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Teleradiology based CT colonography to screen a population group of a remote island; at average risk for colorectal cancer

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ABSTRACT

Purpose: To prospectively assess the performance of teleradiology-based CT colonography to screen a population group of an island, at average risk for colorectal cancer.
Materials and methods: A cohort of 514 patients living in Madeira, Portugal, was enrolled in the study. Institutional review board approval was obtained and all patients signed an informed consent. All patients underwent both CT colonography and optical colonoscopy. CT colonography was interpreted by an experienced radiologist at a remote centre using tele-radiology. Per-patient sensitivity, specificity, positive (PPV) and negative (NPV) predictive values with 95% confidence intervals (95%CI) were calculated for colorectal adenomas and advanced neoplasia ≥6 mm.
Results: 510 patients were included in the study. CT colonography obtained a per-patient sensitivity, specificity, PPV and, NPV for adenomas ≥6 mm of 98.11% (88.6–99.9% 95% CI), 90.97% (87.8–93.4% 95% CI), 56.52% (45.8–66.7% 95% CI), 99.75% (98.4–99.9% 95% CI). For advanced neoplasia ≥6 mm per-patient sensitivity, specificity, PPV and, NPV were 100% (86.7–100% 95% CI), 87.07% (83.6–89.9% 95% CI), 34.78% (25.3–45.5% 95% CI) and 100% (98.8–100% 95% CI), respectively.
Conclusion: In this prospective trial, teleradiology-based CT colonography was accurate to screen a patient cohort of a remote island, at average risk for colorectal cancer.

1. Introduction

Computed tomographic colonography (CTC) was accepted in 2008 by several medical associations as one of many examination tools for screening the patient at average risk for colorectal cancer [1,2], with large trials achieving reliable detection of the significant polyp ≥6 mm [3–6]. However, one has to realize that these excellent results were only reached by a small number of highly trained radiologists, mostly from academic centres of excellence. There is evidence that CTC performs adequately only when there is sufficient experience in its execution and interpretation [7,8]. Faced with variability of results, widespread implementation of CTC with integration into daily clinical practice is difficult. Taking this important step is particularly arduous because of two issues. First, CTC necessitates intensive dedicated training. Second, despite adequate training, many centres are unable to build up sufficient clinical experience because of low patient volumes. Indeed, in many countries CTC is not, or only partially, reimbursed with low demand, suboptimal deployment and disappointing results as a consequence [9,10].

Teleradiology offers the opportunity to access remote, expert subspecialty radiology [11,12]. The use of teleradiology with integration of experienced CTC radiologists, providing expert advice and interpretation, may yield good results for polyp detection and could prove helpful in CTC implementation.

The purpose of the present study was to assess the performance characteristics of teleradiology-based CTC to detect colorectal adenomas ≥6 mm and cancers in the population of a remote island, at average risk for colorectal cancer.

2. Materials and methods

For this prospective trial institutional review board was obtained. The population of Madeira (Portugal), an island of

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250,000 inhabitants in the Atlantic Ocean, was informed through a media campaign that a colorectal cancer screening trial for people aged 50–75 years, at average risk for colorectal cancer, was being organized. Interested people could register and were then invited for an interview to explain the course of the trial and to check eligibility. For eligible patients who decided to participate, an informed consent was provided, fully explained and signed. The exclusion criteria for this study were: total colonic examination in the preceding 10 years, positive FOBT in the last 6 months, iron deficiency anemia, gastrointestinal hemorrhage and/or change in bowel habits in the preceding month, family history of hereditary colorectal cancer, any history of visceral cancer other than colorectal cancer, poor physical condition, renal insufficiency.

2.1. Examination techniques

CTC was performed according to the current guidelines [7]. All patients underwent a colonic preparation consisting of a low residue diet, starting 3 days before CTC, augmented with cathartic colon cleansing and fecal tagging the day before CTC. For cathartic cleansing a combination of 2×5 mg bisacodyl (Dulcolax, Boehringer Ingelheim, Ingelheim am Rhein, Germany) and 2×15.08 g sodium picosulphate (CitraFleet, De Witt, Cheshire, UK) was used. Fecal tagging was obtained with 225 ml of a 4.2% weight/volume barium suspension (EZ Cat, Bracco, Milano, Italy) and 50 ml of meglumine amidotrizoate and sodium amidotrizoate (Telebrix Gastro, Guerbet, Villepinte, France). CTC was performed at the local radiology site in Funchal, Madeira. This department only had practical experience with CTC and did not perform CTC-interpretation. The local radiologist did not follow any dedicated training in CTC, nor did the radiographers. They were performing CTC since 2007 in collaboration with the foreign CTC-teleradiology centre, which initially provided technical and practical advice and which interpreted all CTC via teleradiology during this period. In that way the local department had executed 172 CTC in a time span of 40 months before the start of the trial (=4.3 CTC/month on average). During the trial all CTC were performed under supervision of 1 local radiologist, who was present during all examinations and who performed an initial check of the quality of distension and of eventual complications. After smooth muscle relaxation with 20 mg intravenous hioscin buthylbromide (Buscopan, Boehringer Ingelheim) and automated insufflation of the colon with carbon dioxyde (Protoco2l, Bracco), all patients were scanned in 2 positions. CTC was performed with a 6-slice CT scanner (Emotion 6, Siemens, Forchheim, Germany) using 130 kV (=default setting), with 50 mAs in supine and 30 mAs in prone position, a slice collimation of 1.5 mm, 600 ms tube rotation. This resulted in a CTDIvol of 10.56 mGy.

