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Risk and benefit in paediatric radiology

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Abstract An investigation requiring the use of ionising radiation can be justified by showing that its benefits are likely to exceed its risks. The risks can be estimated from the effective dose by using the system recommended by the International Commission on Radiological Protection. The benefits of investigations in paediatric radiology are currently unquantified. We can assume that some tests have potential benefits so large that further evaluation is unnecessary. Others have a maximum potential benefit so low that they can be discarded. For most investigations, however, research into the magnitude of benefit to the patient is required in order to establish that it is greater than the magnitude of the radiation risk.

Introduction

It is a fundamental role of the paediatric radiologist to determine whether or not a proposed investigation is justified. In general, the benefits of the test should exceed the costs, which include the risk to the patient and, less importantly, the financial costs. The financial costs vary between, and even within, countries, depending on the structure of the health system. The most important task is to balance the potential benefit with the risk to the patient, and this could be considered the first duty of the radiologist.

Most risks in paediatric radiology appear to be quite minor. The most important exception is the additional risk of cancer in patients exposed to ionising radiation. Many radiologists behave as if this risk is very small by comparison with the potential benefits of imaging (or the risk of not performing the study in question). In fact, these factors can sometimes be comparable in magnitude. Some knowledge of the approximate risk and value of each investigation is therefore essential to decide whether the test should be performed [1].

Effective dose and the International Commission on Radiological Protection model

Why do radiologists rarely know the radiation doses their patients receive? There are several possible reasons for this. One is that the word ‘dose’ can be used to represent different quantities. Skin doses or dose-area products are not in themselves very useful measurements for estimating the risk of a radiological procedure. The International Commission on Radiological Protection (ICRP) has adopted the concept of effective dose, *E,* to facilitate estimation of the probability of radiation-induced cancer [2]. The effective dose in sieverts (Sv) is the sum of the weighted equivalent doses in a number of specified tissues and organs [2]:

$$E = \Sigma w_T \cdot H_T$$

where H_T is the equivalent dose to each tissue or organ. The weighting factor for each specified tissue or organ, w_T, has been estimated by the ICRP. Uncertainties in this estimation, and inaccuracies in measuring or deriving H_T, introduce inevitable errors into estimates of radiation risk in children.

Another problem is that effective dose varies widely, even for what appears to be the same investigation. A

study of children undergoing chest radiography showed that some children received 71 times the lowest dose measured [3]. In CT, doses may vary by a factor of two on different scanners of the same model [4], and by even more between scanners from different manufacturers. A request for an abdominal radiograph may produce a single supine film in the United Kingdom, but a series of three films in some centres in the United States. The effective dose of any investigation requiring fluoroscopy and spot films will obviously be difficult to estimate. There will be a different effective dose associated with the same investigation performed at different ages, mainly due to variation in body size [5]. These problems make any simple list of effective doses for each type of investigation inevitably inaccurate, although some data for children are available [5, 6].

The ICRP provides a coefficient for calculating the risk of fatal malignancy associated with a given effective dose. This coefficient is 0.05 Sv^{-1} for the population as a whole, a value estimated from data on atomic bomb survivors, with a correction for factors including the effect of dose rate [2]. In general, the risk is higher at younger ages, probably in the region of 0.10 to 0.15 Sv^{-1} for children [7, 8].

It should be noted that the ICRP system is not universally accepted. The Medical Internal Radiation Dose (MIRD) Committee [9], for example, has recommended against its use in nuclear medicine. The MIRD Committee's paper has in turn been strongly criticised [9]. Perhaps the best argument for the use of this system for this purpose is that it is necessary to have some method of estimating detriment to the patient in order for us to be able to justify any imaging investigation at all.

Individual variation in susceptibility to radiation-induced cancer

It is well known that individuals with certain diseases, such as ataxia telangiectasia, are at increased risk of carcinogenesis from ionising radiation. There is other evidence that susceptibility to radiogenic malignancy is inhomogeneously distributed in the population [10, 11]. In other words, the ICRP coefficient may be an overestimate for most individuals, but a significant underestimate of the risk for a relatively small proportion. The practical importance of this would depend on how readily these groups can be identified. Children with a known or likely predisposition to radiogenic malignancy should only have investigations requiring exposure to ionising radiation where there is clear evidence of benefit. It is probably unjustifiable, for example, to perform follow-up orbital CT in children with bilateral retinoblastoma, since benefit to the child is unproved, and arguably very small, and the risks are not negligible.

Benefits of radiology

What are the proven benefits of paediatric radiological investigations? Even a generous interpretation of the published literature reveals little or no work that tries to show that diagnostic radiology improves the outcome for sick children. This does not mean that paediatric radiology is of no value to patients. It is relatively easy to show the technical efficacy of imaging, but much harder to show improved outcome [12]. We must, however, be very careful in making claims of benefit, and in particular it should be remembered that clinical efficacy may be a poor surrogate measure of outcome [13].

