arTs Università degli Studi di Trieste
Archivio della ricerca – postprint

Adherence to European Society of Gastrointestinal Endoscopy recommendations of endoscopists performing small bowel capsule endoscopy in Italy

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A B S T R A C T

Background: The European Society of Gastrointestinal Endoscopy (ESGE) has recently issued a technical review focused on small bowel capsule endoscopy (SBCE).
Aim: To compare SBCE current practice in Italy to ESGE technical recommendations.
Material and methods: A dedicated per-centre semi-quantitative questionnaire was prepared by a group of SBCE experts. One-hundred-fifty Centres were invited to participate in the data collection concerning SBCEs performed between June 2016 and June 2017. Data were compared with ESGE recommendations.
Results: 120 Centres participated in the data collection. Current practices agreed with ESGE recommendations in 56.3% (9/16) of the issues evaluated. Differences between ESGE recommendations and current practice concerned the management of patients with pacemakers or cardiac implantable defibrillators (which was in agreement with ESGE recommendations in 31.7% and 15.8% of Centres, respectively), the SBCE setting (only 51% of SBCEs were performed as outpatients procedures), the assessment of capsule excretion (timing and modality were in agreement with ESGE recommendation in 20.0% of Centres), and in the involvement of trained nurses or fellows in training as pre-readers (7/120; 5.8%).
Conclusions: Although SBCE is widely used and largely available in Italy, there are still some technical, practical and organizational issues that can be modified to bridge the gap between current practice and ESGE guideline recommendations.

1. Background

Small bowel capsule endoscopy (SBCE) was introduced in clinical practice in Western countries in 2001. An important amount of scientific evidence has been accumulating over the last 17 years, establishing the key role of this examination in many clinical con-

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ditions, such as suspected small bowel bleeding, inflammatory bowel diseases and intestinal polyposis syndromes. Hence, numerous clinical guidelines, addressing the role of SBCE in diagnosis and treatment of small bowel disorders, have been issued and updated over time [1–4].

Nevertheless, technical issues (e.g. preparation schedule, swallowing procedure, reading and reporting protocols, etc.) have been only partially addressed by practical guidelines, although several papers clearly demonstrated their relevant impact on the SBCE diagnostic yield. Therefore, the different Centres dealing with SBCE in clinical practice have developed their own operative protocols concerning pre-exam preparation, SBCE procedure, video reading and reporting, etc. These protocols are generally based on the available scientific evidence; however, they can be significantly affected by the local Centre's features and by practical, organizational and economic models. In April 2018 the European Society of Gastrointestinal Endoscopy (ESGE) issued a comprehensive evidence-based Technical Review [5]. This review addresses practical, organizational and technical issues, providing specific recommendations on how to manage patients undergoing SBCE in everyday practice to maximize the diagnostic yield.

The aim of the present study is to map how SBCE was routinely performed in Italy before the release of technical ESGE guidelines, to identify the main differences between everyday practice and ESGE recommendations.

2. Material and methods

In June 2017, a group of 13 Italian SBCE experts (each of them had evaluated more than 500 SBCEs and participated in multicentre studies on capsule endoscopy) developed a dedicated 41-items questionnaire. It was a per-centre semi-quantitative multiple-choice questionnaire: no data on single patient were collected, and when quantitative or numerical variables were concerned intervals or ranges were requested (the questionnaire is reported in Appendix 1).

The questionnaire had two sections. "Section A" (18 items), was focused on Centre features (e.g. location, number of physicians performing SBCE, number of SBCE performed per year, complication rate, availability of patency capsule, reimbursement policy, etc.). We collected data about Centre location and Centre features, because the Italian Health system has some peculiarities: healthcare is provided to all citizens and residents by a mixed public-private system. The public part is the National Health Service (Servizio Sanitario Nazionale, SSN), which is organized under the Ministry of Health, and is administered on a regional basis. Visits by specialists or outpatient diagnostic tests, such as capsule endoscopy, are provided by the public hospitals or by private ones part of the state-run health care and, when prescribed by the family doctor, require only a copay. Only those procedures included in a dedicated regional "reimbursed outpatient procedure list" are reimbursed. The amount of money reimbursed for these procedures differs from region to region; Table 1 shows the reimbursement for SBCE in the 10 Regions in which it was available at time of data collection. Patients, however, can opt for the "free market" services, provided by both public and private hospitals, which is paid by the patient himself out-of-pocket. Questionnaire "Section B" (23 items), collected data on SBCE technical, organizational and practical protocols. In the latter Section, the following domains were explored: preparation protocols/schedules (e.g. timing and volume of administered laxatives, use of prokinetics or anti-foam agents), management of patients with cardiac pacemaker (PM) and/or implantable cardiac defibrillators (ICD), SBCE setting (e.g. inpatient, outpatient), ingestion and post-ingestion patient management (e.g. use of mobile phones, liquids and food ingestion), capsule excretion assessment (timing and modality), reading protocols (i.e. frame rate, use of automated fast reading softwares, availability of pre-readers) and use of patency capsule. A practical policy/protocol was conventionally considered as Centre's routine practice when applied in more than 80% of SBCE examinations; the routine practice was deemed in line with ESGE technical recommendations if applied in more than 75% of Centres.

