Review Article
J Korean Neurosurg Soc 60 (4) : 385-390, 2017
https://doi.org/10.3340/jkns.2017.0101.007
pISSN 2005-3711 eISSN 1598-7876

Surgical Informed Consent Process in Neurosurgery

Jaechan Park, M.D., Ph.D.,[1] Hyojin Park[2]

Department of Neurosurgery,[1] Research Center for Neurosurgical Robotic Systems, Kyungpook National University, Daegu, Korea
Kosin University College of Medicine,[2] Busan, Korea

The doctrine of informed consent, as opposed to medical paternalism, is intended to facilitate patient autonomy by allowing patient participation in the medical decision-making process. However, regrettably, 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, and its application to cases of an unruptured intracranial aneurysm are all presented. Optimal informed consent process can provide patients with a good comprehension of their disease and treatment, augmented autonomy, a strong therapeutic alliance with their doctors, and psychological defenses for coping with stressful surgical circumstances.

Key Words : Informed consent · Intracranial aneurysm · Neurosurgery.

INTRODUCTION

The doctrine of informed consent, as opposed to medical paternalism, is meant to facilitate patient autonomy by allowing patient participation in the medical decision-making process. Robust efforts to improve the informed consent process have been made in any surgical fields including neurosurgery[22,23]. However, regrettably, the surgical informed consent (SIC) process is invariably undervalued and reduced to a document procedure to protect physicians from possible legal liability. Moreover, residents are rarely trained in the clinical and communicative skills required for the SIC process[2,4].

Notwithstanding, the SIC process has recently become more significant due to new Korean legislation "for the aid of damage due to medical malpractice and mediation of medical disputes." This new legislation, referred to as the "Shin Hae-chul Act," allows the Korea Medical Dispute Mediation and 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.

Accordingly, to increase professional awareness of the SIC

• Received : January 5, 2017 • Accepted : February 20, 2017
• Address for reprints : **Jaechan Park, M.D., Ph.D.**
Department of Neurosurgery, Kyungpook National University Hospital, 130 Dongdeok-ro, Jung-gu, Daegu 41944, Korea
Tel : +82-53-200-5647, Fax : +82-53-423-0504, E-mail : jparkmd@hotmail.com

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, and its application to cases of an unruptured intracranial aneurysm (UIA) are all presented.

HISTORY OF SIC

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.

However, the basic elements included in the current concept of SIC began to develop in the early twentieth century. For example, in the SIC 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. In the more famous SIC case of Schloendorff vs. Society of New York Hospital in 1914, Mary Scholendorff was admitted to New York Hospital and consented to an examination under ether anesthesia to determine whether an abdominal tumor was malignant, yet withheld her consent for surgical removal of the tumor. However, after determining that the tumor was malignant, the surgeon removed the tumor during the same procedure. In his ruling, 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[19]."

Initially, the principles for conveying information about surgical risks were based on a doctor-centered approach, where the UK case of Bolam vs. Friern Hospital Management Committee established the Bolam principle : 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 SIC process must include the possible risks of "not acting or postponing."

CURRENT ELEMENTS OF SIC PROCESS

The legal doctrine of SIC 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[5]. 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[28].

The element of information covers the disclosure of information by the physician and verification of the patient's understanding of this information. 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[36]. 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[2,4]. 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[1]. 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[28].

SIC IN EMERGENCIES

Certain emergency situations can be an exception to the rule of SIC[30]. Principally, if informed consent is suspended in

 https://doi.org/10.3340/jkns.2017.0101.007

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[36]. 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).

Moreover, in certain emergency situations, the patient's competence to understand the information provided, a prerequisite of SIC, can be called into question. In a review of patients with a subarachnoid hemorrhage, less than 20% of those who gave informed consent could remember the process afterwards[28]. 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[17].

OBSTACLES TO PATIENT AUTONOMY AND SIC

There are multiple obstacles to patient autonomy and optimal SIC[25]. First, there are often discrepancies between the patient's understanding and retention of the information provided for SIC and the physician's expectations[15,16]. Two hous following information provision, the average patient has been shown to remember fewer than half of the major risks linked to their proposed treatment. Furthermore, a patient's comprehension of information can be influenced by unforeseen factors, including the patient's personal life experiences and biases[10,12].

