Informed Consent in Contrast-Enhanced CT: Understanding of Risks and Identification of Possible Prognostic Factors

Patientenaufklärung bei kontrastmittelgestützter CT: Risikoverständnis und Identifikation möglicher Prognosefaktoren

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Abstract

Purpose: Aim of our study was to assess understanding of risks associated with intravascular application of contrast media in patients undergoing CT examination. We wanted to evaluate epidemiologic and socio-economic prognostic factors for a higher understanding of risks. Additionally, we evaluated a possible correlation between an extensive, outcome-oriented oral informed consent and better understanding of risks.

Materials and Methods: 120 patients distributed in 2 study arms participated in this prospective study. In study arm I, the treating physician was not informed that his patients participated in a study whereas the physician in study arm II knew about the survey. After the informed consent we performed a standardized, semi-structured interview to enquire the 3 most frequent risks of intravascular application of contrast agents (anaphylactoid reactions, nephropathy and thyrotoxic crisis) and epidemiologic data. The understanding of the risks was evaluated using a 6 point scale.

Results: Patients scored 3.73 points in study arm I and 4.93 points in arm II on average. The statistical difference between both study arms was highly significant ($p < 0.001$). In a combined logistic regression analysis, only "higher education" ($p = 0.001$) and participation in study arm II ($p = 0.001$) showed a significant connection to a better understanding of risks.

Conclusion: Patients profit from an outcome-oriented and individualized informed consent. Due to the significant correlation between educational level and understanding of risks, informed consent should be adjusted to the educational status of the individual patient, e. g. by using didactic aids or individualized information sheets.

Key points:
- The understanding of risk factors is better in patients with a higher educational level.
- Repetitive examinations do not lead to a better understanding of risks.
- A result-oriented pre-examination discussion leads to a better understanding of risk factors.

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Zusammenfassung

Ziel: Ziel der Arbeit war es, das Risikoverständnis von Patienten bezüglich i. v. Kontrastmittelapplikation bei CT-Untersuchungen zu untersuchen. Mögliche epidemiologische oder sozioökonomische Prognosefaktoren bezüglich eines erhöhten Risikoverständnisses sollten identifiziert werden. Zusätzlich wurde ein möglicher Zusammenhang zwischen einem erhöhten Risikoverständnis und einer ausführlicheren, ergebnisorientierten Aufklärung evaluiert.

Material und Methoden: In der prospektiven Studie nahmen 120 Patienten, verteilt auf zwei Studienarme, teil. In Arm I war der aufklärende Arzt nicht von der Studienteilnahme des Patienten informiert, in Arm II wusste der aufklärende Arzt von der anschließenden Befragung. Diese erfolgte mittels standardisierten, halbstrukturierten Interviews. Neben epidemiologischen Daten wurden auch die 3 häufigsten unerwünschten Arzneimittelwirkungen (UAW) einer i. v. Kontrastmittelgabe (allergoide Reaktion, Nierenschädigung, Hyperthyreose) abgefragt. Das Verständnis wurde mittels eines Punktesystems (0 – 6) bewertet.

Ergebnisse: Im Durchschnitt erreichten die Probanden 3,73 Punkte in Arm I und 4,93 Punkte in Arm II. Der Unterschied zwischen beiden Studienarmen war statistisch hochsignifikant (p < 0,001). Der Anteil der Probanden, die alle drei Risiken aktiv und ohne Hilfe nennen konnten, betrug in Studienarm I 17 % und in Studienarm II 42 %. In einer kombinierten logistischen Regressionsanalyse zeigten von den untersuchten Prognosefaktoren nur die „höhere Schulbildung“ (p = 0,001) und die Zuordnung zu Studienarm II (p = 0,001) einen signifikanten Einfluss auf ein hohes Risikoverständnis.

Schlussfolgerung: Die Studie zeigte, dass Patienten von einem ergebnisorientierten und individualisierten Aufklärungsgespräch profitieren. Da sich ebenfalls ein signifikanter Zusammenhang bezüglich des Bildungsstatus und dem Risikoverständnis zeigte, sollte die Patientenaufklärung auch an das Bildungsniveau des Patienten angepasst werden. Wünschenswert wäre daher künftig der Einsatz von didaktischen Hilfsmitteln sowie an den Bildungsstand angepasste Aufklärungsbogen.

