

French National Colon Capsule Endoscopy Observatory (ONECC)

Evaluation and first lessons

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On behalf of the *comité scientifique de l'Observatoire national de l'endoscopie par capsule colique (ONECC)* : Robert Benamouzig, Antoine De Leusse, Edouard Chabrun, Christophe Cellier (France).

“ Diagnostic endoscopy by colon capsule endoscopy is now capable of detecting significant colorectal neoplastic lesions (> 6 mm) with a sensitivity of around 90%. One very specific organization in France, the ONECC, has promoted the training of hundreds of gastroenterologists, the routine use of the capsule in 145 active centers, and the inclusion of 1,200 patients in a prospective cohort. Although the scientific potential of this observatory is still far from fully exploited, the development of colon capsule endoscopy in France is a model of efficiency and rigor. The potential of this observatory in terms of research and analysis of current practices is substantial. The rapidity of case inclusions and the practical feasibility clearly show that there is a role in clinical practice for this diagnostic tool. The place of colon capsule endoscopy in the colorectal cancer screening arsenal remains to be defined. However its use in indications which are currently those for virtual colonoscopy is now unquestionable, due to its simplicity, safety, absence of irradiation, and sensitivity, in comparison with other modalities.”

French National Colon Capsule Endoscopy Observatory: history and rationale

The French National Colon Capsule Endoscopy Observatory (“*Observatoire national de l’endoscopie par capsule colique*”, ONECC) was conceived and established in 2011 as a monitoring center equipped with an e-CRF (electronic case report form) platform, jointly managed by the French Society of Digestive Endoscopy (“*Société française d’endoscopie digestive*”, SFED), the Gastroenterological Groups Reflection Team (“*Club de réflexion des cabinets et groupes d’hépto-gastroentérologie*”, CREGG), and the firm, Given Imaging. The reasons justifying the establishment of this monitoring center were:

- the commercialization of Pillcam Colon 2® in France, authorized by the CE (European conformity) mark (September 2009);
- reliable scientific data regarding the good sensitivity of the second-generation colon capsule for the detection of polyps of a significant size (> 5 mm) [1,2];
- substantial pre-existing experience of the use of colon capsule endoscopy in France, through the implementation of prospective, multicenter national studies for indications of colorectal cancer screening, as well as for the indications endorsed by the ONECC [3,4];
- the need to regulate the use of this new device in current practice, to define the indications and standardized modalities for use.

The ONECC was structured into a Steering Committee, responsible for the overall organization and management of the monitoring center, and a Scientific Committee comprising individuals recognized as experts (through experience and publications) in the field and who are, to a large extent, representatives of SFED. The organization respects the rule, at the Steering Committee level, of an equal representation of the public and private sectors. The ONECC, and in particular its Scientific Committee, works closely with the SFED “Capsule Committee”, especially in the development of colon capsule training modules.

Indications for colonoscopy by video capsule endoscopy endorsed by the ONECC Scientific Committee

Several medical conditions endorsed by the SFED, which correspond to valid indications for virtual colonoscopy as recommended by the

French National Authority for Health (“Haute autorité de santé”, HAS), may be within the scope of a colon video capsule examination:

1. incomplete optical colonoscopy, not related to the presence of an organic colorectal stenosis or a poor preparation (except in cases of poor compliance of the preparation protocol by the patient);
2. severe comorbidities, contraindicating the performance of an optical colonoscopy, in particular where there are risks and contraindications related to anesthesia;
3. refusal of the optical colonoscopy examination by the patient after receiving information regarding the risks of not performing optical colonoscopy and the current limitations of colon capsule endoscopy (CCE).

Activity of the ONECC

Training

Around 20 ONECC training courses have been carried out, each involving 20 to 30 gastroenterologists, with over 500 practitioners trained in the use of CCE (principles, implementation, preparation, reading, interpretation). In France, 145 centers are currently active in this procedure, each with at least one trained gastroenterologist. This includes an equal representation in public and private centers.

Training in the use of colon capsule endoscopy has been evaluated in part, and this has resulted in a conference communication emphasizing the importance of training dedicated specifically to the use of CCE. This CCE training should be clearly distinct from training and evaluation of competence in capsule endoscopy in general [5]. These courses are expected to evolve towards a quantified assessment of the practices using software developed for training in the use of CCE. This CCE practice may be incorporated into the ongoing professional development program of gastroenterologists. The practical skills that will be assessed and that will be taught to the current state of the art are: quality of detection of adenomas and other polyps; specificity of this detection; evaluation of the bowel preparation. The teaching program also includes the modalities of the procedure, the principles of the ONECC charter, and, finally, an update on scientific knowledge concerning CCE.

Practice of colon capsule endoscopy

As of June 1st 2014, 1,250 CCE examinations had been carried out under the framework of the ONECC in France, in 145 active centers including practitioners who have signed the ONECC partnership agreement [6]. The rate of inclusion (*figure 1*) clearly highlights the practical value and role of the examination in the diagnostic arsenal of the gastroenterologist.

