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Commentary

Small bowel capsule endoscopy: It's time for quality assurance

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Quality in the delivery of healthcare has received intense emphasis in the past decade, beginning with the efforts of the Institute of Medicine to define national problems with variation in practice, safety, and lack of accountability in healthcare [1]. This mainstream focus on quality improvement now encompasses all areas of medicine, including gastrointestinal endoscopy, as evidenced by the establishment of quality committees within many of the major gastroenterology organizations, and by the collaborative development of general and procedure-specific quality metrics. The quality of health care can be measured by comparing the performance of an individual or a group of individuals with an ideal auditable benchmark [1–3]. Therefore, the assurance of high quality in endoscopy services requires, first of all, a thorough collection of performance data. Feeding back these data to endoscopists provides metrics that may be used to target interventions designed to improve performance [4]. The above mentioned general principles have been well known for years, but up to now they have mostly been restricted to upper and lower gastrointestinal endoscopy [5,6].

The study by Rondonotti et al. [7] represents the first attempt to collect, in a systematic and organized frame, data concerning technical and procedural issues in small bowel capsule endoscopy (SBCE). At present, similar databases in other countries are lacking and national initiatives, wherever existing, are mostly focused on geographical distribution, demand for capsule endoscopy, organisation of capsule endoscopy services and training, while quality issues are only marginally addressed [8–11]. Authors described how SBCE was performed in everyday clinical practice in Italy in the timeframe June 2016–June 2017, and data were compared with European Society of Gastrointestinal Endoscopy (ESGE) technical guideline recommendations [12]. Data were collected by means of a specifically developed semi-quantitative questionnaire, exploring the following domains: preparation protocols/schedules, management of patients with cardiac pacemaker and/or implantable cardiac defibrillators, SBCE setting, ingestion and post-ingestion patient management, capsule excretion assessment, reading protocols and use of patency capsule. Overall, 120 centres agreed to share their data, showing that SBCE is widely diffuse in Italy. Interestingly, slightly more than half of operative protocols (56.3%) adopted by the participating centres were in line with ESGE technical recommendations. Moreover, authors focused on topics in which significant discrepancies between current practice and ESGE technical recommendations were found, such as the management of patients with pacemakers or cardiac implantable defibrillators, the ideal SBCE setting, the assessment of capsule excretion and the involvement of trained nurses or fellows in training as pre-readers.

Despite authors' effort to make this collection as broad as possible, reaching an impressive 80% response rate, the paper has some methodological limitations, which have partially been acknowledged by them. Firstly, a semi-quantitative questionnaire, abolishing the need to check hospital databases, carries an intrinsic risk of bias (e.g. recall bias or estimator bias), challenging the reliability of the collected data (risk of overestimation or underestimation of the frequency of the measured event). In addition, such a questionnaire lacks in precision and prevents an adequate subgroup analysis, making the identification of factors responsible for variability impossible. Second, the questionnaire was settled per-centre, anonymous and completed online, therefore, the risk of data duplication cannot be fully ruled out, despite clear-cut filling instructions. Third, data were self-reported and one single question for each evaluated issue was included in the questionnaire, preventing any internal validation. Therefore, the collected data have to be mostly considered a rough estimation, more than a precise measure. Last but not least, another relevant limitation does not rely on the study design and methodology, but on the comparator

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itself (ESGE Technical Guideline recommendations): in fact, the aim of the ESGE technical review [12] was to discuss technical issues relating to the use of SBCE, providing guidance for clinicians on optimal performance of this procedure in clinical practice. However, it does not provide numerical quality thresholds or benchmarks to compare with, but only procedural recommendations. At present, there is neither evidence that following these recommendations increase SBCE diagnostic yield, nor that might the deviation from them finally impact on patient care. For example, ESGE guidelines recommend administering laxatives before SBCE, but do not establish the rate of patients with adequate bowel prep to be reached, in order to define this policy as effective. By consequence, the identified discrepancies depend more on the number of centres adopting a specific operative protocol, than on the measurement of the diagnostic process effectiveness. This policy not only leads to select a broad spectrum of technical issues, including those which are not clinically relevant (such as the use of mobile phones during SBCE), but it may also lead to overlook significant variability among Centres as far as key issues are concerned. Opportunely, in the wider frame of the quality improvement initiative, ESGE has recently settled a Quality Improvement Committee, focused on small bowel endoscopy, which is currently drafting SBCE quality standards, which are expected to be published soon.

Despite all these limitations, the collected data provide a reliable picture of the Italian scenario, highlighting noticeable geographical differences in SBCE use across the country, as well as the existing variability among centres in the management of patients undergoing SBCE. However, we strongly believe that the relevance of this paper is not related to the specific technical or procedural topics, which are somewhat related to the peculiarities of the Italian health system and are therefore not widely generalizable. The survey by Rondonotti et al. [7] has the merit of bringing the quality issue into the field of SBCE, showing how a technique, which has been performed for over 15 years, is still subject to considerable variability.

Thus the paper represents the first necessary step to appraise the relevance of starting quality improvement programs, also in the field of the SBCE. Such programs, in fact, are aimed at promoting the standardization of diagnostic-therapeutic procedures, reducing the variability among the operators and maximizing the effectiveness of the health care processes [13]. Moreover, this survey also triggers the conversation about the barriers of successful implementation of clinical practice and technical guidelines or recommendations. While the number of endoscopy high quality guidelines is increasing [5,6], there is a gap regarding the evaluation of their effective communication (stringent terminology, confusing levels of evidence and grades of recommendation), adoption, local adaption, implementation and assessment of their impact on clinical outcomes [14]. While adoption or adaption are mainly related to local setting factors –like the case of different Italian SBCE settings, in the commented manuscript- the difficulty of changing physicians and patients behaviours towards contemporary evidence is the main barrier of effective implementation of a recommendation, not forgetting that potential bias arising from the close collaboration with the industry may make end-users of guidelines suspicious [15].

In our opinion, it is desirable that such a survey will be performed at a supranational, perhaps European, level to make the results more generalizable and comparable with the specific quality SBCE indicators, which are currently under development.

Conflict of interest

None declared.

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