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CLINICAL INVESTIGATIONS

Patients' Knowledge of the Intravenous Contrast Materials and Their Risks: A Cross-sectional Survey*

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Abstract: The aim of this study was to determine the level of knowledge about the intravenous contrast materials (IVCMs) and their risks in patients in an Anatolian city. The study included 156 outpatients who applied for radiographic studies requiring the use of IVCMs. The data were obtained by face-to-face interviews before the radiographic examination. The questionnaire was designed specifically for this study and the respondent was given a total score of 100 points for all correct answers. Patients' information about the IVCMs, their risks, and their role in the diagnosis of some diseases were investigated with this survey. ANOVA, t-test and chi-square test were used for statistical analysis. Most of the patients were found not to have sufficient information about the potential risks and side effects of IVCMs. The mean score was 54.80 ± 12.60 (ranging between 20 and 85) out of 100. The patients who knew about the contrast materials and had higher education levels got higher scores ($P = 0.000$). Scores were significantly higher in patients who had had previous procedures with intravenous contrast material injections compared to the others who had never received contrast materials before ($P = 0.021$). Although the patients with higher education levels were shown to have more knowledge about the contrast materials compared to with lower education levels, most of the respondents still were not sufficiently aware of the risks and side effects of the contrast materials. These results indicate that all patients should be informed about the side effects and potential risks of IVCM injections before the procedure.

Key Words: Contrast media, informed consent, information management

Introduction

The radiologist is obliged to obtain informed consent before performing procedures requiring the intravascular (IV) administration of contrast materials (1). Informed consent is used both to inform patients about procedures and to protect physicians from litigation (2-4). It involves the advantages and disadvantages, risk factors and potential side effects of intravascular contrast materials (IVCMs), other alternatives, and the patient's permission for IVCM use (2,5-7).

Prior written information concerning the risks associated with IV injections of contrast material for diagnostic imaging is rarely given to patients in Turkey.

Previous studies reported that a common reason given for not obtaining informed consent was that the anxiety produced by informing the patient would increase the potential for an adverse reaction (8-10). However, many recent reports suggested that patients would like to be informed about the risks associated with IV injections of contrast materials (3,6,11-14).

IV administration of iodinated contrast materials has been frequently used for the diagnosis of several diseases, especially in computerized tomography (CT) and excretory urography, at many different medical centres such as university, state and private hospitals, and small-scale diagnostic centers in Turkey, and also in our city,

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Afyon. The purpose of this study was to evaluate the level of awareness of patients about IVCMs and to discuss the obligation of obtaining informed consent.

Materials and Methods

Between October 2002 and April 2003, a cross-sectional questionnaire survey was carried out in Afyon, a small city in Anatolia Turkey. The study included 156 cooperative outpatients (62 female and 94 male; mean age 43.39 ± 12.53 years; age range 18-76 years) who applied for radiographic studies, either CT or excretory urography, requiring the use of IVCMs. Nonionic contrast material was used in both examinations. In total, 44 patients were physically unable to complete the questionnaire. When the patients arrived at the radiology department, they were asked by our technicians to read and sign the questionnaire together. Patients were not allowed to use any materials or sources during the test. The questionnaire contained 16 questions, having a combination of true-false and multiple choice answers and 5 points were given for each correct answer. Each patient was scored over a total of 100 points. The following information was evaluated in the questionnaire:

demographic data (age, education and employment), patients' knowledge about the IVCMs, and their role in the diagnosis of some diseases and their risk factors and side effects (see Appendix). This study protocol was approved by our institutional Ethics Committee and informed consent was obtained from all participants.

Statistical Analysis

Statistical analysis was performed using SPSS version 10.0. Among the parametric tests, t-test for 2-group comparison and ANOVA for 3-group comparison were used. For nonparametric analysis, the chi-square test was applied. All results were expressed as means ± SD. A P value of < 0.05 was considered to indicate a statistically significant difference.

Results

Sociodemographic characteristics of the participants and their knowledge about IVCMs are shown in Table 1. Fifty-nine participants (37.8%) had completed primary school and 53 participants (34.0%) were unemployed. Sixty-six participants (42.3%) had no idea about IVCMs.

Table 1. Patients' sociodemographics and their own knowledge about IVCMs.

