Educational and interactive informed consent process for treatment of unruptured intracranial aneurysms

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OBJECTIVE For patients with unruptured intracranial aneurysms (UIAs), the information transfer that precedes informed consent needs to be in-depth and detailed, as most patients with a UIA have no symptoms, yet the risks related to treatment are relatively high. Thus, in this study an educational and interactive program was proposed for patients with UIAs to improve the informed consent process and assess the level of comprehension.

METHODS A total of 110 patients with UIAs underwent the proposed educational and interactive informed consent (EIIC) process and were enrolled in this study. The EIIC process combines patient education using information booklets, a cartoon book, a video, an initial physician-patient interview, answering a questionnaire, a second physician-patient interview based on the questionnaire results, and finally consent. After the first physician-patient interview that provides the patient with specific information, including his or her angiographic characteristics, medical condition, and recommended treatment, the patient is requested to answer a questionnaire composed of 3 parts: demographic information, including the patient's age, sex, and years of education; 13 medical questions to assess the patient's knowledge about his or her UIA; and an evaluation of the usefulness of the educational resources. The control group consisted of 65 patients from 3 other tertiary university hospitals where the EIIC process was not used.

RESULTS The questionnaire scores of the EIIC group ranged from 7 to 13 (mean $\pm$ SD: 11.9 ± 1.3) and were significantly higher than those for the controls (10.2 ± 1.9 , $p < 0.001$). The better comprehension of the patients in the EIIC group was remarkable as they were significantly older than those in the control group (62.7 ± 8.3 years vs 55.9 ± 10.5 years, respectively; $p < 0.001$). For both the EIIC group and the control group, a Pearson correlation analysis revealed a positive correlation ($r = 0.232$ for the EIIC group, $r = 0.603$ for controls) between the years of education and the questionnaire score ($p = 0.015$ for the EIIC group, $p < 0.001$ for the controls), whereas no correlation was found between the patient age and the questionnaire score. For the EIIC group, the verbal information from the attending physician was selected by 90 patients (81.8%) as the most useful and informative educational method, while the most effective reinforcement of this verbal communication was the video ($n = 86$; 78.2%), information booklets ($n = 16$; 14.5%), the Internet ($n = 7$; 6.4%), and the cartoon book ($n = 1$; 0.9%).

CONCLUSIONS The proposed standardized EIIC process resulted in good patient comprehension about UIAs. The verbal information from the attending physician was the most informative, and the video was the most effective reinforcement of the verbal communication. The patient level of comprehension was shown to be correlated with years of education.

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KEY WORDS endovascular; informed consent; intracranial aneurysm; questionnaire; vascular disorders

ABBREVIATIONS EIIC = educational and interactive informed consent; MCA = middle cerebral artery; UIA = unruptured intracranial aneurysm.

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WITH the significant improvement of diagnostic imaging, including MR and CT angiography, the incidence of UIA diagnosis has dramatically increased, along with the incidence of surgical and endovascular treatment. However, the impact of more and more cases of UIA treatment means the health care system is assuming many of the features of an assembly line, none of which enhance patient autonomy.

Informed consent is a key process in achieving patient autonomy and participation in medical decision making, and indeed a fundamental tenet of surgical practice in medicolegal matters.^{5,10,20} In particular, for patients with UIAs, the information transfer preceding the signing of consent needs to be in-depth and detailed, as most patients with a UIA have no symptoms, yet the treatment risks are relatively high.

However, while the quality of the informed consent process has received increasing attention in the neurosurgical field, previous studies have only investigated generalized informed consent processes occurring before such neurosurgical procedures as intracranial and spinal surgeries.^{15,16} Therefore, because the information transfer process for informed consent needs to be both educational and interactive in nature, this study presents an educational program for patients with UIAs to improve the informed consent process and uses a questionnaire to examine and enhance the patient's level of comprehension.

Methods

Patient Population

The proposed educational and interactive informed consent (EIIC) model was implemented at Kyungpook National University Hospital, while the control group was obtained through 3 other tertiary university hospitals (Seoul National University Bundang Hospital, Chonnam National University Hospital, and Dongsan Medical Center) where the proposed standardized multifaceted consent process was not used.