Table 1
Reimbursement for small bowel capsule endoscopy (SBCE) performed as outpatient procedure at time of data collection.

Administrative Region	SBCE reimbursement (€)
Basilicata	1100
Emilia Romagna	850
Friuli Venezia Giulia	345
Lombardia	850
Marche	1320
Piemonte	1100
Trentino-Alto Adige	1120
Umbria	850
Valle d'Aosta	1320
Veneto	833

In July 2017, Medtronic Italia (Medtronic Italia S.p.A., Milano, Italy) uploaded the questionnaire on a web-based platform (www.surveymonkey.com; https://it.research.net/r/PraticaClinicaVCE_06-2016_06-2017); 150 Centres performing SBCE in Italy were invited by email to fill the questionnaire, in August 2017. The questionnaire was available on the website for three and a half months. During this time frame, automatic reminder e-mails were sent monthly to all invited Centres. Only Centres answering more than 90% of questions in each section were included in the data analysis. Both questionnaire Sections were fully anonimized: it was not possible to identify the Centre filling the questionnaire, either for those who sent the invitation or for those who analysed the data. In order to prevent data duplication, a strong disclaimer was included in the invitation e-mail, asking the recipient to provide only one answer dataset per-Centre. In addition, the structural data (i.e. type of Centre, number of SBCE reviewers, mean number of examinations performed etc.) reported in the "Section A" was matched, on a regional basis, to reduce the risk of multiple entries from the same Centre. In case of suspected duplication, only the most recent dataset uploaded was included in the analysis. The data were collected, reviewed and analysed only by the experts who generated the questionnaire and hold the exclusive intellectual property of data. In order to collect reliable data and to map the existing situation in Italy before the publication of ESGE technical recommendations (April 2018), the Centres were asked to answer questions taking into account only SBCEs performed in a definite timeframe (June 1st, 2016–June 1st, 2017). The results were presented and discussed in January 2018, during the "RAVE" (Riunione Annuale Videocapsula Endoscopica), a capsule endoscopy dedicated meeting, to which at least one of the representatives of the Centres that contributed to data collection had been invited.

Frequencies and percentages were used to summarize categorical variables, whereas quantitative variables were summarized using means and standard deviation (SD) or median and interquartile range (IQR), as appropriate. The descriptive statistic analysis was carried out with Excel software (Office package V.2016; Microsoft® Co., Redmonton, Washington, USA).

3. Results

3.1. Questionnaire "Section A": centre's features

One hundred and fifty Centres across Italy (at least one from each of the 20 Administrative Regions) were invited to participate

Fig. 1. Italy Administrative Regions map. Numbers refer to Centres participating in the data collection per each Region. Administrative Regions in which SBCE was not reimbursed at time of data collection are highlighted in black.

in the data collection; 25 of them did not agree to participate, while 5 Centres answered less than 90% of the questions. Therefore, 120 (80%) Centres were included in the analysis. They were located in 18 different regions (18/20; 90.0%); the median participation rate per Region was 83% (IQR: 36%; range: 33–100%). At time of data collection, SBCE was reimbursed in 11 Administrative Regions (11/20; 55.0%) (Fig. 1) and in 84 Centres (70%) participating in the data collection. Patency capsule was available in 77 Centres (64.1%) and it was not reimbursed in any of them. In 10 Centres SBCE was an open-access procedure, whereas in 110 Centres (91.6%) patients referred for SBCE were first evaluated by a SBCE-dedicated gastroenterologist at the Centre performing capsule endoscopy.

