cases); also, 9% of all the cases occurred at multiple stages of the medical care [19, 20].

Intraoperative mistakes result from lack of technical competence/inexperience/faulty surgical technique; wrong surgical decisions; negligence (confusion between structures), visceral and various structure lesions leading to severe complications such as bleeding or abdominal sepsis; communication failure, environmental factors. Many types of intraoperative medical mistakes are „never events”, such as performing a procedure on a wrong patient; wrong operation; wrong patient position; wrong surgical site, wrong side; wrong organ being removed, such as in the case of anatomic segments with symmetrical disposition (e.g.: surgery on the left side when the inguinal hernia is on the right); incomplete, superficial evaluation of the abdomen leading to omission of simultaneous lesions (the „mirage of the first lesion”, such as in the case of performing a cholecystectomy while omitting the presence of a concomitant ulcer); unnecessary operations or visceral removal; inadequate surgical duration (the positive association between the length of the surgery and the occurrence of surgical complications is clearly recognized); retained surgical bodies; wrong insertion of implants or substances into the patient; operating while the patient is awake, not-anesthetized [16, 21, 22].

In Italy, which is the country with the highest number of medical malpractice claims from the world (more than 10000 new criminal proceedings against doctors each year), the most frequent causes of complaints, as reported in Traina's review, are: incorrect surgical technique (around 51% of the cases), failure in the follow-up and misdiagnosis [9]. Such an extensive malpractice lawsuit phenomenon clearly associates negative consequences, leading to more defensive medicine and a huge financial burden. Also, many malpractice claims are related to infections, as abdominal surgery associates a high-risk of infections, such as after colon surgery [8, 23]. As nosocomial and surgical-site infections are quite frequent and can lead to catastrophic adverse events for the patient and even death, a meticulous strategy of implementing interventions to prevent infections after abdominal surgery has been proposed [23]. Another frequently recognized cause of medical error is the incorrect transfer of information “hand-offs „between health care personnel [20].

Commonly reported preoperative mistakes are: insufficient communication between the physician and

the patient that is of significant impact especially when the surgical intervention can lead to infirmity (rectal amputation, radical mastectomy, leg amputation); breach of informed consent; diagnostic errors, misdiagnosis; failure or delay to prescribe the correct medication/treatment following the diagnostic build-up; untimely diagnosis and treatment; lack of interdisciplinary assessment to adequately evaluate the patient anesthetic-surgical risk preoperatively that should be also communicated to be patient and family; administrative failures [8, 24, 25]. Some studies report that the diagnostic errors are the most frequent of all medical errors, greatly increasing morbidity and mortality, as they can affect up to 12 million patients in the US each year [24]. Autopsy studies even show that in up to 44.5% of the cases a major diagnosis was missed that would have changed the prognosis of the patient [26]. Many diagnostic errors occur in emergency departments, due to the high volume of patients a medical doctor must evaluate and to the frequent interruptions that occur in such conditions. In this scenario, the general surgeon can be at a particular risk, as severe abdominal diseases can associate atypical, misleading presentations. Among the most frequent diagnostic mistakes in case of abdominal pain presentation can be: gallbladder pathology; diverticulitis complications; intestinal obstruction, appendicitis and cancer [24]. Failure to diagnose and treat in time small bowel obstruction is a frequent subject of medical litigation, because it usually results in a high mortality rate that could have been otherwise prevented [27].

The mechanisms that are at the basis of diagnostic errors can be: patient-related (such as delayed presentation to the hospital, negligence, uncooperative behavior, substance abuse); physician-related: inadequate anamnesis; insufficient review of patient previous documentation; inadequate physical examination; incomplete filling of the patient medical records; insufficient or wrong diagnostic tests request; failure in following-up the results of the laboratory investigations; failure to order other tests when discovering a laboratory or imaging anomaly; failure to interpret correctly the performed imaging tests. A failure in a thorough preoperative evaluation of the patient can mislead, conducting to a wrong operation and lack of diagnosis of the real cause of the disease. For example, epigastric pain in a patient with sigmoid tumor can be falsely interpreted as an acute ulcer or a colic (biliary or appendicular) leading to wrong organ surgery and omission of the disease real cause treatment. In such cases, an insufficient intraoperative exploration