All the patients in this prospective study completed a questionnaire assessing their level of comprehension after the informed consent process for microsurgical clipping or endovascular coiling of a UIA. The inclusion criteria were patients > 18 years of age, the diagnosis of a UIA based on catheter angiography, and the ability to read and understand the written booklets and questionnaire. The exclusion criteria included patients with a hearing impairment, giant aneurysms with a diameter > 2.5 cm, fusiform aneurysms, and cases of impending rupture (e.g., posterior communicating artery aneurysms inducing oculomotor nerve palsy). This study was reviewed and approved by an institutional ethics committee.

EIIC Processes

Most patients underwent catheter angiography to evaluate the exact size, shape, and location of the UIA with the related vasculature and to determine the radiographic projections for endovascular coiling. The patient EIIC process was initiated during bed rest following catheter angiography, while the patients who brought an angiogram

from another hospital started the education process when they visited our outpatient clinic.

A standardized sequence was implemented, including 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 patients were given 3 information booklets and a cartoon book with the following titles: 1) "Ruptured Intracranial Aneurysms" (booklet, 12 pages), 2) "Microsurgical Clipping for UIAs" (booklet, 13 pages), 3) "Endovascular Coiling for UIAs" (booklet, 25 pages), and 4) "Intracranial Aneurysms" (cartoon book, 21 pages). The booklets were all written by the current authors, and the cartoon book was created based on the 3 booklets.

After reading the written education materials, the patients were also asked to watch a video covering the following 3 topics: ruptured intracranial aneurysms (10 minutes), microsurgical clipping for UIAs (10 minutes), and endovascular coiling for UIAs (20 minutes). The current authors participated in the production of the video and all the written education materials.

The ensuing first physician-patient interview, taking 10–20 minutes, covered general information about the UIA, specific information based on the angiographic characteristics and medical condition of the individual patient, and the recommended treatment. The treatment recommendation was determined in advance on a case-by-case basis by the neurovascular surgeon (J.P.) and endovascular interventionist (D.H.K.), one of whom then conducted the physician-patient interview.

If an aneurysm was amenable to either surgical or endovascular treatment, both treatments were discussed with the patient, although endovascular coiling was primarily recommended. For those patients requiring observation, the patient interview was conducted by the physician linked to the future procedure in the case of aneurysmal change (i.e., a neurosurgeon for middle cerebral artery [MCA] aneurysms and an endovascular interventionist for paraclinoid aneurysms). If there was a case of disagreement between the neurosurgeon and the interventionist, both treatment options were equally presented to the patient by the physician in charge.

The educational materials and interview were intended to allow the patients to understand their condition, their prognosis without treatment, the recommended treatment with the attendant risks and benefits, and reasonable alternatives. The patients then returned home and were encouraged to seek information from other sources, including the Internet. For the final treatment decision, a second physician-patient interview was arranged at the outpatient clinic 1–2 weeks later.

Questionnaire

When visiting the outpatient clinic for the second physician-patient interview, the patients were first asked to complete a questionnaire composed of 3 parts (Table 1): 1) demographic information, including the patient's age, sex, and years of education; 2) medical questions to assess the patients' understanding of their UIA; and 3) an evaluation of the usefulness of the provided educational resources.

TABLE 1. UIA Questionnaire

Part 1	Age ()		
	Gender ()		
	Years of education ()		
Category		Question	Correct Answer
Part 2	Pathophysiology	1. An aneurysm is a balloon-like bulge in a cerebral artery caused by a weakness in the arterial wall, usually where it branches. It takes several years to develop.	Agree
		2. Aneurysms can burst and bleed into the brain, causing serious complications including hemorrhagic stroke, permanent nerve damage, disability, or death.	Agree
		3. Most cerebral aneurysms do not produce symptoms until they either rupture or become very large.	Agree
	Treatment indications	4. Not all cerebral aneurysms need to be treated due to the risk of procedure-related complications.	Agree
		5. Aneurysm treatment, surgical or endovascular, is recommended if the risk of aneurysm rupture is considered significant based on the size, shape, and location of the aneurysm.	Agree
		6. If a patient desires aneurysm treatment due to severe anxiety resulting from harboring a UIA, surgical or endovascular treatment can be applied.	Agree
	Treatment modalities and alternatives	7. The treatment of a UIA always starts with medical treatment.	Disagree
		8. Two treatment options, surgical clipping or endovascular coiling, are available for treating cerebral aneurysms.	Agree
		9. If the aneurysm is not treated, yearly angiographic examinations using CTA or MRA are recommended for life to detect any changes to the aneurysm.	Agree
	Procedural risks	10. Aneurysm surgery itself carries significant risks for the patient. For unruptured non-giant anterior circulation aneurysms, the procedure-related mortality is about 1%, while the major morbidity affecting daily life due to hemiparesis, mental deterioration, and speech problems is about 2%.	Agree
	Other management	11. Patients with a UIA should stop smoking.	Agree
		12. Patients with a UIA should control hypertension.	Agree
	Treatment results	13. After aneurysm treatment, a cerebral aneurysm can recur at the previous aneurysm site or develop de novo at another site.	Agree
Part 3	Indicate the most useful educational resources	Information booklets, cartoon book, video, verbal information from physicians (attending physician, fellow, resident), Internet	
	Indicate the most effective reinforcement of the verbal communication	Information booklets, cartoon book, video, Internet	