Second, there is a general lack of time for the SIC process. Patients seldom have enough time to process all the information they are given and deliberate on their decision. Therefore, instead of informed consent, most patients are actually deciding on whether or not they trust their physician. Meanwhile, physicians have little time to communicate fully and sensitively with their patients, as this communication must be sandwiched between other diagnostic and therapeutic agendas involved in contemporary healthcare. Patients can even have the matter of consent thrust upon them on the way to the operating room, at which point refusal is practically impossible.

Third, patients can often experience alienation during the SIC process. As healthcare is provided by strangers who may or may not share the same basic values and beliefs with the patient, a significant discrepancy can exist between the physician's perceptions of what the patient wants and what the patient actually desires. Linguistic barriers caused by medical jargon and cultural discrepancies between the patient and physician can further alienate patients. All these factors hinder the communication process that is crucial for SIC.

The final obstacle to patient autonomy and SIC is the actual nature of clinical decision-making. The countless possibilities and uncertainties inherent in many clinical processes present a decision-matrix that is inscrutable even to competent and well-informed patients. Thus, the resultant ambiguity and complexity can have a negative effect on patient autonomy.

BENEFITS OF SIC

Despite the many obstacles to patient autonomy and optimal SIC, the process of SIC can provide multiple benefits to both the patient and the physician. First, increased comprehension is a key to patient autonomy and allows patients to maintain a sense of control during the treatment process. Simply knowing the diagnosis and treatment process can turn a fearful threat into a curable problem for patients, eliminating needless anxiety and a sense of helplessness.

Second, preparing patients by explaining the intraoperative and postoperative processes increases the quality of healthcare service. Patients are more able to establish psychological defense mechanisms and cope with or adapt to stressful surgical circumstances. This helps to prevent the patient from becoming panicked or overwhelmed during the process of surgery and postoperative recovery. As a result, better-informed patients have more realistic expectations, higher satisfaction, and heightened treatment cooperation[20].

Third, the SIC process facilitates a solid therapeutic alliance between the physician and the patient[6]. When an active participant in the decision-making process, patients are invariably more cooperative in therapeutic encounters. Understanding clinical uncertainty is also of particular importance, as clinical medicine is not like laboratory experiments where all the variables are controlled. Thus, a frank explanation of the various clinical uncertainties can lead to a more solid thera-

peutic alliance between the patient and the physician, leading to fewer medicolegal disputes when the results are not what were hoped for. Complications can be recognized as the consequence of a joint-decision between the patient and the physician, and not simply the physician's responsibility[14].

Fourth, an interactive discussion on the risks and benefits of a proposed treatment enables physicians to identify patients with idiosyncratic fears, confusion, or misconceptions. Such factors can be counterproductive to treatment and should therefore be identified and rectified if possible. For example, a patient can be needlessly worried or agitated about a surgical procedure with a high success rate. Conversely, a patient can underestimate the threat they are facing. In either situation, the misconception needs to be identified and addressed.

CRITICISMS OF SIC

The most problematic and severe drawback of SIC is the "nocebo" or negative placebo effect[32,36]. This can take place when the risks or side effects of a treatment are overly explained to a patient, which creates an expectation bias of signs of complications. Basically, patients feel what they expect to feel, which can increase dissatisfaction and hinder the treatment process.

Second, the psychological burden of fear and stress can diminish competence, which means that patients can still make irrational and harmful choices after being given the information required for the SIC process. This is surprisingly common as patients are in an unfamiliar and anxiety-inducing hospital environment. Thus, if a patient refuses consent to an appropriate treatment due to general mistrust and fear, the physician would have to respect this decision, even if it endangers the patient.

Third, patients come to the hospital for treatment, not education. Therefore, patients can often be uncooperative during the SIC process and lack interest in listening to the information provided by the physician. Patients are also unlikely to read the informed consent form as meticulously as they should[24].

STRATEGY FOR OPTIMAL SIC PROCESS

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[3,7,9,11,22,28,31,38]. 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, intraoperative, 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[17].

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.

 https://doi.org/10.3340/jkns.2017.0101.007

EDUCATIONAL AND INTERACTIVE INFORMED CONSENT (EIIC) PROCESS FOR UNRUPTURED INTRACRANIAL ANEURYSMS

A standardized EIIC process was proposed for UIAs and implemented at the author's institution[27]. The process includes patient education using various educational materials, an initial physician-patient interview, answering a questionnaire, a second physician-patient interview based on the questionnaire results, and finally consent.

