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Role Of Informed Consent In Neurosurgical Cases, A Retrospective Study.

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ABSTRACT

Informed consent has become the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine. It may be used for legal, ethical or administrative purposes. Although legal and ethical debate persists, but it is agreed that it has implication on the decision-making and the physician should disclose sufficient details for the decision-maker to make an informed choice; the decision-maker should show his or her understanding of the disclosed information; and the decision-maker should freely authorize the treatment plan. A retrospective study of informed consent of 20 cases, operated for different neurosurgical diseases was carried out in department of Neurosurgery, SGPGIMS within 05 months in year 2022 (from January to May, 2022). Total 221 possible issues of complications & sequalae were covered in 20 cases. Out of 221 issues 18 were taken for recurrence of tumors, during fallow up, 15 complications occurred preoperatively out of 221expected complications covered in informed consent. In present study the informed consent of relatives /kin of the patient to be operated was taken in each case, however, patients who were fully conscious and oriented or having spinal pathologies were involved in an informed consent. Their signatures were also taken fallowing explaining the risks and benefits to each case depending on disease of individual case. The consents were recorded by resident doctor as the concerned resident always discussed the case with operating surgeon during rounds and a day prior to surgery. The points to be covered in consent of individual patients were also discussed with operating surgeon. Neurosurgeons have a duty to provide patients with all pertinent information related to disease and operation to be performed in particular case to allow them to make decisions about their case. The alternative and possible interventions available to improve an outcome of disease should be included informed consent. Emergency decisions on table can be taken by operating surgeon depending on severity of problem. Adequate consent offers enough safety to patients and surgeon both.

Keywords- Informed consent, consent in Neurosurgery, consent in medical practice

Introduction: An informed consent for clinical treatment has become a vital part of contemporary medical practice. Informed consent is primarily a legal and ethical concept; although often informed by data [1]. Informed consent has become the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine. It may be used for different purposes in different contexts: legal, ethical or administrative. Although these purposes overlap, they are not identical, thus leading to different standards and criteria for what constitutes “adequate” informed consent [1].

Although the concept of consent is rooted in ancient legal and philosophical precepts, the modern legal precedent for “simple” consent was written in 1914, establishing a patient’s “right to determine what shall be done with his body” [2]. The further obligation for physicians to disclose details about treatment in a process of informed consent did not emerge until the 1950s [3] .

When courts first required physicians to disclose information customarily disclosed by experienced clinicians (e.g., the reasonable physician standard). It was not until 1975 that American courts articulated the reasonable person standard, which required that physicians disclose the information that a "reasonable person" would want to know in a similar situation [4]. Regardless of the standard used, informed consent is further predicated on the patient's or surrogate's capacity to make decisions — not only should the decision-maker understand the relevant information, he or she should also be able to appreciate the information's importance and use it to weigh treatment options in light of their values [5]. Legally, simple consent protects patients against assault and battery in the form of unwanted medical interventions. The higher standard of informed consent further safeguards patients' rights to autonomy, self-determination and inviolability. However, the legal standards that apply to obtaining informed consent vary across jurisdictions, and their interpretation continues to evolve. Some jurisdictions use the reasonable person standard, whereas others continue to use the older standard of the reasonable physician. Therefore, it is important for clinicians to determine the precise standard used in their jurisdiction and to adapt their practice accordingly [1]. The informed consent is intended to shift the ethical paradigm for decision-making away from physician-centered models to more patient-centered approaches. The ethics literature regarding informed consent also emphasizes that it is not an event, but a process that precedes the "signing" of the document and continues for as long as the choice remains relevant. The consent form should not be confused with the consent process; the form merely documents that the process has occurred [1].

For the sake of compliance, the informed consent document serves the administrative purpose of a systems-level check to ensure that a consent process has occurred. Patients simply do not advance to the operating room, for example, without a signed consent form. Unfortunately, pressures for efficient workflow may shift the focus of the informed consent process from robust conversation to the mere requirement of getting a signature [1].

Although legal and ethical debate persists, most stakeholders in the informed consent process agree on at least four basic elements for discussions of informed consent: the decision-maker (i.e., the patient or a surrogate) should have the capacity to make decisions; the physician should disclose sufficient details for the decision-maker to make an informed choice; the decision-maker should show his or her understanding of the disclosed information; and the decision-maker should freely authorize the treatment plan [1].

In current clinical practice, these four elements translate into five components that should be included in a discussion seeking to obtain informed consent: the diagnosis, the proposed treatment, the attendant risks and benefits of the treatment, alternative treatments and their risks and benefits, and the risks and benefits of declining treatment [1].

The surgical informed consent (SIC) process is invariably underestimated and reduced to a documentary procedure to protect physicians from legal liability. Moreover, residents are rarely trained in the clinical and communicative skills required for the SIC process. Accordingly, to increase professional awareness of the SIC process, a brief history and introduction to the current elements of SIC, the obstacles to patient autonomy and SIC, benefits and drawbacks of SIC, planning of an optimal SIC process [7].

