

MEDICO LEGAL ASPECTS OF ANASTHESIA PRACTICE WITH REFERENCE TO INDIAN LAWS - A CASE STUDY

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ABSTRACT: Anesthesiology is a high risk specialty subject and normally the patients surgery depends on anesthologist. Many people are not aware of the risks involved in Anesthesia. In the present system of healthcare in India, Anesthesia practice in particular there is not much scope for interaction between the patient and the Anesthologist. Though the Medical Council of India rules and laws that are existing presently in India insists that it is the duty of the Anesthologist to explain to the patient or the accomplices of the patient regarding the health condition of the patient and the anesthesia that is going to be given to the patient before procedure and the complications, reactions, side effects that may arise during and after procedure to the patient, things are not conducted as mentioned above. Lack of knowledge of the patient and the accomplice regarding the importance of anesthesia and the effects thereon before and after procedure and their reluctance to know are some of the causes, for the patients to complain after the introduction and applicability of Consumer Protection Act to the medical professionals things have become more difficult to the anesthologists.

Anesthetic death is defined as,

"death occurring normally within the 24 hours of the administration of Anesthesia of the patient".

The American society of Anesthologists (ASA) has devised a classification system to grade the pre-operative condition of the patient. In India, if the patient dies when a surgical procedure to the patient is performed under anesthesia, the anesthest is often accused unfairly, causing death. However, it is the duty of the pathologist to examine cause of death and liability of anesthest and to what extent. There are no diagnostic finding at autopsy in most instances of anesthesia related deaths because there are no path gnomie pathological changes found in deaths caused neither by anoxia nor in acute cardiovascular collapse unless there is something underlying cause, such a myocardial infarction. In this article an analysis is made regarding Anesthetic risk and cause of deaths due to other factors and liability of an anesthest and medico legal aspects related to anesthetic deaths.

Keywords: Anesthetic mortality, pre and post anesthetic checkups, medical negligence, criminal, civil and Consumer Protect Act, lack of experience, error of judgment, consent.

INTRODUCTION

Anesthesiologist: An Anesthesiologist is a medical Doctor who has been trained to safely administer anesthetic to include a temporary loss of sensation or consciousness. This involves a variety of drugs ranging from local numbing agents to general anesthesia used to render unconscious. An Anesthesiologist is a board certified physician who has attained either a Doctor of medicine (M.D.) or Doctor Osteopathic medicine (D.O.) degree and choose to specialize in the field of Anesthesiology. Anesthesiologist are an integral part of the surgical team, which surgeons, surgical assistances, nurses and surgical technologists. The core function of Anesthesiology is the practice of anesthesia this involves the use of topical injected or inhaled medications to produce a loss of sensation. Without anesthesia many surgical and non surgical procedures could be intolerable and unfeasible. To administer anesthesia safely the Anesthesiologist must have expert knowledge of physiology, pharmacology and the techniques used to support vital functions during an anesthetic procedure. They include,

1. Management of Airways and Respiration
2. Use of Hemodynamic monitors to measure blood pressure
3. various methods of cardio vascular (heart) and pulmonary (lung) resuscitation should these organ systems suddenly fail
4. Anesthesiologist must also expected to have a broad general knowledge of all areas of medicine and surgery.

To become an Anesthesiologist it is required a commitment to the medical profession. One should have bachelors degree in medicine and M.D. Anesthesiologist or a Doctor of Osteopathic Medicine (D.O.)

Anesthetists: Anesthetists and Anesthesiologist are two types of medical professional who administer anesthesia to patients during medical procedure. They often work together to provide pain relief before, during and after a patient's surgical, obstetrical

and a dedication to the years of training. An Anesthetist also known as a nurse anesthetist is a registered nurse trained to safely administer anesthesia. With specialized training in anesthesia, a nurse anesthetist can give anesthesia to a patient, monitor patient's vital signs during procedures and adjust anesthesia as needed during a procedure. A nurse anesthetist also performs all the duties of a nurse including getting needed information about the patient and helping to manage his health. To become a nurse anesthetist one must get both Bachelor and Master Degree in nursing after completing required course work and training one must then get licenses as a registered nurse after passing national certification examination. Thereupon one should attend an accredited an anesthetist program to enter the speciality.