Thirty Centres included in the analysis were University or Research Hospitals (30/120; 25%), 81 were Public Hospitals (81/120; 67.5%), 9 (9/120; 7.5%) were Private Hospitals part of the state-run health care (in which SBCE is performed with rules similar to those of public hospitals), whereas no Private Hospitals outside the state-run health care participated in the present data collection. Most Centres (117/120: 97.5%) performed the majority of SBCE examinations in adult patients, whereas 3 Centres were paediatric Hospitals. These 120 Centres were equipped with 136 SBCE platforms overall: 103 from Medtronic, (Medtronic Italia S.p.A., Milano, Italy), 16 from Intromedic (Intromedic Co., Ltd., Seul, Korea), 8 from OMOM (Jinshan Science and Technology Company, Chongqing, China), 5 from Capsovision (Capso-Vision, Saratoga, California, USA) and 4 from Olympus (Olympus Co., Shinjuku, Tokyo, Japan). At time of data collection, 94 Centres (94/118: 79.6%) had been performing capsule endoscopy for over 5 years. The median number of capsule endoscopy readers in each Centre was 2 (IQR: 2; range 1–7) and 73.3% of readers had evaluated more than 100 CE examinations.

Between June 2016 and June 2017, 6024 CE examinations were performed in the 120 Centres (median SBCEs per centre 40; IQR: 41.2; range 4–420) participating in the data collection. Suspected small bowel bleeding was the main clinical indication (it accounted for over 70% of all capsule endoscopy examinations) in 71.2% of Centres. SBCE was performed within 72 h in a minority of patients with suspected small bowel ongoing overt bleeding (detailed data are reported in Table 2). The mean retention rate, regardless the clinical indication for SBCE, was 0.85% (+SD: 2.7%), whereas the mean retention rate in the subset of patients with suspected small bowel bleeding was 0.57% (+SD: 1.87).

Table 2
Rate of small bowel capsule endoscopies (SBCEs) performed within 72 h in patients with suspected small bowel ongoing overt bleeding.

Rate of SBCEs performed within 72 h in patients with suspected small bowel ongoing overt bleeding	Number of Centres
<5%	24 (20.0%)
5–10%	35 (29.3%)
11–30%	16 (13.3%)
31–50%	14 (11.7%)
51–70%	16 (13.3%)
71–90%	11 (9.1%)
>90%	4 (3.3%)

3.2. *Questionnaire "Section B": procedural protocols*

All 120 participating Centres answered all 23 questions of Section B. Sixteen questions (see Appendix 1, questions 1–10, 14, 18–22) described practical protocols which were addressed in the ESGE recommendations. Nine of these (9/16; 56.3%) (Appendix 1, questions 1–3, 8, 9, 14, 19, 20, 22) were in agreement with the ESGE recommendations. Conversely, major discrepancies between the practice protocols and the ESGE recommendations were observed for 7 (7/16; 43.7%) questions (Appendix 1, questions 4–7, 10, 18, 21). The discrepancies concerned the following issues:

- Administration of antifoaming agents: 93 participating centres (77.5%) did not administer antifoaming agents systematically at the time of SBCE;
- Management of patients with PM: these patients routinely underwent SBCE without any special precautions in 38 Centres (31.7%), whereas they received telemetric or clinical surveillance for the entire SBCE recording time in 54 Centres (45%) (details about policies adopted in the participating Centres are reported in Fig. 2);
- Management of patients with ICD: patients with ICD routinely underwent SBCE without any special precautions in 19 Centres (15.8%), whereas they received telemetric or clinical surveillance for the entire SBCE recording time in 67 Centres (55.9%) (details about policies adopted in the participating Centres are reported in Fig. 2);
- SBCE setting: 51.0% of SBCEs were performed as outpatient procedures, 35.5% as inpatients procedures and 13.5% in a day hospital setting;
- Use of mobile phones during CE examination: 22 Centres (18.3%) did not provide any guidance, 17 Centres (14.2%) let the patients free to use mobile phones without any restriction, 39 Centres (32.5%) recommended to avoid the use of mobile phones during the procedure and 42 Centres (35%) allowed only short (<5 min) telephone calls;
- Assessment of capsule excretion: abdominal X-ray was planned at 7 or 15 days after capsule ingestion in asymptomatic patients not noticing capsule excretion, regardless of the position reached by the capsule at the end of the examination, in 32 (26.7%) and 31 (25.8%) Centres, respectively. Conversely, in 14 (11.7%) and 24 (20.0%) Centres respectively an X-ray test was planned 7 or 15 days after ingestion, only in asymptomatic patients not noticing capsule excretion, in which the colon was not reached at the