Introduction

As the average patient changes, physicians must also adjust the way they interact with patients. During the more paternalistic era, which lasted into the middle of the 20th century, it was accepted practice to withhold from the patient important details about his or her disease, diagnosis and therapy ("white lies") [1, 2]. Over the last few decades, the physician-patient gap has significantly narrowed. In use since 1957, the term “informed consent” supposedly grants the patient independent decision-making power over his or her health and treatment options and thus implies an enlightened, responsible patient. However, achieving an equal and partnership-like physician-patient relationship continues to be challenge in routine medicine and demands sufficient transfer of information during patient briefing. Optimal patient briefing should not just address and build on the patient's existing knowledge, but should also detect and correct possible misconceptions. The new German Patient's Bill of Rights (German Civil Code (BGB) § 630a – § 630 h), which went into effect on 26 February 2013, emphasizes the importance of patient briefing.

Countless examinations legally requiring a declaration of informed consent from the examined patient are performed every day in radiology departments, institutes and private practice offices. Prior to any computed tomography examination, the patient must be briefed on the radiation exposure and the possible risks of any required intravenous application of contrast media. Factors frequently occurring in routine clinical settings, such as time constraints, emergencies, interruptions, and spatial considerations often complicate conducting a calm and focused pre-examination briefing. The briefing physician is often confronted with the question of whether a sufficient information transfer occurred at all. While knowledge about radiation exposure and the associated risks is increasingly the focus of radiological studies [3, 4], very little research has been conducted thus far on the understanding of potential adverse drug effects of intravenous application of contrast medium prior to computed tomography (CT). Studies evaluating the transfer of knowledge in patient briefings have originated primarily from the fields of anesthesiology and surgery.

The aim of this study was to examine to what degree patients actually understood the issues relevant to them concerning complications after being briefed by a physician about a contrast-enhanced CT. The study also sought to identify possible prognostic factors of increased understanding of risk and evaluate to what extent patients benefit from a comprehensive, results-oriented briefing.

Material and methods:

Participating in this two-armed, prospective study conducted over a period of 3 months were 120 patients receiving contrast-enhanced CT examination during an inpatient stay at or an outpatient visit to a university radiology department of a maximum care hospital. During routine operation, patient intake personnel randomly selected 3 patients each day and included them in the study. All patients included in the study were adults, who were capable of being briefed, were scheduled for contrast-enhanced CT and were proficient in German. The first 60 patients were assigned to study arm I, with the next 60 patients being assigned to study arm II. In the first study arm, the treating physician was not informed of his or her patients' participation in the study. It can thus be assumed that these physicians were providing regular routine briefing. In the second study arm, the treating physician was aware that his or her patients would subsequently take a survey.

The pre-examination briefing was conducted by different residents from the radiology department, each of whom had at least 12 months' experience in CT. In addition to covering radiation exposure, the pre-examination briefing addressed the three typical side effects of contrast agents containing iodine: anaphylactoid reaction, thyrotoxic crisis and contrast agent-induced nephropathy. The briefing was semi-structured and based on a commercially available, preprinted briefing sheet for contrast-enhanced CT (Dokumentierte Patientenaufklärung [Documented Patient Briefing], published by: proCompliance at Thieme Compliance GmbH, technical editor.: Prof. Dr.med V.Barth, Author Prof. Dr.med. V.Barth, legal consultants: RA Dr.jur. A.Schwerdtfeger, Scientific illustration: All rights reserved by Thieme Compliance GmbH, Copyright: 2010)

Following the pre-examination briefing and immediately before the CT examination was performed, patients underwent a survey conducted by a research associate in the form of a semi-structured interview using a standardized questionnaire (**Fig. 1**). The presence of dementia was ruled out using a modified Mini Mental State Test [5]. In addition to being evaluated on their temporal, spatial and situational orientation (1 point each), the patients were tested on their logical cognitive ability (maximum 3 points) and short-term memory (maximum 3 points). For the short-term memory test, the patients were given three words to remember, which they would be asked to recite at the end of the interview. The patients were also asked to perform a "math assignment" which involved subtracting 3 from 100a total of 3 times. The results were represented objectively through the total number of points achieved, a total of 9 points being the maximum score achievable. Sufficient capacity for comprehending the pre-examination briefing was assumed at a score of 6 or higher.

Part 1: Inform consent

1. Are you satisfied with the informed consent?
   - ☐ Best briefing during this hospitalisation
   - ☐ Very good ☐ Good ☐ Satisfactory ☐ Unsatisfactory
2. Did you have the opportunity to ask questions?
   - ☐ Yes ☐ No
3. What is your condition? .....
4. Which part of the body is going to be examined?

