Case Report and Review of the Literature
The Difference Between Malpractice and Adverse Event: Report of a Case and Review of the Literature

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ABSTRACT

Background/Aim: The practice of surgery may lead to unexpected results and most such results come due to risk in the practice of medicine. Our aim is to identify the difference between malpractice and adverse event.

Case Presentation: A young male patient who experienced a cascade of adverse events after a laparoscopic cholecystectomy and even though he had the ultimate treatment an unknown and extensive atherosclerotic coronary arteries disease had led to a fatal left ventricular corruption due to an extensive myocardial infarction.

Results: The relatives of the patient filed a lawsuit against the surgeon due to the perception that death was caused by malpractice.

Conclusion: Evidence-based medicine should not become defensive, since not every unpleasant event is due to malpractice or negligence.

Introduction

The practice of surgery may lead to unexpected results. Sometimes they are good, sometimes not. Not all unpleasant events, however, are the result of malpractice or negligence. In fact, most such results come due to risk in the practice of medicine, which cannot be prevented simply through fear of disciplinary action.

Case Presentation

A 36-year-old male patient admitted to the emergency department of our hospital due to epigastric pain and fever. Physical examination and further lab tests and imaging investigation revealed biliary colic (white blood cell count: 18,620K/μL, AST/ALT: 114/190U/L, and an ultrasound scan that showed gallbladder debris). Laparoscopic cholecystectomy was the procedure of choice. The patient consented to a surgical approach after being thoroughly informed on his clinical condition and the two therapeutic options: either urgent surgical treatment (as internationally recommended), or a conservative-first approach and a scheduled cholecystectomy four weeks post admission.

The patient was led to the operating theatre where he underwent a laparoscopic cholecystectomy. At the end of the operation, hepatic parenchymal bleeding occurred at the gallbladder bed site. In the attempt to control hemorrhage - as it was discovered later- the cystic artery endoclip may have been removed, and an emergency laparotomy was decided during which the cystic artery conduit was identified and ligated. No other site of active bleeding was observed in the abdomen during laparotomy.

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On the first postoperative day, the patient demonstrated a good general condition, while the subhepatic drain tube accumulated a total of 30ml. During the second and third postoperative days he continued to display a normal clinical course, and despite the fact that the hematocrit decreased, he was not hemodynamically unstable as expected in the context of the intraoperative hemorrhage. At this point, we would like to point out our decision not to transfuse the patient as there was no indication of active bleeding, knowing the undesirable effects of a transfusion, such as nosocomial or postoperative infections, and always weighing the benefit of the patient. The transfusion of blood has been related to various clinical adverse events in the last decades. A meta-analysis including 45 patients, who were transfused with red blood cells, showed undesirable clinical outcome to 42 out of 45 of them [1]. A postoperative ultrasound scan was negative for intraperitoneal effusion, and the drain tube was removed. On postoperative-day-five, he is thoroughly informed and discharged under exit permit. An appointment is scheduled since a new blood count check was needed.

On the sixth postoperative day, he was urgently readmitted after a syncopal episode. Physical examination showed hemodynamic stability, and all laboratory tests were unremarkable. He stayed hospitalized and on postoperative-day-seven, due to a fall in hematocrit level, a computed tomography scan was performed. A peritoneal effusion was present, without any alteration or damage to an intra-abdominal organ.

After a department council, we decided conservative monitoring since computed tomography scan did not identify any cause of bleeding. Hematocrit level responded to blood transfusion. On postoperative-dayten (with a hematocrit of 32%), a second fainting episode and a rapid hematocrit decrease, led us to the operating room. A laparotomy was conducted and hemoperitoneum was discovered. A large blood clot is found in the lesser sac as well as a rupture of the splenic capsule at its lower pole, without injury of the parenchyma at the site of the organ’s hilum. Splenectomy was decided. It was observed that the ligaments of the spleen were absent (neither splenocolic nor gastrosplenic were present). There was also the impression of spleen detachment from the hilar vessels. The spleen the resected, and its vessels were dissected and ligated. Patient was then transferred intubated to the intensive care unit (ICU). As far as the spleen hemorrhage is concerned, this complication of laparoscopic cholecystectomy is regarded as very rare and few cases have been reported to literature [2–4]. Probably, both the existence of adherences and the absence of normal splenic ligaments to other abdominal organs are factors which contributed to a subcapsular spleen hematoma during pneumoperitoneum. This hematoma continued to enlarge until a rupture was occurred. At this point, we should highlight that a direct check of the spleen at the end of the surgery can lead to earlier recognition and more effective management of the lesion.

