REVIEW ARTICLE

Medico-legal Aspect Of Minimal Access Surgery In Resource Limited Countries

***+ Shah RC**
*Amcmet Medical College, India
+Legal Cell Convenor, Associations Of Surgeons Of India

Introduction

Life in medicine occurs within a legal framework that begins in medical school and continues throughout clinical practice. A touchstone of modern medical ethics is the oath attributed to Hippocrates. The Oath of Hippocrates protected the rights of patients and represented principles to be practiced by physicians. The "Hippocratic Oath" was probably written in the 5th century BC by a group of Greek physicians who constituted a "school" on the island of Cos. Modified extensively over the centuries, the oath attributed to Hippocrates underlines the present day medical ethics and legal practice [1-3].

Crimes are public wrongs against the state or the public at large. The "people" bring action against the perpetrator of a crime. The purpose of criminal proceedings is to protect the interest of the public and punish the offender. Torts, in contrast, are private civil wrongs usually between individuals in which the remedy is a common law action for damages. Medical malpractice is a tort that arises from the breech of legal duty one person owes another to act reasonably in a way that will not harm another person or his property. Medical Malpractice is injurious or unprofessional treatment or culpable neglect of a patient by a physician or surgeon. The basis of any medical malpractice suit is an assessment of fault that caused an injury to a patient. Fault centers on what is expected of a physician in the practice of medicine. Fault implies that the physician did not have the necessary amount of skill and care and, because of this lack or failure, a patient was injured. Simply put, the doctor is expected to act as a medical professional with a "reasonable" degree of skill and care [4-6].

Correspondence to:
Dr R C Shah
E Mail : Drrcshah@gmail.com
Www.medicolegalconsultants.org

Essential ingredients

To prove that malpractice has occurred, the plaintiff (injured patient) must prove four basic elements. (1) **Duty to care :** The obligation of a physician to care for a patient arises from establishing a doctor-patient relationship. A physician has no obligation or duty to accept all patients. However, once a doctor accepts a patient, he or she has a duty to adhere to a certain level or standard of care. The doctor-patient relationship can be established on an (even implied) acceptance to treat a patient even by way of medical prescriptions prescribed over the telephone, or the mere scheduling of an appointment may be sufficient to establish a legal doctor-patient relationship. Once established, this duty or obligation requires that the physician provide care for the patient. (2) **Breach of Duty :** This means that the doctor didn't conform to the standard of care. Standard care is "reasonable care" as provided by a "reasonable doctor." This standard usually implies that physicians must possess and employ the skill and knowledge of physicians in the same and similar circumstances and with regard to the state of the profession at that time. (3) **Causation :** the doctor didn't conform to the standard of care and harm came to the patient due to that. The doctor's negligence must be the reason for or proximate cause of the injury or damage caused to the patient (4) **Damages** : the monetary compensation claimed / awarded to a patient for losses suffered [4].

Informed Consent

Informed consent is a more recent development in medical malpractice litigation having evolved over the last century. Every human being of adult years and sound mind has a right to determine what shall be done with his own body. A surgeon who performs an operation without his patient's consent commits an insult for which he is liable in damages.

The issue of informed consent was more fully developed into its present form in the 1972 case of Canterbury v. Spence. In this court ruling, the duty to disclose all significant or material risks was outlined in absolute rather than relative terms. According to the court, all material must be disclosed regarding "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely

if the patient remains untreated." Implicit in recent legal rulings is that informed consent is not a 'form' or 'statement'. Rather it is the process of a physician communicating with a patient about proposed treatments or procedures during the preoperative period [4,5,7-9]. It is important to note that if a record of the informed consent discussion was not written into the patients chart, including a discussion of the operative procedure, its risks, complications, alternatives and their risks and reasonable expectations, legally speaking, that discussion did not occur. One of the judgments of the Supreme Court of India in Samira Kohli v Dr Prabha Manchanda deals with some aspects of informed consent which were hitherto ambiguous [10]. After this judgment, consent for "Laparoscopy & proceed" or "Laparotomy & proceed", which is so often used by surgeons, is invalid. Laparoscopy or Laparotomy indicates only an access to the abdomen. This, by itself, does not permit the surgeon to undertake major procedures inside the abdomen especially removal of an organ or permanently altering the structural anatomy of the intra-abdominal structures. Secondly, this landmark judgment has also clarified that the informed consent has to be taken from the patient himself and nobody else except when the patient is a child or of unsound mind or unconscious / incompetent to consent. If during the course of surgery, the surgeon feels something else needs to be done for which consent had not been taken, the surgery be closed, patient allowed to fully recover from anesthesia, the issues discussed with him and in case he gives consent for the same, go back and do the surgery again. The surgeon is liable even if the extended procedure was done in the patient's best interest. What is in the best interests of the patient with respect to his body, has to be decided by the patient himself and no one else. There is also no place for taking consent for 'extended procedures' from the patient's relatives, as was taken in this case from the mother of the patient. It was also clarified that emergency, life threatening situations are an exception, where, in fact, no consent is required.