   .....
5. Is this
   - ☐ Your first CT scan ☐ A re-scan
6. Is this your first CT scan in this hospital?
   - ☐ Yes ☐ No
7. What are the adverse side effects of contrast agents containing iodine?

   .....

   .....

   .....
8. Why are you going to be examined?
   - ☐ Aftercare
   - ☐ Inflammation
   - ☐ Search for tumor or metastasis
   - ☐ Don´t know
   - ☐ .....
9. Do you know that you can refuse the CT-scan?
   - ☐ Yes ☐ No

Fig. 1a Patient questionnaire, part 1: Questions concerning patient education.

In addition, the patient's socio-economic data, such as age, sex, level of education was gathered, and the patient was asked whether he or she had an underlying malignant disease (**Fig. 1**). The sex of the briefing physician was also documented. Furthermore, it was ascertained whether the patient was undergoing a first-time or repeat examination. Level of education was categorized into the four groups: "completed lower secondary school", "completed intermediate secondary school","completed higher secondary school" and "completed college". These categories were then clustered into the two groups "lower educational status" and "higher educational status", with graduates of lower and intermediate secondary schools being grouped together. Patients were also surveyed concerning their satisfaction with the pre-examination briefing. Patients could indicate whether it was the "best briefing during the hospital stay" and additionally classify it as "very good", "good", "satisfactory" and "unsatisfactory". The patients' knowledge of their right to refuse was also ascertained.

The patients were then surveyed regarding the side effects of contrast agent specified in the pre-examination briefing, receiving 2 points for each risk they were able to state on their own, 1 point for risks they were able to recall only with assistance (**Fig. 1**) and 0 points for risks they were unable to name even with prompting. For objectively identifying the patients who were optimally informed regarding their understanding of risks, a so-called "high performer" group was defined. Included in this group were patients who were actively able to recall all 3 possible risks of i. v. administration of contrast agent without any assistance. High-risk patients were study participants who had a history of documented anaphylactoid reaction to contrast agents containing iodine, impaired kidney function (serum creatinine > 1.4 mg/dl or patients on dialysis with intact residual excretion) or laboratory results showing latent hyperthyroidism. To evaluate the patients' understanding of their disease and the planned radiological examination, they were then

Part 2: Personal questions

1. Age ..... years
2. Sex
   ☐ Female ☐ Male
3. Do you have a malignant disease?
   ☐ Yes ☐ No
4. Marital status:
   ☐ Married ☐ Single ☐ Divorced ☐ Widowed
5. Children :
   ☐ None ☐ 1 - 2 ☐ ≥ 3
6. Level of Education:
   ☐ Completed lower secondary school
   ☐ Completed intermediate secondary school
   ☐ Completed higher secondary school
   ☐ Completed college
7. What day is it?
   ☐ Monday ☐ Tuesday ☐ Wednesday ☐ Thursday ☐ Friday
8. What year is it? .....
9. In which city are you now? .....
10. Where exactly are you right now? .....

Part 3: External assessment

Short-term memory:

☐ 1 ☐ 2 ☐ 3

Logical cognitive ability:

☐ 1 ☐ 2 ☐ 3

Assessment:

☐ Oriented ☐ Disoriented

Fig. 1b Patient questionnaire, part 2 and 3: Questions concerning patient education.

asked about the body parts being examined and the reason for the examination.

Because the study was conducted with both the patients and the respective briefing physicians being anonymized, the responsible local ethics committee did not see the necessity of requiring an ethics application.

The point totals in each of the study arms were examined for differences using the Mann-Whitney U test. The number of "high performers" in both groups was tested for significant differences using a chi-square-test. To identify additional influencing factors on the dependent variable "high performer", the variables of malignant underlying disease, educational level, subjective patient satisfaction, risk patient, physician of the same or different sex and follow-up examination were examined in addition to group in bivariate logistic regression models. All significant influencing factors were subsequently analyzed in a multi-variable logistic regression analysis. The difference was considered to be statistically significant if p-value was below 0.05. Evaluation was performed using the statistical program IBM SPSS Statistics Version 22.

