RAPID COMMUNICATION



# Appropriateness of colonoscopy: Diagnostic yield and safety in guidelines

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## Abstract

**AIM:** To evaluate if the guidelines for the appropriateness of performing colonoscopy by American Society for Gastrointestinal Endoscopy (AGSE) and Italian Society of Digestive Endoscopy (SIED) yield a good diagnostic efficacy and do not present risks of missing important colonic pathologies in an Italian population sample.

**METHODS:** A total of 1017 consecutive patients (560 men and 457 women; mean age  $64.4 \pm 16$  years) referred to an open-access endoscopy unit for colonoscopy from July 2004 to May 2006 were evaluated according to ASGE and SIED guidelines for appropriateness of performing the procedure. Diagnostic yield was defined as the percentage of relevant colonic pathologies of the total number of colonoscopies performed.

**RESULTS:** About 85.2% patients underwent colonoscopy that was considered appropriate based on at least one ASGE or SIED criterion, while it was considered inappropriate for 14.8% of patients. The diagnostic yield of colonoscopy was significantly higher for appropriate colonoscopies (26.94% *vs* 10.6%, *P* < 0.001) than for inappropriate colonoscopies (5.3%). There was no missed colorectal cancer following the ASGE/SIED criteria.

**CONCLUSION:** ASGE/SIED guidelines have shown a good diagnostic yield and the rate of missing relevant colonic pathologies seems very low. Unfortunately, the percentage of inappropriate referrals for colonoscopy in an open-access endoscopy system is still high, despite the number of papers published on the issue and the definition of international guidelines. Further steps are required to update and standardize the guidelines to

increase their diffusion and to promote educational programs for general practitioners.

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Key words: Colon; Colonoscopy; Endoscopy; Guidelines

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## INTRODUCTION

Colonoscopy is a widely available diagnostic modality that has replaced barium enema for colorectal examination<sup>[1]</sup>. The growing demand of gastrointestinal (GI) endoscopy in most developed countries has determined an unavoidable increase of health care costs, therefore health care systems are experiencing a cost crisis<sup>[2,3]</sup>. Colonoscopy is relatively expensive and associated with a small but definite rate of complications<sup>[2]</sup>. To maintain or enhance the quality of care in an increasingly cost-conscious environment, the ability to determine appropriateness of the care may be essential<sup>[4]</sup>.

Appropriateness of procedures, such as colonoscopy, is defined by the fact that the health benefit exceeds the health risk by a sufficiently wide margin of security<sup>[5]</sup>. To define the correct use of GI lower endoscopy, the American Society for Gastrointestinal Endoscopy (ASGE) has developed indication criteria for diagnostic endoscopic procedures<sup>[6]</sup>. However, the exclusive use of these criteria cannot be considered a safe approach, since many studies reported that a significant percentage of relevant pathologies could be found even in colonoscopies defined as not appropriate by ASGE criteria<sup>[4,7]</sup>.

Approximately 20% of colonoscopies in Italy were performed with indications not considered appropriate by ASGE criteria<sup>[2,3,7]</sup>. More recently, the Italian Society of Digestive Endoscopy (SIED) supplied different appropriateness criteria for colonoscopy<sup>[8]</sup> (Table 1).

The aim of the present study was to evaluate the appropriateness of performing colonoscopy in an open access Italian endoscopy unit using the ASGE/SIED guidelines and the efficacy of the above-mentioned guidelines to detect relevant diseases (particularly neoplasms) without missing relevant pathologies.

## MATERIALS AND METHODS

This prospective study was carried out from July 2004 to May 2006 in an open-access endoscopy unit in Asti, Italy. All consecutive outpatients referred to our endoscopy unit for colonoscopy by primary care physicians entered the study. A written informed consent and confidential medical information were obtained from all patients before the procedure, and the study was conducted according to the local ethical rules following the principles of the Helsinki Declaration (Edinburgh revision, 2000).

The protocol included: (1) accurate patient interview and examination, evaluation of previous diagnostic tests (fecal occult blood, barium contrast enema, anemia, etc.) and determination of the indication category specified by the ASGE/SIED guidelines with definition of appropriate or inappropriate colonoscopy before the procedure; (2) performance of colonoscopy by an endoscopist while its appropriateness was determined by another endoscopist. The study did not include those who could not complete the colonoscopy because of the presence of a neoplastic stenosis. Inpatients and asymptomatic outpatients referred for the government's colorectal cancer screening program, therapeutic and emergency colonoscopies were also excluded from the study.