CTA = computed tomography angiography; MRA = magnetic resonance angiography.

For the medical questions, the patients were asked to agree or disagree with 13 questions about the pathophysiology, treatment indications, available treatment modalities with alternatives, procedural risks, other management, and treatment results for UIAs. The 13 questions were designed to assess the patient's level of comprehension of his or her medical condition, and the results provided a focus for additional education during the second physician-patient interview. The medical question data were analyzed by calculating the scores, where each correct answer scored 1 point.

To evaluate the relative contribution of the educational materials in providing an understanding of UIAs, the patients were asked to rank the usefulness of the different educational methods: information booklets, cartoon book, video, Internet, and verbal information from the attending physician.

After using the results of the medical questions to provide additional information to the patient during the second physician-patient interview, the final treatment deci-

sion was confirmed, and the treatment schedule given to the patient.

Statistical Analysis

The statistical analyses were performed with the aid of commercially available statistical software (SPSS version 19.0, IBM Inc.). In this case-control comparison, a t-test was used for the quantitative variables (age, years of education, and questionnaire score), while a chi-square analysis was used for the categorical variable (sex). In addition, a Pearson correlation analysis was used to investigate the relationship between the questionnaire score and the related variables (age and years of education). The results were considered significant for probability values less than 0.05.

Results

Patients

A total of 110 patients with UIAs went through the proposed EIIC process, where the conditions included a

TABLE 2. Comparison of patients who went through the EIIC process and the control group

Variable	EIIC Group (n = 110)	Control Group (n = 65)	p Value*
Mean age $\pm$ SD (yrs)	62.7 $\pm$ 8.3	55.9 $\pm$ 10.5	<0.001†
Sex (%)			0.417‡
Male	44 (40.0)	22 (33.8)	
Female	66 (60.0)	43 (66.2)	
Mean years of education $\pm$ SD (yrs)	11.5 $\pm$ 3.4	11.6 $\pm$ 3.7	0.869†
Mean questionnaire score $\pm$ SD	11.9 $\pm$ 1.3	10.2 $\pm$ 1.9	<0.001†

* Boldface type indicates statistical significance.

† The t-test was used.

‡ The chi-square test was used.

single UIA at the internal carotid artery (n = 24), anterior cerebral artery (n = 28), MCA (n = 45), and vertebrobasilar artery (n = 5), or multiple UIAs (n = 8).

Demographic Comparisons

The patients in the EIIC group were significantly older than those in the control group (mean $\pm$ SD: 62.7 $\pm$ 8.3 years vs 55.9 $\pm$ 10.5 years, $p < 0.001$). However, there was no statistically significant between-group differences in patient sex and years of education (Table 2).

Questionnaire Results

The questionnaire scores for the EIIC group ranged from 7 to 13 (mean 11.9 $\pm$ 1.3) and were significantly higher than those for the controls (range 6–13, mean 10.2 $\pm$ 1.9; $p < 0.001$). The better comprehension of the patients in the EIIC group was especially remarkable as they were significantly older than the patients in the control group (Table 2).

