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No. 61

Radiation Protection in Newer Medical Imaging Techniques: CT Colonography

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RADIATION PROTECTION IN NEWER MEDICAL IMAGING TECHNIQUES: CT COLONOGRAPHY

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RADIATION PROTECTION IN NEWER MEDICAL IMAGING TECHNIQUES: CT COLONOGRAPHY

JOINTLY SPONSORED BY THE
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INTERNATIONAL COMMISSION ON
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FOREWORD

Multislice/detector computed tomography (CT) scanning, applied to visualization of the colon in CT colonography (CTC), also known as virtual colonoscopy (VC), is a relatively new application of CT introduced in recent years. The possibility of its application in population screening techniques raises a number of questions. Effort is required to ensure that the benefit of this new practice will not pose an undue level of detriment to the individual in multiple examinations.

For practitioners and regulators, it is evident that innovation has been driven by both the imaging industry and by an ever increasing array of new applications generated and validated in the clinical environment. Regulation, industrial standardization, safety procedures and advice on best practice lag (inevitably) behind the industrial and clinical innovations being achieved. This series of Safety Reports (Nos 58, 60 and 61) is designed to help fill this growing vacuum, by bringing up to date and timely advice to bear on the problems involved.

Under its statutory responsibility to establish standards for the protection of people against exposure to ionizing radiation and to provide for worldwide application of these standards, the IAEA has developed the Fundamental Safety Principles and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS). The BSS was issued by the IAEA and co-sponsored by the Food and Agriculture Organization of the United Nations (FAO), the International Labour Organisation (ILO), the OECD Nuclear Energy Agency (OECD/NEA), the Pan American Health Organization (PAHO) and the World Health Organization (WHO), and requires radiation protection of patients undergoing medical exposures through justification of the procedures involved and through optimization. The IAEA programme on radiation protection of patients encourages the reduction of patient doses without losing diagnostic benefits. To facilitate this, the IAEA has issued specific advice on the application of the BSS in the field of radiology in Safety Reports Series No. 39. In addition, it has embarked on a series of coordinated research projects (CRPs) in radiology, mammography and CT, the results from which will appear in other publications. This series of Safety Reports is a further contribution to the resources provided by the IAEA in support of the implementation of the BSS.

The International Action Plan for the Radiological Protection of Patients, approved by the General Conference of the IAEA in September 2002, requires that:

"The practice-specific documents under preparation should be finalized as guidance rather than regulations, and they should include input from professional bodies, from international organizations and from authorities with responsibility for radiation protection and medical care."

This Safety Report — the third in a series (the others being Nos 58 and 60) — is issued in this spirit. It provides guidance and advice for those involved in one of the more dose intensive areas developing in radiology and gastroenterology today. It is jointly sponsored by WHO and the International Society of Radiology, with contributions from the International Commission on Radiological Protection (ICRP).

The IAEA thanks F. Mettler, Jr. for his role in compiling the initial text. In addition, the major role of J. Malone in bringing the final draft to fruition is gratefully acknowledged. The IAEA officer responsible for this publication was M.M. Rehani of the Division of Radiation, Transport and Waste Safety.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. BACKGROUND

Computed tomography (known as CT or CAT scanning) uses an X ray tube that rotates around the body to produce detailed anatomic images. There are several generations of CT scanners. The earlier machines obtained an image of a 'single slice' using one set of detectors. The patient table was then moved or indexed and an image of another slice obtained. This type of system took 10–20 min to complete a thorax scan. In more recent generations, the X ray tube rotates continuously around the patient and the table is moved through the gantry at a constant speed. Newer CT systems are multidetector, capable of obtaining images of multiple slices with a single rotation of the tube around the patient. Scans of the entire chest or abdomen can be obtained in a few seconds. The images are depicted in 2D slice cross-sectional formats or in 3D. These systems are now achieving widespread application in new areas including imaging of the colon.

1.2. OBJECTIVE

This publication addresses some of the requirements of the Fundamental Safety Principles [1] and the International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources (BSS) issued by the IAEA [2]. It brings the principles and standards in these foundational documents, particularly justification and optimization, to bear on the new applications in this field. In particular, this Safety Report focuses on radiation protection of the patient when using CT for colonography. The guidance is provided within the framework envisaged in the supporting Safety Report No. 39, Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures Using X rays [3]. The focus is directed on when it is appropriate to use these techniques, which is important given the widespread concern about high patient doses in spiral and multislice CT (MSCT). There is a strong impetus to find an acceptable technique for screening asymptomatic patients [4–8] and computed tomography colonoscopy (CTC) is now an accepted screening test among others in the USA for particular groups [9].

1.3. SCOPE

This report provides information on patient dose levels in well established centres, which will be helpful in assessing optimization issues. Relevant background information on CT and other colorectal cancer screening techniques (including their associated risks) is provided in Sections 2, 3 and 4. The concepts of justification and optimization, which are central to the BSS approach to patient protection, are outlined in Section 5 and applied in later sections.