Robust efforts to improve the informed consent process have been made in any surgical fields including neurosurgery. Moreover, residents are rarely trained in the clinical and communicative skills required for the SIC process.

This new legislation, referred "Shin Hae- to as the chul Act," allows the Korea Medical Dispute Mediation Arbitration Agency to commence a mediation process without the doctor's consent in potential malpractice cases that resulted in severe disability, a coma lasting one month or longer, or death of the patient. This is especially relevant for neurosurgeons, as the higher incidence of major postoperative complications in the neurosurgical field will create a higher risk of legal disputes under the new law. Therefore, the SIC process can play an important role to lessen this risk by providing a basis for a therapeutic alliance between physicians and patients [7]. The current retrospective study has been carried out to know the effect of informed consent in neurosurgical cases, and operated in span of 5 month in a tertiary care institute of national importance in India. We tried to know the short coming, if any while taking consent.

Material & Method:

Retrospective study of informed consent of 20 cases, operated for different neurosurgical diseases was carried out in department of Neurosurgery, SGPGIMS within 05 months in year 2022 (from January to May, 2022). As per the department policies the consent was taken under 3 heading of each case related with intra-operative complications including anesthetic consequences, postoperative complications & tumor related complications. 13 cases had cranial tumor and rest were spinal pathologies. Consent for 20 cases was taken under 60 broad heading e. anesthesia related bleeding related & injury to brain structural neurovascular structure related complications, etc. Total 221 possible issues of complications sequale were covered in 20 cases. Out of 221 issues 18 were taken for recurrence of tumors, during fallow up 15 complications occurred perioperatively out of 221expected complications covered in informed consent process. However, there was no written consent for any tumor or operative procedure, where surgeon may fail to take out tumor in toto, though it was explained every time, we know these are enough chances , that part of tumor may be left behind, in order to predict vital structures of brain.

As per the departmental protocol of Neurosurgery, each point of particular disease in a case stated for surgery is noted in consent form. All the disease related complications are noted in consent form and explained to patient/ relative depending on patient condition, as they are several cases who are neither fully conscious nor well oriented enough for consent. The concerned doctor, patient & relative and one staff nurse puts in their signature on consent form as witness. The patient who are fully conscious or having spinal pathologies remain the part of informed consent was recorded by concerned resident doctor following through discussion about approach procedure & possible complications in each case with operating surgeon & with entire unit during clinical round as when deemed fit & applicable. In case of unexpected complication on operation table or in need of changing approach/ need of some implant (i.e. aneurysm clip) the decision was taken by operating surgeon. If some staff nurse is available hence permitted the patient relative were informed then there.

Discussion:

The first documented case of surgical informed consent is Slater vs. Baker and Stapleton in 1767, where a doctor was sued for experimenting with an external fixating mechanism without informing the patient and obtaining approval prior to the surgical procedure [7]. In the Surgical Informed Consent case of Mohr vs. Williams in 1905, a surgeon was sued for operating on both ears, when consent was only given to operate on the right ear [7]. Justice Benjamin Cardozo wrote: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained [8]. Any surgeon should tell their patients what other surgeons also tell theirs. A more patient-oriented point of view was subsequently instituted by Canterbury vs. Spence in 1972, which determined that all risks and alternatives of a procedure must be explained to a patient. Furthermore, Truman vs. Thomas in 1980 determined that the information provided in a Surgical Informed Consent process must include the possible risks of “not acting or postponing” [7]. The legal doctrine of Surgical Informed Consent has three main elements: preconditions, information, and consent. The preconditions include competence and voluntariness, meaning that a patient should be capable of making decisions about their body without outside influence. In most cases, a patient’s competence is presumed if their communication is normal [9]. However, it should also be noted that, for valid informed consent to take place, a patient should not be cognitively impaired by medication, as this would not satisfy the precondition of voluntariness [8]. Any legally valid process of informed consent should include instructions to the patient regarding: 1) the diagnosis, 2) the recommended procedure along with its risks and benefits, 3) the results or prognosis if no procedure is attempted, and 4) possible alternatives to the proposed procedure with their attendant risks and benefits [7,11,12].

In present series we took informed consent of relatives /kin of the patient to be operated in each case, however, patients who were fully conscious and oriented or having spinal pathologies were involved in an informed consent. Their signatures were also taken fallowing explaining the risks and benefits to each case depending on disease of individual.

The discussion on informed consent should be conducted by the physician directly involved in the proposed treatment. In surgical cases, the attending surgeon is most appropriate, as residents can sometimes provide inaccurate descriptions of the proposed process and alternatives [8, 13]. All competent patients should receive such information, except when the patient's life or wellbeing is seriously threatened if the treatment is not performed immediately, or cases when disclosure of the information itself could cause serious physical or psychological harm.