The results of the medical questions on the questionnaire are presented in Table 3. For the EIIC group, the score was ≥ 10 for 105 patients (95.5%); 13 for 46 patients (41.8%), 12 for 31 patients (28.2%), 11 for 18 patients (16.4%), and 10 for 10 patients (9.1%). All the medical questions, with the exception of 2, were correctly answered by the patients with an incidence $> 90\%$. The incorrect answers were most frequently related to 2 questions about treatment indications: question 4 (“Not all cerebral aneurysms need to be treated due to the risk of procedure-related complications” [correctly answered by 87 patients]) and question 6 (“If a patient desires aneurysm treatment due to severe anxiety resulting from harboring a UIA, surgical or endovascular treatment can be applied” [correctly answered by 93 patients]). In contrast, in the control group, only 5 of the 13 questions were correctly answered by the patients with an incidence $> 90\%$.

Regarding the most useful and informative educational method, 90 patients (81.8%) in the EIIC group selected the verbal information and communication from the attending physician, followed by the video presentation (n = 12; 10.9%), information booklets (n = 7; 6.4%), cartoon book (n = 1; 0.9%), and the Internet (n = 1; 0.9%). In terms of the most important reinforcement of the verbal com-

TABLE 3. Number of patients with correct answers to 13 questions about UIAs*

Question	EIIC Group (n = 110)	Control Group (n = 65)
Pathophysiology		
1	102 (92.7)	39 (60.0)
2	107 (97.3)	64 (98.5)
3	109 (99.1)	62 (95.4)
Treatment indications		
4	87 (79.1)	27 (41.5)
5	107 (97.3)	56 (86.2)
6	93 (84.5)	39 (60.0)
Treatment modalities and alternatives		
7	100 (90.9)	41 (63.1)
8	105 (95.5)	61 (93.8)
9	102 (92.7)	49 (75.4)
Procedural risks		
10	104 (94.5)	55 (84.6)
Other management		
11	104 (94.5)	59 (90.8)
12	100 (90.9)	56 (86.2)
Treatment results		
13	100 (90.9)	59 (90.8)

* All data given as number of patients (%).

munication, most patients selected the video presentation (n = 86; 78.2%), followed by the information booklets (n = 16; 14.5%), Internet (n = 7; 6.4%), and cartoon book (n = 1; 0.9%).

Years of Education Affecting Patient Comprehension

For both the EIIC group and the controls, the Pearson correlation analysis showed a positive correlation ($r = 0.232$ for the EIIC group and $r = 0.603$ for the control group) between the years of education and the questionnaire score ($p = 0.015$ for the EIIC group, $p < 0.001$ for controls), whereas no correlation was found between the patient age and the questionnaire score.

Discussion

The current study presents a standardized EIIC process for patients with UIAs. Following this process, most patients exhibited a good comprehension of the natural course of UIAs, recommended treatment with attendant risks and benefits, and reasonable alternatives. The level of comprehension was shown to be affected by the patient's education level (years of education).

An optimal informed consent process can have several positive effects.^{4,12} First, better comprehension leads to augmented autonomy and a greater sense of control for the patient. Second, a basis is provided for a strong and enduring therapeutic alliance between the surgeon and the patient, resulting in better treatment cooperation from patients and fewer medicolegal claims. Third, explaining what to expect intra- and postoperatively has a direct im-

pact on the quality of health care services. Preoperative disclosure of such information allows the patient to establish psychological defenses for coping with stressful surgical circumstances and prevents the patient from being overwhelmed by the sensations accompanying surgery.

The treatment decision for a UIA is based on a combination of the natural history of the given UIA, the patient's life expectancy, and the treatment risks related to surgical clipping and endovascular coiling. The final treatment decision can be complex and often poorly understood due to the presence of some uncertainty despite a series of management recommendations and guidelines.^{14,23} First, the risk of rupture is estimated based on the angiographic characteristics, including the size, shape, and location of the UIA. Yet, angiograms are contrast column images showing a luminal space rather than depicting the aneurysmal wall, which is the most crucial factor determining the rupture risk. Some patients present with a ruptured aneurysm that is very small in size. Second, a patient's life expectancy cannot be precisely assessed. Third, the risks related to surgical or endovascular treatment vary greatly depending on the individual hospital and surgeon. Such uncertainties are particularly problematic when the patient's condition is borderline between required treatment and observation. A shared acknowledgment of such clinical uncertainties can reinforce the physician-patient relationship, leading to a strong therapeutic alliance.¹²

Optimally, the informed consent discussion should be conducted by the physician who is directly involved in the proposed surgical or endovascular procedure,^{1,3} as relatively unqualified health care professionals such as residents and physician assistants are more likely to present the benefits of the procedure rather than the risks or alternatives.¹ The current physician-patient interviews were all performed by the attending surgeon or attending interventionist.