1.4. SETTING

The fact that CTC can be applied in the context of screening symptom-free patients, as opposed to diagnosing those presenting with symptoms or a high level of risk, raises special concerns in the area of justification. However, there are well developed precedents for the development of mass screening programmes using radiological techniques. Mammographic screening for breast cancer is an example [10, 11].

Colorectal cancer is common among older persons. For example, it is the second leading cause of deaths from cancer in the European Union. There has been a decrease in the USA, generally attributed to screening, early detection, reduced exposure to risk factors and improved treatment. It is estimated that screening programmes may decrease fatality by approximately 15 to 30%. Thus, many health authorities have concluded that the benefits of some types of screening for colorectal cancer substantially outweigh the potential harm. Over 90% of colorectal cancers occur after the age of 50 and, thus, most screening programmes use 50 as the lower cut-off age [12, 13]. In many Western countries, the risk of a person age 50 being subsequently diagnosed with colon cancer is about 5% and the mortality is about one third to one half of this. Five year survival is 90% if the disease is diagnosed while still localized, 68% for regional disease and only 10% if distant metastases are present [9].

About 80% of colorectal cancers arise in persons with no known specific risk factors, and the rest occur in high risk persons. More than 80% of colorectal cancers also arise from adenomatous polyps which have undergone several genetic transformations. While most carcinomas arise from polyps, the vast majority of polyps do not become carcinomas. There is a direct relationship between the size of a polyp and its likelihood of becoming malignant. Ten per cent of adenomatous polyps greater than 1 cm become malignant in ten years. An average of 5–6 years is required for transformation of a polyp >10 mm to a cancer and an average of 10–15 years is required for

small adenomatous polyps to become a cancer [14–17]. Very small polyps may be either adenomatous or hyperplastic and their clinical significance appears to be limited [18]. Finally, all of the detection techniques have some risk or unpleasantness, or both, associated with them; decisions on proposed screening methods must deal with these, and ensure that they are proportionate with the benefits they offer. This publication is largely concerned with the justification and optimization of the radiation risks, and the associated benefits.

2. CT COLONOGRAPHY

After appropriate patient preparation (see Section 4.2), CT can be used to visualize the colon (large intestine) and rectum. The objective is to identify small growths (polyps) within the bowel that may grow further and become cancerous (Fig. 1). The examination is called computed tomography colonography, and is also variously referred to as virtual colonoscopy, virtual colonography or CTC.

CTC takes about 15 min. It requires a tube to be introduced into the rectum, allowing the bowel to be filled with air or carbon dioxide. Images of the colon are then obtained which are interpreted by a trained radiologist. The procedure was first described around 1993. The number of CTCs currently being performed is not known, but in a 2003 national survey in the United Kingdom, 36% of radiology departments offered CTC [19]. If the technique were to become the screening method of choice for colorectal cancer in persons over the age of 50, the potentially exposed population could run to hundreds of millions of persons worldwide [20].

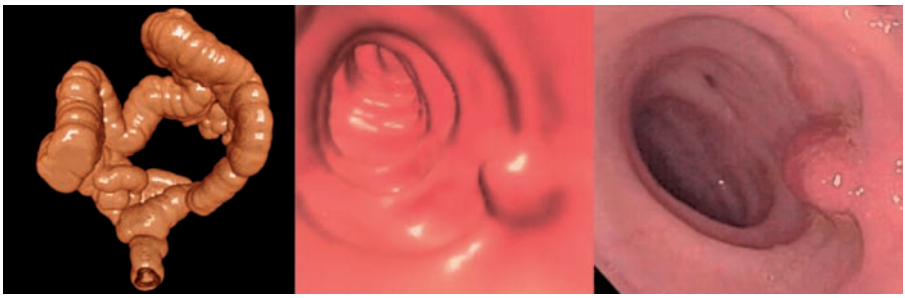

FIG. 1. CT colonography. A 3D reconstructed image shows a growth protruding into the lumen of the colon.

3. OTHER METHODS OF SCREENING FOR AND DETECTING COLON CANCER

3.1. TESTS THAT FIND BOTH POLYPS AND CANCER

3.1.1. Flexible sigmoidoscopy

This test involves placing a flexible tube with a camera on the end into the colon to look for cancer or polyps. It visualizes about 60 cm of the colon (the lower one third) where about one third of colorectal cancers occur. This technique also decreases mortality [13, 21].

3.1.2. Double contrast barium enema

In this test, barium is instilled in the rectum and colon followed by air. Fluoroscopic or fluorographic images, or standard radiographs are obtained. The retrospective sensitivity of barium studies for detecting colon cancer has been reported to be about 70–90%, but on a prospective basis the sensitivity decreases to about 50–75%, or even less [22, 23]. No trial has examined the ability of the air contrast barium enema (ACBE) to reduce the incidence of or mortality from colorectal cancer. The effective radiation dose from a barium enema is about 5–10 mSv [24].

