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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This work was supported by the Ewha Womans University Research Grant of 2012

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 informed, 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.

Comparison of understanding and satisfaction between informed consent groups

There were no significant differences in the age, sex, and educational level of participants 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 informed group (Table 1). Table 2 shows comparison of understanding and satisfaction by informed consent method. The mean values of understanding about adverse effects were relatively higher in the video-assisted informed group (Table 2). Table 3 shows demographic characteristics of attending staff group and house staff group. There were no significant differences in sex, age, and educational level of attending staff group and house staff group (Table 3). Table 4 shows comparison of understanding and satisfaction by proficiency of informer. Mean values of understanding about adverse effects were relatively higher in the group where the video-assisted informed group (Table 4).

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

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

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

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

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>Attending Staff Group (n=120)</th>
<th>House Staff Group (n=339)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding (mean±SD)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Purpose</td>
<td>0.70±0.24</td>
<td>0.67±0.13</td>
<td>0.39</td>
</tr>
<tr>
<td>Examination process</td>
<td>0.62±0.22</td>
<td>0.68±0.24</td>
<td>0.43</td>
</tr>
<tr>
<td>Adverse effects</td>
<td>5.65±1.72</td>
<td>4.35±1.52</td>
<td>0.02*</td>
</tr>
<tr>
<td>Treatment of adverse effects</td>
<td>2.04±0.53</td>
<td>1.77±0.69</td>
<td>0.04</td>
</tr>
<tr>
<td>Satisfaction (mean±SD)</td>
<td>3.83±0.47</td>
<td>2.67±0.53</td>
<td>0.00*</td>
</tr>
</tbody>
</table>
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 satisfac-
tion among patients was higher in the at-
tending 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 con-
trast-induced side effects. In addition, the
number of patients with chronic diseases,
such as diabetes mellitus and hyperten-
sion, 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 in-
formation regarding diagnostic tests and
procedures, caused by a different percep-
tion towards medical services by consum-
ers. (7,8)

However, due to overcrowding and the
fact that emergency physicians are under-
staffed, sufficient time to thoroughly ex-
plain the procedure is not available, mak-
ing the process rather perfunctory. (9,10)
As emergency departments becomes over-
loaded, the need for thorough explanation
regarding invasive procedures and diag-
nostic 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 un-
derstanding 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’ un-
derstanding, specifically of the possible ad-
verse effects of using a contrast media. Our
results show that using video-assisted in-
formed consent yields higher intravenous
contrast knowledge scores in patients re-
quiring 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 conven-
tional informed consent group. Our find-
ings 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 pa-
tients in both the video and routine in-
formed 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 phy-
sicians to patients. Another possibility may
be difficulty in comprehending and unfa-
miliarity with the questions on the intrave-
nous contrast knowledge measure.

This study focused on the patients’ un-
derstanding, specifically on the possible
adverse effects, of using a contrast me-
dia. 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 expe-
rience of medical staff would result in a dif-
ference 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 under-
standing, as well as higher chances of con-
sent by patients, when a procedure is ex-
plained by a more experienced emergency
physician. A more experienced emergency
physicians can exchange a difficult or unfa-
miliar 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 alterna-
tives 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 correla-
tion with patients’ satisfaction.

**LIMITATIONS**

This study showed a lack of attending staff
as compared to their counterparts. Also,
the failure to categorize residents and in-
terns 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 com-
prehension 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 expla-
nations by a board-certified medical staff
member.

The busy emergency department, due to
factors such as overcrowding, is expected
to see benefit from appropriately utiliz-
ing multimedia visual aids, and also from
more experienced medical staff providing
information. This will have positive ef-
effects on the understanding and satisfac-
tion 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.
REFERENCES