The educational materials include information booklets, a cartoon book, and video for providing information about the ruptured intracranial aneurysms, microsurgical clipping of UIAs, and endovascular coiling of UIAs[8,13,18,21,26,29,33-35,37]. The subsequent physician-patient interview covers specific information and the treatment recommendation based on the angiographic characteristics and medical condition of the individual patient, along with general information about the UIAs. The treatment recommendation is determined in advance on a case-by-case basis by the neurovascular surgeon and endovascular interventionist. The educational materials and physician-patient interview are intended to allow the patient to understand their condition, their prognosis without treatment, the recommended treatment with the attendant risks and benefits, and reasonable alternatives.

The patient then returns home and is encouraged to seek information from other sources, including the Internet. A second physician-patient interview is arranged a couple of weeks later, during which a questionnaire is completed to assess the patient's level of comprehension and the patient's treatment decision is confirmed. The results of the questionnaire are used to provide additional information to the patient. The proposed standardized EIIC process was shown to result in better patient comprehension about UIAs than at other institutions.

CONCLUSION

Neurosurgeons who take care of high-risk patients need to understand the rationale, current elements, and obstacles to patient autonomy and SIC. An optimal informed consent process can provide patients with a good comprehension of the disease and treatment, augmented autonomy, a strong therapeutic alliance with their doctors, and psychological defenses for coping with stressful surgical circumstances.

References

1. Ali V : Consent forms as part of the informed consent process: moving away from "medical Miranda". **Hastings Law J 54 :** 1575-1591, 2003
2. Angelos P, DaRosa DA, Bentram D, Sherman H : Residents seeking informed consent: are they adequately knowledgeable? **Curr Surg 59 :** 115-118, 2002
3. Aremu SK, Alabi BS, Segun-Busari S : The role of informed consent in risks recall in otorhinolaryngology surgeries: verbal (nonintervention) vs written (intervention) summaries of risks. **Am J Otolaryngol 32 :** 485-489, 2011
4. Bean S, Magwood B, Abdoh AA, Chen J, Hochman J : Informed consent: exploring surgical residents' beliefs, attitudes and practices. **Healthc Q 13 :** 68-73, 2010
5. Bernat JL, Peterson LM : Patient-centered informed consent in surgical practice. **Arch Surg 141 :** 86-92, 2006
6. Brenner LH, Brenner AT, Horowitz D : Beyond informed consent: educating the patient. **Clin Orthop Relat Res 467 :** 348-351, 2009
7. Chan Y, Irish JC, Wood SJ, Rotstein LE, Brown DH, Gullane PJ, et al. : Patient education and informed consent in head and neck surgery. **Arch Otolaryngol Head Neck Surg 128 :** 1269-1274, 2002
8. Chyatte D, Porterfield R : Functional outcome after repair of unruptured intracranial aneurysms. **J Neurosurg 94 :** 417-421, 2001
9. Delp C, Jones J : Communicating information to patients: the use of cartoon illustrations to improve comprehension of instructions. **Acad Emerg Med 3 :** 264-270, 1996
10. Faden RR, Beauchamp TL : Decision-making and informed consent: a study of the impact of disclosed information. **Soc Indic Res 7 :** 313-336, 1980
11. Farrell EH, Whistance RN, Phillips K, Morgan B, Savage K, Lewis V, et al. : Systematic review and meta-analysis of audio-visual information aids for informed consent for invasive healthcare procedures in clinical practice. **Patient Educ Couns 94 :** 20-32, 2014
12. Fellner CH, Marshall JR : Kidney donors--the myth of informed consent. **Am J Psychiatry 126 :** 1245-1251, 1970
13. Güresir E, Vatter H, Schuss P, Platz J, Konczalla J, de Rochement Rdu M, et al. : Natural history of small unruptured anterior circulation aneurysms: a prospective cohort study. **Stroke 44 :** 3027-3031, 2013
14. Gutheil TG, Bursztajn H, Brodsky A : Malpractice prevention through the sharing of uncertainty. Informed consent and the therapeutic alliance. **N Engl J Med 311 :** 49-51, 1984
15. Hekkenberg RJ, Irish JC, Rotstein LE, Brown DH, Gullane PJ : Informed consent in head and neck surgery: how much do patients actually remember? **J Otolaryngol 26 :** 155-159, 1997
16. Herz DA, Looman JE, Lewis SK : Informed consent: is it a myth? **Neurosurgery 30 :** 453-458, 1992