The **Minimal Access Surgery (MAS)** technique has introduced a new way of operating but has also brought some new problems, including medico-legal issues, with it. The close dependence on instruments and technology, indirect vision and pneumo-insufflation differentiate this method of surgery from the conventional operating technique. This necessitates a period of learning, un-learning and re-learning for the surgeon and his team members. Shortcuts in soliciting / acquiring patients or in the performance of the surgical procedure or in the post-operative care can raise serious issues – medical, legal and social, especially where the resources are limited. Indian scenario offers healthcare establishments of wide range of resources. The high end, tertiary care hospitals (whether government or private) have no reason to provide anything but the best technology, skills and care to the patients. The smaller hospitals providing primary and secondary care (whether government or private) are not resourceful enough to provide that level of technology, skill and care. But to compensate for that, the surgeon in such hospitals with compromised resources, must know his limitations well and inform his patients of these limitations. He should be selective in choosing his patients for surgery, he should provide personal attention and vigilance in pre-operative assessment and post-operative care and have a low threshold for seeking second opinions, conversion from laparoscopic to conventional surgery and for referral to a higher center as and when situation demands. It is also very important for the smaller hospitals with limited resources to resist the temptation of being 'the first' to acquire a new procedure. It is doubtful whether advanced laparoscopic surgery should be performed in such hospitals. The surgeons need to clearly differentiate 'can do' from 'should do' philosophy and the guiding principle has to be the patients' best interests and patient safety rather than the surgeons' technical competence or the hospital's commercial interests [5,7,9].

Modern endoscopic surgery has introduced several new elements into the medico-legal process not present heretofore. For example, it is recognized that endoscopic surgery is guided by electronic imaging and requires manipulation of intra-cavitary organs with instruments remote from the operative field. Additionally, the operative procedure is represented as a two-dimensional display on a video terminal and does not mimic the three-dimensional reality of everyday surgical experience. These factors of remote, minimally invasive, electronic image-guided surgery have changed the character of modern operative intervention.

LaparoscopicVideo-recording

Foremost of the laparoscopic elements now available to the courts has been the production of high quality video tapes, dynamically recording the operative procedure. Many legal scholars consider unedited video tapes as a "disinterested observer" of the operative procedure accurately recording events in a way not possible with written documentation or human memory. For the first time, a graphic, dynamic, visual record of the operative event is available to aid the physician in defense of his actions. Unfortunately, this legal weapon may work for or against the surgeon, depending upon the circumstances. This unimpeachable source would appear to be a perfect ally in the defense of a malpractice claim,

if the operative findings and surgical procedure exactly corroborate the surgeon's version. Reality, however, has proven somewhat different. Video tapes present a magnified view of the surgical procedure and can distort reality. The laparoscopic instruments may appear to the untrained eye to be clumsily manipulated during "real-time" video recordings. These images are frequently magnified many times. Small bleeding arterioles can appear to be fountains of unrestrained blood loss. The focused view of the camera precludes observation of the operative field at large and may be misleading as to the actual status of the operative procedure. Clever plaintiff lawyers have been able to distort the information presented on laparoscopic video images and sway judges as to their content. For this reason, many laparoendoscopic surgeons do not routinely tape their operative procedures. Other controversial factors that mitigate against routine taping of surgical procedures include: 1) expense of tapes and taping equipment 2) cost of storing video tapes in an appropriate environment 3) length of time tapes must be preserved 4) which entity, surgeon or hospital, is responsible for tape storage, maintenance and security 5) who owns the video – patient or the hospital 6) confidentiality issues 7) conflict between desire for transparency and desire for publicity 8) whether consent should be taken for such recording – for nominative images as well as non nominative images 9) should nominative images be taken as part of the medical record of the patient 10) should videos for instructional use remain anonymous and can they be equated to excised tissue. There is no law established on such issues [8].

