SCIENZE MEDICO-LEGALI, SOCIALI E FORENSI

► Sub-optimal awareness of radiological dose Among patients undergoing common cardiac stress imaging examinations

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Abstract

Background: A too detailed information on radiological dose and risk may result in undue anxiety. An information economical with the truth may violate basic patients' rights well embedded in ethics (Oviedo convention 1997) and law (97/43 Euratom Directive 1997).

Aim: To assess the information perceived by patients on radiological dose of exams they perform

Methods: Multiple choice survey of patients undergoing a cardiac rest-stress Technetium-99m sestamibi scan, which gives an effective dose of 10 milliSievert (mSv), corresponding to a dose equivalent of 500 chest x-rays (European Commission Medical Imaging Guidelines 2001) and an estimated extra lifetime attributable risk of 1 cancer in 1,000 exposed subjects (Biological Effects of Ionizing Radiation VII Committee 2005).

Results: One hundred and nine patients (66 men, age 66±10 years) were included. One out of 5 patients, with the remaining underestimating of at least 300 times their own exposure, correctly estimated dose exposure. One out of 4 patients, with 1 out of 3 substantially underestimating their own risk, correctly described estimated risk.

Conclusion: Patients undergoing common cardiac imaging examinations involving significant exposure have little or no awareness about radiological dose exposure (and

corresponding risk). This ineffective communication poses significant ethical problems, with high litigation potential.

Introduction

Every radiological and nuclear medicine examination confers a definite (albeit low) longterm risk of cancer, but patients undergoing such examinations often receive no or inaccurate information about these risks, directly related to the radiological dose received (1,2). A too detailed information on radiological dose and risk may result in undue anxiety, but an information "economical with the truth" may violate basic patients' rights well embedded in ethics (Oviedo convention 1997) (3) and law (97/43 Euratom Directive 1997) (4). In fact one of the three fundamental principles of the "charter of medical professionalism" in the new millennium is the principle of patient autonomy: "Physicians must empower their patients to make informed decisions about their treatment" (5). How are these generally accepted principles translated into clinical practice involving common ionizing testing? The aim of this study was to assess the information perceived by patients on radiological dose of common nuclear medicine exams they frequently perform.

Methods

The questionnaire evaluated the awareness of physical radiation dose and of the associated cancer risk. The effective dose is the sum of the absorbed doses in all organs of the body, each weighted according to their radiation sensitivity. The relative effective dose was expressed in milliSievert (mSv), and in terms of chest X-ray equivalent units, a method of communication previously found to be user-friendly to physicians and patients (6-8) and endorsed as an effective way to communicate radiological risk by the UK College of Radiologists (6), EU Medical Imaging guidelines (7), and Italian National Medical Imaging guidelines (8). The dose exposure is 0.02 mSv for a single postero-anterior chest X-ray (7-9). Cardiac rest-stress Technetium-99m sestamibi scan gives an effective dose of 10 mSv, corresponding to a dose equivalent of 500 chest x-rays (European Commission Medical Imaging Guidelines 2001) (9). The estimated extra lifetime attributable risk corresponds to 1 cancer in 1000 exposed subjects (Biological Effects of Ionizing Radiation VII Committee 2005) (10).

The survey was performed in Nuclear Medicine of Sant'Orsola-Malpighi Hospital (Bologna, Italy). Responses were tailored to a multiple-choice format to aid ease completion. Radiological information of patients was collected, before the examination, by a structured written questionnaire which consisted of 4 very simple questions regarding: 1) perception of individual biorisks; 2) perception of dose exposure of cardiac rest-stress Technetium-99m sestamibi scan; 3) information perceived by the prescribing physician; and 4) information perceived by the physician practising myocardial stress perfusion scintigraphy. Each question had 4 multiple-choice answers (only one correct).

Question 1): "The long-term extra-risk of cancer for a stress cardiac perfusion scintigraphy is": Answers: a) 0 (zero); b) 1 in 1 million (minimal); c) 1 in 100,000 tests (very low); d) 1 in 1000 tests (low). The correct answer is d) (10).

Question 2): "The radiological exposure of a myocardial stress perfusion scintigraphy is": Answers: a) 0 (zero); b) similar to a chest X-ray; c) one-half a chest X-ray; d) 500 times a chest X-ray. The correct answer is d) (9).

Question 3): "the information perceived by the patient after interaction with the prescribing physicians was": Answers: a) excellent, as the patient received the information about the benefits, the doses and the long term risks; b) good, as he/she was informed about the benefits and the doses; c) sufficient as he/she was informed about the benefits; d) poor, as he/she was not informed about the benefits, the doses and the long term risks.

Question 4): "the information perceived by the patient after interaction with the practising physician was": a) excellent; b) good; c) sufficient; d) poor, all defined as in question 3.

Statistical analysis

The statistical analyses of the data were performed with SPSS (version 11.0, SPSS Inc., Chicago, Illinois). Descriptive data were reported as charts, percentages, means and standard deviations. The results of each question were treated in a binary fashion (correct/wrong, 1/0).

Results

One hundred and nine patients (66 men, age 66±10) were included. Dose exposure was correctly estimated by 27% of patients, with the remaining 73% underestimating of at least 300 times their own exposure (Fig. 1). Eighty percent wrongly estimated the dose exposure of myocardial stress perfusion scintigraphy as equal to "zero" or to "one", or "one-half" that of a chest X-ray or "don't say"(Fig. 2). Only 11% of patients has judged excellent the information perceived by the physician prescribing the exam as it has talked to him about the benefits, the doses and the long-term risks (Fig. 3). Of note, however, of this 11% of patients who received "excellent" information, 92% substantially estimated the risk of cancer and doses (Fig. 3). Only 21% of patients have judged excellent the information perceived by the practising physician (Fig. 4). Of note, however, of this 21% who thought they received "excellent" information, 87% substantially underestimated the doses and the risks of the examination they performed.