Further research is clearly required. It is obviously impractical to evaluate all the tests currently used if we define a test as the use of a particular radiological investigation in a certain clinical setting. Extrapolation from the results of carefully designed studies will therefore be necessary. Some imaging tests are of such importance that radiation risk is truly of negligible significance. It would be unethical, for example, to randomise children who are unconscious after head injury into a group who do not undergo cranial CT. Most of our work does not fall into this category, however, and should be thoroughly assessed.

Maximum potential benefit

Until these studies have been performed it will be necessary to use indirect methods to assess the value of radiological investigations. One way of doing this is to examine the maximum potential benefit available from a given test.

Consider, for example, unifocal Langerhans' cell histiocytosis (LCH) of bone, a condition with a 15-year survival rate of close to 100 % [14]. Even the presence of multiple bone lesions may not affect management: half of all patients will not require chemotherapy because their lesions will heal spontaneously [15]. LCH has a poorer prognosis (and this has been used to justify more aggressive therapy) when it involves organs other than bone and when it occurs at a young age. Visceral involvement is typically diagnosed without imaging tests, and the presence of imaging abnormalities without organ dysfunction does not predict outcome [15]. There is, therefore, very little room for us to improve the outcome for a child who is discovered to have an apparently solitary LCH lesion in bone, and radiological studies are particularly unlikely to contribute significantly.

Risk estimation

Bar-Sever et al. [16} have suggested that thallium-201 scintigraphy may be appropriate at diagnosis, and even

follow-up, in patients with LCH of bone. In view of the limited potential benefit, it would seem appropriate to estimate the risk to the patient involved in this strategy. Recommended activities for thallium-201 scintigraphy in children usually lie between 50 and 150 MBq [17–18]. Bar-Sever et al. used 37 MBq in their patient. Effective dose can be estimated from activity using the age-dependent coefficients published by the ICRP [19] and others [20–21]. [These sources actually use an older quantity known as effective dose equivalent, and this could lead to a moderate overestimation of risk. Coefficients for effective dose per unit activity for thallium-201 are not yet available from the ICRP (Valentin J, ICRP, personal communication). This relatively small error does not weaken the general point.] It can be seen that a very high effective dose can be delivered, particularly in young children. As an example, a 1-year-old child given 37 MBq would receive an effective dose of:

$$E = 37\ \text{MBq} \times 3\ \text{mSv MBq}^{-1} = 111\ \text{mSv}$$

This effective dose implies the same risk of fatal malignancy as a whole-body equivalent dose of 111 mGy. Using a coefficient of 0.12 Sv^{-1} [7–8], we can estimate this risk at 1.3%. It should be noted that the effective dose equivalent per unit activity for neonates has been estimated to be as high as 11 mSv MBq^{-1} [20–21] and the minimum activity recommended by at least one authority is 111 MBq [17]. The calculation given above appears, therefore, to be a reasonable estimate. This level of risk is much too high for us to adopt routine or repeated thallium scanning in children with an essentially benign condition such as (apparently) unifocal LCH of bone, even if the sensitivity in this context were 100%, which it is certainly not [18]. Bar-Sever et al. [16] conclude that a large prospective study should be performed to evaluate the role of thallium-201 in skeletal LCH. The benefits of thallium-201 scintigraphy in this context are the detection of, at most, a few lesions not found by skeletal survey and bone scintigraphy, without likely change in management, in a disease which is largely self-limited. These benefits could never outweigh the risks of the examination, which could, in fact, exceed the mortality of the underlying disease. Their proposed study should not be performed, and we should instead direct our limited resources to the evaluation of imaging strategies with a more plausible net benefit to our patients.

Other methods of estimating risk

When only a single organ is irradiated, the concept of effective dose is inappropriate, and it is better to calculate the risk of malignancy associated with a certain absorbed dose to a single tissue. The same approach can be used when the dose to a single organ with high susceptibility to radiogenic malignancy contributes a significant fraction of the effective dose. For example, studies of radiation-induced breast cancer permit the estimation of the excess relative risk of radiation exposure in childhood [10] from calculated absorbed dose in the breasts during radiological procedures.

Dose reduction techniques

It is quite striking that although there has been much research into reduced-dose CT in children, clinical practice and published recommendations lag well behind research findings. For example, in the case of CT of the pelvis, it has been shown that at 120 kV, reduced-dose (80 mA s) images provide diagnostic information equivalent to high-dose (240 mA s) images [22]. Despite this, a recent review [23] recommended obtaining images at considerably higher doses than this, with no explanation of why this additional irradiation was considered necessary.

Conclusion

The estimation of radiation risk in paediatric radiology is inevitably approximate. It seems likely, however, that in many clinical situations its magnitude is comparable to the benefits derived from imaging. In some, as shown above, the risks almost certainly exceed the maximum potential benefit. It will be necessary to perform a large number of carefully designed studies, using patient outcome as an index of benefit, before we can be certain that paediatric radiology is doing more good than harm. In the interim, certain practices should be abandoned if it can be shown that their maximum possible benefit is small relative to the estimated radiation risk. All possible dose reduction techniques should be explored and, where shown to result in adequate image quality, should be universally adopted. Radiologists should be wary of recommendations for new applications of radiological tests. Authors of protocols for radiological examinations should include an estimate of the effective dose involved.

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