Anesthesiology is a High Risk Specialty Medical Profession: However the public at large are not aware of the risks involved in Anesthesia. Anesthesia is from the Greek word means "*Loss of Sensation*". Anesthesia allows invasive and painful procedures to be performed on the patient with little distress or pain to the patient. In the present system of Anesthesia practice in India there is not much scope for interaction between the patient or his / her accomplices and the anesthologist, causing unhappy situations if some things goes wrong in the procedure. There are three main types of Anesthesia.

1. **General Anesthesia:** In this procedure the patient is sedated, using either intravenous medications or gaseous substances and occasionally muscles paralyzed, requiring control of breathing by mechanical ventilation.
2. **Regional Anesthesia:** This process involves administering anesthetic drugs directly in or around the spinal cord blocking the nerves of the spinal cord (Epidural or Spinal Anesthesia). In this method of Anesthesia the benefit is ventilation is not required. Normally regional anesthesia described as central and peripheral anesthesia.
3. **LOCAL ANESTHESIA:** The Anesthetic is applied to one site, usually topically or subcutaneously.

TYPES OF CASES:

An anesthologist can be dragged to a court either by criminal or civil laws or consumer protection act, depending upon the nature of the case and the liability of the anesthologist and to what extent.

CRIMINAL CASE: The aggrieved party viz., the patient or his /her authorized person can file a complaint against the Anesthologist in a police station for investigation and if proved guilty the Government (Judiciary) prosecute the concerned anesthologist. This happens normally when the offence is of a serious in nature. The judicial proceedings and criminal cases to punish the Anesthologist for the lapses on his/her part. However in criminal cases no monetary benefit / compensation will be given to the effected party (patient) or his legal representative in case of death or permanent disability.

CIVIL CASE: In civil proceedings the aggrieved party viz., the patient or his / her authorized person can approach the civil court of that jurisdiction to seek compensation for harm (damage) caused by the application of Anesthesia before procedure or after the procedure (within 24 hours).

CONSUMER PROTECTION ACT, 1986:⁽¹⁾ After the introduction of consumer protection act and the Apex Courts observation and bringing medical profession also under Consumer Protection Act, 1986 because the patient pays the money to receive the desired service from the medical professional comes under Consumer Protection Act, 1986. This has given a boost to the patients to get a reasonable compensation from the medical professionals under medical negligence due to damages caused due to breach of that duty.

Irrespective of the fact whether the death is due to anesthetic effect or not the natural tendency of the patient or their personal is first to accuse the Anesthologist. All these acts of the Anesthologist comes under medical negligence.

Grounds for Action:^(2,3,4,5) To prove the medical negligence of a medical professional especially the Anesthologist the following ingredients of negligence are to be established to get the desired compensation or punishment to the erring medical professional (Anesthologist).

1. **Duty:** The Anesthologist owed him / her duty
2. **Breach of duty:** that the Anesthologist failed to fulfill his / her duty
3. **Damages:** Because of this breach of duty the actual damages resulted to the patient.
4. **Causation:** The reasonable relationship between Anesthologist's acts and the resultant injury.

Once the Anesthologist examines the patient before procedure (pre operative examination) and after analyzing the physical, mental condition of the patient, and if the Anesthologist agrees to provide anesthesia care to that patient, the duty to the patient by the Anesthologist is established. In addition any medical professional when consulted by a patient owes him certain duties such as, a duty of care in deciding whether to undertake the case, if so what treatment and a duty of care in the administration of treatment to that patient. Breach of any of these duties by the medical professional, the patient gets a right to take appropriate action. In addition the Anesthologists are responsible for those they supervise and that are employed by the hospitals. Since it is impossible to delineate specific standard the courts have introduced the word "*reasonable and prudent physician*". Any medical professional who undertakes a duty of care should have a reasonable degree of skill and knowledge in addition to required qualification and must exercise a reasonable degree of care. This can be decided by the judiciary on case to case and professional to professional basis only. While deciding any case against Anesthologist, the circumstances under which the Anesthologist was

practicing at that time in question and various conditions such as cardiac, respiratory, haematological and other aspects of the patient, medical care decided treatment to be rendered, nature of procedure, availability of equipments must be taken into consideration.