17. Jones JW, McCullough LB, Richman BW : A comprehensive primer of surgical informed consent. **Surg Clin North Am 87 :** 903-918, viii, 2007
18. Juvela S, Poussa K, Lehto H, Porras M : Natural history of unruptured intracranial aneurysms: a long-term follow-up study. **Stroke 44 :** 2414-2421, 2013
19. Katz J : Reflections on informed consent : 40 years after its birth. **J Am Coll Surg 186 :** 466-474, 1998
20. Kessler TM, Nachbur BH, Kessler W : Patients' perception of preoperative information by interactive computer program-exemplified by cholecystectomy. **Patient Educ Couns 59 :** 135-140, 2005
21. Komotar RJ, Mocco J, Solomon RA : Guidelines for the surgical treatment of unruptured intracranial aneurysms: the first annual J. Lawrence pool memorial research symposium--controversies in the management of cerebral aneurysms. **Neurosurgery 62 :** 183-193; discussion 193-194, 2008
22. Kondziolka DS, Pirris SM, Lunsford LD : Improving the informed consent process for surgery. **Neurosurgery 58 :** 1184-1189; discussion 1184-1189, 2006
23. Krupp W, Spanehl O, Laubach W, Seifert V : Informed consent in neurosurgery: patients' recall of preoperative discussion. **Acta Neurochir (Wien) 142 :** 233-238; discussion 238-239, 2000
24. Lavelle-Jones C, Byrne DJ, Rice P, Cuschieri A : Factors affecting quality of informed consent. **BMJ 306 :** 885-890, 1993
25. Lipetz MJ, Bussigel MN, Bannerman J, Risley B : What is wrong with patient education programs. **Nurs Outlook 38 :** 184-189, 1990
26. Murphy K : ISAT and ISUIA: the impact on informed consent. **Tech Vasc Interv Radiol 8 :** 106-107, 2005
27. Park J, Son W, Park KS, Kang DH, Lee J, Oh CW, et al. : Educational and interactive informed consent process for treatment of unruptured intracranial aneurysms. **J Neurosurg 126 :** 825-830, 2017
28. Paterick TJ, Carson GV, Allen MC, Paterick TE : Medical informed consent: general considerations for physicians. **Mayo Clin Proc 83 :** 313-319, 2008
29. Raaymakers TW, Rinkel GJ, Limburg M, Algra A : Mortality and morbidity of surgery for unruptured intracranial aneurysms: a meta-analysis. **Stroke 29 :** 1531-1538, 1998
30. Schats R, Brilstra EH, Rinkel GJ, Algra A, Van Gijn J : Informed consent in trials for neurological emergencies: the example of subarachnoid haemorrhage. **J Neurol Neurosurg Psychiatry 74 :** 988-991, 2003
31. Shukla AN, Daly MK, Legutko P : Informed consent for cataract surgery: patient understanding of verbal, written, and videotaped information. **J Cataract Refract Surg 38 :** 80-84, 2012
32. Simes RJ, Tattersall MH, Coates AS, Raghavan D, Solomon HJ, Smartt H : Randomised comparison of procedures for obtaining informed consent in clinical trials of treatment for cancer. **Br Med J (Clin Res Ed) 293 :** 1065-1068, 1986
33. Sonobe M, Yamazaki T, Yonekura M, Kikuchi H : Small unruptured intracranial aneurysm verification study: SUAVe study, Japan. **Stroke 41 :** 1969-1977, 2010
34. Thompson BG, Brown RD Jr, Amin-Hanjani S, Broderick JP, Cockroft KM, Connolly ES Jr, et al. : Guidelines for the management of patients with unruptured intracranial aneurysms : a guideline for healthcare professionals from the American Heart Association/American Stroke Association. **Stroke 46 :** 2368-2400, 2015
35. UCAS Japan Investigators, Morita A, Kirino T, Hashi K, Aoki N, Fukuhara S, et al. : The natural course of unruptured cerebral aneurysms in a Japanese cohort. **N Engl J Med 366 :** 2474-2482, 2012
36. Wear S : **Informed consent : patient autonomy and physician beneficence within clinical medicine.** Dordrecht : Kluwer Academic Publishers, 1993
37. Wiebers DO, Whisnant JP, Huston J 3rd, Meissner I, Brown RD Jr, Piepgras DG, et al. : Unruptured intracranial aneurysms: natural history, clinical outcome, and risks of surgical and endovascular treatment. **Lancet 362 :** 103-110, 2003
38. Wollinger C, Hirnschall N, Findl O : Computer-based tutorial to enhance the quality and efficiency of the informed-consent process for cataract surgery. **J Cataract Refract Surg 38 :** 655-659, 2012

 https://doi.org/10.3340/jkns.2017.0101.007