Laparoscopic Learning Curve

Most general surgeons of the late 20th century were not exposed to laparo-endoscopic technique during their residencies. Large numbers of established surgeons were first introduced to laparoscopy at two-day post-graduate courses / workshops. Typically, these courses offered didactic presentations of laparoscopic energy sources, instruments and technique sometimes coupled with hands-on animal training. A two day course, however, can provide only an introduction to laparoscopic instruments and procedures. It was quickly recognized that more time and experience were required to attain proficiency for "the standard of care" in laparoscopic surgery. Proficiency in operative technique requires practice, repetition and time. The time and case load to gain proficiency in a laparoscopic context has become known as the "learning curve." Initially, a certain minimal number of procedures was thought to assure negotiation of the learning curve. Individuals, however, varied in their capability to transition from hands-on three-dimensional surgery to two-dimensional, electronic image-guided operative technique. The learning curve was found not to be static, a "one size fits all" entity, but rather a period of time and experience that varied from individual to individual. In the United States, each hospital or institution has the responsibility to credential a surgeon in the areas that surgeon is permitted to practice. There is general agreement that a surgeon must first be credentialed in open surgery before being considered for laparoscopic credentialing. Adequate training for surgeons not exposed to laparoscopic surgery in a residency program requires attendance at an accredited laparoscopic course that offers both didactic presentations and hand-on animal experience. This introduction to laparoscopic methodology should be followed by experience as first-assistant to a mentor surgeon well versed in the operative procedure. After adequate experience as a first-assistant, the physician transitions to primary surgeon, observed and monitored by the department of surgery. A preceptor, one who is expert in the laparoscopic procedure, may be required to assist the newly trained operative surgeon during initial case work. Finally, if deemed necessary by the department of surgery or institution governing board, a proctor may be invited to observe the surgeon and submit a report to the board as regards the operator's technical competence. Smaller institutions may not be able to provide the experience or personnel to fulfill the above training in an even-handed manner. In these instances, failure to document adequate training can open the door to questions of not negotiating the learning curve and failure to attain the minimal standard of care necessary to perform laparoscopic procedures. The fact remains that in a country with poor resources, it is all the more important to be very cautious in starting the MAS program. The surgeon should fully train himself as well as his team members including the anesthetist and the paramedics. He should also ensure proper instrumentation and the monitoring equipment for the operative and post-operative management. If these preparations cannot be made / afforded, it might be a good idea to continue with the 'safe' conventional surgery rather than to start a 'glamorous' unsafe MAS program.

Learning curve for basic procedures and advanced laparo-endoscopic procedures

Basic laparoscopic surgery includes procedures like Diagnostic Laparoscopy, Laparoscopic Cholecystectomy and Laparoscopic Appendicectomy. Training and proficiency acquired in these procedures is not enough to perform advanced laparoscopic procedures or other forms of MAS, in a safe manner. For each such category of advanced procedure, one has to

undergo the training involving knowledge, observation, assisting and performance under supervision. It may also involve practicing on an endo-trainer, some specific maneuvers for safe execution. In case of medical litigation, if an allegation is made that the surgeon is not adequately trained, the respondent surgeon will have to submit evidence to convince the court about this training. No doubt, even after the requisite training one can have complications but if the training was inadequate or absent then there is no way to rebut the allegation. The professional bodies must lay down the guidelines for training and minimum standards of technical facilities. In that case if the surgeon has followed those guidelines, he will not be faulted on that ground.

Equipment & its maintenance

Equipment failure generally suggests negligence and lack of vigilance by the surgeon / hospital. Although the surgeon may not be the owner of the equipment and therefore responsible for its maintenance yet the surgeon remains the main organizer of the facilities for the operation for the patient who has entrusted himself to him for the surgery. A proper Annual Maintenance Contract with a proper record of the maintenance services goes a long way to rebut such an allegation.

Quality of technical facilities

The courts usually do not go by the latest or the most recent materials / equipments. They rely on reasonable facilities under the circumstances. They are likely to rely on the current recommendations by the professional bodies in the field. It is therefore important for the relevant professional bodies to periodically give the recommendations / prohibitions to its members[6].

Disposable equipment

The disposable equipment is meant to be a single use material. The tendency to re-sterilize and re-use the same may invite legal problems. As a matter of fact, nowadays there is a growing incidence of litigations on account of hospital acquired infections. If it is shown to be related to a re-use of a disposable equipment, the liability will fall upon the surgeon if no proper consent is taken.

Complications related to patient position during surgery

In some laparoscopic surgery cases, for example, Gynaecological surgery or Bariatric surgery, extreme positions are required for technical reasons. There might occur a complication related to such forcible flexion / abduction of limbs. This can be serious if there are neurological sequel with or without functional consequences. Such accidents can be prevented if the surgeon is conscious of these problems and takes personal care in patient positioning in each case that he operates.

Shorter hospital stay

Short hospital stay no doubt is a desirable goal in each case. However if this is done under pressure of insurance companies or the patient's family, this may become dangerous. Cautious & safe surgery should never be compromised by any such pressures. The professional bodies and the hospitals should address this issue with the insurance companies, keeping patient safety in mind. The courts are not likely to accept the excuse of the insurance company guidelines, to justify a complication that might arise out of early discharge. For example, hospitalization permitted for laparoscopic cholecystectomy is two days. Some of the complications tend to present on the 3rd or 4th post operative day. If the surgeon succumbs to the insurance company guidelines and discharges the patient in 2 days, even if the patient did not appear to be normal, such a discharge is medically & legally incorrect. Such a patient is likely to develop problems at home and there will occur significant avoidable delay in the detection and management of the complication. The courts will not accept such a defence based on the requirements of the insurance company. The recent trend for 'ambulatory laparoscopic surgery' needs careful planning to ensure patient safety and minimize legal problems[4,6].