Single-contrast enemas (without air instillation) are much less sensitive (about 15% for polyps >5 mm) and are typically only of value in locating large or obstructing lesions. As with CTC, when a colonic lesion is identified with a barium enema, the patient must still have endoscopic colonoscopy to biopsy the lesion.

There is a risk of bowel perforation with a screening barium enema. The size of the risk reported varies ranging from 1 in 2500 [25] to 1 in 25 000 [26].

3.1.3. Conventional endoscopic colonoscopy

Endoscopic colonoscopy was traditionally performed with flexible scopes in which the image was conveyed by a fiberoptic bundle. However, fiberoptic imaging pathways have been generally replaced by video or digital imaging technology. Throughout this report, conventional endoscopy is taken as referring to flexible endoscopy in which the imaging technology can be fiberoptic, video or digital. Conventional endoscopy is considered to be the gold standard against which other tests are judged. It has the value of direct

visualization, no radiation burden and the possibility of further intervention, including immediate biopsy and/or lesion removal should either be required.

Its disadvantages include its invasiveness and the unpleasantness of preparation for patients (see Section 4). Failure to visualize the entire colon occurs with endoscopy in about 5–10% of patients and is operator dependent [27].

As with barium enemas, screening colonoscopy involves some complications, including bowel perforation or significant bleeding, both of which require hospitalization. Approximately 0.2–0.3% of patients have these. For therapeutic colonoscopy (e.g. when polypectomy is performed), the rates are about 0.07–0.72% for perforation and 0.2–2.7% for bleeding. Perforation is a serious complication that has been reported to lead to death in 1 in 16 000–27 000 patients. The complication rate is dependent upon the experience and skill of the endoscopist.

3.2. TESTS THAT PRIMARILY FIND CANCER

3.2.1. Faecal occult blood testing

This is a relatively simple test used to detect blood in the stool. It is safe and inexpensive, and is often referred to as the guaiac based Faecal Occult Blood Test (FOBT) (some of the reagents used come from the guaiac tree). The sensitivity of a single test is about 15–30%, but with repeats it increases to about 75%. False positive results are common; the blood detected is often from the upper gastrointestinal tract not the colon. There are also some cancers and polyps that do not cause much bleeding which result in false negatives. When this test is used alone, it has been reported that it can reduce mortality in the range of 15–35% [28].

3.2.2. Faecal immunochemical test

The Faecal Immunochemical Test (FIT) looks for blood in the stool, a possible sign of cancer [29–31].

3.2.3. Stool DNA test

Stool DNA testing is a relatively new screening technique which attempts to detect the various DNA markers that are exfoliated by colonic neoplasms. The DNA mutations of interest include the *K-ras*, *APC* and *p53* genes. These tests are presently rather expensive for routine application.

4. SOME CONSIDERATIONS WHEN PERFORMING CT COLONOGRAPHY

This section deals with some of the considerations that arise when a patient is referred for CTC. Radiation dose issues are dealt with in Sections 5 and 6, and are not addressed here.

4.1. PATIENT SELECTION

CTC has been advocated for a number of uses. The most common of these is for colorectal cancer screening, but it may also be appropriate for other reasons, for example, in patients with failed endoscopic colonoscopy, in evaluation of the colon proximal to an obstructing lesion, and in patients who refuse or are medically unsuitable for fiberoptic or video colonoscopy.

As mentioned earlier, patients are not usually screened for colorectal cancer until they are at least 50 years of age. Most authors recommend that patients at high risk (e.g. because of familial polyposis, inflammatory bowel disease, family history of colorectal cancer, previous polyps, etc.) have conventional colonoscopy rather than CTC, because suspected polyps or cancer can be removed at the same time. Patients in whom polyps of 6 mm or greater are found at screening CTC should be offered colonoscopy in order to remove these polyps or should be offered CTC surveillance if colonoscopy is declined or unsuitable.

While pregnancy is not likely in a population over 50, it would have to be considered when younger female patients are referred. Pregnancy would be a strong contraindication for screening examinations. However, in individual cases with symptomatic referral, the justification would have to consider the overall benefit set against the risk to both the foetus and the mother [2, 32]. In this, the procedure would be much like any abdominal or pelvic CT, in which it is generally felt that special attention must be paid to justification.

Most children do not need colon screening and CT should be used in children only after careful consideration. Use of low dose CTC in children, however, has been reported in the literature [33].

4.2. PATIENT PREPARATION

Conventional colonoscopy requires a laxative preparation that patients generally do not like. The preparation for CTC varies somewhat and there is presently some discussion on whether it is necessary to use this approach.

