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Informed Consent for Radiation in Interventional Radiology Procedures

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Abstract

Purpose: To explore the patient perception on radiation-related cancer risk from interventional radiology (IR) procedures and whether informed radiation consent is warranted.
Methods: A multiple-choice survey was prospectively administered to 68 adults undergoing a body or neuro-IR procedure with ionizing radiation exposure. Subgroup analysis with chi-square or Fisher exact test was performed based on patient past IR history ($P < .05$).
Results: A total of 81% of patients wanted to be informed if there was a radiation-related 3% increased cancer risk over 5 years. Although 55% considered 3% a small risk, 28% wanted to further discuss the risks and alternate options, and 15% would have only proceeded if it were a life-saving procedure: 89%, 80%, and 67% of patients wanted to be informed with exposure risks of 1 in 100, 1 in 1000, and 1 in 10,000, respectively. Only 53% were aware they were going to be exposed to radiation, irrespective of past IR history ($P = .15$). Most patients believed radiation consent should include radiation-related cancer risks (85%). No past IR history was significantly associated with wanting consent to include cancer-related risk (100% vs 76%; $P = .01$) and deterministic risks (70% vs 41%; $P = .04$). A majority (69%) believed both the referring physician and the interventional radiologist were responsible for obtaining radiation consent, and 65% of patients wanted verbal consent followed by signed written consent, regardless of past IR history.
Conclusions: Many patients want to discuss cancer-related radiation risks with both radiologists and physicians. Informed radiation consent should be considered for procedures with high anticipated radiation doses.

Résumé

Objet : Analyser la façon dont les patients perçoivent le risque de cancer associé à la radioexposition en radiologie d'intervention (RI) et évaluer la pertinence d'un consentement éclairé à cet égard.
Méthodes : Un sondage à choix multiples a été réalisé de façon prospective auprès de 68 adultes devant subir une intervention neurologique ou au tronc avec exposition à un rayonnement ionisant, dans un contexte de radiologie d'intervention. Une analyse des sous-groupes a été réalisée au moyen du khi carré ou de la méthode exacte de Fisher en fonction des antécédents des patients en matière de radiologie d'intervention ($P < 0{,}05$).
Résultats : Au total, 81 % des patients souhaitent qu'on les informe d'un risque accru de cancer de l'ordre de 3 % sur 5 ans attribuable au rayonnement. Bien que 55 % des patients considèrent qu'il s'agit d'un faible risque, 28 % disent vouloir discuter davantage des risques et des options de rechange et 15 % indiquent qu'ils n'iraient de l'avant que si l'intervention visait à leur sauver la vie. Ainsi, 89 % des patients veulent être informés des risques relatifs à l'exposition de l'ordre de 1 sur 100, 80 % des risques de l'ordre de 1 sur 1 000 et 67 % des risques de l'ordre de 1 sur 10 000. Quels que soient leurs antécédents en matière de radiologie d'intervention, seuls 53 % des patients savaient que leur intervention supposait une exposition à un rayonnement ($P = 0{,}15$). Par ailleurs, la majorité des patients (85 %) estiment que le consentement relatif à la radioexposition devrait inclure les risques de cancer liés au rayonnement. Aucune corrélation significative n'a toutefois pu être établie entre des antécédents en matière de radiologie d'intervention et le désir d'intégrer le risque de cancer (100 % contre 76 %, $P = 0{,}01$) et les risques d'effets déterministes (70 % contre 41 %; $P = 0{,}04$) au consentement. La majorité des patients (69 %) croient que le médecin traitant et le radiologiste d'intervention ont tous deux la responsabilité d'obtenir un consentement à la radioexposition. Enfin, quels que soient leurs antécédents en matière de radiologie d'intervention, 65 % des patients souhaitent un premier consentement verbal, suivi d'un consentement par écrit.

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Conclusions : Bon nombre des patients souhaitent discuter des risques de cancer liés au rayonnement avec le radiologiste et le médecin. La mise en place d'un formulaire de consentement éclairé à l'égard de la radioexposition devrait être envisagée pour les interventions habituellement associées à des doses élevées de rayonnement.