Results

The entire patient cohort of 120 test subjects was included in the study. None of the participating patients quit the survey. The median age of study participants was 61.6 years with a standard deviation of 12.6 years and a spread of 26 to 85 years. The median was 61.3 years (SD 12.35) for arm I and 61.9 years (SD 12.95) for arm II. With the study including a total of 42 female and 78 male test subjects, patient

Memory / Intelligence / Orientation

Before the interview:

Patients are given 3 words to remember:

- Tree
- Car
- House

Point out to the patients that they are asked to recite these words at the end of the interview.

During the interview:

Assistance in recalling risks of the contrast agent:

- Is there an effect on the function of an organ? If so, which one?
- May the contrast agent cause harm to an organ? If so, which one?
- What can happen when the contrast agent is applied?

After the interview:

- Short-term memory test

Reciting Words (tree, car, house) – 1 point each → 0, 1, 2, 3 points

- Logical cognitive ability

Subtracting 3 from 100 a total of 3 times

97 → 1 point
94 → 1 point
91 → 1 point → 0, 1, 2, 3 points

- Temporal orientation:	Date	1 point	
- Spatial orientation:	City	1 point	
- Situational orientation:	Hospital	1 point	→ 0, 1, 2, 3 points

Fig. 1c Patient questionnaire: Questions concerning patient education.

	all (n = 120)	study arm I (n = 60)	study arm II (n = 60)	p-value
age, median (SD)	61.6 (12.60)	61.3 (12.45)	61.9 (12.95)	0.801
sex, n (%)				0.702
– female	42 (35.0)	22 (36.7)	20 (33.3)	
– male	78 (65.0)	38 (63.3)	40 (66.7)	
education, n (%)				0.345
– lower/intermediate secondary school	98 (81.7)	47 (78.3)	51 (85.0)	
– higher intermediate school and college	22 (18.3)	13 (21.7)	9 (15.0)	
first CT exam, n (%)	20 (16.7)	9 (15.0)	11 (18.3)	0.624
at-risk patient, n (%)	19 (15.8)	12 (20.0)	7 (11.7)	0.211
malignant disease, n (%)	79 (65.8)	40 (66.7)	39 (65.0)	0.847

Table 1 Patient characteristics over n = 120, study arm I (n = 60) and II (n = 60). In terms of "patient age", "sex distribution" and "educational level", an even distribution between the two study arms can be assumed. The groups are also homogenous in terms of the factors "first CT exam", "at-risk patient" and "malignant underlying disease".

arm I had 22 women and 38 men, while patient arm II had 20 women and 40 men. In total, 22 (18.3 %) of patients completed higher education (college graduation/completion), 13 of these test subjects being in arm I and 9 in arm II. The remaining 98 (81.7 %) participants completed lower or intermediate secondary school, with 47 of these patients being in study arm I and 51 in study arm II (**Table 1**). In terms of sex distribution, patient age and educational level an even distribution can be assumed.

Of the examinations, 20 (16.7 %) were first time CT examination, 9 (15 %) of which were in arm I and 11 (18.3 %) in arm II. A total of 23 patients rated the pre-examination briefing as the "best briefing during the hospital stay", 11 of these patients being in study arm I and 12 in study arm II. The grades (1 – 4), which are analogous to the grading scale used in the German educational system, for subjective satisfaction with clarification of risks showed no statistically significant difference between the two groups (p = 0.482). Of the 120 patient briefing, 44 (36.7 %) were conducted by female doctors, while the remaining 76 (63.3 %) were conducted by male doctors. The number of high-risk patients was 12 (20 %) in study arm I and 7 (11.7 %) in study arm II. Of the 120 total patients, 79 (65.8 %) reported suffering from an underlying malignant disease, with 40 (66.7 %)

being in study arm I and 39 (65 %) being in study arm II (Table 1). Furthermore, 15 % of the test subjects indicated that they were not aware of their right to refuse, 13 of these subjects being in group I and 15 in group II. While 5 patients from group I reported that there had not been time for questions, all patients from group II stated that there was time for questions.

With a maximum score of 6 points being awarded for naming the risks of receiving contrast medium, the study participants achieved a median score of 4 points (IQR 2 – 5) in arm I and 5 points (IQR 4 – 6) in arm II. The median of the pair differences according to the Hodges-Lehmann estimator is 1 (95 % confidence interval: 1 – 2). Here we showed a significant relationship ($p < 0.001$) between participation in study arm II ("more in-depth, results-oriented briefing") and a better understanding of risk (Fig. 2).