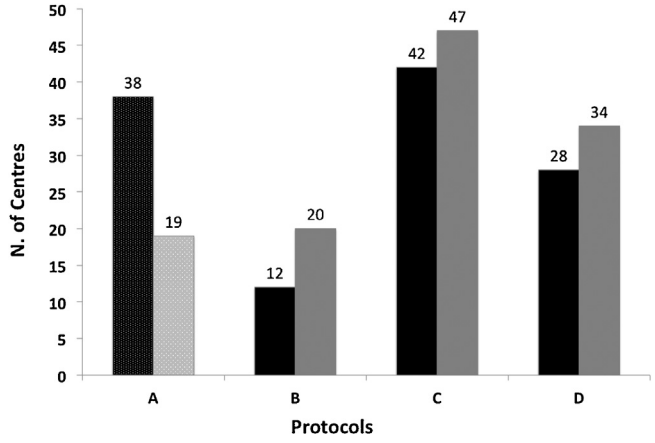

Fig. 2. Management of patients with pacemakers (black columns) and implantable cardiac defibrillator (grey columns) undergoing small bowel capsule endoscopy (SBCE). The columns with dotted pattern identify Centres in which the applied protocol is in line with the European Society of Gastrointestinal Endoscopy (ESGE) recommendations. (A) No special precautions; (B) SBCE performed under routine telemetric control; (C) patient remains in hospital for the entire SBCE recording for clinical surveillance (no telemetry) (D) other policies (e.g. specific management decided case-by case, patient referred to other Centres, systematic cardiologist evaluation before SBCE, planning small bowel tests other than SBCE etc.).

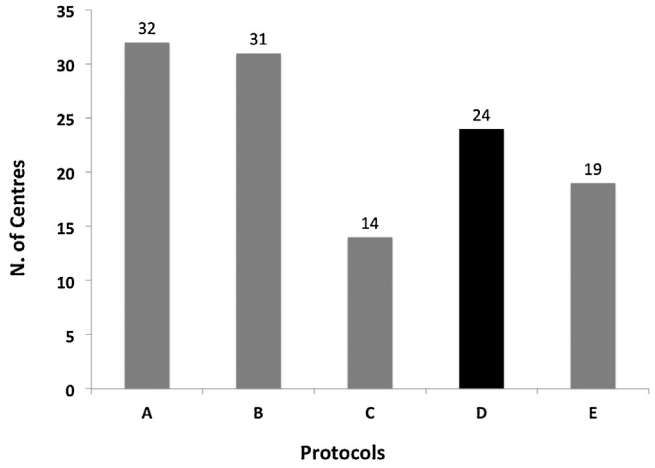

Fig. 3. Capsule excretion assessment: timing and modality. The black column identifies Centres in which the applied protocol is in line with the European Society of Gastrointestinal Endoscopy (ESGE) recommendations. (A) Abdominal X-ray performed 7 days after capsule ingestion in all patients; (B) abdominal X-ray performed 15 days after capsule ingestion; (C) abdominal X-ray performed 7 days after capsule ingestion only in patients in which the colon was not reached during the recording time; (D) abdominal X-ray performed 15 days after capsule ingestion only in patients in which the colon was not reached during the recording time; (E) other (e.g. no tests were systematically planned, other tests and/or other timing).

end of the examination. Other examination methods and/or other times were adopted in 19 (15.8%) Centres (Fig. 3);

- SBCE readers: in 7 Centres (5.8%), the SBCE video reading was a two-steps process: a pre-reading was performed by a trained nurse (1 Centre) or by a fellow in training (6 Centres), followed by a final approval/report signing (second step) by a SBCE-dedicated gastroenterologist. In the remaining 113 Centres (94.2%), there was no pre-reading and the entire SBCE videos reading process was carried out by a dedicated gastroenterologist.

