

Informed Consent for Intravenous Contrast Administration in the Emergency Department: Understanding and satisfaction among patients using the video-assisted vs. traditional methods

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ABSTRACT

Background. Computed-tomography (CT) is increasingly performed among patients who visit an emergency department (ED), many of whom require the administration of intravenous contrast, to make an accurate diagnosis of their condition and offer prompt treatment. Though the safety profile of new intravenous contrast agents has improved, patients are still exposed to significant risk from potentially life-threatening reactions.

Materials and Methods. This is a prospective study. Subjects were patients over the age of 18, or their family representative, who visited the ED. Subjects were randomly assigned to either the original routine explanation for consent or the video-assisted explanation. Patients completed a questionnaire about contrast adverse effects and the proposed treatment.

Results. Mean values of the degree of understanding of informed consent were relatively higher in the video-assisted group. When assessing the proficiency of the informer, the score for understanding and satisfaction was higher in the attending staff informed group than the house staff informed group.

Conclusion. This study showed a higher level of understanding in the group that was provided information using visual aids, rather than in the traditional way. Also, a higher level of understanding and satisfaction was shown among those who

were given explanations by an attending staff member.

The busy ED, due to factors such as overcrowding, is expected to see benefit from appropriately utilizing multimedia visual aids, and also from more experienced medical staff providing information.

Key words: informed consent, intravenous contrast, visual aids

INTRODUCTION

Computed-tomography (CT) is increasingly performed among patients who visit an emergency department (ED), many of whom require the administration of intravenous contrast, to make an accurate diagnosis of their condition and offer prompt treatment. Though the safety profile of new intravenous contrast agents has improved, patients are still exposed to significant risk from potentially life-threatening reactions. Previous studies have demonstrated that physicians inconsistently obtain informed consent before the administration of intravenous contrast, and, when consent is obtained, there is wide variability in the quality of the process. (1,2) Studies have also demonstrated that patients want to know about the risks of intravenous contrast before receiving it, but due to overcrowding in the ED, it is difficult for doctors to provide detailed informed consent to patients. (3,4)

The ethical imperative of informed consent requires physicians to provide information about procedures. Depending on the experience of clinicians, the urgency of patients and the situation in the ED, a patient's understanding and satisfaction with informed consent varies.

We hypothesize that video-assisted informed consent would produce a difference in mean intravenous contrast knowledge scores compared with those undergoing routine informed consent. We also aim to explore whether using videos would lead to greater satisfaction with the informed consent process. We also hope to determine whether the understanding and satisfaction with informed consent varies by provider level.

MATERIALS AND METHODS

This is a prospective study. Subjects were patients over the age of 18, or their family representative, who visited either one of two tertiary university hospitals in Seoul. The test group consisted of patients that needed to consent to enhance CT imaging. Those who had previously received such imaging, those who declined to participate in the study, or those that were clinically unstable were excluded from the study.

This study took place from November 2014 to April 2015, and subjects were randomly assigned either to receiving the original oral explanation for consent, or the video-assisted method.

The group given the video-assisted explanation, consented to the procedure after watching a video file, which was explained to them at the same time by a faculty of emergency medicine, resident, or intern. The file that was utilized in the explanation included the following: (1) the purpose and advantages of contrast enhanced CT, (2) the types, risks, and timing of possible adverse effects that can come from using a contrast media, (3) the prophylactic measures used to reduce the risk of adverse effects, (4) treatment measures if adverse effects take place, (5) diagnostic tools that can be used if a contrast enhanced CT cannot be used. The original video file was produced in this hospital and the content was the same as in the conventional documents. The play time of the video file is about 5 minutes. The participants in the video-assisted informed consent group watched the video on personal computers in the counseling room of the ED. Further explanation was provided by ED faculty, or other doctors, including residents and interns, concurrently watching the video. As for the traditional group, faculty, residents and interns provided the same information as on the video file, but only using conventional documents.