A medical professional possessing special skill and knowledge and accepts the responsibility and undertakes the procedure and the patient submits to his / her directions and procedures accordingly. The medical professional owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the procedure: and no contractual relation is between them. The law requires a fair and reasonable competence. If the patient's death has been caused by the defendant's indolence or carelessness and shows that he/she has no sufficient knowledge, unskillful, gross negligence and if he/she cannot prove that he/she was diligent in attending the procedure but the patient has been killed, he/she is liable for prosecution and breach of contract. The doctor will have discretion in choosing the procedure (kind of anesthesia to be given and the dosage) to be administered on the patient and such discretion is relatively correct during emergency and in such circumstances the medical professional (Anesthologist) is not liable on the ground of breach of duty.

Error of Judgment: Lord Denning MR said

"we must say and say it firmly, that, in a professional man, an error of judgment is not negligence".⁽⁶⁾

Indian courts have also taken this approach in delivering the Judgments. Wrong diagnosis if it is not fatal is not deficiency in service. Medical profession is peculiar in nature and there is always room for differences of opinions, practices and procedures, courts cannot decide that one procedure is better than the other as the basis for coming to a conclusion of negligence.

Mistake: For claiming compensation arising out of medical negligence (Anesthologist negligence, and type of anesthesia in deciding doses) which is not fatal nor permanent disability but a temporary discomfort. Such mistakes may be excusable that is why the Apex Court in one Judgment which is now followed by all other courts subordinate to the apex court, that, for compensation, the negligence / mistake should be **gross medical mistake / negligence**. Use of wrong drug or wrong gas during anesthesia leads to imposition of liability and in some situations even the principles of **res ipsa loquitur** may be applied. Always the degree of care should be proportionate with the magnitude of risk. For example when an Anesthologist handling a dangerous substance which was known to be highly inflammable and he knew of the hazard arising from electro static sparks in an operating theatre, the degree of care required from the Anesthologist was proportionately high and he was bound to take special precaution to prevent injury to the patient ^(3,7,8,9).

General Duties: All the medical professional including anesthologists owes certain duties to the patients and breach of this duties may also serve as basis for proceedings (cases)

Informed Consent: It means

'shared decision - making, patients right to self-determination and anatomy'.

However the extent of requirement of disclosure of risk depends on the procedure, circumstances and condition of the patient. The duty of the medical professional (Anesthologist) to disclose is limited to such disclosures that are reasonable in practice made under such similar circumstances. There is no obligation on the part of the medical professional to inform the patient about the risk of death from general anesthesia. Standard NHS Concerned Form contains the clause,

"no assurance has been given to me that the operation / treatment will be performed and administered by any particular practitioner". (MPS - Medical Protection Society General Consent Form, 1988).

The duty to disclose and the risks that are involved depends on the circumstances of each case a medical professional administering the procedure on the patient will decide to what extent the disclose, is necessary to the patient or to the accomplices.

However, in certain procedures like cosmetic surgery warranties are taken by courts more seriously in deciding the cases.

SLADE L.J., in *eyre Vs. Measday* said

"In my opinion in the absence of any express warranty as to the results of an intended operation, the court should be slow to imply against a medical man an unqualified warranty as to the results of an intended operation, for the very simple reason, that, objectively speaking, it is most unlikely that a responsible medical man would intend to give a warranty of this nature. Of course, objectively speaking it is likely that he would give a guarantee he would do what he had undertaken to do with reasonable skill and care." ⁽¹⁰⁾

Records: Under the Indian laws that are existing till date and today, a case, based on **medical negligence can be filed within three years of the occurrence of the incident. However in the case of Consumer Protection Act, 1986 the period of limitation is two years.** As there is a time gap of few years between the incident and hearing of the case it is difficult for the courts to rely on the memories of the parties in evaluating the evidence. On the other hand there is no other way for evaluating the situation other than the evidence because except the parties none could say what happened between the four walls of the operation theatre (O.T). Hence they rely more on the records prepared and preserved by the medical professionals and some records that are available with

the patients. *Anesthesia record itself should be as accurate, complete and neat as possible. The record was not considered proper when the previous history and condition of the patient prior to application of anesthesia was not recorded and preserved.*

Burden of proof: Both the parties viz., the complainant and accused (petitioner/respondent) have every right to produce expert witness in support of their claims. Any licensed physician may be an expert however during examination the expert should disclose his qualification training, nature and scope of practice, memberships and affiliations and publications to his / her credit. This is necessary because by collecting such information the courts can judge the weightage that should be given to such expert's opinion. Largely the success of a case depends primarily on the structure and believability of the expert witness and that expert should not be related to or close to either of the party in suit. There are also number of cases wherein the courts have dismissed the complaints due to lack of expert opinion in the form of witness to substantiate their claim.

