

Lessons from high-quality trials on computed tomographic colonography: the French experience

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Title: Accuracy of computed tomographic colonography in a nationwide multicentre trial, and its relation to radiologist expertise.

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Journal: *Gut* 2011;60:658-665

Summary

CT colonography (CTC) represents a minimally invasive imaging technique able to identify the adenomatous precursors of colorectal cancer (CRC) as well as colorectal masses. However, its use in CRC screening and diagnosis is still controversial due to the lack of consistent evidence in favor. A study by Heresbach et al addressed the accuracy of CTC for ≥ 6 mm polyps or masses in a multicenter, nationwide prospective study that included 845 patients undergoing same-day colonoscopy with segmental unblinding of CTC findings [1]. All radiologists attended an adequate training before the procedure. Both cathartic preparation and fecal tagging were performed by the patients before the procedure. The study showed that sensitivity and specificity of CTC for ≥ 6 mm lesions was 69% and 91% with a 67% positive predictive value. The authors also found that the sensitivity for ≥ 6 mm lesions in the training set was an independent predictor of radiologist performance.

Opinion

CTC has been proposed as an adequate technique for CRC screening based on its high accuracy for ≥ 6 mm polyps and masses. However, such a high accuracy had been mainly extrapolated from single-center studies from tertiary centers [2], leading to some uncertainty on the generalization and

reproducibility of this technique. For this reason, in recent years, there have been great expectations for the publication of the results of the first nationwide, multicenter studies on CTC. The first two studies, namely the ACRIN (based in the United States) and the IMPACT (based in Italy) studies, led to contrasting results regarding the CTC sensitivity for small (6-9 mm) and large (≥ 10 mm) polyps, failing to solve the underlying uncertainty [3,4]. The results of the present nationwide multicenter French study were therefore critical for a definitive assessment of CTC performance [1]. In order to avoid any pitfalls, the study design was meticulous. All patients underwent state-of-the-art CTC, including cathartic preparation, fecal tagging, CO₂ insufflation, and high performance CT machines were used. All the radiologists received an intensive training program based on a 2-day training session and a further set of 52 colonoscopy-verified CTC cases. However, as opposed to the ACRIN study [3], there was no pre-study selection of the radiologists according to the results of a qualifying examination. In other words, all the radiologists were allowed to enter the French study, irrespectively of their performance on the initial training set of 52 cases. Disappointingly, the present study showed a suboptimal performance by CTC with a only a 69% per-patient sensitivity for ≥ 6 mm lesions, as compared with the 78% of the ACRIN study [1,3]. Moreover, despite the authors' failure to provide the exact estimate, sensitivity for ≥ 10 mm polyps (i.e. large) was apparently less than 80%, as compared with the 90% reported by the ACRIN study [1,3]. When investigating the reasons for such poor CTC performance, the authors showed that the radiologists' performance was independently related with his/her performance in the training set [1], indirectly suggesting that the apparently superior performance in the ACRIN study could be due to the artificial pre-selection of the radiologists to be entered in the study.

When cumulatively considering the results of the three studies (i.e. ACRIN, IMPACT, French), CTC does not appear to be a reproducible technique, precluding at this stage its implementation as an alternative to colonoscopy for CRC screening or diagnosis.

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Conflict of Interest: Cesare Hassan has acted as a consultant for Given Imaging Ltd, Yoqneam, Israel, for the development of the colon capsule

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Received 17 December 2011; accepted 21 December 2011

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