Patients or guardians were then asked to fill a questionnaire consisting of 13 parts. The questionnaire asked patients about the information they were provided while giving consent, and their satisfaction with the process. The questionnaire consisted of one question about the purpose of the investigation, one question about the examination process, 8 questions on adverse effects, and 3 questions on the treatment of adverse effects. Each question was scored one point if the answer was correct, and if not, the score was zero. Satisfaction with the explanation provided was divided into 4 stages, which the patients were also asked to choose.

Data were analysed using Wilcoxon-Mann-Whitney test and Chi-square test as appropriate. Statistical analyses were conducted using SPSS ver. 18.0 (SPSS Inc., Chicago, IL, USA). A value of $p < 0.05$ was considered statistically significant.

This study was conducted in agreement with the Declaration of Helsinki, and the Institutional Review Board of the hospital.

RESULTS

A total of 684 participants were eligible for the study. Of these, 225 were excluded (participation declined or incomplete questionnaire) and 459 were randomized.

Table 1. Demographic characteristics of the verbally informed group and video-assisted informed group

	Verbally Informed Group (n=300)	Video-Assisted Informed Group (n=159)	P
Sex,n(%)			0.386
Male	114(38%)	72(45%)	
Female	186(62%)	87(55%)	
Age(M±SD years)	46.3±22.54	48.70±23.49	0.512
Level of education			
≤ High school	99(33%)	60(38%)	0.510
≥ University	201(67%)	99(62%)	

Table 2. Comparison of understanding and satisfaction by informed consent method

	Verbally Informed Group (n=300)	Video-Assisted Informed Group (n=159)	P
Understanding (mean±SD)			
Purpose	0.65±0.22	0.67±0.31	0.43
Examination process	0.67±0.34	0.62±0.19	0.37
Adverse effects	4.24±1.34	5.88±1.27	0.00*
Treatment of adverse effects	1.74±0.84	1.97±0.66	0.50
Satisfaction (mean±SD)	2.73±0.76	2.70±0.82	0.67

Table 3. Demographic characteristics of attending staff group and house staff group

	Attending Staff Group (n=120)	House Staff Group (n=339)	P
Sex,n(%)			0.631
Male	56(47%)	138(41%)	
Female	64(53%)	201(59%)	
Age(M±SD years)	44.3±22.28	47.83±22.73	0.379
Level of education			
≤ High school	42(35%)	113(33%)	0.510
≥ University	78(65%)	226(37%)	

Table 4. Comparison of understanding and satisfaction by proficiency of informer

	Attending Staff Group (n=120)	House Staff Group (n=339)	P
Understanding (mean±SD)			
Purpose	0.70±0.24	0.67±0.13	0.39
Examination process	0.62±0.22	0.68±0.24	0.43
Adverse effects	5.65±1.72	4.35±1.52	0.02*
Treatment of adverse effects	2.04±0.53	1.77±0.69	0.04
Satisfaction (mean±SD)	3.83±0.47	2.67±0.53	0.00*

Comparison of understanding and satisfaction between informed consent groups. There were no significant differences in the age, sex, and educational level of partici-

pants in the verbally informed group and video-assisted informed group (table 1). Mean values of understanding about adverse effects were relatively higher in the

video assisted group (5.88 ± 1.27 vs. 4.24 ± 1.34 “ p ”= 0.00). There were no significant differences in the purpose, treatment and satisfaction between the two groups (table 2).

COMPARISON OF UNDERSTANDING AND SATISFACTION BY PROFICIENCY OF INFORMER

There were no significant differences in age, sex, or educational level between the attending staff group and house staff group (table 3).

The degree of understanding and satisfaction among patients was higher in the attending staff informed group than in the house staff informed group, except for the understanding of purpose. Mean values for the understanding of adverse effects and satisfaction with informed consent were higher in the attending staff informed group, (5.65 ± 1.72 vs. 4.35 ± 1.52 “ p ”= 0.02, 3.83 ± 0.47 vs. 2.67 ± 0.53 “ p ”= 0.00) (table 4).