Res ipsa Loquitur: A legal phrase means "*things speaks for themselves*". It applies to such events that would not have occurred in the ordinary situation except in the absence of medical negligence and in such cases the burden of proof shifts from complainant to the defendant and the defendant has to prove that he/she is not negligent in his / her act. However in case of Anesthologist use of wrong drug or wrong gas during Anesthical procedure will frequently lead to the imposition of liability and the principle of *res ipsa loquitur* is applied ⁽⁷⁾.

The following doctrines should be taken into consideration for deciding a case:

1. The injury is of such nature that typically would not occur in the absence of negligence.
2. The injury must be caused by something under the exclusive control of the Anesthologist.
3. The injury must not be due to any of the contribution on the part of the patient.

Where a patient developed massive tissue emphysema (*meaning: a lung condition featuring an abnormal accumulation of air due to enlargement or lungs are grossly enlarged, causing great breathlessness*) due to wrong placement of needle for jet ventilation of lungs, the Anesthologist was held liable because if the needle had been placed correctly into the trachea (*meaning: wind pipe - you cannot breath without this*), tissue emphysema would not have occurred.

Following an operation under general anesthesia patient sustained hypoxic brain damage (*meaning: brain not getting enough oxygen*) in recovery ward the Anesthologist was held liable.

If a person goes in for a medical routine procedure, and is subjected to anesthetic without any special features and there is a failure to return the patient to consciousness, to say that, that does not call for an explanation from defendants would be in defiance of justice.

An explosion occurred during the course of administering anesthetic to the patient when the technic had been frequently been used without any misshape.

Surgical mop (*meaning: spongy mass*) left in the abdomen during LSCS under Spinal Anesthesia.

Artery forceps left in the abdomen during the operation. Compensation granted by the state commission and enhanced by the National Commission.

Surprisingly the artery forceps left in the abdomen during the operation found in the cremation ground by the relatives when they went to collect the mortal remains.

Anesthetic risk and classification: The American society of Anesthologist (ASA) has devised a classification system to grade the preoperative condition of the patient.

1. A Normal healthy individual
2. Those with a serious disease but have no limitation of their activities. (the condition may be pre existing or the result of the condition requiring surgery). Mild Hyper Tension. Mild enigma, Chronic bronchitis are some of the examples.
3. Those with a serious disease causing some limitation of their activities. Examples: Moderate Engina, Previous myocardial infarction (heart attack).

Utter horror of waking up during anesthesia:

General Anaesthetic is supposed to make surgery painless. But, nowadays there is evidence that one person in 20 may awake when doctors think they are under. For years anesthesia awareness has been shrouded in mystery also extreme experiences are rare, there is now evidence that around 5% of people may wakeup on the operating table. As somebody said,

"we once knew surprisingly little about why anesthesia works. Now, however, researches are striving to understand more about the nature of going under the circumstances in which anesthesia does not work, in the hope of making advances that might reduce the risk of anesthesia awareness"

The aim is not to produce a loss of consciousness but simply to remove the sensation from a particular part of the body. General Anesthesia, in contrast aims to do justice that, creating an unresponsive drug - induced COMA or controlled unconsciousness i.e., deeper and more detached from reality even than sleep, with no memories of any events during that period.