of the abdomen also adds to the medical mistake that has been initiated preoperatively. Also, there are cases when emergency operation is required and that do not allow for a preoperative prolonged patient investigation. Therefore, treatment temporizations/delays in such cases are an example of severe medical error, because they can rapidly lead to major complications and patient death (e.g.: major bleeding cases; trauma, where severe visceral and vascular lesions are anticipated; decompensated intestinal obstruction, when a rapid restoration of the intestinal transit has to be achieved with/without the removal of the obstructive cause; decompensated peritonitis, when the removal of the septic contamination source and managing complications become emergency requirements; enteromesenteric infarction; organ torsions; acute pancreatitis, where the assessment of the need of a surgical operation should be immediately performed (even though the primary treatment is not commonly surgical). Incorrect preoperative diagnosis leading to a forced surgical indication for the patients that do not present a surgical disease can ultimately lead to major complications (fecal peritonitis after right hemicolectomy or temporary colostoma) and patient physical harm or even death that could have been otherwise prevented [8, 14, 15, 25]. Actually, superficial clinical assessment with the inadequate evaluation of the patient abdomen is one of the most frequent preoperative medical errors that will extend its impact on all the phases of the medical care [5]. However, it is generally considered that diagnostic mistakes can be prevented [15] by knowledge of the cause of errors and effective preventive strategies.

Frequently reported postoperative mistakes invoked in malpractice claims are: failure to monitor/follow-up patients; delayed diagnosis and treatment of postoperative complications (such as abdominal sepsis following anastomotic leakage or textilomas); lack of correct postoperative care and medication (failure in administering antiseptic or anticoagulant medication); inadequate record of the postoperative evolution of the patient; lack of interdisciplinary assessment of various postoperative complications; administrative failures [25]. For example, untimely diagnosis and treatment of intestinal obstruction is a cause of mortality in approximately 69% of the cases, meaning an average compensation of 1136220 dollars. Also, a delayed diagnosis of bile-duct injury following laparoscopic cholecystectomy leads to worse patient outcomes and greatly increases medical costs [17].

Human and system-related surgical errors in malpractice claims

Therefore, the main causes/contributing factors for the surgical errors are human or system-related, such as: judgment errors; lack of knowledge; lack of attention; failure of memory; inexperience, lack of technical expertise/competence/training (technical errors)- low hospital volumes; communication deficits; excessive surgeon's fatigue and workload; emergency surgery; time of the day when the surgery is performed; also, patient-related and system-related factors (lack of adequate medical technology, lack of tools, device errors, hospital system inadequacy) [7, 20, 28].

Patient-related factors play a significant role in the mechanism of medical mistakes, being described in more than 44% of the medical mistake cases, but are many times unpreventable. Such factors are: extreme obesity, difficult, atypical anatomy, modified anatomy landmarks in reoperated patients; behavior problems, including non-compliance, lack of education, cognitive deficits, socioeconomical limitations or substance abuse [7, 15].

An important type of contributing factor to medical errors is related to communication failure. Inadequate communication can take place between: the doctor and the patient; doctor-nurse; members of the same team; between the surgical resident/trainee and supervising doctor; between the doctor and his/her superiors; interdisciplinary and across departments or even hospitals; between the medical personnel and the administrative staff of a hospital. Often, communication failure means inadequate handoffs or a lack in establishing clear lines of tasks and responsibility [7, 15]. Inadequate communication between the physician and the patient with breach of informed consent is a frequent cause of medical malpractice claims [7].