On the third postoperative day he was transferred from the ICU to the surgical wards. On the sixth postoperative day and while being hemodynamically stable and in good general condition, he exhibited epistaxis which was treated with cauterization. His laboratory tests showed neither a change of hematocrit nor a coagulation disorder. Later the same day, while sleeping, he woke up due to back pain and dyspnea. He was urgently transported to the coronary care unit (CCU) where the ultrasound scan revealed cardiac tamponade. Subxiphoid pericardiocentesis was performed which aspirated a large amount of hemorrhagic fluid. A drainage catheter was placed. He was immediately transferred to a cardiothoracic surgery department for further investigation. Patient expired during thoracotomy. An autopsy was performed, and the cause of death was an extensive left ventricular infarction. Histological examination of the heart, revealed severe stage IVa and V atherosclerotic lesions through the heart vessels, causing extensive stenosis in most of the heart vessels and a 90% constriction in the anterior descending branch. His relatives filed a lawsuit against the surgeon due to the perception that death was caused by malpractice. The verdict was acquittal both in the multi-member First Instance Court and in the Court of Appeal as well.

Discussion

Like any other endeavor involving judgment, the practice of surgery may lead to surprise. Sometimes the surprise is good, sometimes not. Not all unpleasant medical events, however, are the result of malpractice. In fact, most such events are the result either of the inherent risk in the practice of medicine, or due to system errors, which cannot be prevented simply through fear of disciplinary action.

Common terms used interchangeably to refer to such events arising from medical treatments include “complication”, “side effect”, “sequela”, “adverse reaction”, and “malpractice”. Malpractice should be strictly distinguished from adverse events such as complications, side effects (aftereffects), and sequelae [5]. Complications refer to other diseases or symptoms that occur in relation to a given disease.

Side effects refer to undesirable effects that occur concomitantly with the originally intended outcome. Sequelae refer to the symptoms that remain after an illness or to the adverse reactions occurring after an event. For example, patients after total pancreatectomy become diabetic. Malpractice refers to a medical negligence or an error, including inadequate treatment and misdiagnosis by doctors. Complications refer to unexpected events that may occur even after adequate treatment, such as postoperative neurologic injury, infection, hemorrhage, hematoma, and drug-related side effects. Complications can be resolved without any serious problems if the cause is detected early and adequate treatment provided. In this case, it is rare for the medical staff to take legal responsibilities.

The three main terms (which include all others mentioned above) are: a) malpractice, b) adverse event and c) system error. At this point we should take it a step further and compare these three basic terms in pairs using common examples.

1 Adverse Event vs Malpractice

It is important to understand one fundamental concept; there is a difference between adverse events and negligence. In jurisprudence, malpractice means an illegal act of professional negligence. The most common examples of medical malpractice include leaving gauze or instrument at the site of operation following surgery, causing trauma to body parts unrelated to the treatment site or performing on the wrong part of the body [5].
On the other hand, when a patient with pneumonia, is prescribed an antibiotic and develops an unforeseeable allergic reaction to this drug, causing i.e., short-term kidney failure and hospitalization, this injury consists of an adverse advent. This is not negligence. Negligence is the failure to provide a standard level of care or, in other words, the delivery of substandard care. In the above scenario, it would have been negligence if the physician had neglected to check the chart, which stated that this patient was allergic to this antibiotic. Patients are not identical in health, habits, immunity or healing power, and have varying susceptibility to complications. Complications are adverse. A mistake due to negligence, however, assumes there was a lapse of either quality or control by the surgeon out of keeping with normal expectation.

Here is another example: during thyroidectomy, injury to the recurrent laryngeal nerve may cause permanent hoarseness. If the surgeon does not find the nerve and injures it as a result, this is a surgical mistake. If he does find it, preserves it, and the nerve loses its blood supply and a palsy results, this is a complication. If tumor invades the nerve and it has to be sectioned, this is a complication. Many adverse events occur in the practice of medicine, but relatively few are due to negligence. A Harvard Public Health Study by Brennan et al. estimated that only 27% of adverse events were due to negligence [5]. Medicine is not an exact science, and complications are an inherent feature of any procedure or medical intervention.

