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ABDOMINAL RADIOLOGY

The Italian consensus to virtual colonoscopy

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Abstract
Objectives To produce an informed consent for CT colonography (CTC), to be diffused by the Italian Society of Radiology, aimed to make patients and referring physicians aware of CTC examination protocol, advantages and disadvantages, limits and potential related risks.
Materials and methods Delphi method was used to create a consensus among experts on an informed consent for CTC. The overall agreement among different consulted specialists was evaluated and ranked using the Cronbach's correlation coefficient (α) at two time points: after the first and the second 'round' of consultation.
Results The Cronbach index was 0.84 at the end of the first round and 0.93 at the end of the second round. The number of disagreements dropped from an overall of 11–5, from the first to the second round.
Conclusions The experts were able to produce an informed consent for CTC, hoping that this may be the beginning of a process focused on implementation of quality standards in CTC.

Keywords Informed consent · Colonography · Computed tomography · Virtual colonoscopy

On behalf of SIRM, Section of Gastrointestinal and Abdominal Radiology.

The list of contributors and their affiliations are given in "Appendix".

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Introduction

CT colonography (CTC) or virtual colonoscopy is a radiological technique for colon evaluation, with inherent peculiarities: minimal invasiveness [1, 2], good patient compliance [3] and high sensitivity in detecting clinically significant mucosal lesions [4–7].

Technical standardization of the examination protocol [8] and the diffusion of the technology essential to its execution (Multidetector CT ≥16 rows and dedicated software for image analysis) will allow a further diffusion of CTC, particularly in peripheral centers. Thanks to the recent publication of ESGE (European Society of Gastrointestinal Endoscopy)–ESGAR (European Society of Gastrointestinal and Abdominal Radiology) guidelines on indications for CTC [9]; a further increase in patient referrals from gastroenterologists will be expected.

The first consequence of an increased number of examinations will be the risk of a reduced quality of CTC and a downturn in accuracy.

To guarantee quality control, avoiding inhomogeneities or technical improperness [10], the Section of Gastrointestinal and Abdominal Radiology of the Italian Society of Radiology decided to constitute a working group dedicated to develop and codify the standards of quality in CTC.

The first activity of this group was dedicated to the production of a common informed consent, shared by different Italian researchers active in CTC.

The purpose of this work was to realize an informed consent to be diffused by the Italian Society of Radiology, aimed to make patients and referring physicians aware of CTC examination protocol, advantages and disadvantages, limits and potential related risks.

Materials and methods

A group of four members (EB, NF, FI, GJ) of the Gastrointestinal and Abdominal Section of the Italian Society of Radiology, supervised by the President of the Section and three expert members on CTC (AL, EN, DR), worked together using a modified Delphi method [11] aimed to write a model of informed consent. A member of this group (EB) chosen as a facilitator was charged with writing a first model of informed consent, merging the informed consents used in other Italian and foreign centers of references for CTC [Pisa University, La Sapienza University of Rome, Institute for Cancer Research of Candiolo (Turin), S.Paolo Hospital, Milan, and the King's College in London].

That text is gathering complete and quick information, written in an easy Italian form, understandable to any potential patient. This text, at a later stage, was sent to a mailing list of twelve specialists in CTC, including seven radiologists external to the original group. The choice of these specialists was made on the basis of essential categories: (1) curriculum vitae, (2) daily activity in centers where a minimum of 400 CTCs/year are performed, (3) the candidate must have participated to Italian Courses of CTC, (4) he must have participated in publications with impact factor, in the last 24 months, having a main focus on CTC.

An evaluation of each paragraph of the consensus text has been requested to all elected specialist, and they were requested to express their agreement or disagreement or partial agreement, choosing one of the given options. In this first phase, every specialist also had the option to give a 'free' answer: allowing the participant to give us some suggestions, with personal impressions.

After this first 'round' of consultation, all points of agreement or disagreements were gathered and evaluated. The suggestions, sent by mail, were integrated respectively in each paragraph.

In a second step, after a meeting between experts in the group, the facilitator and the President of the Study Section, any statement marked 'completely disagree' was modified and re-built in a new digital questionnaire.

Four months following the previous consultation, this new form of the consensus was sent to the same researchers, for a second consultation. This procedure was done in a similar way to the previous one. The only exception was forbidding any modification of the statements, asking the participants only to express their agreement or disagreement to the statements.

