Legal sanctity of consent for surgical procedures in India

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ABSTRACT

As surgeons, we are morally committed to respecting the right of self-determination of patients, thus an informed consent is necessary before any operative intervention. Many neurosurgical patients are incapable of giving consent because of impaired consciousness. Moreover, neurosurgical procedures involve high risks and often are time sensitive; therefore obtaining consent is a challenging job. Patients and their family members need immense courage, understanding, and trust before giving consent for a surgical procedure to a doctor. Lawsuits against doctors are on the rise and it is important to understand "what is consent?" in legal parlance.

Key words: Consent, Indian penal code, legality, neurosurgery, surgical procedure

INTRODUCTION

Health awareness has also led to a paradigm shift in doctor–patient relationship. The old trust has lost its way to new skepticism and it is a sword that is cutting both ways. Highly informed patients ask pertinent questions. In order to avoid litigation, surgeons are attempting to inform even the rarest of complications to patients even if it does not help an already anxious patient. Lines between ethical obligation and legal compulsions are getting blurred. Many neurosurgeons are ill-informed about the legal aspects of what constitutes an "Informed Consent" (IC). This half-baked knowledge occasionally converts "consent taking" into a bureaucratic and additional paperwork.

The concept of patient consent arises from the ethical principle of patient autonomy and basic human rights. This aspect of medical practice has often been the subject of litigation. The lack or absence of valid patient consent can expose doctors and medical institutions to claims of medical malpractice.

METHODOLOGY

Research for case studies for this article was done on online legal databases Manupatra and Indian Kanoon; books referred to include the 10th Edition of Sanjiva Row's Commentary on Law Relating to the Contract Act, 1872 and Tenders, 29th Edition of Ratanlal and Dhirajlal on the Indian Penal Code, 8th Edition of Sarkar on Criminal Procedure Code. We also consulted a team of eminent lawyers on the subject including Rakesh Tiku, Senior Advocate and former Chairman of the Delhi Bar Council and Rishi Bhatnagar, Advocate. Pubmed database was also searched for "IC in neurosurgical practice" and available literature was reviewed.

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DISCUSSION

The concept of patient consent is a critical issue in the neurosurgical practice today. It is consistently under judicial scrutiny due to the "tug-of-war" situation, which involves the individual rights of a patient on one hand and the duty of a doctor to take due care of patients on the other.

Consent—legal meaning in context of medical practice

In legal terms two or more persons are said to consent when they agree upon the same thing in the same sense.[1] Further, a "free consent" is an essential requirement of a valid contract.[2] Consent is said to be free when it is not caused by coercion, undue influence, fraud, misinterpretation, or mistake.[3] Moreover, to be construed as valid consent, the consent must be taken from persons competent to contract.[4] Therefore, for a patient's consent to be legally valid, the following criteria must be must be fulfilled:

i. Free consent/voluntariness
ii. Competence of parties/capacity
iii. IC/knowledge

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Free consent/voluntariness

The consent should be given willingly or should be "free consent," i.e., willingness of a patient to undergo treatment without any kind of pressure, misrepresentation/mistake/misunderstanding as to any aspect of the medical treatment. The core legal assumption about the doctor-patient relationship is that it is a fiduciary relationship, i.e., based on mutual trust and confidence. Patients are often submissive in their relationship with their doctors and are more than willing to go by the wishes and recommendations of the doctors compromising their own voluntariness. The fiduciary duty of doctors toward their patients extends to informing about the illness, its treatment, pros and cons, cost, etc. of the treatment and giving patients the ultimate authority to decide the course of their medical treatment.

Competence of parties/capacity

The consent must be taken from persons competent to contract, i.e., the patient should have the capacity to enter into a contract; and as per Indian law, only the following persons are competent to contract:

1. Persons who are of age of majority, i.e., 18 years or older
2. Persons who are of sound mind
3. Persons who are not disqualified from contracting by any applicable law to which they are subject.

It follows that minors, persons of unsound mind, and persons disqualified from contracting by any applicable law cannot make a valid contract. The above law is founded on the manifest need of such persons to be protected from undue advantage being taken of their situation.

As regards the age of majority, every person domiciled in India is deemed to have attained majority on completing 18 years of age.[5] It is interesting to note that the Indian Penal Code does not consider consent given by a child below 12 years of age to be valid.[6] Going by this provision of Indian Penal Code taking consent from a person aged 12 years or older for medical/surgical treatment can be said to be a valid consent. The Indian Penal Code also provides 18 years as the age for giving consent for acts not intended and not known to be likely to cause death or grievous hurt.[7] But the applicability of this provision to medical practice may be questionable as some medical treatments/surgeries are known to be risky and likely to cause death or irreversible harm. These provisions of the Indian Penal Code are not specifically directed at medical treatment and hence seem obscure in context of valid consent in medical procedures. Since there is no separate legislation in India regarding age for consent for medical treatment, 18 years is considered standard for giving valid consent for medical examination and procedures.