There was a more significant relationship between study group and optimal briefing of risk. The chi-square test showed that participants in arm II actively named all risks of contrast-enhanced CT ("high-performer") significantly more frequently ($p = 0.003$) than those in study arm I, with 25 test subjects (41.7 %) versus 10 subjects (16.7 %) demonstrating this ability.

The bivariate logistic regression models showed that in addition to the study arm, higher level of education (OR = 5.73; $p = 0.002$) and a subjectively high satisfaction with the briefing (OR = 2.97; $p = 0.032$) are significant predictors for better understanding of risk. The variables "high-risk patient", "repeat examination", "underlying malignant disease", "patient's sex" and "sex of the briefing physician" examined in further detail showed no statistically significant relationship with an increased or decreased understanding of risk (Table 2). The subsequently performed multivariate logistic regression analysis showed higher level of education (OR = 6.26; $p = 0.001$) and assignment to study arm II (OR = 5.16; $p = 0.001$) to have, as independent variables, a significant influence on a high understanding of risk. In the combined analysis, the relationship between subjective satisfaction with the pre-examination briefing and a high understanding of risk was no longer significant (OR = 2.29; $p = 0.129$). With an odds-ratio of 2.29, there was, however, a trend of better understanding the subject matter of the pre-examination briefing (Table 2).

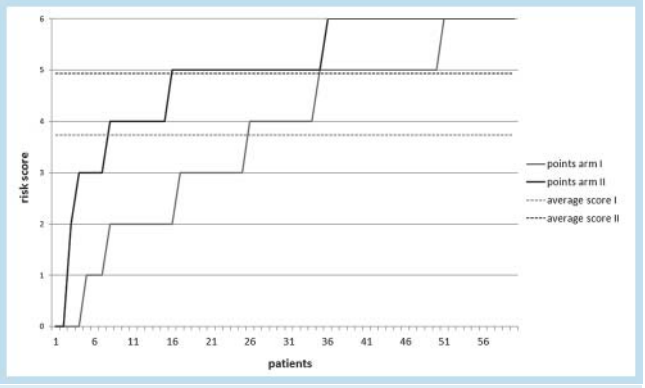

Fig. 2 Recitation of risks/adverse effects of i. v. administration of contrast agents containing iodine for CT examination; absolute number points achieved in both groups (n = 60) in comparison; at 4.93 points, subjects in study arm II achieved a higher average score than their counterparts in study arm I ($p < 0.000$).

Discussion

In contrast to radiation exposure, which has become a subject of increased focus among the general public, the possible adverse side effects of i. v. administration of contrast medium cannot be viewed as common knowledge, as the study conducted by Neptune et al. has demonstrated. The basic idea for evaluating understanding of the risk involved with contrast-enhanced CT arose from routine practice at a maximum care hospital, which can involve interruptions in the pre-examination briefing for a variety of reasons. The briefing doctor is thus frequently confronted with the question of whether the patient has grasped the subject matter presented to him or her consistent with the concept of "informed consent". However, it is difficult for the doctor to gauge the degree of patient understanding, given that the patient's ability to articulate what information he or she needs can be complicated by socioeconomic (e. g. expertise, language ability), psychological (e. g. inhibitions) and finally also practical factors (e. g. the physician being under time constraints).

Study arm I can be assumed to involve routine briefing, since neither the participating patient nor the briefing physician was aware of the study. We were able to demonstrate that the patient obtained a certain understanding of risk following "informed consent". Overall, an average point score of 3.73 (out of a maximum of 6 possible points) was

Table 2 Analysis of predictors for a better understanding of risk ("high performer").

	bivariate logistic regressions[1]		multivariate logistic regression	
	odds ratio (95 % CI)	p-value	odds ratio (95 % CI)	p-value
study arm ii	3.57 (1.52; 8.37)	0.003	4.79 (1.83; 12.48)	0.001
malignant tumor	0.69 (0.30; 1.63)	0.400	–	–
repeat examination	1.03 (0.35; 3.06)	0.963	–	–
high-risk patient	1.03 (0.32; 3.28)	0.961	–	–
briefed by person of the opposite sex	0.66 (0.29; 1.51)	0.324	–	–
higher education	5.73 (1.93; 17.00)	0.002	5.00 (1.63; 15.33)	0.005
satisfaction with person providing briefing	2.97 (1.10; 8.00)	0.032	2.29 (0.79; 6.68)	0.129