Minimizing the size of the 'key hole'

The recent trend of decreasing the size of the ports from 10 mm to 5 mm to 3 mm or decreasing the number of ports to single port (SILS) or NOTES, makes little surgical sense though it sounds very attractive for soliciting patients. In a way, by so doing, the surgeon is making the procedure technically more difficult with increased potential for complications. If the surgeon wants to perform in such a manner, he should not only undergo proper training for it and have a low threshold for conversion to standard MAS approach or to conventional surgery but also discuss the limitations of the procedure / approach during the informed consent discussion and documentation.

Failure to convert when needed

Conversion from Laparoscopic to conventional form of surgery, we all know, is a sign of maturity of the surgeon since it greatly helps him in averting a probable complication with serious consequences. Unfortunately, the surgeon is sometimes hesitant to convert or just does it too late. This usually occurs when the surgeon has not discussed this issue of conversion with the patient / family members in the pre-operative period or if the surgeon has a tendency to boast about his laparoscopic surgery skills or when he is in a hurry. So the safeguard is to be realistic and discuss the options with the patient / family with tactful honesty, so that you neither scare

away the patient nor put yourself to avoidable stress. In the absence of due information to the patient about a possible conversion, the actual conversion may still not be a complication in the medical sense but may become a complication in the legal sense. Define your threshold for conversion both in emergency situations and in the elective situation. For example, in one of the centers the guideline for elective conversion is (a) when any member of the surgical team or the anesthesiologist suggests conversion or (b) when there is no headway for more than 20 minutes in dissection or in defining the anatomy, conversion is resorted to without questions. One should remember that you will never be penalized by the court for conversion but you may get the decision against you for failure to convert when the situation was difficult.

Surgical complications

Complications are bound to occur in any surgical procedure even in the best of surgical centers and in the best of hands. MAS is no exception. Surgical complications, per se, do not amount to medical negligence. But the courts are likely to decide against the surgeon if the complication is due to the lack of requisite training or lack of experience or failure to properly investigate the patient pre-operatively or inadequate pre-operative preparation. The courts will also not spare the surgeon if it proved that there was a significant error of omission or act of commission during surgery, responsible for the complication. It is also very important to provide the necessary post operative care & monitoring. It will amount to negligence if there was an avoidable delay in the detection of the complication or if the patient was not provided prompt & proper management of the complication. The surgeon is also expected to honestly inform the patient & his family members about the nature of the complication, the plan of management, the risks involved, the prognosis and the long term consequences if any. He should answer all their queries, provide information on the different options available with their pros & cons and seek second opinions if required or if requested by the patient. If the patient requires a referral to a higher center, it should be done well in time, to a proper center, with proper medical support and with requisite medical records. It is easily understood by anybody who has seen CBD injuries after Laparoscopic cholecystectomy, that such injuries, if not managed prudently, can result in a biliary cripple and even a mortality.

Travelling Surgeon

There is a class of surgeons who travel from one center to another, to perform MAS. It looks all fine if the patient does well. But if the patient develops complications, there will be issues regarding post-operative care in the host center and the delay in arrival of the surgeon to attend to the problem. One also sometimes witnesses a conflict between the surgeon and the host center, blaming each other for the complication. When the travelling surgeon carries his own instruments from one center to the other, there can be problems of compromise with instrument sterilization[5,7].

Future laparoscopic legal issues

Laparoscopy is a maturing field, and it is becoming evident that there are aspects of image-guided, endoscopic surgery that need to be addressed. A debate is emerging as to who should perform endoscopic interventional procedures. Heretofore, only those specialists trained in the surgical arts were permitted to perform interventional procedures. This practice was guided by the principle that only those practitioners who could handle all complications of an intervention should perform that intervention. The distinction between surgeon-interventionist and nonsurgeon-interventionist, however, has blurred. Today, radiologists are beginning to examine the possibility of performing endoscopic peripheral vascular procedures under radiological guidance. Stereotactic breast biopsies and coronary angioplasty are other examples of nonsurgeon-interventionists performing procedures for which they may not be qualified to handle all of the complications of that procedure. The legal ramifications of nonsurgeons performing interventional procedures that may require open exploration to handle complications of that intervention has not been completely addressed. It will be necessary for all parties involved in health care to examine this issue and protect the interests of the patient while maintaining fairness for all practitioners of modern, technology-driven surgery. The Robotic surgery, which is evolving to further revolutionize surgery, will bring with it its own medico-legal issues. It may be too premature to speculate on this.

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