For example, surgical procedures generally carry a 3%-4% risk of infection. Sterile techniques, preoperative cleansing, and prophylactic antibiotics are all used in an attempt to minimize infection. Nonetheless, even in the most capable hands and under the best of circumstances, infection can occur. This would be an adverse event, but not one due to a medical error. It would instead be a risk inherent in the practice of medicine. Similarly, pneumonia may result in a patient’s death despite him receiving the proper antibiotics, blood clots may develop despite administration of proper anticoagulation agents, and nerve injuries may result despite properly performed procedures [6].

It is important to differentiate between adverse events and medical errors (or mistakes), because punishing adverse events per se would have a chilling effect on treating complex conditions or performing difficult procedures [7-9]. It would also discourage care of high-risk patients with multiple comorbidities. An ideal oversight system would, therefore, not punish adverse events, but rather identify and target medical errors. Surgeons who tackle more difficult surgery will have more complications and should not be penalized for dealing with them. If surgeons operate, complications will occur.

In our case, as far as the spleen hemorrhage is concerned, this complication of laparoscopic cholecystectomy is regarded as exceedingly rare and few cases have been reported to literature [2-4]. Probably, both the existence of adherences and the absence of normal splenic ligaments to other abdominal organs are factors which contributed to a subcapsular spleen hematoma during pneumoperitoneum. This hematoma continued to enlarge until a rupture was occurred. At this point, we should highlight that a direct check of the spleen at the end of the surgery can lead to earlier recognition and more effective management of the lesion.

Concerning the myocardial infarction, our case was a young patient, without known risk factors for cardiogenic disease, suitable for surgery since preoperative management was normal. As a result, the extensive atherosclerotic lesions could not be suspected. The myocardial infarction was an event unrelated to the cholecystectomy and the spleen rupture. The rupture of the wall of the left ventricle, which occurred to the subject, caused cardiogenic shock, and constitutes the main cause of death after myocardial infarction. 66% of deaths in the first cardiac event are a result of the rupture mentioned above. It appears the first week after the myocardial infarction, usually the fourth or fifth day, but it can even appear the first minutes after the cardiac event [10]. This could not be prevented, and both the time of appearance and the severity of the cardiac rupture led to the unavoidable death of the patient despite medical efforts.

II Malpractice vs System Error

Another important concept to understand is the difference between malpractice and system error. Negligence, as discussed above, is failure to meet a standard level of care. It is an incorrect decision. For example, it is considered negligent if the standard of care for kidney failure is dialysis, and this is not ordered.

A system error, on the other hand, is an occasional, simple human error. Deterrents cannot reduce these errors because they are made unintentionally. From time to time, humans unwittingly make errors, such as mistaking salt for sugar when baking, mistaking an oxygen tank for a nitrogen tank during airplane maintenance, or mistaking “1.2 mg” for “12 mg” or “12µg” when administering medication. This is not a decisional error, and so is not negligence. It is considered a system error because good organizations recognize the human error component and safeguard against it. Patients may hide or forget information when giving history; Health care providers misread handwriting occasionally because they are human; however, a good system could reduce system errors by instituting computerized medication orders. Another example of a system safeguard is the use of ID bracelets to prevent confusion between patients with similar names.

According to a landmark paper by Kohn et al., To Err is Human, most medical errors are the result of unavoidable human error, which can only be reduced through system changes [11]. Punishment for errors will not reduce future errors, to ensure a safer system. On the contrary, it might incentivize workers to hide rather than report these errors. Furthermore, physicians as a group are already ethically motivated to avoid negligent behaviour, and the threat of litigation does not add to this motivation [11]. Instead, litigation has a negative effect on physician behaviour. On a personal level, it creates an environment of fear and anxiety, disrupting the physician–patient relationship and causing physicians to fear patients as potential litigants. On a societal level, litigation causes physicians to practice defensive behaviours and avoid offering high-risk services. Both situations are undesirable.