Statistical analysis was performed with the Chi-square test; and values of P < 0.05 were considered statistically significant.

## RESULTS

From July 2004 to May 2006, we performed 2245 colonoscopies on 1133 inpatients and 95 outpatients referred for the government's colorectal cancer screening program. And 172 were incomplete and excluded. As a result, a total of 1017 patients entered the study, including 560 (55.1%) men and 457 (44.9%) women. The mean age was 64.4 years with a range of 16-89 years. In this series, cecal intubation was not possible in 3.5% of cases due to neoplastic stenosis. A total of 866 colonoscopies (85.2%) were defined appropriate based on at least one ASGE or SIED criterion, while 151 (14.8%) were defined inappropriate.

The indications for appropriate colonoscopies were found in 866 patients, and are listed in Table 2. The most frequent indications were hematochezia (23.7%), presence of occult fecal blood and/or iron deficiency anemia (16.7%), and surveillance of polyps (14.8%). Indications for inappropriate colonoscopies are listed in Table 3. The most frequent inappropriate indications were surveillance of colonic polyps and colorectal carcinoma at different intervals from those recommended (32.4%), and sporadic non-specific abdominal pain or chronic abdominal pain with previous endoscopic investigations (19.9%).

The rate of clinically relevant diagnosis was significantly higher in patients whose colonoscopy was classified as appropriate (233 of 866 patients, 26.9%) than in those with inappropriate indications (16 of 151, 10.6%, P < 0.001). Aspecific colitis and diverticulosis were not considered as clinically relevant endoscopic findings. The most frequent pathologic findings in appropriate colonoscopies are listed in Table 4, the low grade dysplasia adenomas and colorectal cancer were more common.

Only 1 case of adenoma with high-grade dysplasia, 2 cases of adenoma with low-grade dysplasia and 5 with unretrieved polyps of less than 5 mm in size had pathologic findings in inappropriate procedures.

### DISCUSSION

Over the recent years the number of colonoscopies has grown exponentially, due to the increase of the demand by population and primary care physicians. This has led to long waiting lists and unavoidable economic consequences on the management of the Health Care System, which is experiencing a very severe cost crisis in Italy. Thus, the appropriateness of colonoscopy performance can reduce overuse, improve quality of care and decrease costs<sup>[5]</sup>, especially in those countries where the digestive endoscopic services function on an open access system basis. Defining strong criteria for the appropriateness of endoscopic procedures is therefore needed to face the health care demand of the population and the government to reduce costs.

ASGE has developed and published the indication categories for diagnostic colonoscopy procedures<sup>[6]</sup>. More recently, however, authors from different countries<sup>[4]</sup> have suggested that the ASGE guidelines require modifications. Colonoscopies performed following ASGE indications demonstrated clinically relevant findings only in a slightly higher prevalence than those performed without these indications (28.8% versus 20.2%), suggesting that the exclusive use of these criteria cannot be considered a safe approach<sup>[8]</sup>. Charles *et al*<sup>[9]</sup> reported that 40% of the patients undergoing colonoscopy for an ASGE approved indication have pathological results, compared to 22% of those with inappropriate indications. Similarly, Morini *et al*<sup>[10]</sup> reported a positive diagnosis of 43% for appropriate colonoscopies and 16% for inappropriate procedures.

A more recent study indicated that the proportion of patients in "not listed" category was about 16%, with a diagnostic yield of 13.4%, about three times higher than the diagnostic yield of colonoscopy with inappropriate indications. The two most frequent unlisted indications in this study were unexplained weight loss and alterations of bowel habits; the authors conclude that these unlisted indications must be included in the future version of the ASGE guidelines<sup>[11]</sup>. The same opinion has been supported by Chan<sup>[4]</sup> in a cross-sectional study performed at the University of Malaya. These indications are included in the SIED guidelines for colonoscopy. In fact, three colorectal carcinomas in our study were diagnosed in patients only complaining of recent and persistent constipation.