Statistical process of data

We evaluated the overall agreement, concerning every voted paragraph, among different consulted specialists. This analysis was ranked evaluating the Cronbach's correlation coefficient (α) [12] at two time points: after the first and a second 'round' of consultation. No threshold value was defined a priori. Statistical software (SPSS, 15.0 Statistics, Chicago, USA) was used for the entire analyses.

Results

The Cronbach index, calculated among the interviewed physicians on the basis of the degree of their agreement about different paragraphs of the consensus, was 0.84 at the end of the first consultation or 'round'. A definitive version of the informed consensus (Fig. 1) was formulated at the end of the second round reporting a Cronbach index of 0.93 (Table 1). The number of disagreements dropped from an overall of 11–5, from the first to the second round.

Table 2 reports the results at the end of the first round and shows the precise indication of agreement/disagreement observed in any statement proposed.

The statements that were modified are those evaluated either with 'I don't agree' from almost two interviewed experts, or 'I completely disagree', even by a single expert. Table 3 reports results at the end of the "second round".

In the paragraph "preparation to the examination and modalities of technique", all methods of intestinal cleansing and fecal tagging, available for patients, were listed, because the preference for a specific method depends on the reference center. It is important to consider the exclusion of every single patient, if potentially allergic to iodine. The use of either 'room air' or CO_2 for colon distention is considered, since not all centers are equivalent from this point of view.

The paragraph 'Indications to the virtual colonoscopy' was modified according to the introduction of the concept

THE ITALIAN INFORMED CONSENT TO VIRTUAL COLONOSCOPY

On behalf of the Section of Gastrointestinal and Abdominal Radiology of the Italian Society of Radiology

Patient's Data
Family Name: ……..……
First Name: ……...
Date of Birth: _____/_____/_____

Space customizable by radiological centre

CT COLONOGRAPHY (CTC) or VIRTUAL COLONOSCOPY

What is CT colonography

CT Colonography (CTC), also known as Virtual Colonoscopy, is a radiological examination studying the colon and aiming to detect colonic cancers and polyps.

CTC is performed with a multi-detector CT scan (MDCT) using an extremely low dose of ionizing radiation (X-rays).

Preliminary information

Both General Physicians and GI Specialists can request CTC. Radiologists who justify and perform the examination have to be informed about your clinical history, previous colonic examination (e.g. conventional colonoscopy, double contrast barium enema), surgical records and pharmacological therapy.

Radiation from CT scan may be harmful to an unborn child and all females must sign a form to exclude pregnancy.

Bowel preparation

Before the examination you must follow a specific diet and bowel preparation (laxatives or oral contrast agents), according to the suggestions of your referring radiological centre. The day before the examination, or the day of the examination, a iodinated contrast agent, administered either orally or rectally, will be used to mark faecal residues inside your colon. If you are allergic to iodinate contrast agents, their use should be avoided.

If you are taking oral drugs (e.g. for hypertension or diabetes), you are allowed to continue your therapy also on the day of the exam.

During the Procedure

You are lying on the CT table. The nurse or doctor introduces a thin and flexible rubber tube into the rectum to allow the distension of the colon with air or carbon dioxide. Colon distension is generally well tolerated. You may feel a mild abdominal distension, rarely painful; in some cases (at the discretion of the radiologist) a drug (Buscopan), which relaxes the intestinal muscles reducing pain, can be used.

The examination is performed in supine and prone position and lasts 15 to 20 minutes.

After the procedure you can safely return to your daily activities.

After the exam, you can feel a sensation of bloating, which generally decreases and disappears in the next half hour. If the pain lasts longer than two hours after the exam, or if you notice blood in the stool, you should contact the radiology center where you performed the exam or your family doctor or go to the nearest emergency room with clinical documentation in your possession.

Fig. 1 Final version of the informed consensus for CT colonography

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Benefits of CT Colonography

CTC Colonoscopy allows to:

- detect more than 90% of polyps larger than 1 cm, the significative polyps with the highest risk of malignant transformation.
- detect a malignant tumor at an early stage in asymptomatic patients, anticipating treatment.
- complete the study of the entire colon in patients with incomplete conventional colonoscopy.
- detect and make a balance of diverticular disease

Risks of CT Colonography

CTC is safe. Very rarely, bowel perforation can occur, but usually it does not require surgery. The risk of bowel perforation is greater in people affected by acute diverticular disease or affected by inflammatory chronic bowel disease: in these cases CTC is not indicated.

Rarely, vaso-vagal reactions due to colonic overdistension have been reported. Symptoms of vagal reaction are feeling of faintness, sweating, nausea.