4. Discussion

Global data about the Centres performing SBCE in Italy are not available at the present time. However, the overall number of invited Centres, the high response rate, the geographical distribution and the overall number of procedures performed suggest that the present data collection might provide a reliable picture of the diffusion and use of SBCE in Italy in the timeframe June 2016–June 2017. Data collected in the first section of the questionnaire showed that SBCE is widespread all over the Country, most Centres participating in the collection have long-lasting experience and a relevant median number of procedures per Centre is performed, with a spectrum of clinical indications and complications in line with literature data [6,7]. While for other endoscopic methods (e.g. gastroscopy, colonoscopy etc) [8–10], there are well-defined quality measures, for capsule endoscopy similar standards are lacking. At the best of our knowledge, there is only one other nationwide SBCE survey conducted in 2010–2011 in the United Kingdom [11,12]. It was aimed at determining the demand for capsule endoscopy services, at exploring clinical indications and appropriateness, and at evaluating the role of SBCE training. McAlindon et al. did not collect data on practical issues and operative protocols. This issue, along with the differences in the data collection timeframe, in the health system organization and in the number of participating Centres, make our data collection and the UK survey difficult to compare.

Interestingly, our data collection showed that most of the technical issues and practical protocols explored through our dedicated questionnaire are in agreement with the ESGE recommendations. Nevertheless, we were mainly interested in differences between current practice and ESGE recommendations. In fact, in our opinion, appraising the existing discrepancies represents the first necessary step to plan corrective measures to bridge the gap between the current clinical practice and recommendations. For this purpose, the collected data were returned to the participating centres and, during a capsule endoscopy meeting, a dedicated presentation was organized to present these data and to analyse factors which may influenced differences among different protocols. The issues, which emerged during the discussion, are included in the following paragraphs.

Some policies that differ from ESGE recommendations, such as the use of the mobile phone during the procedure and the administration of antifoaming agents, represent minimal deviations from recommendations, and can be easily implemented in the everyday practical protocols. Conversely, relevant discrepancies were observed in the management of patients with PM and ICD. If on one hand they represent a minority of SBCE patients, on the other hand in this subgroup SBCE frequently identifies small bowel findings (mainly vascular) with a significant impact on the subsequent clinical management, as well as on the clinical outcome [13,14]. Although several papers reported an excellent SBCE safety profile in patients with PM and ICD [11–15], the majority of Italian Centres tend to apply a prudential approach, planning SBCE with active (by telemetry) or passive (by keeping the patient in hospital during the entire recording) surveillance. In addition, some Centres, which chose the option “Other”, specified that they avoided performing SBCE in patients with PM or ICD, planning other examinations for the small bowel evaluation (such cross-sectional imaging tests) that have lower accuracy when compared with SBCE [16,17]. This policy might be partially due to capsule manufacturer’s indications, which still list the presence of PM or ICD among relative SBCE contraindication, at least for SBCE with radiofrequency transmission, in the product brochure [18,19]. Although SBCE not using radiofrequency for data transmission (namely Capsocam^{TM}-Capso-Vision, Saratoga, California, USA and Mirocam^{TM}-Intromedic Co., Ltd., Seul, Korea) [20] might represent the safest alternative in these patients, these systems are a small minority (21/136; 15.5%) of available platforms in Italy. Moreover, this prudential attitude not only reduces the accessibility to the procedure by increasing the organisational issues, but can also have a detrimental effect on SBCE recording: telemetry or the permanence in environments with strong magnetic fields, such as hospital wards, may cause significant loss of

SBCE images [21]. Thanks to the availability of formal ESGE recommendations on this topic, it is now reasonable to expect an increase in the number of Italian Centres performing SBCE in patients with PM and ICD without any surveillance.

Another practice protocol, which differs from ESGE recommendations, is the assessment of capsule excretion, which is based, once again, on a prudential approach. In fact, about half of the Centres plan an abdominal X-ray regardless of the bowel segment reached by the capsule during the recording, and a third of them adopt a restrictive timing, checking the patient 7 days after capsule ingestion. The ESGE recommendations are based on the observation that the retention of the capsule in the colon is an extremely rare event [22] and suggest a timing of 15 days, according to the definition of retention in asymptomatic patients provided by experts [23]. By combining these two features it is possible to carefully select those who really need to receive further tests, avoiding unnecessary radiological examinations.