Many use an approach requiring a set of pills or cathartic liquid the night before the procedure [19, 20, 34], sometimes along with a clear liquid diet on the day before. This has the disadvantage that patients generally find it unpleasant and it would probably reduce compliance/participation in a screening programme. In addition, some of these preparations may be contraindicated in patients with heart, liver or kidney disease. On the other hand, there are now less demanding versions of this approach. In addition, some authors do not go the cathartic route, and advocate the use of faecal tagging as an alternative. This is done by giving the patient barium or iodine with meals in the days before the procedure. This mixes the contrast agent with faecal material, hopefully allowing better differentiation of a polyp from adherent faecal material at the time of the examination [35].

At the beginning of the procedure, the colon is filled with carbon dioxide or air. Some authors feel that use of carbon dioxide results in less cramping. The patient is asked to roll over into several different positions to obtain an optimal colon distention; then CT images are taken. CT scans are done in both prone and supine positions.

4.3. TECHNIQUE PROCOTOL

The variations in the literature regarding accuracy of CTC are partly due to variations in technique. Attempts have been made to develop consensus methodology [36]. Oral sodium phosphate is the laxative most preferred. The situation with respect to faecal tagging is unresolved, but shows promise, particularly for larger polyps. Most radiologists do not use intravenous contrast. Spasmolytics are not usually necessary.

4.4. SENSITIVITY AND SPECIFICITY

The accuracy of CTC has been the subject of debate and many publications. It is most often compared to direct fiberoptic or video colonoscopy. Its reported accuracy varies depending on many factors including the patient population selected, patient preparation, polyp size and shape, reader expertise, equipment and technique. The procedure is highly specific

TABLE 1. SENSITIVITY OF CTC FOR POLYPS OF DIFFERING SIZES
(based on the meta-analysis by Mulhall et al. [37])

Polyp size	Sensitivity (%)	95% CI
<6 mm	48	25–70
6–9 mm	70	55–84
>9 mm	85	79–91

and the reported sensitivity range is wide. In one large recent meta-analysis [37], the CT sensitivity improved with polyp size varying from 48 to 85% as illustrated in Table 1. Specificity was about 92% regardless of polyp size. Somewhat better results were obtained in asymptomatic adults with a sensitivity of 89% for polyps at least 6 mm in diameter, 94% for polyps at least 8 mm in diameter and 94% for polyps at least 10 mm in diameter [34]. When optical colonoscopy is performed by experts, the sensitivity is >95% although lower values (about 93%) have been reported in some large studies.

While it is sometimes asserted that the accuracy of CTC is the same as that for conventional colonoscopy, many authors dispute this. In a 2005 study, there was a comparison of ACBE, CTC and conventional colonoscopy in over 600 high risk or symptomatic patients who each received all three procedures (Table 2) [38, 39]. The results of both ACBE and CTC were poor compared with conventional colonoscopy. It is also evident that the results of this study are different to those noted in Table 1 above. It is not clear why the results of the studies are so different but the reason is probably multifactorial [40]. However, there is an emerging consensus that for polyps 10 mm or greater, the sensitivity of CTC approaches that of endoscopic colonoscopy, but for smaller sizes the endoscopic approach is, at present, better [5, 41]. A 2007 meta-analysis of 30 published studies arrived at the same conclusions [42]. The American College of Radiology Imaging Network (ACRIN) launched a study in 2005 involving more than 2500 asymptomatic patients. The results were released at the ACRIN 2007 Fall Meeting. The main result was a convincing demonstration that CTC is at least as sensitive and specific as conventional colonoscopy in detecting adenomas 10 mm in diameter or larger when performed by a trained radiologist.

For small polyps, the accuracy is less but some authors contend that very small polyps are not clinically significant [34]. Flat or depressed polyps are less well seen on CTC and may have a higher malignant potential [43]. Most flat

TABLE 2. COMPARISON OF SENSITIVITY OF ACBE, CTC AND CONVENTIONAL COLONOSCOPY IN 600 SYMPTOMATIC PATIENTS *(after Rockey et al. [39])*

Test	Sensitivity (%) polyp >10 mm	Sensitivity (%) polyp 6–9 mm
ACBE	48	35
CTC	59	51
Conventional endoscopy	98	99

lesions need to be 2 mm or more in height and 7 mm or more in diameter to be visualized [44].

Effective colonic screening requires that the entire colonic surface be adequately visualized. The amount of surface actually visualized with CT depends on the software and reading methodology used. With 3D fly-through software, retrograde reading from the rectum to the caecum shows only about 75% of the colonic surface area. Antegrade reading in addition increases the visualized surface area to 90–95% [45]. However, it is also the case that the entire colon surface is not always seen during endoscopic colonoscopy.