IC/knowledge

An IC can be said to have been given based on a clear appreciation and understanding of the facts, implications, and future consequences of an action. A doctor must provide a patient with information about the nature of the treatment, its expected benefits, its material risks and side effects, alternative courses of action, and the likely consequences of not having the treatment. A doctor cannot assume that a patient has sufficient background or may not be interested in the information. Without full information, the patient does not have sufficient background to make informed health care decisions and consent may not be valid.

Surgical care is the most intrusive private action that may be done to a person. To be competent to give a legally effective consent, the patient must be endowed with the ability to weigh the risks and benefits of the treatment that is being proposed to him.

IC involves more than simply obtaining the signature of a patient on a form. It follows that if the physician does not make the necessary disclosures and does not receive the patient's "IC," he or she is exposed to liability for malpractice. The first case, which led to, the notion of IC, is in the case of Mohr v Williams.[8] In this case, Ann Mohr gave her consent to surgeon for an operation on her right ear. While operating, the doctor felt that actually her left ear needed surgery instead of right and conducted the surgery on it. The judge in his judgment opined that doctor needs to advice a patient regarding the intervention and only after this does the patient enter into a contract, which authorizes a surgeon to operate only to the extent of the consent given.

The amount of information to be disclosed in an IC has been a matter of debate. Disclosure of material risk is mandatory in Canadian and United States laws. However, as per Delhi Medical Council, patients must be given sufficient information in a manner to enable them to exercise their right to make informed decision about their treatment.[9] The Supreme Court of India has laid the principle in this regard that doctor should disclose (a) nature and procedure of the treatment and its purpose, benefits and effect; (b) alternatives if any available; (c) an outline of the substantial risks; and (d) adverse consequences of refusing treatment. But there is no need to explain remote or theoretical risks involved, which may frighten or confuse a patient and result in refusal of consent for the necessary treatment.[10] However, alternative form of treatment options like gamma knife vs embolization vs surgery in cases of arteriovenous malformations or clipping vs coiling in aneurysms must always be explained and preferably be documented.

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What should be disclosed to obtain IC?

The following information should ideally be disclosed to a patient[11]:

- The condition/disorder/disease that the patient is having/suffering from
- Necessity for further testing
- Natural course of the condition and possible complications
- Consequences of nontreatment
- Treatment options available
- Potential risks and benefits of treatment options
- Duration and approximate cost of treatment
- Expected outcome
- Follow-up required

Patient should be encouraged to ask questions and doubts should be clarified. This consent should be voluntary and patient has a right to revoke the consent.[12]

It is necessary that proper consent is taken for photographing a patient for scientific purposes and especially so when identity of the patient is likely to be revealed. Moreover, consent is a must for participation in clinical trial and research projects.[11]

Exceptions to the patient consent

Emergency cases

An unconscious or delirious patient cannot consent. If a patient is unconscious and there is an imminent danger to the life of the patient and no relative is present then in such a scenario law presumes that consent has been deemed to be given. Supreme Court of India and National Consumer Redressal Commission have repeatedly emphasized the need for rendering immediate medical aid to injured persons without procedural formalities or patient consent.[13] In the case of Dr. T.T. Thomas v. Smt. Elisa and Others,[14] the patient diagnosed with "perforated appendix with peritonitis" was advised immediate surgery but was not operated upon by the doctor due to want of consent and eventually the patient expired. The Kerala High Court held the doctor to be negligent and observed

The consent factor may be important very often in cases of selective operations which may not be imminently necessary to save the patient's life. But there can be instances where a surgeon is not expected to say that "I did not operate him because, I did not get his consent". Such cases very often include emergency operations where a doctor cannot wait for the consent of his patient or where the patient is not in a fit state of mind to give or not to give a conscious answer regarding consent. Even if he is in a fit condition to give a voluntary answer, the surgeon has a duty to inform him of the dangers ahead or the risks involved by going without an operation at the earliest.

In fact, Section 92 of the Indian Penal Code, 1860, specifically declares that nothing is an offence by reason of any harm which it may cause to a person for whose benefit the act is done in good faith even without that person's consent if the circumstances are such that it is impossible for that person to signify consent or if that person is incapable of giving consent and has no guardian or other person in lawful charge of him from whom it is possible to obtain consent in time for the thing to be done for his benefit. Law, therefore, expressly declares that an act done in an emergency will not be called in question for want of consent.

A real-life situation that is being daily encountered in neurosurgical practice is that patients are brought to hospital in obtunded state needing urgent/emergent treatment but relatives want time for considering their options (treatment/second opinion, etc.). Such delay can be detrimental to patients' health and as a doctor you are treading a fine line between ethics, morality, and economics of the corporatized health care sector. We recommend that every such delay due to indecision on part of relatives or extraneous reasons be properly documented in file and countersigned by relatives and an independent witness. In case of nonavailability of beds/trained staff, the option of seeking treatment in other hospital/center should also be explained.

Incompetence

Incompetent patients such as delirious, unconscious, senile, and psychotic nature are unable to make rational decision. The physician must identify and obtain consent from an appropriate substitute/proxy decision maker. A physician must provide the proxy decision maker with the information that would otherwise have been given to the patient to enable him or her to make an informed decision as to consent.