In fact, in our prospective study on an open access system, based on general practitioners' demand, the indications for colonoscopies according to the ASGE and SIED criteria were appropriate in 85.2% of cases and inappropriate in 14.8%, with an appropriateness higher than that reported in literature. We found very

#### Table 1 ASGE and SIED selection criteria for colonoscopies

| ASGE                                                                         | SIED                                                                             |  |  |  |
|------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--|--|--|
| Abnormality on barium enema                                                  | Abnormality on barium enema, <sup>1</sup> Computerized Tomography scan, Magnetic |  |  |  |
|                                                                              | Resonance Imaging, Ultrasonography                                               |  |  |  |
| Haematochezia-Fecal occult blood test positivity-melena after negative upper | Haematochezia-Fecal occult blood test positivity-Melena after negative upper     |  |  |  |
| GI endoscopy                                                                 | GI endoscopy                                                                     |  |  |  |
| Unexplained iron deficiency anemia                                           | Unexplained iron deficiency anemia                                               |  |  |  |
| Surveillance for colonic neoplasia and colonic polyps                        | Surveillance for colonic neoplasia and colonic polyps                            |  |  |  |
| Clinically significant diarrhea of unexplained origin                        | <sup>1</sup> Persistent and significant alterations of bowel habits              |  |  |  |
| Surveillance of inflammatory bowel diseases patients                         | Surveillance of inflammatory bowel diseases patients                             |  |  |  |
| Evaluation of inflammatory bowel diseases of colon when colonoscopy will     | Evaluation of inflammatory bowel diseases of colon when colonoscopy will         |  |  |  |
| influence immediate management                                               | influence immediate management                                                   |  |  |  |
| Chronic abdominal pain: once to rule out disease                             | Chronic abdominal pain: once to rule out disease                                 |  |  |  |
|                                                                              | <sup>1</sup> Unexplained weight loss                                             |  |  |  |

<sup>1</sup>Different criteria between ASGE and SIED guidelines.

| Table 2 921 indications in 866 appropriate colonoscopies                                                                                                         |     |      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|------|
| ASGE/SIED guidelines                                                                                                                                             | n   | %    |
| Haematochezia                                                                                                                                                    | 218 | 23.7 |
| Occult faecal blood presence                                                                                                                                     | 154 | 16.7 |
| Surveillance after endoscopic polypectomy                                                                                                                        | 136 | 14.7 |
| (3-5 yr intervals following adequate clearance of neoplastic polyps)                                                                                             |     |      |
| Persistent change in bowel habits                                                                                                                                | 105 | 11.4 |
| Surveillance after resection of cancer                                                                                                                           | 100 | 10.8 |
| (colonoscopy to remove synchronous neoplastic lesion at or around time of curative resection of cancer followed by colonoscopy at 3 yr and 3-5                   |     |      |
| yr thereafter to detect metachronous cancer)                                                                                                                     |     |      |
| Chronic abdominal pain                                                                                                                                           | 57  | 6.2  |
| Unexplained iron deficiency anemia                                                                                                                               | 54  | 5.9  |
| Family history of sporadic colorectal cancer before the age of 60: colonoscopy every 5 yr beginning at the age of 10 yr earlier than the affected                | 42  | 4.6  |
| relative or every 3 yr if adenoma is found                                                                                                                       |     |      |
| Abnormality on imaging                                                                                                                                           | 28  | 3.0  |
| Unexplained weight loss                                                                                                                                          | 18  | 1.9  |
| Chronic inflammatory bowel disease of colon, if more precise diagnosis or determination of the extent of activity of disease will influence immediate management | 9   | 1.0  |
| In patients with ulcerative or Crohn's pancolitis $\geq$ 8 yr or left sided colitis $\geq$ 15 yr every 1-2 yr with systematic biopsies to detect dysplasia       |     |      |