Technical errors appear to be most frequently associated to elective surgery and could be explained by several factors: abnormal or difficult patient anatomy; lack of clear anatomic lines; morbid patient obesity; interruption/distraction; lack of supervision (surgical trainees errors); lack of communication; judgment errors and failure of memory (less frequently) [19]. In Rogers *et al.* and Gawande *et al.* studies a lack of technical competence (errors of manual technique) was found in 41% to 53% of the analyzed cases, sometimes being related to a surgical trainee's inexperience (in 40% of cases), but surprisingly even more frequently in already qualified general surgeons (58% of the cases), when lacking sufficient experience with a certain type of surgery [7, 20]. For example, the inexperience of a surgeon in

adrenalectomy can lead to the erroneously ligation of the renal artery and need of performing a nephrectomy [7]. However, the presence of the trainees significantly contributed to medical errors by: communication failure; lack of supervision, and it was manifested especially in emergency surgical care. Lack of supervision was found in Rogers *et al.* study to be a contributing factor in 18% of the medical error cases [7]. Usually, however, there is a simultaneous contribution from several factors, at multiple levels of failure (a systems failure), involving multiple healthcare professionals and less frequently the effect of a sole, isolated factor [15, 19, 20]. Other factors can also come from the difficulty and unpredictability of the medical care that can lead to unpreventable errors [15]. Although the attending surgeon is responsible for the medical mistake in almost all of the cases (92% of the cases according to some authors), in the majority of the cases, more than one clinician contributes to the medical error. Malpractice claims occur even against medical residents, as they can be frequently commit medical mistakes resulting in permanent disability or death. Surgical trainees' malpractice cases can occur as a result of insufficient supervision, lack of knowledge, decision errors, technical inexperience and communication faults [29].

The requirement for a root cause analysis and preventive strategies of surgical errors

Nonetheless, for prevention strategies, several initiatives can be considered. An example is the safer surgery checklist time out procedure proposed by the World Health Organization, which has been already implemented in many hospitals. This type of preoperative checklists or short team briefing in the operating room, in which all involved surgical team members comprising surgeons, anesthesiologists and nursing staff participate, can prevent/decrease a considerable number of never-events and other types of medical errors if performed correctly. Such a checklist includes: the correct surgeon and patient identification; adequate patient position; correct site, side and procedure; review and counting of the surgical items that will be used (medical textiles, surgical instruments) or implanted; medication and blood that will be administered to the patient. Even if conducted completely, such a checklist is easy to perform, does not require specific training and is inexpensive [22]. Such checklists are at the basis of a safer surgery and of better communication between surgeons and anesthesiologists [30, 31].

Strategies to reduce communication breakdown are also essential in preventing medical errors. The

communication breakdown leading to errors can occur in all the phases of care. They can occur within the same surgical team, frequently intraoperatively, as well as within a department, interdisciplinary or even between institutions. The breakdown appears most frequently in concern with verbal communication that is inaccurately transmitted or even never transmitted, such as inadequate hand-offs from one healthcare professional to the next. In this regard, preventive strategies involve a standardized approach of hand-offs; use of trigger lists that signal for obligatory communication with the surgeon from the part of nursing staff and other physicians and trainees; standardized team briefings and checklists; standardized transfer of protocols and of responsibility; and even computerized systems that allow for duty of care transfer from one resident to the next [31]. Important strategies for risk management involve preventive interventions to reduce the occurrence of retained surgical bodies [20, 32-39].

In conclusion, as medical errors and malpractice claims are extremely numerous, leading to significant patient harm and costs for the medical system, a root cause analysis becomes a requisite for preventive strategies.

However, understanding the etiology of the medical mistakes is a difficult and complex process. A major limitation comes from the understandable lack of reporting of medical errors and near-misses by healthcare professionals that fear of legal consequences. Nonetheless, several hospitals already report the beneficial effects of various preventive strategies, such as: preoperative checklists, short team briefing in the operating theatre; strategies to reduce communication breakdown; standardized approach of hand-offs; use of trigger lists that signal for obligatory communication with the surgeon from the part of nursing staff and other physicians and trainees; standardized team briefings and checklists; standardized transfer of protocols and responsibility; computerized systems that allow for duty of care transfer from one resident to the next ; preventive interventions to reduce the occurrence of retained surgical bodies. Therefore, a worldwide implementation of such strategies should be therefore considered to decrease the number of preventable surgical complications that fuel the already overwhelming malpractice war.

Conflict of interest

The authors declare that they have no conflict of interest.

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