4.5. PERFORATION OF THE BOWEL

Perforation of the wall of the large intestine may occur during CTC, barium enema or fiberoptic colonoscopy even in patients without known colonic disease [46, 47]. The risk of perforation depends on the expertise of the physician, the presence or absence of accompanying disease and the approach to insufflation used. For screening populations, the perforation risk with CTC is reported to be less than 1 in 2000 [48]. In symptomatic patients, serious adverse events occurred in just under 1 in 1000 patients [49]. The results from three recent studies, which taken together involved 50 000 patients, demonstrated no fatalities associated with the reported perforations [45].

These rates for perforation with CTC are higher than the rate quoted for barium enemas and lower than that for conventional colonoscopy. Perforation is a serious complication as it carries some risk of fatality. It must be compared with other risks such as bleeding and the radiation risks involved.

4.6. READER EXPERTISE

Training of the radiologist, or the physician performing or reading the examination has a significant impact on the accuracy of CTC. A high level of expertise is required and will give rise to significant new education and training needs [5, 7]. Perception errors regarding residual stool and flat lesions are the dominant cause of false positive interpretations [50]. CT tends to overestimate polyp diameter. Measurement of polyp size has also been shown to be subject to significant interobserver variation [51].

4.7. CONSEQUENCES OF POSITIVE FINDINGS

Polyps detected with CTC should, optimally, be removed. As a result, one can expect that a significant fraction of patients who have a polyp found by CT will still need to undergo a conventional colonoscopy. If serial screening is performed and obvious polyps are removed, the population studied at subsequent examinations will likely have a higher percentage of harder to see polyps [52]. The net consequence of this should be improved detection and survival. However, it will also involve an increase in the demand for endoscopy, with the consequent manpower and resources issues.

4.8. INCIDENTAL LESIONS

The literature indicates that in up to about 40% of patients having CTC, abnormalities will be found outside the colon; many will have more than one. Many of the lesions may not be of clinical interest (e.g. simple renal cyst) but about 14% required additional medical evaluation in some studies. From the 14%, 2.7% had non-colon cancers and 1% had abdominal aortic aneurysms [53, 54]. The number of incidental findings will inevitably increase with the age of the population studied. The approach to incidental findings, such as these, their workup, the costs and potential morbidity involved are important to consider when developing policy on CTC as a screening tool [55].

5. RADIATION PROTECTION OF THE PATIENT: GENERAL ASPECTS

The International Commission on Radiological Protection (ICRP) has recommended a multi-step approach to protection of the patient [56–58]. First, a practice is identified (such as the use of CT scanning to perform colonography). The second step is to justify this practice; that is, does CTC contribute more benefit than harm to society? This is assessed by performing large clinical population studies. When the practice is justified, it should then be optimized (i.e. can the practice be done at a lower radiation dose while maintaining its efficacy and accuracy?).

Two subsequent steps normally apply to the individual having the CT scan. There should be individual justification. This asks whether the examination will really benefit the patient about to be studied. For example, CTC is not likely to be useful for individuals who are very young, very old or who have a well known or widespread tumour. Such a decision is best made by a physician familiar with the patient and the medical history. However, in the case of a screening programme, the question of justification takes on special features and particular attention must be paid to the population, the protocol and the circumstances in which it is applied. The last step is optimization of the examination for the specific individual. This step asks the question as to whether the examination can be effectively performed in a way that reduces dose for that particular patient (e.g. can a lower dose be used because the patient is very thin or can the irradiated volume be reduced?). This is obviously also particularly important in screening programmes.

6. CT COLONOGRAPHY DOSES AND POSSIBILITIES FOR DOSE REDUCTION

As with other medical procedures involving radiation, there is a wide variation in doses reported for the same type of CT scan. The absorbed dose received during CTC varies depending on the type of scanner, the protocol and the technique used. As mentioned earlier for this procedure, two CT scans are done. These are referred to as a paired scan (one obtained in the prone position and one in the supine position). Thus, when an effective dose is quoted in the

literature, it is important to know whether it is per CT scan or for the paired scans that are usually done for the examination.

There are significant differences in technique and doses between single slice and multi-detector CT (MDCT) or MSCT scanners. It has recently been shown that even when exactly the same technical parameters are entered on the scanners of different manufacturers, or on different models from the same manufacturer, the colon dose can vary by almost a factor of two. Many factors can contribute to this, including the volume scanned; the collimation; the number, thickness and overlap of slices; the tube current, scan time and other technical factors[1].

Effective dose values reported in the literature for CTC range over a factor greater than ten (1–18 mSv). The effective doses from MDCT scanners are usually higher than from single slice scanners, in part, due to use of narrower collimation which increases overlap, and hence effective dose [59, 60]. For most MDCT colonography protocols, effective doses are in the range of 2–6.5 mSv per scan or 4–12 mSv for the examination. The effective dose can be roughly estimated from the mAs per slice (all other parameters being constant) since with the MSCT used in the study, the mA is automatically adjusted to the pitch [61]. The effective dose from CTC is about 30% higher in females than in males (due, to a large extent, to the fact that the ovaries are within the direct radiation beam).