The acquired data sets were anonymized and sent to the teleradiology site by secured transfer using a commercially available web-based cloud collaboration system (YouSendIt, Campbell, CA, USA).

All examinations were interpreted by one radiologist with an experience of >5000 CT colonographies, using a primary three-dimensional interpretation method (Vitrea, Vital Images, Minnetonka, MI, USA). No CAD was used. The CTC-reader was blinded to the results of optical colonoscopy (OC). The purpose was to report all polyps and tumoral lesions $\geq$6 mm. In case of diagnostic issues a second radiologist, with a similar experience in CTC, was consulted.

All patients underwent same-day OC without additional colonic preparation. OC was performed by five colonoscopists, having an experience of $\geq$15 years colonoscopy practice. The endoscopists were blinded to the CTC results. All detected polyps were recorded by the principle investigator and sent for pathology examination. Lesions were divided in non-neoplastic polyps, adenomas (low grade and high grade dysplasia), carcinoma and advanced neoplasia [13]. Advanced neoplasia was defined as an adenoma $\geq$10 mm, an adenoma with >25% of villous components, an adenoma with high grade dysplasia and, a carcinoma [14].

2.2. Lesion matching

CTC and OC were compared for polypoid and tumoral lesions $\geq$6 mm. In case of incomplete OC, both examinations were compared for the segments examined by OC. All lesions were compared for size and location. OC compared the lesion size to an open biopsy forceps. On CTC, lesions were measured on the two-dimensional images using a window/level setting of 1500/−200 Houndsfield units [15–17]. The lesions were categorized as $\leq$5 mm, 6–9 mm and $\geq$10 mm. A lesion was considered a match if belonging to the same or closest size category or if the lesion was any size larger than the lesion detected at OC [18], and with the lesion located in the same or adjacent colonic segment. As segmental unblinding was not possible, because CTC was interpreted in the teleradiology centre after performing OC, a more detailed lesion localization method was adopted as compared with previous trials. The colon was divided in 10 segments: inferior rectum (part of the rectum below the inferior rectal valve), mid/upper-rectum (part of the rectum above the inferior rectal valve), sigmoid, descending colon, splenic flexure, transverse colon, hepatic flexure, ascending colon, ileo-cecal valve, cecum. This method allowed for more accurate matching of lesions. For the final listing of lesions the colon was divided into 6 segments. In case CTC was highly suggestive for a lesion $\geq$6 mm with normal OC, it was proposed that patients undergo a repeat OC with the endoscopist knowing the CTC result. Detection at CTC with high confidence was considered in case of a pedunculated or sessile luminal defect with soft tissue density or a mass visible on the same location in the colon on both acquisitions. If repeat OC confirmed the CTC finding, this was considered a false negative for OC. If repeat OC was normal or in case patients refused repeat OC, patients were proposed to undergo a repeat CTC. In case repeat CTC confirmed the same lesion at the same location, the result for this patient was considered inconclusive and patient was withdrawn from results calculation because of the likelihood of false negative OC and because additional examinations could not be covered by the trial. In case repeat CTC was normal, this was considered a false positive for CTC.

2.3. Statistical analysis

The sample dimension was calculated at 500 patients for a maximum estimation error of 5% with 95% confidence. It was estimated that around 50% of the population 50 years or older was eligible for the study. Sensitivity, specificity, positive and negative predictive values, positive and negative likelihood ratios with 95% confidence intervals were calculated for all lesions, adenomas and advanced neoplasia $\geq$6 mm, 6–9 mm and $\geq$10 mm, respectively. The reference standard was the initial OC augmented with lesions detected in patients at repeat OC or surgery.

3. Results

Between May 2010 and May 2011, 514 patients were enrolled. CTC and OC data were available in 510 patients (206 males, 304 females, range 50–74 years, mean age 59.7, S.D. 6.4): 2 patients refused OC and CTC data of 2 other patients were inadvertently deleted in the local department before the transfer to the teleradiology site. OC was incomplete in 30 patients corresponding to a completion rate of 94.1%. In these patients OC was able to examine a total of 85 segments. These segments were included in the study.