Characteristics	No. of Patients (n = 156)	%
Sex		
Male	94	60.3
Female	62	39.7
Educational level		
Illiterate	7	4.5
Not school educated, but literate	11	7.1
Primary (0-5 years)	59	37.8
Secondary (6-8 years)	24	15.4
High (9-11 years)	33	21.2
University (12-17 years)	22	14.1
Employment		
Unemployed	53	34.0
Employed	67	42.9
Retired	36	23.1
Knowledge about IVCMs		
More than sufficient	8	5.1
Sufficient	8	5.1
Partially sufficient	20	12.8
Insufficient	54	34.6
No idea	66	42.3

We also planned to check the awareness of participants about radiation. Surprisingly, 126 participants (80.8%) correctly answered the question about the energy type used in their examination.

In 151 of the patients (96.8%), no history of allergy to any materials such as foods or drugs was obtained. A previous history of IVCM injection was valid for 62 patients (39.7%). Of these, 26 patients (17%) had had IV contrast-enhanced CT and 42 patients (27%) had had IV excretory urography before.

There were 2 questions about the indications for using IVCMs. Most of the patients correctly answered both questions. Of these, 130 patients (83.3%) knew that these materials were used for better visualization of some tissues and 141 patients (90.4%) were aware of their importance for diagnosis. These questions had 2 responses (true or false), and so the probability of giving the correct answer was 50%. However, a much greater proportion answered these questions correctly.

Information about patients' knowledge of risk factors and serious adverse reactions to IVCMs is given in Table 2. Of all the patients, 93 (59.6%) thought that IVCMs could be administered to anyone safely. While 99 patients (63.5%) were conscious these materials should

not be given to patients with a history of allergic reaction, the risks of IVCM application in patients with kidney disease and asthma were not known by 119 patients (76.3%) and 123 patients (78.8%), respectively. Most of the patients were shown to have insufficient information about potential serious reactions to IVCM administration.

One hundred twenty-four participants (79.5%) knew that IVCMs could cause insignificant side effects such as nausea, vomiting or a rash, while 106 of them (67.9%) knew that serious adverse reactions, although rare, could occur. However, the responses to the question about the risk of death attributed to the use of IVCMs, proved a lack of awareness among the participants. The question had 2 responses, and so the probability of giving the correct answer was 50%. Ninety-two patients (59.0%) gave the wrong answer to this question. They did not know that IVCM use could lead to death, although very rarely.

When the scoring was done for each correct answer, the mean score was 54.80 ± 12.60 (range 20-85). Comparisons of responses of each group according to the scores are shown in Table 3. As expected, the patients who had previous information about IVCMs got higher scores ($P = 0.000$). Scores were significantly higher in

Table 2. Knowledge about risk factors and serious adverse reactions against IVCMs.

Characteristics	No. of Patients (n = 156)	%
The risk factors associated with IVCM are		
cancer	98	62.8
cardiovascular disease	70	44.9
history of allergy	99	63.5
tuberculosis	142	91.0
asthma	33	21.2
renal disease	37	23.7
previous history of IVCM administration without any reaction	135	86.5
The serious side effects IVCM are		
shortness of breath	73	46.8
loss of consciousness	56	35.9
increased heart rate	56	35.9
diarrhea	61	39.1
itching	65	41.7
convulsion	31	19.9

Note.— Values are numbers of correct responses.

Table 3. Comparison of each group's responses according to scores.

(First group) vs (second group)	First group score (n) (mean ± SD)	Second group score (n) (mean ± SD)	P Value*
(Male) vs. (female)	56.32 ± 13.30(94)	52.50 ± 11.15(62)	0.054
(Primary school and lower) vs. (higher)	50.58 ± 10.97 (77)	58.92 ± 12.77 (79)	0.000
(Previous history of IVCM administration) vs. (not)	57.66 ± 12.66 (62)	52.92 ± 12.25 (94)	0.021
(Knowledge about IVCM more to partially sufficient) vs. (not sufficient and no idea)	65.83 ± 12.62 (36)	51.50 ± 10.58 (120)	0.000

* Compared by using the t-test

patients who gave a history of procedures with IVCM injections compared to those who did not (P = 0.021). Not surprisingly, education level was also an important factor in having sufficient knowledge about IVCM (P = 0.000). Although the difference was statistically insignificant, men seemed to know more about IVCM than did women (P = 0.054) and the unemployed group got lower scores compared to patients with different occupations (P = 0.001). The important point supporting the last 2 results was that the unemployed group was composed of only women, because all of the men in the study population were employed. Chi-square analysis revealed that the application ratios of IVCMs to both men and women before were almost equal (P = 0.830) and there was a significant difference in the level of education between the 2 genders (P = 0.000), i.e. women were found to have lower education levels.

