Impact of Written Informed Consent on the Number of Intravenous Contrast−Enhanced CT and MR Studies[1]

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Rationale and Objectives. The purpose of this study was to evaluate the impact of written informed consent on the number of intravenous contrast−enhanced CT and MR imaging studies.

Materials and Methods. On December 2002, the Conference of Physicians and Medical Directors in our institution decided that all referring physicians must obtain written informed consent in each case before intravenous injection of contrast material for CT and MR imaging studies. The numbers and proportions of contrast-enhanced CT and MR imaging studies before introduction of the written informed consent requirement (January 2002−December 2002) were compared with those after (January 2003−December 2003).

Results. The number of contrast-enhanced CT studies decreased from 5930 (50.6% of all CT studies) to 5539 (49.0% of all CT studies) (odds ratio [OR]: 0.94, 95% confidence interval [CI]: 0.89−0.99). The number of contrast-enhanced MR studies also decreased from 1895 (46.5% of all MR studies) to 1712 (43.4% of all MR studies) (OR: 0.88, 95% CI: 0.81−0.96).

Conclusion. Findings suggest that the written informed consent requirement reduces the number of intravenous contrast−enhanced CT and MR imaging studies.

Key Words. Informed consent; ethic of care; health care economics; social problems; patients rights.

Informed consent is considered a prerequisite for any medical intervention. Its purpose is to give patients the opportunity to determine what they want to be done and what will be done and to make sure they understand the reasons, possible outcomes, and potential side effects of the health care interventions they have agreed to undergo (1,2). Informed patients are more likely to actively participate in their care, make wiser decisions, come to a common understanding with their physicians, and adhere more fully to treatment (3). Informed consent is increasingly being used before administration of intravenous contrast material for most radiological procedures in Japan. A major concern is that it is becoming almost impossible for a physician to obtain informed consent for every contrast material injection, given the increasing number of computed tomography (CT) and magnetic resonance (MR) imaging examinations being performed (4,5). So, what will happen when all physicians are obliged to obtain written informed consent in each case before intravenous injection of contrast material for CT and MR imaging? To our knowledge, no study has ever measured the influence of the requirement for written informed consent

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on the number of intravenous contrast−enhanced CT and MR imaging studies. Here, we conducted a retrospective cohort study to examine the impact of written informed consent on the number of intravenous contrast−enhanced CT and MR imaging studies. Our hypothesis was that the necessity to obtain written informed consent would reduce the number of intravenous contrast−enhanced CT and MR imaging studies.

MATERIALS AND METHODS

Our hospital is a large provincial university hospital with a hospital information system (HIS) and a picture archiving and communication system (PACS). All radiological examinations, including CT and MR imaging, are ordered through the computerized ordering system, which is available 24 hours a day. Referring physicians can order radiological examinations by the online reservation system if it is available. There is no restriction on the number of CT or MR imaging studies in an emergency. Referring physicians can specify whether a contrast agent should be injected or not.

On December 2002, the Conference of Physicians and Medical Directors decided that all referring physicians must obtain written informed consent in each case before intravenous injection of contrast material for CT and MR imaging studies. Under the direction of the conference, the Department of Radiology made a uniform consent devised for each referring physician to use. All referring physicians must explain the necessity of intravenous administration of contrast material, the possibility of potentially fatal complications (e.g., anaphylaxis) and the indemnity payments. This regulation became effective on January 1, 2003. The numbers and proportions of contrast-enhanced CT and MR studies during the 12 months (January 1, 2002−December 31, 2002) before the start of this regulation were compared with those during the 12 months (January 1, 2003−December 31, 2003) after the start. The CT and MR imaging studies were divided into four categories: (a) head and neck, (b) chest, (c) abdomen, and (d) musculoskeleton. We also compared the numbers and proportions of CT and MR studies in each category between the two groups.

During the study periods, there was no significant change in the number of health care professionals, areas of specialization, severe adverse events, three CT scanners (TCT 900S, Toshiba, Tokyo, Japan; Aquillion 4, Toshiba, Tokyo, Japan; and Somatom plus, Siemens, Erlangen Germany), or two 1.5-T MR scanners (Magnetom Vision, Siemens, Erlanger, Germany; and Signa, GE Medical Systems, Milwaukee, WI). The mean numbers of outpatient visits were almost the same: 1410/day in 2002 versus 1422/day in 2003. The mean numbers of inpatients were also comparable: 564/day in 2002 versus 580/day in 2003.

Statistical Analysis

We evaluated the association between the written informed consent and the numbers of contrast-enhanced CT and MR imaging studies. The odds ratio (OR) was used as an estimate of relative risk and, for ease of presentation, the results are described in terms of relative risk. We calculated ORs and 95% confidence intervals (CIs) using logistic regression. ORs were calculated directly, without any adjustment, because no obvious potential confounding variables were apparent. If the 95% CI does not include 1, we judged the difference to be statistically significant.

RESULTS

The total number of contrast-enhanced CT studies was 5930 (50.6% of all CT studies) prior to the introduction of the written informed consent requirement. The total number of contrast-enhanced CT studies significantly decreased after the introduction of the written informed consent requirement to 5539 (49.0% of all CT studies) (OR: 0.94, 95% CI: 0.89−0.99) (Table 1). However, the numbers of contrast-enhanced CT studies in each category were not significantly different.

The total number of contrast-enhanced MR studies was 1895 (46.5% of all MR studies) prior to the introduction of the written informed consent requirement. The total number of contrast-enhanced MR studies significantly decreased to 1712 (43.4% of all MR studies) (OR: 0.88, 95% CI: 0.81−0.96) after the introduction of the written informed consent requirement (Table 2). The numbers of contrast-enhanced MR studies of the chest and the musculoskeleton also significantly decreased after introduction of the written informed consent requirement (OR: 0.65, 95% CI: 0.44−0.98; OR: 0.67, 95% CI: 0.48−0.94, respectively).

DISCUSSION

The use of informed consent before intravenous administration of contrast material has been and remains a