The probability of allergic reactions to oral iodinated contrast medium is very low; the radiologist should be informed in case of known hypersensitivity to iodinated contrast media.

Biological damage related to radiation dose in CTC for adult should be considered null.

Limits of CTC

CTC is less sensitive than conventional colonoscopy for the detection of small polyps (less than 6 mm), that have very low probability of malignant transformation, and of rare flat lesions, difficult to identify also for the other examinations.

Low dose of radiation reduces the visibility of extra-colonic lesions.

When polyps are identified, it is necessary to explore the colon with conventional colonoscopy in order to remove them. The detection of any disease requires an appropriate management.

References

-Pickhardt PJ. Incidence of colonic perforation at CT colonography: review of existing data and implications for screening of asymptomatic adults. Radiology 2006 May; 239(2):313–6
-Iafrate F, Iussich G, et al. Adverse events of computed tomography colonography: An Italian National Survey. Dig Liver Dis. 2013 Aug; 45(8):645-50
-Pendsé DA, Taylor SA. Complications of CT colonography: A Review. Eur J Radiol. 2013 Aug; 82(8):1159-65

I certify this form has been fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in and I understand its contents

THIS IS A LEGAL CONSENT FORM.
PLEASE READ IT CAREFULLY AND BE SURE YOUR QUESTIONS
HAVE BEEN ANSWERED BEFORE SIGNING

Date: _____ Time: _____ a.m. / p.m.

_____ _____
Witness to Signing Signature of Patient or Legal Representative

_____
Relationship to Patient

Options, risks and benefits of procedure discussed and accepted by Patient: _____
Date Time

_____
Physician Signature

Fig. 1 continued

Table 1 Mean scores of agreement obtained from the first and second round of consultation are reported for each paragraph

Consensus paragraphs	First round		Second round	
	Mean score	Cronbach's index	Mean score	Cronbach's index
Virtual colonoscopy definition	3.6	0.84	3.8	0.93
Indications	3.5		3.9	
Preparation	3.2		3.9	
Examination's technique	3.5		3.7	
Advantages	3.6		3.6	
Risks	3.4		3.5	
Limits	3.2		3.6	

Cronbach indices for each round are also reported

Table 2 Judgements of experts for each paragraph in the first round are reported

	Definition	Indications: who may undergo to virtual colonoscopy	Preparation and technique of examination	The advantages of CTC	The risks of CTC	Limits
Completely agreed	8	6	8	8	7	7
Agreed	3	3	3	2	3	1
Didn't agree	1	2	0	2	2	4
Completely disagreed	0	1	1	0	0	0

Table 3 Judgements of experts for each paragraph in the second round are reported

	Definition	Indications: who may undergo to virtual colonoscopy	Preparation and technique of examination	The advantages of CTC	The risks of CTC	Limits
Completely agreed	8	7	5	7	8	8
Agreed	3	5	6	4	3	3
Didn't agree	1	0	1	1	1	1
Completely disagreed	0	0	0	0	0	0

that a physician who prescribes this procedure is required: the term of 'physician who prescribes' means a physician who decides the procedure is necessary, and we added that he may even be a specialist (a gastroenterologist or similar).

In the paragraph 'the benefit of virtual colonoscopy', an extensive modification of the language was needed to achieve an immediate understanding of the concepts by a reader unfamiliar with medical terminology. As an example, the term 'neoplastic transformation' was modified into 'if it becomes a tumor'.

We added a separate paragraph to manage the quick description of 'The limits of CTC' to help the patient (and the referring physician) in easily detecting CTC limits during the discussion of the informed consent. In this paragraph, in particular, we addressed the issues of low X-ray dose and detection of extracolonic lesions and the potential underestimation of 'flat lesions'.

The paragraph 'the risks of CTC' was focused, apart from risk of colon perforation, on vasovagal reactions.

The final part of the questionnaire, the same in all versions of the informed consent, is required to guarantee the validity of the consensus, because it is mandatory that patient freely chooses to give his permission to the examination. Signatures requested at the bottom of the document must be legible.

Discussion

The expert group produced an informed consent model for CTC, with an overall agreement of 93 %.

The purpose of writing this consensus was to guarantee maintenance of an acceptable level of technical quality in every center where CTC examination will be performed. To obtain this result, the informed consent to CTC gathered more specialists, working in writing and discussing the text, showing that the standardization process is possible, realizing a document shared and accepted following different integrated opinions.