Discussion

As Hippocrates advised 'Primum non nocere', a physician's primary duty is to do what is beneficial for the patient and not to cause unnecessary harm (11). In our daily practice, the fact that the probability of a serious or life-threatening reaction against IVCMs is very low on average leads many to think that written consent is not required (6). This point is debatable when it is considered from the view of patient's right to be aware of the application's risks.

In fact, we observed that most of the patients knew that contrast materials were used for better visualization of tissues by enhancing them and for facilitating the diagnosis of most diseases. However, they that IVCMs could be safely given to everybody. According to our

survey, they did not have sufficient information about the risk factors and potential side effects of IVCMs (Table 2).

Several investigators have reported that the informed consent process may increase anxiety and the prevalence of adverse reactions among patients informed of the risks associated with IVCM usage (8-10). Studies from Turkey on this issue have given different results. While Bozkurt et al. (15) found that anxiety levels increase in informed patients, another study, by Sakan et al. (16), showed no change in the anxiety level of informed patients. Although we did not evaluate the anxiety levels of patients after they received information, we observed that the participants became anxious when reading the questions about the serious side effects of IVCMs and death. At the end of the survey, the ratio of correct answers of the participants about potential serious side effects and death was 19.9%-46.8%. In other words, patients did not expect serious risks like death as a consequence of such a simple procedure required for the diagnosis of a disease.

However, in some other studies, different results have been obtained. Regardless of the severity or low frequency of the risks of IVCMs, the vast majority of patients demanded and accepted information before IVCM administration about the risk factors and side effects (3,6,11-14). It was found that informing patients of the risks associated with IVCMs did not increase anxiety or the frequency of adverse reactions. It was suggested that the use of therapeutic privilege in not obtaining informed consent to avoid an increase in anxiety-induced adverse reactions against IVCMs was not justified (11).

In our study, the mean score showing knowledge about IVCMs was better than in previous studies (4,17),

which used informed consent before IVCM administration. However, Neptune et al. (4) reported that the average patient was still inadequately informed. From this country, Belet et al. (17) suggested giving information about the contrast material before the examination, since their study population had a lower knowledge about IVCMs and their side effects.

Belet et al. (17) also found no significant differences related to sex, age, education level or previous contrast material administration. In contrast to previous similar studies (4,9,10), our results suggested that women had lower knowledge scores than did men although the difference was statistically insignificant (Table 3). Furthermore, the unemployed group, composed of only women, had lower knowledge scores. Additionally, women had a lower level of education than did men. All these findings pointed out the necessity of giving more attention and care to educating and informing women. The higher scores of men can be explained by their having a higher level of education and forming an employed and freely communicating and interacting group.

Not surprisingly, patients who had undergone previous procedures with IVCM injections answered more questions correctly than those who had not. It was not unexpected that patients with higher education levels also had a higher baseline knowledge (Table 3).

It is the patient's natural right to be informed of all potential risks caused by the procedure applied to him or her (11,14). However, this is usually a time-consuming process. Of the information provided to the patients, to what extent do they retain it and how much of it is sufficient? In a recent study, answers to these questions were sought. No information was given to a group of patients and a generic permission form was signed by each of them. It took a total of 51 min of the technologist's time. If a physician were to be counselled for detailed information, almost 6 h would be required each day (6). Although informing each patient leads to deterioration of the workflow of technologists and radiologists in radiology departments, which are always too busy, this service should be supported. Written or illustrated brochures informing people can be distributed

to patients during the waiting period before all contrast-enhanced and non-enhanced radiological procedures.

Supporting our results, patients having a higher level of education will both understand the information given to them more easily and will be informed repeatedly each time they undergo a new procedure. Consequently, each patient will be better informed and more conscious compared to those who have never been exposed to IVCMs. Moreover, for informing much greater populations, especially those with lower levels of education, panels designed for people, in particular the unemployed and those spending most of their time at home, can be arranged or the media (local written and oral press: radio, television (soap operas), internet and newspapers, etc.) can be used.

In conclusion, although patients with higher education levels and a previous history of IVCM administration were shown to have more knowledge about IVCM compared to patients with lower education levels and no previous experience with IVCMs, most of the attendants still were not aware of the risks and side effects of IVCMs. These results indicate that all patients should be informed about the risk factors and potential adverse reactions of IVCMs before the procedure. It is the patient's ethical, legal and medical right to be aware of the potential side effects of procedures applied to them.

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