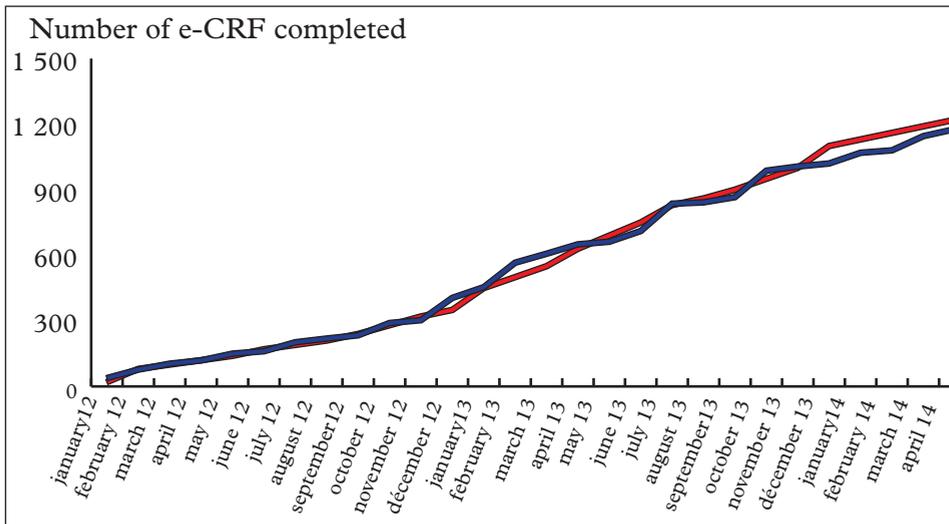


Figure 1. ONECC inclusion curve in France (actual in blue, theoretical in red).

The indications for these examinations have been perfectly respected and are divided in almost equal parts between the three recommended indications. One single examination was performed outside of these indications, in a heart-transplant patient after the approval of the Scientific Committee of ONECC was obtained, as specified in the ONECC regulations. Technically, relatively few problems have been reported, confirming the feasibility of use of this examination in everyday practice, under the right conditions. Finally, bowel preparation was estimated as good (data not verified by a second reading) in 80% of examinations (excellent or good on a scale of 4). Impressively, relatively few second opinions regarding the images obtained from the capsule have been requested from the Scientific Committee (in contrast to the multitude of requests relating to current use of the small bowel capsule). One possible explanation for this is the relative simplicity of

interpretation of these images by practitioners who are experienced in the analysis of colorectal images, in addition to the relative similarity of capsule images with colonoscopic images.

Evaluation of colon capsule endoscopy practice

The ONECC observatory is not closed in terms of inclusions, thus the collection of results relating to diagnostic performance is partial. These results will be the subject of a scientific publication. As of December 31st 2013, examination by video capsule from the colon to the anus had been complete in 829 patients, allowing the detection of polyps larger than 5 mm in 16–25% of patients for whom the use of colon capsule endoscopy had been justified (failure of, contraindication to, or refusal of, colonoscopy) (*figure 2*). The capsule is thus useful in practice, detecting lesions of a significant size in around 20% of patients (and at least one polyp in 38% of patients)..

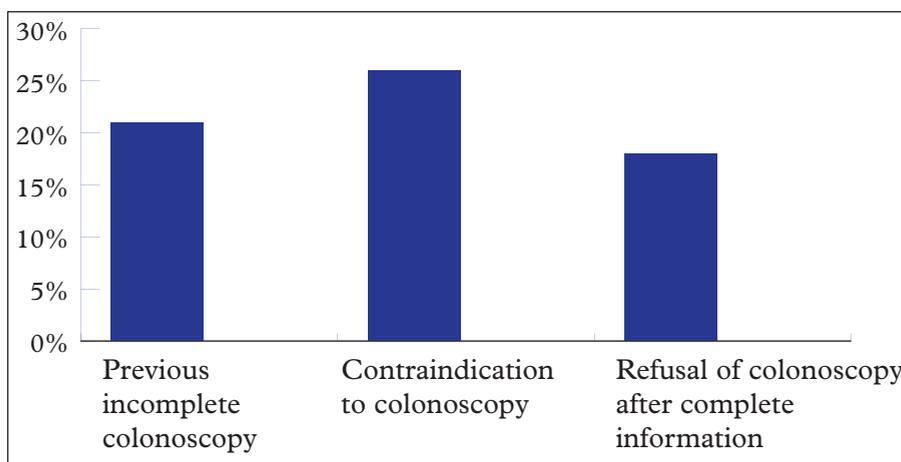


Figure 2. Prevalence of significant colorectal polyps (> 5 mm diameter) according to the ONECC indications for colon capsule endoscopy.

Concerning the analysis of practice, it is interesting to note that 23% of examinations, despite showing no significant polyp (> 6 mm) nevertheless led the gastroenterologist to perform a colonoscopy. The analysis of these 45 cases was carried out using data from the e-CRF. This indicates that the principal practical problem encountered is the question of how to proceed in cases where small polyps are present (43/45 cases, 95.5%). Gastroentero-

logists tend to privilege the option of colonoscopy, even for small colorectal lesions. The results of these colonoscopies are still pending, and the important goal of the ONECC is (as soon as possible) to be able to complete this data collection.

Perspectives

The aims of the ONECC in 2015 are as follows:

- complete the data collection, in particular data regarding colonoscopies, lesions detected, lesions treated, and histological results. These tasks will require time and effort and are currently being organized;
- continue clinical activity, which appears to be important and useful in light of the rapid constitution of the cohort, both in the public and private sectors;
- develop collaborative research projects based on existing centers of expertise (cancer screening, bowel preparation, comparison with virtual colonoscopy, new indications) and the IT network already in place, probably with an upgrade of the e-CRF;
- optimize and evaluate training and competence in CCE.

Conflicts of interest

Jean-Christophe Saurin is a speaker and consultant for: Covidien (GI Solutions) Given Imaging, Intromedic, and Caspovision.

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