As Robert Sanders, an anesthetist at a university of Wisconsin - Madison, put it

"We have apparently ablated this period of time from that person's experience"

Causes of Anesthetic deaths:^(11,12,13)

1. *Death due to respiratory failure*
2. *Airway obstruction*
3. *Pneumothorax (meaning: presence of air /gas in the cavity between the lungs and chest walls)*
4. *Aspiration of gastric content*
5. *Respiratory depression*
6. *Death due to equipment failure*
7. *Due to cardio vascular failure*
8. *Hypovolaemia (meaning: decreased blood volume or diminished body fluids)*
9. *Cardiac Arrhythmia (meaning: improper beating of the heart - too fast or too low)*
10. *Diminished myocardial contractility*

Complications of Regional Anesthesia^(11, 12)

- I.
 1. *Despite spinal anesthesia patients experience pain.*
 2. *Post Dural headache*
 3. *Hypotension and bradycardia (meaning: abnormally low heart beat) through blockade of nervous system*
 4. *Limb damages*
 5. *Respiratory failure if blocks are too high direct nerve damage*
 6. *Partial or permanent damage to spinal cord*
 7. *Spinal Infection*
 8. *Aseptic meningitis (meaning: serious inflammation of the linings of the brain)*
 9. *Urinary retention*
- II. Adverse drug reaction
- III. Death due to other factors

Liability of Anesthetic and Medico Legal Case aspects related to anesthetic deaths.^(11, 12)

Often the anesthetic is accused of causing death during surgical procedure though the other factors are cause of death. As per Sec. 39 of Cr.P.C., all deaths occurring in the course of surgery and anesthesia should be treated as unnatural deaths and should be reported to the police for an inquest. Failing which of this act by the medical professional leads to punishment under section 202 of IPC for intentional omission to give information of offence to police by the person who is bound to give information. During trial the presiding officer is likely to consider the following questions,

1. *Doctors duty in anesthetic practices*
2. *Informed consent*
3. *Reasonable degree of skill*
4. *precaution and defence*

Examination of Anesthetic death:⁽¹⁴⁾

Normally anesthetic deaths are examined by pathologists (expert opinion) and they should bear in mind the following

1. **History:** History of the patient before hospitalization
2. **Condition** requiring surgery
3. Condition of the patient before surgery to classify whether it is low risk or high risk
4. **Pre Anesthetic Medication:** Error in relation to preoperative procedure giving wrong medication, over medication, or no medication which precipitated the patient's death
5. **Anesthetic Agents:** Inadvertent mixing of the anesthetic gases may cause death
6. **Burn or Explosion:** Death from anesthetic explosions - occurs rarely
7. **Hemorrhage**
8. **Blood Transfusion:** Transfusion reactions and incompatibility should be investigated
9. **Resuscitative Measures:** the measures adopted should be noted
(*Resuscitative meaning: an emergency procedure that combines chest compressions with artificial ventilation*)
10. **Equipment:** Whether appropriate equipment handled by qualified individuals correct mixing percentages are to be examined.

Conclusion: Indian laws allow three different types of damages

- a. **General Damage:** such as pain and suffering which directly result from the injury.
- b. **Special Damage:** are those actual damages which are a consequence of the injury such as medical expenses, lost income etc.,
- c. **Punitive Damages:** are intended to punish the medical professional for negligence which was reckless, wanton, fraudulent or willful.
- d. **Exemplary Damages:** are awarded to make an example of this case to prevent any other medical professional doing the same mistake.

As Lord Dennig L.J. commented, ⁽¹⁵⁾

"It is so easy to be wise after the event and to condemn as negligence that which was only misadventure. We ought to always be on our guard against it, especially in cases against hospitals and doctors".

A reasonable man may foresee the majority of possible risks that occur during anesthetic procedure and it is impossible for any Anesthologist to take precaution against every risk which he visualizes.

Though the modern practice of medical procedures including anesthesia is largely good enough and safe with latest equipment and advanced technology still the Anesthologist should keep in mind that they are dealing with human entities and should have the **human touch** and the **human feeling** else things always go wrong.

I acknowledge and express my sincere thanks to,

S.C. Parakh consultant Anesthologist in *India* who has elaborately written on this subject with good examples of decided cases in his concluding remarks in the article "legal aspects of anesthesia practice, Indian J Aneasth 2008;52:247-57" has given a submission stating that

"Indian society of Anesthologist must come out with protocols to be followed by its members in different clinical situations. Once this is done the courts will decide the issue of medical negligence by the fact that the protocol was followed or not. Thus the Anesthologist following the protocols will not be held guilty of negligence. This will also improve the patient's care and the outcome." ⁽¹⁶⁾

With full regard and respect to Dr. S.C. Parakh for his valuable suggestion, I too whole heartedly support his submission because it gives much more relief than now for the medical professionals, more so Anesthologists who are the backbone of every surgical procedure.

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