DISCUSSION

As the number of patients visiting an ED increases, so does the incidence of invasive diagnostic as well as therapeutic measures being performed. A CT exam is one of the most common diagnostic modalities used in an ED for various types of trauma or diseases. It results in the increased use of contrast media and the incidence of contrast-induced side effects. In addition, the number of patients with chronic diseases, such as diabetes mellitus and hypertension, as well as the elderly, is increasing, which leads to a higher chance of severe adverse effects, such as renal dysfunction. (5,6) To add to that, there is an increasing demand for precise and comprehensive information regarding diagnostic tests and procedures, caused by a different perception towards medical services by consumers. (7,8)

However, due to overcrowding and the fact that emergency physicians are understaffed, sufficient time to thoroughly explain the procedure is not available, making the process rather perfunctory. (9,10) As emergency departments become overloaded, the need for thorough explanation regarding invasive procedures and diagnostic tools is increasing. This results in the

need for a time-effective and easy method for providing clear information to patients and family members. (10,11) As a solution to such a problem, visual aids, as well as multimedia tools, have recently been tried as tools for informed consent. (8)

In previous studies, Sahai et al reported that the degree of patient satisfaction was relatively higher following video assisted information for endoscopic surgery. (12) In Cowan et al, the degree of patient understanding was found to be relatively higher in the group where a video-assisted informed consent was made as compared with that where a verbal informed consent was made (71.0% vs. 54.3%). (13)

This study focused on the patients' understanding, specifically of the possible adverse effects of using a contrast media. Our results show that using video-assisted informed consent yields higher intravenous contrast knowledge scores in patients requiring informed consent for intravenous contrast administration in the ED. In our study, mean scores on the post-consent intravenous contrast knowledge measure were higher in the video-assisted informed consent group compared with the conventional informed consent group. Our findings are consistent with a previous study of an interactive media tool used to educate patients about intravenous contrast risks, benefits, and alternatives in other invasive procedure or an outpatient setting.

Although video education shows higher intravenous contrast knowledge, our patients in both the video and routine informed consent groups achieved low mean intravenous contrast knowledge scores. One reason for low mean scores in the routine informed consent group may be variability in information provided by physicians to patients. Another possibility may be difficulty in comprehending and unfamiliarity with the questions on the intravenous contrast knowledge measure.

This study focused on the patients' understanding, specifically on the possible adverse effects, of using a contrast media. The group that received information via the video file showed a higher level of understanding compared with the group that was given the traditional explanatory documents. As for the level of satisfaction, there was no significant difference.

This study supposed that the level of experience of medical staff would result in a difference in understanding and satisfaction

of patients, thus the comparison between the attending staff group and the house staff group. Patients who were provided information by an attending staff member showed higher levels of understanding and satisfaction.

We can expect a higher level of understanding, as well as higher chances of consent by patients, when a procedure is explained by a more experienced emergency physician. A more experienced emergency physician can exchange a difficult or unfamiliar question in the survey with an easier one, that has the same meaning. According to a study, 78% of residents are not fully aware of the risks, benefits, and alternatives of procedures, and feel uneasy about getting consent from patients. (14) This lack of information on the residents' part, will relate to the lack of information for the patients, and is believed to show a correlation with patients' satisfaction.

LIMITATIONS

This study showed a lack of attending staff as compared to their counterparts. Also, the failure to categorize residents and interns by their experience, and lack of its correlation to the level of comprehension and satisfaction, will act as limitations in this study.

CONCLUSION

This study showed a higher level of comprehension in the group that was provided information using visual aids, rather than the paper document group. Also, a higher level of comprehension and satisfaction was shown in those who were given explanations by a board-certified medical staff member.

The busy emergency department, due to factors such as overcrowding, is expected to see benefit from appropriately utilizing multimedia visual aids, and also from more experienced medical staff providing information. This will have positive effects on the understanding and satisfaction of patients and their families in terms of treatment, diagnosis and procedures. The development of tools and education of medical staff will increase that effect.

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