Discussion

Informed consent for radiological examinations is often not sought, and when it is, patients are often not fully informed, even for considerable levels of radiation exposure and long term risk (2). Dose exposure of myocardial stress perfusion scintigraphy was correctly estimated by 1 out of 5 patients, with the remaining underestimating of at least 300 times, and estimated risk was correctly described by 1 out of 4 patients, with 1 out of 3 substantially underestimating their own risk.

Comparison with previous studies

Our data are consistent with previous, extensive data showing substantial unawareness of radiological doses, and risks, not only of patients but of prescribing and practising doctors as

well. In theory, good medical practice warrants knowledge of the doses and long-term risks of these tests - which can be judiciously employed when they are most appropriate. The results of a survey performed on British physicians shows that 1 out of 20 doctors does not realise that ultrasound does not use ionizing radiation, that 1 out of 10 does not realise that magnetic resonance imaging does not use ionizing radiation, and 97% of doctors grossly underestimate (on average by sixteen times) the doses of radiation for most commonly requested investigations (11). Another survey on Israeli orthopaedists shows that the mortality risk of radiation induced carcinoma from bone scan has been identified correctly by less than 5% of respondents and senior orthopaedists estimated lower risks than did residents (12). Among radiologists, 5% of respondents thought that a computed tomography scan dose was less than one chest radiograph, and 56% estimated the computed tomography scan dose between 1 and 10 chest radiographs, with dramatic underestimation of the true dose (about 500 chest radiographs) (13). In another survey conducted in a tertiary care referral centre of adult and paediatric cardiology, the correct dose of a stress sestamibi myocardial scintigraphy (corresponding to 500 chest x-rays) was correctly estimated by 29% of physicians, whereas 71% wrongly estimated the dose exposure as equal to one (13% of respondents), or one half (9%) or three times (49%) that of a chest x-ray (14). A similar, stunning unawareness was found among pediatricians. When estimating the effective dose of various pediatric radiological investigations, 87% of all responses were underestimates and only 6% were correct in their estimates of the quoted lifetime excess cancer risk associated with radiation doses equivalent to pediatric CT. Forty % of pediatricians underestimated of 100-1000 times the dose of a CT head pre- and post-contrast and 4% thought that abdominal ultrasound scan was associated to ionizing radiation exposure (15). Only 15% of radiology institutions inform patients about radiation risks of a CT scan, whereas 84% inform about allergic risks (16). This may help to explain why 30% of tests involving ionising radiation are inappropriate, that is, patients take a long-term risk without a commensurate acute benefit (15-17).

The proposal of a new standard of informed consent form

Non-specialists (and sometimes specialists) often do not understand the difficult jargon of radiation protection, in which doses are expressed in different, often exoteric, units (megaBecquerel, milliCuries, kilovolts, dose-area product, etc), and simple information on doses and risks is difficult to find and hard to interpret (2). The pressures of an old-fashioned paternalistic view of medicine and of a more modern efficientism act against the building of a really informed consent (2). Nevertheless, in an "ideal" informed consent form, the principle of patient autonomy in current radiological practice might be reinforced by making it mandatory to obtain explicit and transparent informed consent form for radiological examination with high exposure (\geq 500 chest x-rays) (2). The form should spell out the type of examination, the exposure in effective dose (mSv), the dose equivalent in number of chest radiographs, the lost life expectancy (days), the equivalent period of natural background radiation (years) and the risk of cancer as number of extra cases in the exposed population.

Table 1 reports an example applied to 4 types of stress perfusion imaging with 4 different protocols: Tc-99m tetrofosmin rest stress (10 mSv); Tc-99m sestamibi 2-day stress rest (17 mSv); Tl-201 stress and reinjection (25 mSv); Dual-isotope (Tl-201 and Tc-99m) stress imaging (16). The associated proposed graph (Fig.5) underlines the linear relation between dose and risk and might be useful for passing information from doctors to patients and between doctors because the figure format is more easily understood than the traditional table format and the colour coding helps readers to understand risk levels (2). This simple, evidence based communication strategy, if used when obtaining informed consent, will increase the currently suboptimal level of radiological awareness among doctors and patients. Better knowledge of risks will help us to avoid small individual risks translating into substantial population risks (17-19). Consent forms would also help reduce pressure from patients for redundant and often useless examinations (20).

Conclusion

Patients undergoing common imaging examinations involving significant exposure have little or no awareness about radiological dose exposure (and corresponding risk). This ineffective communication poses significant ethical problems, with high litigation potential. Informed consent is a procedure needed to establish a respectful and ethical relation between doctors and patients.

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Table 1. Ways to communicate risk

Procedure	Effective	Equivalent	Lost life	Equivalent period of	Lifetime additional
	Radiation Dose	Number of chest	expectancy	natural background	risk of
	(mSv)	radiographs	(days)	radiation (years)	cancer/examination
Tetrofosmin	10	500	2	4	1 in 1000
Sestamibi 2-days	7	850	3	6.5	1 in 600
Thallium scan	25	1250	4	10	1 in 400
Dual isotope	27	1350	4.5	11	1 in 200