The role of the facilitator and that of the consulted specialists, all members of the Section of Abdominal and Gastrointestinal Radiology of the SIRM, allowed modifying the paragraphs more critically.

The agreement degree was maximum for paragraphs of 'preparation' and 'technique of the examination' presumably because the literature favors the sharing of preparation and technical protocols among virtual colonoscopists. Radiologists show maximal observance of prescription and they agree with rules and modalities of examination, where the literature is clear, showing maximal clearness and unity of judgement.

Some minor criticisms were explained on the basis of the excessive brevity of the text: in some experts' opinion, this conciseness prevents a correct discussion and description of benefits, risks and limits of the CTC. Nevertheless, the reduction of the text was essential to make use of the consensus content for all the patients and involved physicians easier and understandable.

The need of a partial autonomy for every center, which uses the consensus, was respected. In relationship to the intestinal preparation modality and the use of fecal tagging, the text allows some options but the choice is free among them.

To optimize the understanding of the Italian text, we followed the indications of the literature [13] to improve the simplicity of the Italian text: we used a layout from the left side of the page, simple sentences, briefs, without technical words. We substituted expressions as 'neoplastic proliferation' with an easier 'growing of the tumor', or in simple description of the feeling along the intestinal distension, we used more known terms ("abdominal distension" in substitution of "abdominal bloating").

On the same A4 format, we arranged the first part of the text, regarding 'information to virtual colonoscopy for the patient' and the second part, more properly regarding the 'consent'. On the second page, the last part, the agreement or disagreement is traced ("I give my consent" or "I don't give my consent").

In conclusion, the group of experts was able to produce an informed consent for CTC, hoping that this may be the beginning of the proliferation of similar initiatives, focused on quality assurance in CTC procedures.

Conflict of interest The authors declare that they have no conflict of interest.

Ethical standards This article does not contain any studies with human participants or animals performed by any of the authors.

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References

1. Pendse DA, Taylor SA (2013) Complications of CT colonography: a review. Eur J Radiol 82:1159–1165
2. Neri E, Faggioni L, Cerri F, Turini F, Angeli S, Cini L et al (2010) CT colonography versus double-contrast barium enema for screening of colorectal cancer: comparison of radiation burden. Abdom Imaging 35:596–601
3. Moawad FJ, Maydonovitch CL, Cullen PA, Barlow DS, Jenson DW, Cash BD (2010) CT colonography may improve colorectal cancer screening compliance. Am J Roentgenol 195:1118–1123
4. Johnson CD, Chen MH, Toledano AY, Heiken JP, Dachman A, Kuo MD et al (2008) Accuracy of CT colonography for detection of large adenomas and cancers. N Engl J Med 359:1207–1217
5. Kim DH, Pickhardt PJ, Taylor AJ, Leung WK, Winter TC, Hinshaw JL et al (2007) CT colonography versus colonoscopy for the detection of advanced neoplasia. N Engl J Med 357:1403–1412
6. Pickhardt PJ, Choi JR, Hwang I, Butler JA, Puckett ML, Hildebrandt HA et al (2003) Computed tomographic virtual colonoscopy to screen for colorectal neoplasia in asymptomatic adults. N Engl J Med 349:2191–2200
7. Ianora AAS, Moschetta M, Pedote P, Scardapane A, Angelelli G (2012) Preoperative local staging of colosigmoideal cancer: air versus water multidetector-row CT colonography. Radiol Med 117:254–267
8. Neri E, Halligan S, Hellström M, Lefere P, Mang T, Regge D et al (2013) The second ESGAR consensus statement on CT colonography. Eur Radiol 23:720–729
9. Spada C, Stoker J, Alarcon O, Barbaro F, Bellini D, Bretthauer M et al (2015) Clinical indications for computed tomographic colonography: European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Guideline. Eur Radiol 25:331–345
10. Colagrande S, Origgi D, Zatelli G, Giovagnoni A, Salerno S (2014) CT exposure in adult and paediatric patients: a review of the mechanisms of damage, relative dose and consequent possible risks. Radiol Med 119:803–810
11. Graham B, Regehr G, Wright JG (2003) Delphi as a method to establish consensus for diagnostic criteria. J Clin Epidemiol 56:1150–1156
12. Cronbach LJ (1946) A case study of the split-half reliability coefficient. J Educ Psychol 37:473–480
13. Kim S, Jabori S, O'Connell J, Freeman S, Fung CC, Ekram S et al (2013) Research methodologies in informed consent studies involving surgical and invasive procedures: time to re-examine? Patient Educ Couns 93:559–566