Two policies, that differ from the ESGE recommendations, are mainly due to the economic and organisational peculiarities of the Italian national health system: the high percentage of SBCE performed as inpatients or in a day hospital setting (49% overall) and the low rate of Centres evaluating SBCE videos with a two-step approach (with trained nurses or fellow in training as pre-readers). Regarding the first issue, in the time interval June 2016–June 2017, the reimbursement for SBCE as outpatient procedure was available in 10 Regions only (Table 1), whereas two more Regions (Puglia and Sardegna) settled a SBCE reimbursement in the following months (in October 2017 and in June 2018, respectively). Therefore, in some Centres to meet the costs of the procedure, it was necessary to perform SBCE hospitalizing patients (with at least 3 days of hospital stay) or in a day hospital setting. Unfortunately, this policy is still the routine practice in many Centres, although there is increasing evidence showing that the adoption of an outpatient reimbursement involves an economic saving and a greater accessibility to the procedure [24–26]. In fact, this issue may partially explain why, as observed in the questionnaire Section A, only a minority of patients with ongoing overt small bowel bleeding receives SBCE within 72 h, as recommended by ESGE clinical guidelines [1]. The literature also supports the active involvement of trained nurses as pre-readers [27–29] to optimize the reading process and to reduce costs related to physicians' working-time. However, the nurses' role and training widely differ among Countries; in common everyday practice in Italy the endoscopy nurses are seldom actively involved in the diagnostic process of any endoscopic procedure, including capsule endoscopy. These two issues are so closely linked to structural and organizational features of the Italian national health system that, despite the availability of ad-hoc guidelines, substantial changes appear unlikely in the near future.

Although, to the best of our knowledge, the present study represents the most extensive SBCE data collection carried out in Italy and, as of today, the first comparison between guidelines and clinical practice in the field of capsule endoscopy, we have to acknowledge some limitations. First, although the questionnaire was designed ad hoc by a group of experts, it was semiquantitative: on one hand this allowed to fill in data anonymously, quickly and easily, not requiring the consultation of hospital databases for most of the topics; on the other hand the collected data lacked in precision, did not allow accurate subgroup analyses (e.g. according to centre expertise, Centre's type, etc.) and might have increased the risk of biases (e.g. recall bias or estimator bias) affecting the reliability of the collected data (risk of overestimation or underestimation of the frequency of the measured events). Second, in the questionnaire there was one single question for each issue/protocol evaluated: this policy did not allow any "internal validation", but it should have decreased possible data redundancy, which is usually a relevant source of bias within questionnaire-based data collections. Third, a web-based questionnaire was implemented to facilitate data collection, so we could not fully rule out typing or filling errors. Fourth, we deliberately limited the observation period to 12 months: this allowed focusing on a definite timeframe, but we could not verify if significant changes occurred over time. Fifth, we did not evaluate the clinical outcomes and SBCE impact on patients' clinical history, focusing only on procedural and technical issues, therefore we were not able to verify if the deviation from ESGE recommendations might finally impact on patient care and on patient outcomes. Last but not least, the partnership with one of the companies that market endoscopic capsule, even if unrestricted and made for logistical purposes only, could have contributed to introduce a selection bias among Centres. However, as reported in the first section of the questionnaire, Centres with equipment other than that of Medtronic participated in the collection; in addition, the questions were not related to any specific platform. Taking into account all these methodological limitations, the collected data has to be mostly considered an estimation, rather than a precise measure.

In conclusion, this data collection, which involves 120 Centres all over Italy, clearly demonstrates that although SBCE in Italy is widely used and largely available, there are still some technical and practical/organizational issues that can be improved to bridge the gap between current practice and ESGE guideline recommendations. This data collection might be considered as the first step of a quality improvement process. Therefore, we plan to circulate again the same questionnaire in 2–3 years, to verify if significant changes have occurred in the management of patients undergoing SBCE. At that stage, we are also planning to measure patient outcomes, in order to verify if practical and operational issues impact on patient management and clinical outcomes. In addition, since ESGE is currently undertaking a "Quality Improvement Initiative" to develop performance measures for capsule endoscopy, it might be also interesting to test, across the same group of gastroenterologists participating into the present data collection, if Italian Centres match the predefined quality thresholds.

Conflict of interest
None declared.

Funding

Medtronic (Medtronic Italia S.p.A., Milano, Italy) provided unconditioned logistic support for the data collection, settled the web-based platform and invited Centres to participate. The Authors did not receive any funding support. No fees or payback were provided to Authors or Centres participating in the data collection. The group of experts who developed the questionnaire and analysed data holds the exclusive intellectual property of data.

Acknowledgements

We would sincerely like to thank all the colleagues from the Centres that participated in the data collection: with their dedication they made this project possible. We would also like to thank Vincenzo Angrisani, Matteo Mozzi, Umberto Pagliusi and Marco Ferrari from Medtronic Italia (Medtronic Italia S.p.A., Milano, Italy) for the unconditioned support.

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