## Table 3 Indications in 151 inappropriate colonoscopies

| 1. 2                                                                                                                                                       |   | 0/   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|---|------|
| Indications                                                                                                                                                | n | %    |
| Surveillance of colonic polyps out of recommended intervals (3-5 yr intervals following adequate clearance of neoplastic polyps)                           |   | 32.4 |
| Transitory or already endoscopically investigated unmodified chronic abdominal pain                                                                        |   | 19.9 |
| Transitory change in bowel habit                                                                                                                           |   | 13.9 |
| Colorectal carcinoma surveillance out of guidelines (colonoscopy to remove synchronous neoplastic lesion at or around time of curative                     |   | 13.2 |
| resection of cancer followed by colonoscopy at 3 yr and 3-5 yr thereafter to detect metachronous cancer)                                                   |   |      |
| Melena with upper gastrointestinal source already identified                                                                                               | 9 | 6.0  |
| Screening in patients with family histories of sporadic colorectal cancer before age of 60 out of guidelines (colonoscopy every 5 yr beginning at          |   | 4.0  |
| the age of 10 yr earlier than the affected relative or every 3 yr if adenoma is found)                                                                     |   |      |
| Hematochezia in patients < 40 yr without previous rectal evaluation                                                                                        | 4 | 2.6  |
| Follow-up for inflammatory bowel diseases out of recommended intervals. Chronic inflammatory bowel disease of the colon, if more precise                   | 3 | 2.0  |
| diagnosis or determination of the extent of activity of disease will influence immediate management                                                        |   |      |
| In patients with ulcerative or Crohn's pancolitis $\geq$ 8 yr or left sided colitis $\geq$ 15 yr every 1-2 yr with systematic biopsies to detect dysplasia |   |      |
| Anal symptoms                                                                                                                                              | 3 | 2.0  |
| Rectal incontinence                                                                                                                                        | 2 | 1.3  |
| Abnormal serologic markers (CEA, carcino Embriogenic Antigen, Cancer Antigen 19-9)                                                                         | 2 | 1.3  |
| Metastatic adenocarcinoma of unknown origin without colonic symptoms when it will not influence management                                                 | 1 | 0.7  |
| Inguinal hernia                                                                                                                                            | 1 | 0.7  |

few pathologic elements in the inappropriate series (10.59% in not indicated versus 25.40% in indicated), which constitutes a lower percentage than the reported

percentage<sup>[2,3,7,10]</sup>. This may be due to the wider criteria applied or due to the fact that we did not consider as clinically relevant diagnosis of other diseases, such as

| Table 4 P | Pathologic findings in appropriate colonoscopies |
|-----------|--------------------------------------------------|
|-----------|--------------------------------------------------|

| Pathologic findings              | 866 appropriate |      | 151 inappropriate |      |
|----------------------------------|-----------------|------|-------------------|------|
|                                  | n               | %    | n                 | %    |
| Low grade dysplasia adenoma      | 92              | 41.8 | 9                 | 6.0  |
| Colorectal cancer                | 71              | 32.3 | -                 | -    |
| Undetermined polyps              | 25              | 11.0 | 5                 | 3.3  |
| (unretrieved polyps size < 5 mm) |                 |      |                   |      |
| High grade dysplasia adenoma     | 25              | 11.4 | 2                 | 1.3  |
| Inflammatory bowel diseases      | 17              | 7.7  | -                 | -    |
| In situ adenocarcinoma           | 3               | 1.4  | -                 | -    |
|                                  | 233             | 26.9 | 16                | 10.6 |

diverticulosis and aspecific colitis. In our study there was no missed colorectal cancer diagnosis following the ASGE/SIED criteria and even the percentage of less relevant pathologies was very low.

However, the main issue we want to stress is that it is highly necessary to improve the diffusion of appropriateness criteria so as to give better diagnostic safety in the population and to reduce the heavy medical costs. The use of detailed and explicit appropriateness criteria for colonoscopy significantly enhances the identification of relevant lesions, especially colon cancer<sup>[12]</sup>, but further studies are required<sup>[13-15]</sup>, including better educational programs for general practitioners to improve patient selection for colonoscopy, thus contributing to enhancing the quality and efficiency of health care.

## COMMENTS

#### Background

Colonoscopy is a widely available diagnostic and therapeutic procedure for which demand continues to grow. This has resulted in an increase in overall costs and waiting lists. Specific guidelines for colonoscopy have been published and periodically updated to increase the diagnostic yield of the procedure.

#### **Research frontiers**

To increase the effectiveness and safety of colonoscopy, studies have been published about the optimization, standardization and communication of international guidelines.

#### Innovations and breakthroughs

Many recent articles in literature focused on the comparison among different guidelines, while others pay more attention to the economic impact if strict adherence to guidelines is followed.

#### Applications

A further exploration of the aspects presented in this paper and other similar studies in a future perspective could lead to a better understanding of the relationship between quality of care and humans, technological and financial economic resources.

#### Terminology

Appropriateness of care is defined by the fact that in any given procedure, the benefits exceed the risks by a wide enough margin to make it worth providing it. The diagnostic yield of an endoscopic procedure is defined as its capacity of identifying a lesion that is potentially important to patient care.

The selection of patients who should undergo endoscopic procedures is one of the key points of the diagnostic process, which should avoid the excessive use of invasive and expensive tests as well as the underestimation of potentially harmful diseases.

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