Samira Kohli v. Dr. Prabha Manchanda and Another[10]: In this case, a 44-year-old unmarried female consulted her doctor and was advised to undergo a laparoscopy. A few consent forms were taken from her, of which one was for admission and another one was for the surgery. The relevant one among such consent forms gave the doctor an allowance to carry out a "diagnostic and operative laparoscopy" and there was an additional endorsement that a "laparotomy may be needed." When the patient was in the operation theater (and was unconscious), another proxy consent was taken from her mother for a hysterectomy. Her uterus, ovaries, and fallopian tubes were removed. Subsequently, when an action was brought, it was held that the operation was conducted without real consent and the doctors were held liable. For the first time in India, the Supreme Court ruled that

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however broad consent might be for diagnostic procedure, it cannot be used for therapeutic surgery. The court observed, "where a surgeon is consulted by a patient and consent of the patient is taken for diagnostic procedure/surgery, such consent can't be considered as authorization or permission to perform therapeutic surgery either conservative or radical (except in a life-threatening or emergent situations)". Furthermore, the court observed that "… where the consent by the patient is for a particular operative surgery, it cannot be treated as consent for an unauthorized additional procedure involving removal of an organ only on the ground that it is beneficial to the patient or is likely to prevent some danger developing in the future, where there is no imminent danger to the life or health of the patient."

Therapeutic privilege

If doctor suspects that passing full information could have detrimental effect on the health of the patient, then he could modify or withhold information and can be excused of obtaining consent from the patient. However, full information must be disclosed to the competent relative(s) of the patient.

Other situations

Where consent need not be obtained:

- Government orders for examination, testing, specimen collection, and treatment in cases of pandemic, untreatable diseases.
- Arrested person: In criminal cases when examination of an arrested person can lead to vital evidence related with the commission of crime, he can be examined by the doctor without his consent and even using force, if the application for examination is from a person not below the rank of Sub-Inspector.[15]

Types of Consent

Consent may be of the following types:

Implied consent

An implied consent is not written or expressly asserted. The fact that a patient comes to a doctor for treatment of an ailment implies that he is agreeable to medical examination in the general sense and is legally effective. This is implied consent and would encompass general physical (not intimate) examination, palpation, checking of blood pressure, etc.

Expressed consent

Expressed consent is one which is expressed explicitly, in written or verbally. For instance, when a patient specifically grants the permission to examination of private parts; examination for determining age, potency and virginity; giving anesthesia, or any surgery, etc. Expressed consent is a must in any examination beyond routine physical examination. Oral expressed consent, when properly witnessed, is as valid as written expressed consent, but latter has the advantage of easy proof and permanent record.

The concept of obtaining consent from patient, especially written consent, has assumed great importance in medical practice these days as it gives greater ease to medical practitioners in proving consent in case of litigation. Moreover, the Medical Council of India (MCI) requires physicians to take written consent of patient or guardian or husband/wife, as the case may be, before performing an operation.[16] It may be noted that the MCI requires written consent only in case of operations and not other treatments.

There is also a practice of taking a blanket consent that authorizes the doctor or hospital to do anything that is in the best interest of the patient, without mentioning anything in specific. Such consent, even in writing, may be of little or no value in case of litigation as patient consent is considered valid only for a specific procedure/surgery.

Documenting the consent

It is extremely important from legal point of view to properly document the consent. Following points must be legibly documented in the file[17]:

1. Clearly mention the procedure with antecedent risks and benefits
2. Explain and mention the alternative treatment options including no treatment with their antecedent risks and benefits
3. Document the fact that patient and relatives were allowed to ask questions and their queries were answered to their satisfaction
4. Signature of the patient or proxy decision maker authorizing the procedure
5. Signature of the surgeon and a witness who is not part of the operating team confirming the patient/proxy decision maker's authorization.

Liability of doctors vs liability of hospitals

Under the theory of "Respondent Superior," an employer (hospital) could be held jointly liable with an employee (doctor) whose failure to obtain IC could be shown to have caused injury and damage to a patient. A hospital policy must govern the procedure by which consents are obtained. In the 1957 case of Bing v. Thunig,[18] hospital was held liable under corporate negligence doctrine for acts of its employees. In this case the nurses spilled an inflammable alcoholic antiseptic, onto the bed while applying it to a patient's back. The patient suffered burns when the surgeon applied an electric cautery as the bed was soiled with above substance.

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CONCLUSION: NEED TO EDUCATE SURGEONS AND CHANGE PATERNALISTIC ATTITUDE

Due to lack of proper training in taking IC, newly qualified surgeons in India do not fully understand the process of engaging patients in this important endeavor. Communicating with patients and their families is an art and teachers should help students acquire this during the training period. In India, surgeons sometimes take a paternalistic approach toward a patient. Patient's belief of "doctor knows best" is changing to "tell me more." Therefore, instead of unilateral decision making a mutual practice which upholds the right of patient's autonomy is being emphasized. Taking IC is a likely solution to avoid legal complications and build a healthy doctor–patient relationship.

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