Negligence is rarely present in most alleged cases of medical malpractice [12]. In one study by Localio et al., adverse events were reported in 3.7% of all hospitalizations. In over 70% of these cases, however, no negligence was present. In another closed claim study performed at
And in a 2005 Congressional Report, over 80% of malpractice cases reviewed contained no negligence [13]. One explanation for this is that health care providers, from medical assistants and nurses to physicians, tend to be highly motivated individuals [14]. Rather than being motivated by money, most health care practitioners tend to be motivated by professional or moral ideals to deliver high quality care and to “do no harm.” As such, negligence is not usually at the heart of most medical errors.

It is important to differentiate between system errors and negligence errors to identify those errors that can be deterred through the legal system (negligence) and those errors that can be reduced only with system safeguards (system errors). A rational oversight system will devote more energy towards preventing the more commonly made errors.

### III The Current Medical Malpractice Tort System and Reform Efforts in the United States

Currently, in the United States, medical errors are prosecuted under the tort system. According to Prosser and Keeton on Torts the goals of the litigation system are to compensate plaintiffs injured by negligence; discourage the practice of negligence; and exact corrective justice [14]. Some important limitations must be understood here. First, the litigation system can only deter negligence and compensate patients for injuries attributable to negligence. This means that most patients experiencing adverse events will have no recourse through the litigation system. Consider that only 27% of adverse events occur through medical error, and that only a fraction of those medical errors is attributable to negligence, and it is quickly apparent that very few patients who experience adverse events will be entitled to compensation [5].

This, however, does not prevent them from suing. Many patients sue when there is injury, failing to understand the fundamental differences between an adverse event and a medical error, or the difference between system errors and true negligence. The result is an overwhelming amount of time and money spent on fruitless litigation that serves neither to compensate the injured patient nor to improve the health care system.

Over 60% of all filed lawsuits in medical malpractice cases end up summarily dismissed as having no grounds to even have been filed in the first place and, according to a claim trend analysis from malpractice insurers, less than 1% of all filed medical malpractice claims actually end up in a verdict for the plaintiff [8, 14]. Even in these cases, most of the award is consumed by the attorney and administrative costs [12, 15]. So, of the $76 to $126 billion spent each year in the United States on medical malpractice litigation, extraordinarily little actually ends up truly compensating the patient. In other words, litigation is expensive and inefficient [16].

Graskemper has reported that malpractice could be significantly reduced by risk management, which facilitates a close cooperation among medical staff, ensures that patients receive a thorough explanation of the treatment process, and helps to minimize negligence during treatment [17]. Proper diagnosis, treatment planning, surgical techniques, and detailed patient information are crucial for minimizing treatment-related claims. Moreover, it has been highly recommended that referrals be made to relevant specialists for high-risk treatments [18, 19].

Various issues and medicolegal problems occur due to medical practices that involve direct or indirect contact with patients. If problems are detected early and adequately resolved, conflicts with patients rarely occur. However, if serious harm is done to a patient due to inadequate treatment, civil and criminal disputes become unavoidable. Moreover, if malpractice is identified as a clear cause, it can result in medical administrative and criminal penalties. Healthcare professionals are required to faithfully fulfill the duty of care and provide prior explanation, help medical staff and patients maintain close relationships, and promptly deal with any problems that may arise.

Within the above-mentioned framework, the new generation of tort reform in the United States, involves alternative dispute resolution (ADR), which refers to any of a number of dispute resolution techniques that help plaintiffs and defendants resolve conflicts outside of the courtroom. The most popular ADR techniques are mediation and arbitration, which differ in both their binding nature and their formality [14]. One advantage of ADR is that it is better suited to adverse events than is the tort system. Litigation can only compensate patients who are harmed by negligence. ADR can potentially reach all patients who experience adverse events, whether due to negligence or not.

### Conclusion

The medical field is different from the business world. Most business decisions are driven by a cost-benefit analysis. Without the threat of lawsuits, it is possible that a cost-benefit analysis would favour the introduction of marketable yet unsafe products. The tort system in such situations helps create a safer society by increasing the “cost” side of the analysis and discouraging the production of unsafe products. Health care providers, however, are not trained to engage in cost-benefit analysis. Rather, physicians are driven by professional ethics to first “do no harm” and second to heal the patient. Therefore, evidence-based medicine should not become defensive, since not every unpleasant event is due to malpractice or negligence.

### Ethics Statement

All human studies have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

### Conflicts of Interest

The authors declare that they have no conflict of interest and they have full control of all primary data and that they agree to allow the journal to review their data if requested.
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