Key Words: Informed consent; Interventional radiology; Patient-centred care; Radiation

In the last decade, there has been increased discussion regarding the stochastic risks associated with radiation exposure in medical imaging [1–7]. This has largely occurred in the wake of rapidly increasing computed tomography (CT) utilisation [8]. It has been estimated medical imaging accounts for nearly half of an individual's yearly cumulative ionizing radiation dose, and that 1.5%-2% of future cancers may relate to radiation exposure from CT [1].

Prior studies have uncovered that both physicians and patients have a profound lack of awareness regarding CT radiation dose, whereby up to 95% of patients were not aware of the associated risks and benefits [2]. A prior study examining a heterogeneous radiology patient cohort found that up to 82% of interventional radiology (IR) patients were unaware of radiation exposure in diagnostic examinations [3]. To date, research has concentrated on diagnostic radiology (DR) patients and referring physician knowledge of radiation-related risks specifically relating to radiography and CT despite the fact that radiation exposure is inherent in IR, and many diagnostic and therapeutic IR procedures may pose a greater threat to an individual's cumulative dose exposure, as compared with a single CT examination [3,9,10].

The impact of radiation exposure in medical imaging and the notion of radiation consent are currently important and controversial topics of debate [4,5]. Informed consent requires the disclosure of rare yet potentially significant risks. Although a potential exposure of 1 mSv has been suggested as a cutoff for provision of risk information in DR, as it corresponds to a 1 in 10,000 cancer risk [5–7], a formal disclosure threshold relating to dose has not been established.

Given that patient-centred decision making increasingly has been viewed as an eminent quality of care indicator [11], assessment of patients' desire for information about radiation exposure is imperative. The purpose of this study was to investigate IR patient: 1) awareness of radiation exposure; 2) perception of radiation-related cancer risk and its influence on treatment decision making; and 3) perspective on informed radiation consent for IR procedures. In addition, the purpose was to assess if there was any difference between the perception of patients with versus without past IR history, and those undergoing body versus neuro-IR procedures.

Materials and Methods

Study Design

This prospective survey questionnaire-based study was approved by the institutional research ethics board. Completing the survey questionnaire implied consent, and signed written consent was waived by the board. Signed written consent was obtained separately for each patient's IR procedure by a member of his or her clinical team.

Survey Questionnaire

A multiple-choice survey was designed to investigate the following questions:

1. Are patients aware about radiation exposure in IR procedures?
2. Do patients want to be informed about IR procedure related radiation exposure and risk?
3. Would knowledge about radiation-related cancer risk influence patients' treatment decisions?
4. How, and under what circumstances, do patients want to be informed about radiation exposure related to IR procedures?
5. Does a patient's past IR-related medical history influence his or her perspective?

The survey was developed using radiation risk levels and scenarios based on the published literature [5–7,12], as well as discussion among study team members and with 2 nonphysician patients who had previously undergone IR procedures. The survey was written by 2 interventional radiologists and 1 radiology resident, and it was peer reviewed by 3 other interventional radiologists, a diagnostic radiologist, and a neuro-IR fellow for content validity (Appendix 1). The survey was pilot tested with 3 current IR patients, and was revised further for clarity and ease of use, to minimize potential ambiguity in the survey questions.

Previous prospective questionnaire studies investigating the patient perspective on risk disclosure and informed consent for otolaryngology [13], radiation therapy [14], and hernia repair [15] had sample sizes of 50, 82, and 98 subjects, respectively. As such, it was determined that a minimum sample size of 50 patients was required for this survey.

Study Population and Subject Selection

The study population consisted of hemodynamically stable adult patients scheduled to undergo a nonemergent body or neuro-IR procedure involving radiation exposure at our tertiary care hospital. Non-English speakers, cognitively impaired individuals, hemodynamically unstable patients (ie, trauma patients, acute septic patients), obstetrical patients,