There are clear opportunities for dose reduction with almost any type of CT scan [57, 58]. Of importance are using the highest pitch and lowest tube current (mAs) consistent with acceptable images. Increasing the pitch from 1.0 to 2.0 usually reduces the dose by half [62]. Tube current should be set at the lowest level that allows adequate visualization of the colonic wall and dose reductions of about 35% are feasible [63]. Most protocols use a kVp between 110 and 120. A number of authors have developed innovative colonic phantoms to help optimize CTC protocols with regard to detector collimation, section thickness and tube current [64–66].

Ultra-low dose protocols result in an effective dose of 1–2 mSv. These have been shown to be capable of a sensitivity of over 80% for polyps >5 mm and a specificity in excess of 95% [67, 68]. Imaging of polyps with doses as low

[1] For single slice units, the pitch is usually two and the slice thickness is often 5 mm, resulting in an effective slice thickness of 6–7 mm. The largest slice thickness felt to be acceptable by many authors is 3 mm and most use an effective slice thickness of 1–3 mm. Motion artefacts are much less frequent with MDCT. The technical factors often include a pitch of 1–1.5, collimation of 1 × 5 to 4 × 2.5, and mAs per section of 30–100 [59].

as 0.05 mSv has been shown to be feasible. When compared with results from 8–12 mSv scans, the lesion detectability did not change significantly although image noise increased substantially [69]. The latter problem can be ameliorated through use of noise reduction filters and image smoothing. Of particular interest is a feasibility study that demonstrated in simulations that the sensitivity for polyps >5 mm was above 74% with mAs values down to 1.6. Below this, sensitivity decreased [61]. This adds to the widely shared opinion that there is much scope for dose reduction, with some loss of image quality, but without significant reduction in lesion detectability [70].

In IAEA and ICRP publications, such as Refs [2, 3, 71], the use of formally established reference or guidance doses for medical procedures is recommended to assist in the implementation of optimization programmes. The dose values cited here provide a valuable basis for comparison, and represent what has been achieved in some experienced centres. However, they are not guidance or reference levels, as these remain to be established.

The CTC doses cited here are consistent with the published values for pelvic CT dose in various surveys [72–76]. It is instructive to compare the doses from CTC with that from a standard radiographic contrast barium enema. Effective dose from a double contrast barium enema is typically about 10 mSv [25]. Comparison to other sources/procedures is also shown in Table 3.

Conventional endoscopy, ultrasound and magnetic resonance imaging (MRI) have the advantage of not using any ionizing radiation and do not have any known cancer risk. Currently, ultrasound is not useful for colorectal cancer screening. MRI has been proposed as an alternative modality for CTC but has not achieved wide usage [77]. As already mentioned, conventional endoscopy is the gold standard for sensitivity, but it has problems in respect of its invasiveness, patient acceptability, costs and associated morbidities.

7. RADIATION RISK FROM CT COLONOGRAPHY

At the dose level from a CT scan, radiation risk primarily derives from the potential for radiogenic cancer induction. Individual radiation risk from a CT examination varies significantly depending upon many factors including the absorbed dose, age and sex of the patient, and expected lifespan. Risk is generally higher in children and younger patients compared to adults. The risk is somewhat higher in females than in males. In those persons over the age of 50, the most radiosensitive tissues relative to cancer induction are lung and bone

TABLE 3. EFFECTIVE RADIATION DOSE FROM CTC COMPARED TO OTHER COMMON SOURCES

Source	Approximate effective dose (mSv)[a]
CTC	8 (with a range of 1–18)
CT pelvis	6–10[b]
Barium enema	4–7
Annual natural background radiation	2.4
Chest X ray (single film)	0.02
Lumbar spine X ray	1.3

[a] From Ref. [78] or sources cited in text.
[b] From Refs [72–76].

marrow which receive relatively small doses from CTC. Notwithstanding this, there is considerable concern at the level of individual and population risk arising from newer CT applications, particularly screening programmes [79].

Excess cancer risk has not been demonstrated by epidemiological studies at doses below 100 mSv. Since doses from CTC are lower than this, the potential risk can only be estimated by assuming a dose–response relationship. Various approaches are used. ICRP has estimated that the radiogenic fatal cancer risk for an adult population is about 5%/Sv [56], which, using the linear non-threshold dose–response hypothesis, is equivalent to 0.005%/mSv. With the protocols in use to date, the effective dose for a paired scan is about 8 mSv (Section 6 and Table 3). This, using the ICRP estimates, gives an approximate risk for a fatal radiogenic cancer of 0.04% or 1 in 2500, as set out in Table 4. This must be taken in the context of a spontaneous risk of cancer incidence and fatality of about 40% and 20%, respectively. The risk values are comparable with those that would prevail for a barium enema, which would be regarded as a moderately high dose procedure.

