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Alimentary Tract

Adverse events of computed tomography colonography: An Italian National Survey☆

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ABSTRACT

Aim: To retrospectively study the frequency and magnitude of complications associated with computed tomography (CT) colonography in clinical practice.
Methods: A questionnaire on complications of CT colonography was sent to Italian public radiology departments identified as practicing CT colonography with a reasonable level of training. The frequency of complications and possible risk factors were retrospectively determined. Responses were collated and row frequencies determined. A multivariate analysis of the factors causing adverse events was also performed.
Results: 40,121 examinations were performed in13 centers during the study period. No deaths were reported. Bowel perforations occurred in 0.02% (7 exams). All perforations were asymptomatic and occurred in patients undergoing manual insufflation. Five perforations (71%) occurred in procedures performed following a recent colonoscopy. There was no significant difference between perforations associated with rectal balloon (0.017%) and those that were not (0.02%). Complications related to vasovagal reaction (either with or without spasmolytic) occurred in 0.16% (63 exams). All vasovagal reactions resolved in less than 3 h, without any sequelae.
Conclusions: Perforation rate at CT colonography in Italy is comparable with elsewhere in the world, occurring regardless of the experience of radiology centers. Although the risk is very small, it may not be negligible when compared with the risk of diagnostic colonoscopy.

1. Introduction

Computed tomographic colonography (CTC) is increasingly used as a relatively non-invasive method of colonic investigation both for colorectal cancer (CRC) screening [1–3] and for patients with symptoms suggestive of CRC [4–7]. Data from large studies on screening cohorts have suggested that CTC and conventional colonoscopy have similar sensitivity for polyps ≥6-mm in diameter [8,9]. Moreover, patients generally prefer CTC instead of barium enema examination or colonoscopy [10–13]. However, concerns were raised about recommending CTC as routine screening tool because of potential harm [14,15]. While CTC is widely considered to be much safer than colonoscopy [16–18], it is not exempt from potential serious complications, mainly represented by large bowel perforations [18–22]. The National Survey of United Kingdom [18] has suggested a perforation rate, for diagnostic studies, of 1 in every 1889 examinations. Similarly, in a large population-based cohort, the incidence of perforations was 0.058%, or one in 1696 studies, with one in 2967 patients requiring surgical intervention [19]. These rates are higher than those reported by the International Working Group on Virtual Colonoscopy [20,21]. In this survey the total perforation rate for all patients was 0.009% (2 in 21,923 studies) and symptomatic perforation rate (requiring further treatment) was 0.0054% (1 in 21,923). Higher rates of adverse events (AEs) may be a sign of poor quality hospital care and many complications can be prevented if hospitals follow procedures based on the best practice and scientific evidence [20,21]. Ideally, for the standard best practice, continuing training should be required to

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radiologists or technologists performing CTC examinations at their institutions [19,23,24].

Thus, the purpose of this nationwide survey is to assess the frequency and the magnitude of complications associated with CTC in daily clinical practice at well-trained centers. This setting is of interest since previous studies have provided data from specialized centers [19,20] and it remains unknown whether results from these studies can be generalized.

2. Methods

A questionnaire about complications of CT colonography was sent to Italian public radiology departments identified as practicing CT colonography with a reasonable level of training. The frequency of complications of CT colonography and possible risk factors were retrospectively determined. Ethical approval and informed consent were waived, since this study was deemed a clinical audit and patients would not be approached. At the time of this survey, in Italy, there were 40 public Departments offering CTC in their everyday clinical practice with different levels of standard care and another unknown number of private centers, whose expertise is unknown [25]. A preliminary letter was mailed to the clinical directors of all public departments. The letter included a brief description of the study and the permission to collect anonymous data from the Institution. The respondent centers were re-contacted to establish eligibility. To be eligible, departments had to attend or organize at least 2 CTC courses recognized by the Italian Society of Radiology (SIRM). This criterion was applied to select centers attaining the goal of providing best practice. Although there were no rules to define principles of best practice, it was assumed that radiologists and technicians at qualified centers had to undergo training including continuing medical education accredited courses [23,25]. Thus, two approved training programs was the minimum requirement. Of the 24 (60%) respondents, 8 centers were excluded because they did not meet our inclusion criterion; three additional centers were also excluded because eligibility was never established despite multiple attempts. Between December 2010 and December 2012, an email was sent to the Lead Gastrointestinal Radiologist of each participant center asking to complete a detailed questionnaire (supplementary Table S1). The questionnaire included when the CTC service was started (year) and the total number of examinations performed at the time of the present survey. The radiologists were asked how many complications (e.g., colonic perforations and vasovagal effects) they had experienced in their institution. Additional questions were asked including the type of gas inflated (air or carbon dioxide – CO_2), the type of catheter used for inflation (rigid or flexible, with or without balloon), the use of spasmolytics (i.e. Hyoscine N-butylbromide 20 mg/ml, 1 ml injectable vials), the bowel preparation given to the patient (including diet, the use of laxatives and fecal tagging agents); complications were registered along with possible deaths. If a complication was recorded, additional details related to that event were asked. If a perforation occurred, the staff member performing the inflation (radiologist, resident, nurse or technician), the severity of the event, the perforation site (intra or retroperitoneal, determined on CT images by the distribution of gas in the abdomen) and the type of treatment (conservative or surgical) were recorded. Additional information on patient demographics including sex, age, comorbidities, previous surgical intervention and previous recently performed CC was also reported.