[1] All models contained group assignment as additional independent variable; in the bivariate logistic regressions, "Study arm II" (p 0.003), "higher education" (p 0.002) and subjective "satisfaction with person providing briefing" (0.032) were significant; in the multivariate logistic regressions, only "study arm II" (0.001) and "higher education" (0.005) were significant.

achieved. Of the 60 patients surveyed, only 4 were unable to name any of the potential risks. This additionally reflects that conveying the possible risks of receiving contrast medium is taken very seriously by the briefing radiologist. In study group I, 10 of 60 patients were able to actively name all risks ("high performer"). The significantly greater number of "high performers" in study arm II (n = 25) additionally demonstrates that the test subjects once again clearly benefit from a results-oriented and individualized pre-examination briefing.

Because the combined logistic regression identified only educational level as being a more significant prognostic factor for improved understanding of risks, the briefing should be adapted to the patient's educational level. However, there are conflicting study results concerning this finding. Mexas et al. recently examined the understanding of patient briefing as part of a clinical study, but did not identify education as a significant influencing factor [7]. However, this particular study involved a small cohort of 61 tuberculosis patients with the bias that a majority of the test subjects (67 %) lived in the slums around Rio de Janeiro and had only limited access to education. In contrast to our study, understanding was tested using 8 to 10 dichotomous questions, thereby allowing test subjects to possibly answer correctly even if they did not know the answer. In a systematic review, Flory et al. analyzed how understanding during the pre-examination briefing can be increased in the context of clinical studies [8]. Similar to our results, this review revealed a significant relationship between educational level and understanding in 12 independent studies. Factoring in the influence of educational level, the use of didactic aids and informational brochures that are adapted to educational level and thus individualized is an option for increasing the understanding of risk. This idea is reinforced by the "IOM Report" on the topic "Health Literacy", which confirms that over 90 million Americans have difficulty grasping the explained risks or even medical information in general. According to the IOM Report "Health Literacy: A Prescription to End Confusion" [9], over 300 studies demonstrate that brochures and medical information sheets greatly exceed average reading ability.

It should be mentioned that a repeated briefing ("repeat examination") in particular has no significant impact on the understanding of risk. Nevertheless extensive briefing is indispensable even following prior CT examinations. This statement should be qualified, however, by pointing out that the questionnaire used in the current study did not ascertain how much time had elapsed since the previous study.

Also interesting is the fact that 8 of the 12 high-risk patients (66.7 %) were able to actively name their respective risks after receiving routine briefing (study group I). This is especially desirable, since by actively naming their risk factors, patients can positively influence a risk situation. The group of high-risk patients additionally benefits from an even more extensive, results-oriented briefing. Thus as a result, all high-risk patients in study arm II were able to actively name their respective risks.

In addition, we showed a correlation between subjective patient satisfaction and the understanding of the subject matter presented in the pre-examination briefing. A positive atmosphere during the physician-patient briefing must accordingly be given high priority. However, in a routine hospital setting, a partner-like physician-patient interaction is frequently compromised by time constraints and interruptions. In conclusion, it is also worth mentioning that 15 % of the patients reported not being aware of their right to refuse. In view of the defined goal of "informed consent", this number is much too high. After receiving extensive information and being presented with treatment alternatives, the patient should be able to independently decide on his or her treatment options. This absolutely requires being aware of one's right to refuse.

The main limitation of this study would be the relatively small patient cohort. To avoid creating too many subgroups of excessively small size, educational level was clustered. Because, however, the influence of educational level was demonstrated, finer differentiation here would be desirable. Furthermore, it must be taken to account that the knowledge of participating in a study alone can influence the behavior of the briefing physicians and thus the results of the study (Hawthorne effect). To bypass this effect, the briefing physicians in study arm I were not informed of their participation in the study to ensure a realistic "routine briefing". It must also be kept in mind that the rise in the number of risks named in the survey can possibly be attributed to a memory effect and is thus possibly misinterpreted as increased understanding. These points could be the subject of more in-depth evaluations.

In the present study on the evaluation of the understanding of risks associated with contrast-enhanced CT we were able to show that both an intensive, results-oriented pre-examination briefing and a higher level of education go hand-in-hand with improved understanding of risk. For the medical practice, this means that the content of patient briefing should be individually tailored to the patient and a positive discussion atmosphere should ideally be present. When it comes to understanding risk, patients additionally benefit from a results-oriented, extensive briefing.

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