One of the difficulties with the ICRP estimates is that they are undifferentiated with regard to age. Hence, they are not well suited to application for risk calculations in this context, where there is a strong age bias in the population of interest. The US National Academy of Sciences BEIR VII Committee has recently provided radiogenic cancer risk estimates by age and sex [80]. Table 5 lists calculated age and sex dependent risks based on these, using simple linear extrapolations. The values are for fatal radiogenic cancers following a paired CTC procedure giving an effective dose of 8 mSv. Clearly, the values presented are less than those from ICRP in Table 4, reflecting the older age profile of the colonoscopy group. The risk is higher for women than

TABLE 4. COMPARISON OF EFFECTIVE DOSE AND RISK FROM SEVERAL TYPES OF COLON IMAGING PROCEDURES PERFORMED ON AN ADULT

	Approximate effective dose (mSv)	Approximate risk per scan of fatal radiogenic cancer (%)[a]	Approximate spontaneous risk of fatal cancers (%)
CTC	8	0.04	20
Double contrast barium enema	10	0.05	20
MRI	0	0	20
Conventional colonoscopy	0	0	20

[a] The risk calculation is based on Ref. [56]. Radiogenic and spontaneous cancer incidence is approximately twice the fatal risk.

TABLE 5. POTENTIAL LIFETIME RADIOGENIC FATAL CANCER RISK FOR CTC AT VARIOUS AGES

	Age at exposure	Fatal radiogenic cancer/leukaemia risk (%)[a]
Male	30	0.030
	40	0.030
	50	0.029
	60	0.026
	70	0.020
	80	0.012
Female	30	0.043
	40	0.041
	50	0.038
	60	0.033
	70	0.026
	80	0.015

[a] Adapted from BEIR VII Table 12 D-2, calculated for a scan with 8 mSv effective dose [80]. Risks for varying doses may be estimated using simple proportionality.

for men, and declines with age. The risk at 70 is about half that at 50 for both men and women.

The values for risk estimates reached by different authors vary somewhat depending on underlying assumptions. For example, van Gelder et al. have indicated that a paired CTC on a 50 year old would yield a lifetime fatal cancer risk of about 0.02% and about half this value for a 70 year old [69]. This is somewhat different to the values noted in Tables 4 and 5, but is a function of the assumptions and values used in the calculations. On the other hand, even larger differences arise in the approach in Refs [70, 79] where the absolute lifetime cancer risk of a 50 year old having paired CTC scans has been calculated as 0.14%. While this appears high, it must be discounted for the difference in risk between incidence of cancers and fatality from them.

All of these individual radiation related cancer risks/probabilities seem low compared with the spontaneous incidence. However, a different and less acceptable perspective is obtained if one views the risk in terms of the number of extra cancer cases that will arise in a large screened population. For example, if 100 000 persons received a CTC (8 mSv effective dose) each year from age 40 to 70, there could be about 2000 extra cancer or leukaemia cases and about 1000 additional fatalities based on the NAS/BEIR VII data [80]. This may not appear very large on top of the spontaneous incidence of about 40 000 (all cancers) and the roughly 20 000 fatalities that follow from them. However, it is relatively large when set beside the natural incidence of about 5% (5000) for colon cancers, and the fatality of about one third to one half of this (1500–2500) in a group of 100 000 [13].

In view of the above, the present reticence of some professional bodies with respect to widespread deployment of virtual colonography as a screening technique was not surprising [5]. However, additional considerations are brought to the issue, including the sensitivity and specificity of the test, the complications such as perforation, the reporting format of lesions and the reporting of the incidental findings, none of which are fully treated here. However, in respect of the radiation dose issue alone, there is much scope for improvement in the above figures. For instance, an effective screening programme is unlikely to require an annual CTC, the most frequently proposed interval being five years. In addition, there is much room for selection of suitable subpopulations and for dose reduction; some authors estimating that a factor of five to ten is readily achievable with optimized protocols [61, 70]. Such moves have greatly enhanced the benefit–risk ratio involved, and tipped the debate in favour of more widespread use of CTC for screening purposes. Some authors already strongly advocate this from a perspective of rigorous patient preparation regimes and low radiation dose techniques [20] and a broad consensus of American societies (American Cancer Society, American College

of Gastroenterology, American Gastroenterological Association Institute, American Society for Gastrointestinal Endoscopy and American College of Radiology) have recently added CTC to the colorectal cancer screening tools for patients over 50 at average or high risk [9].

8. RECOMMENDATIONS OF OTHER BODIES REGARDING SCREENING

Practices throughout the world vary greatly, as do the recommendations of professional bodies. However, screening progress, particularly in the USA has demonstrated that mortality can be significantly reduced. The only test that has been comprehensively validated from this point of view is FOBT (Section 3).