Patients included in the survey underwent CTC for both screening and diagnostic indications. All CTC procedures were acquired by using dual positioning (prone and supine scans) and a supervising radiologist or resident, that could promptly recognize the adverse event during CTC examination with real-time evaluation of images, was on call at each center.

Table 1
Characteristics of the included centres.

Center	CTC studies *n* (%)	Perforations *n* (%)	Vasovagal reactions n (%)
Center 1	1.030 (2.6)	1 (0.097)	3 (0.03)
Center 2	565 (1.5)	0 (0)	1 (0.18)
Center 3	1.190 (2.9)	0 (0)	3 (0.25)
Center 4	1.088 (2.7)	0 (0.09)	4 (0.37)
Center 5	1.267 (3.2)	1 (0.078)	11 (0.87)
Center 6	3.420 (8.5)	0 (0)	3 (0.09)
Center 7	500 (1.3)	0 (0)	3 (0.6)
Center 8	9.322 (23.2)	0 (0)	9 (0.096)
Center 9	6.029 (15.0)	2 (0.03)	11 (0.18)
Center 10	6.177 (15.4)	0 (0)	0 (0)
Center 11	5.034 (12.5)	0 (0)	4 (0.079)
Center 12	3.183 (7.9)	3 (0.09)	6 (0.188)
Center 13	1.316 (3.3)	0 (0)	5 (0.38)
Total	40.121 (100)	7 (0.017)	63 (0.16)

2.1. Statistical analysis

Descriptive analysis included the calculation of rates and proportions for count data. Univariate analysis was carried out with chi-square procedures. Multivariate analysis of the main predictors of complications was performed by using logistic regression model [26,27]. Because the unit of observation (patient) was different from the unit of analysis (center), a within-center correlation of outcomes was taken into account by means of a random-effect analysis with grouping by center [28]. Centers were also separated according to the hospital academic status (academic vs. non-academic center). The number of years of experience with performing CTC procedure was also calculated for each center. The effects of factors of interest (whether categorical or continuous) were evaluated by odds ratios (ORs), along with confidence intervals (CIs) as well as model-based Wald tests. All statistical analysis was performed by using software (R; the R Foundation, Vienna, Austria) [29,30]. *P*-values <0.05 were considered to indicate statistical significant.

3. Results

Thirteen centers were identified as eligible and included in the analysis. Of these, 6 (46%) were located in northern Italy, 5 (39%) in central Italy and 2 (15%) in southern Italy. Overall 6 (46%) centers were academic, 7 non-academic. During the evaluated period from 2000 to 2011, the mean number of CTC procedures performed annually by each center ranged from 83 to 847. By 2011, all centers had accumulated 4 or more years of experience with performing CTC procedure. Nine (69%) centers had 8 or more years of experience in CTC procedure, with more than 1000 CTC examinations per center performed (129–847 procedures per year). Two centers (15%) reported offering CTC service in 2005, having performed a total of 500 and 1088 examinations, respectively. The remaining 2 (15%) centers offered CTC service in 2006 and 2007 (263 and 141 mean procedures/year, respectively).

3.1. Examinations performed

In total, 40,121 CTC examinations were performed at the 13 participating centers between 2000 and 2011 (mean number of exams 3086 ± 2773; range, 500–9322). Table 1 reports the distribution of CTC exams per center. The six academic centers contributed 28,752 patients to the total 40,121 (72%).