Lastly, the element of consent covers the final decision of the patient and authorization to proceed with treatment. Here, the requirements vary by country, as written consent in the form of the patient's signature is needed in the US, whereas a note in the patient's medical chart is sufficient in the UK. Notwithstanding, it should be remembered that the medical consent form is merely evidence that the process of consent occurred, while the dialogue between the patient and the physician is the core of the SIC process [10]. In our series the consents were recorded by resident doctor as the concerned resident always discussed the case with operating surgeon during rounds and a day prior to surgery. The points to be covered in consent of individual patients were also discussed with operating surgeon. Being a tertiary care facility and being department, a protocol based informed consents with disease specific consents were taken in each case.

Certain emergency situations can be an exception to the rule of SIC [14]. Principally, if informed consent is suspended in an emergency, it should be because the time it would take to make disclosure and obtain the patient's decisions would work to the disadvantage of some compelling interest of the patient [12]. In practice, a treatment process can proceed without informed consent in cases where: 1) there is an obvious, serious, and immediate threat to the patient's life and limb, 2) the time required to gain informed consent would seriously jeopardize the patient's recovery or increase mortality and morbidity, and 3) the patient exhibits factors that can undermine competence (such as shock, hypoxia, or severe blood loss) [7]. In a review of patients with a subarachnoid hemorrhage, less than 20% of those who gave informed consent could remember the process afterwards [10]. When an emergency exception applies, the physician presumes consent and is required to provide the treatment that most medical practitioners would deem appropriate or standard for the patient's condition. In present series, when decisions were taken on table as emergencies, the relatives were informed fallowing procedures. In case of financial involvement the staff nurse or the available doctor talked with patient relative to be recorded subsequently.

The Fallowing strategies were opted for optimal consent:

1. The SIC process needs to include both the patient and their family. Involving the family in the original decision-making based on understanding the treatment and attendant risks can be especially important in the case of postoperative complications when the patient becomes unconscious.

2. While information communicated verbally by the physician is the most effective, the educational intervention using supplementary learning materials, such as pamphlets and videos, can also be used to reinforce the SIC process. These materials can be provided in advance of the physician-patient interview. In particular, the appearance of the physician in a video can boost patient trust.

3. The information conveyed must include the patient's problem or diagnosis, prognosis if no intervention is attempted, the recommended intervention with the attendant benefits and risks, and any significant alternative modalities with their attendant risks and benefits.

4. Any clinical uncertainties, possibilities, and probabilities should be openly explained to the patient, facilitating the therapeutic alliance between the physician and the patient.

5. The patient should receive a full explanation of the surgical procedures and management, plus the clinical events that will be experienced during the preoperative, intra-operative, and postoperative periods. This way, the patient can create psychological defenses to cope with the stressful circumstances of surgery and avoid being emotionally overwhelmed.

6. The physician should encourage the patient to ask questions and verify the understanding of the patient

7. The transmission of information needs to be initiated well in advance of the surgical procedure, a few weeks if the situation allows, giving the patient the necessary time to make a major life decision.

8. As patients come to hospital for treatment, not education, they can be uncooperative during the transmission of information. Thus, patient interviews should be coordinated with hospital visits for diagnostic or pre-surgical management.

9. Patient comprehension of their disease and related treatment can be ascertained using a questionnaire. The questionnaire results can then be used as data for supplementary education [7].

The application of informed consent to patient encounters is an important facet of clinical practice. Neurosurgeons have a duty to provide patients with all pertinent information to allow them to make decisions about their care. A baseline patient comprehension and capacity, interventions to improve informed consent, need to be explained; it appears that determining the proper capacity to provide informed consent and considering informed consent as a process that depends on the setting are important. There is room to improve the informed consent process centered on baseline patient health literacy and understanding as well as clear communication using multiple modalities [15].

As our institute caters the variable society including highly educated group to illiterate patient, hence consent information was tailored according to the education, comprehension and understanding of patient & available also relatives of patient. Because neurosurgery has complex problems of diseases, marked analogy & functioning of brain and spinal cord hence a simple language & oral language was adopted depending the familiarity of patient relatives.

Conclusions

As informed consent should be tailored according to disease process, options of treatment, expected complications and their management, suspected neurological deficits and possibility of residual disease following surgery if any. It is better to include about a future need of follow up of individual case. The education, comprehension and understanding of patient & available relatives of patient should also be given due importance. Because neurosurgery has complex problems of diseases, extreme variability of ailments & alteration in functioning of brain and spinal cord depending of disease process, hence a simple language & local dialect may help in explaining the issues covered in consent process. An adequate written informed consent is an umbrella of safety to operating team as well as an appropriate decision making by patients and relatives for their satisfactory treatment.

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