From the techniques mentioned in Section 3, the recommendations of the American Cancer Society for colorectal cancer for screening of those over 50, include one of the following approaches:

— Flexible sigmoidoscopy every five years;
— Colonoscopy every ten years;
— Double contrast barium enema every five years;
— CTC every five years;
— FOBT annually;
— FIT annually;
— Stool DNA test (interval still unclear).

Implementation has been hampered by cost, invasiveness, availability of resources, false positives, false negatives, knock-on impact on health services and patient acceptance. For most common screening tests, the cost is generally between $10 000–25 000 per life saved and, based on available current literature, the most effective strategy appears to be conventional colonoscopy about every ten years with the combination of annual FOBT and sigmoidoscopy every five years [81] although recent work suggests that optimally used CTC, directed towards larger polyps, may have an even lower cost per life saved [82]. New developments in all of the above are under way.

Clearly, these options did not involve CTC until recently. The American Gastroenterology Association has maintained an interest in CTC and has been

associated with statements on it in the last few years [5–8]. In 2004, the immediate past president noted:

> "The findings … suggest that CTC does have potential to become a suitable technique for colorectal cancer/polyp screening. However, it is clear that the current data are insufficient to justify its use in unselected populations and further that achieving efficacy sufficient to warrant use as a screening tool will likely depend on further technical improvements rather than simply better studies of existing technology".

Much progress has been achieved since this, but its reserve continued to have an evidential base. The American Gastroenterology Association statement at the end of 2006 echoes this reserve, while emphasizing issues such as training. Other national or professional groups echo this caution [36, 83–87]. It is also worthy of note that there are individual enthusiasts for the technique, who have excellent low risk and highly effective protocols that probably justify their enthusiasm. The Augusta Medical Center, the US multi-society task force on colorectal cancer and the American College of Radiology issued guidelines in 2008 that include CTC as one of the screening tests for colorectal cancer for those at average or high risk [9]. However, the skill necessary to reproduce the success of innovators in this area on a widespread basis requires enormous efforts in education and training. Finally, it is important to emphasize that factors such as the level of patient preparation and sedation required may, with the population radiation risk, have a decisive influence on the final acceptability of CTC as a screening tool by the patients and professionals involved.

9. CONCLUSIONS

The appropriate clinical indications for and accuracy of CTC remain controversial in some countries. While it has some advantages over conventional colonoscopy, CTC is not as accurate with all users and in all circumstances. Whether CTC protocols and techniques can be standardized sufficiently, and enough radiologists, physicians and support staff can be trained to the level necessary remains to be seen. This issue alone could be sufficient to prevent its adoption and use as a general screening examination [86, 87]. Similarly, the acceptability of the patient preparation required may

have a decisive impact. In addition, the statements of the US Preventive Services Task Force, and the Canadian and Belgian groups indicate some controversy about the adoption of CTC for general screening purposes [5–8, 81, 83–86]. However, it has been accepted in the USA as a screening tool for colorectal cancer for patients at average or high risk [9, 88]. Its pattern of use in symptomatic patient groups is still emerging and being defined.

Health authorities and professional groups in various countries should evaluate many factors before recommending adoption of CTC screening programmes. These include, but are not limited to, prevalence and severity of disease in the population; age of the proposed screening group; accuracy of the test, including the influence of lesion size; frequency of the procedure; costs (including false positive and false negative results); expected effects on outcome; radiation dose including the possibility of dose reduction; and, finally, evaluation of potential risks. Careful application of the principles of justification and optimization to these issues could dramatically influence the final positioning of the technique.

The radiation dose from CTC that might arise in screening programmes is relatively well documented and the potential risk of radiogenic cancers has been estimated. In the decision to use CTC or not, radiation dose could be a relatively minor factor, when all the processes mentioned above are optimized. However, very frequent screening of unselected individuals with a poorly optimized CT technique could lead to a situation in which there is little or no net health gain. Thus, the potential radiogenic risk should not be ignored and methods to reduce exposure while maintaining diagnostic accuracy should be vigorously applied, even at some cost to image quality. On the other hand, justification of CTC in persons who are symptomatic, at high risk or in whom conventional colonoscopy fails, should be a matter for individual evaluation by a physician to determine what is appropriate and/or necessary.

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This publication focuses on radiation protection of the patient when using computed tomography (CT) for colonography. The guidance is directed at when it is appropriate to use these techniques, which is important given the widespread concern about high patient doses in spiral and multislice CT, and the strong impetus to find an acceptable technique for screening asymptomatic patients. This report also provides information on patient dose levels in well established centres, which will be helpful in assessing optimization issues. Relevant background information on CT and other colorectal cancer screening techniques (including their associated risks) is provided, as are the concepts of justification and optimization.

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