The way that information is presented has an important impact on the comprehension level and information retention by patients. Educational intervention in the form of written material, cartoon illustrations, and audiovisual presentation is already known to significantly increase patient comprehension when compared with simple verbal communication.^{2,5,7,8,20,26} However, the proposed EIIC process uses repeated educational intervention in various forms to optimize the patient's understanding before the physician-patient interview and thereby reduce the time and effort involved in the physician-patient discussion.

The transmission of information for the consent process needs to be initiated well in advance of the procedure, allowing the final decision to be made with the time necessary to make a major life decision. Processing the information related to a decision does not finish immediately after the transmission of the information.^{11,17,21} In the proposed EIIC process, the patients were requested to make a decision 2 weeks after the educational process and first physician-patient interview, and if needed the patients were allowed to delay their decision. The short hospital stay for the catheter angiography provided an ideal opportunity to conduct the informed consent process. The surgical or endovascular procedure was then commonly scheduled 1–3 months thereafter.

The natural course of a UIA should be explained based on previous well-designed large studies including the International Study of Unruptured Intracranial Aneurysms (ISUIA) and the Small Unruptured Intracranial Aneurysm Verification (SUAve) study.^{9,14,18,22,24,25} Any estimation of the risk of aneurysm rupture should take into account the size, shape, and location of the UIA.^{13,24,25} In addition, the surgical results should be considered when making a decision on whether to proceed with treatment for an individual patient. In a meta-analysis of the mortality and morbidity resulting from surgical clipping of UIAs by Raaymakers et al.,¹⁹ the overall mortality and morbidity was reported as 2.6% and 10.9%, respectively. However, for patients with non-giant anterior circulation aneurysms, the mortality and morbidity was 0.8% and 1.9%, respectively.

The aneurysm treatment recommendation should be determined by both an experienced cerebrovascular surgeon and an endovascular interventionist as a multidisciplinary decision, based on the characteristics of the patient and the aneurysm. The surgeon's experience and the treatment outcomes of an individual hospital should also be considered and presented to the patient.⁶ The current neurovascular team treats aneurysms according to the following principles: 1) the treatment modality (surgical vs endovascular) is a joint decision by a vascular surgeon and endovascular interventionist based on previous treatment results; 2) if an aneurysm is amenable to either treatment for complete and safe obliteration of the aneurysm, endovascular treatment is preferred because it is less invasive; and 3) to reduce patient reluctance for surgery in cases with proper indications, minimally invasive surgical procedures are pursued, such as a superciliary keyhole approach.

Although the current study is limited based on a case series from a single institution, a well-designed informed consent process using a variety of educational materials, verbal information from the attending physician, and questionnaire-based supplementary education were found to enhance the patient's level of comprehension about UIAs. In addition, the medical questions included in the questionnaire were limited to the basic knowledge applicable to most patients. Because the advantages and disadvantages of the two treatment modalities (surgical vs endovascular) differ according to the size, shape, and location of the aneurysm and the age and medical condition of the patient, the questionnaire did not include any questions on the differences between the two treatment modalities. However, a comparison of the two treatment modalities, the recommended treatment specific to the patient, and reasons for selecting this treatment modality were all discussed during the physician-patient interview.

Conclusions

The proposed standardized EIIC process for informed consent—combining patient education using various educational materials, an initial physician-patient interview, answering a questionnaire, and questionnaire-based supplementary education during a second physician-patient interview—was shown to result in good patient compre-

hension about UIAs. The verbal information and advice from the attending physician was found to be the most informative method of education, while videotaped information was the most effective reinforcement of the verbal communication. The patient's level of comprehension was found to be correlated with his or her educational level (years of education).

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Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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Conception and design: J Park. Acquisition of data: Son, KS Park, Oh, Kwon, TS Kim, CH Kim. Analysis and interpretation of data: Son, KS Park. Drafting the article: J Park. Reviewed submitted version of manuscript: Kang. Approved the final version of the manuscript on behalf of all authors: J Park. Statistical analysis: Lee. Administrative/technical/material support: Kang. Study supervision: J Park.

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