A nine-year audit of open-access upper gastrointestinal endoscopic procedures: Results and experience of a single centre

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BACKGROUND: The appropriateness and safety of open-access endoscopy are very important issues as its use continues to increase.

OBJECTIVE: To present a review of a nine-year experience with open-access upper gastrointestinal endoscopy with respect to indications, diagnostic efficacy, safety and diseases diagnosed.

METHODS: A retrospective, observational case series of all patients who underwent open-access endoscopy between January 2000 and December 2008 was conducted. Indications were classified as appropriate or not appropriate according to American Society of Gastrointestinal Endoscopy (ASGE) guidelines. Endoscopic diagnoses were based on widely accepted criteria. Major complication rates were assessed.

RESULTS: A total of 20,620 patients with a mean age of 58 years were assessed, of whom 11,589 (56.2%) were women and 9031 (43.8%) were men. Adherence to ASGE indications led to statistically significant, clinically relevant findings. The most common indications in patients older than age 45 years of age were dyspepsia (28.5%) and anemia (19.7%) in the ASGE-appropriate group, and dyspepsia in patients younger than 45 years of age without therapy trial (6.6%) in the nonappropriate group. Of the examinations, 38.57% were normal. Hiatal hernia and nonerosive gastritis were the most common findings. Important diagnoses such as malignancies and duodenal ulcers would have been missed if endoscopies were performed only according to appropriateness. There were only two major complications and no mortalities.

CONCLUSIONS: Open-access upper gastrointestinal endoscopy is a safe and effective system. More relevant findings were found when adhering to the ASGE guidelines. However, using these guidelines as the sole determining factor in whether to perform an endoscopy is not advisable because many clinically relevant diagnoses may be overlooked.

Key Words: ASGE indications; Gastroscopy findings; Gastroscopy indications; Open-access endoscopy

Un audit de neuf ans sur les endoscopies œsogastroduodénales à accès libre : Les résultats et l’expérience d’un seul centre

HISTORIQUE : La pertinence et la sécurité de l’endoscopie à accès libre sont des enjeux très importants, car le recours à cette intervention continue d’augmenter.

OBJECTIF : Présenter une analyse d’une expérience de neuf ans sur les indications, l’efficacité diagnostique et l’innocuité de l’endoscopie œsogastroduodénale à accès libre et sur les maladies qu’elle permet de diagnostiquer.

MÉTHODOLOGIE : Série rétrospective de cas d’observation de tous les patients qui ont subi une endoscopie à accès libre entre janvier 2000 et décembre 2008. Les indications étaient classées comme pertinentes ou non selon les lignes directrices de l’American Society of Gastrointestinal Endoscopy (ASGE). Les diagnostics d’endoscopie se faisaient sur des critères largement acceptés. Les chercheurs ont évalué les taux de complications majeures.

RÉSULTATS : Au total, les chercheurs ont évalué 20 620 patients d’un âge moyen de 58 ans, dont 11 589 (56,2 %) étaient des femmes et 9 031 (43,8 %), des hommes. Le respect des indications de l’ASGE donnait lieu à des observations pertinentes et sur le plan clinique et statistiquement significatives. Les principales indications chez les patients de plus de 45 ans étaient la dyspepsie (28,5 %) et l’anémie (19,7 %) dans les groupes pertinents selon l’ASGE, et la dyspepsie chez les patients de 45 ans sans essai thérapeutique (6,6 %) dans le groupe non pertinent. Parmi les examens, 38,57 % étaient normaux. La hernie hiatale et la gastrite non érosive étaient les observations les plus courantes. Des diagnostics plus graves, tels que des tumeurs malignes et des ulcères duodénaux, n’auraient pas été repérés si les endoscopies avaient été effectuées uniquement selon leur pertinence. Les chercheurs ont constaté seulement deux complications majeures et aucun décès.

CONCLUSIONS : L’endoscopie œsogastroduodénale à accès libre est un système sécuritaire et efficace. Les observations étaient plus pertinentes lorsqu’on respectait les lignes directrices de l’ASGE. Cependant, il n’est pas conseillé d’utiliser ces lignes directrices comme seuls facteurs pour déterminer la pertinence d’effectuer une endoscopie, car on risque alors de rater de nombreux diagnostics pertinents sur le plan clinique.

We performed a retrospective study to examine the outcome of OAE at the Bnai Zion Medical Center. The present study outlines the indications for OAE performed at our facility, defines the relationship of these investigations according to national practice guidelines (ie,
TABLE 1
Open-access endoscopies per year (2000 to 2008)

| Year | n   | Total, % |
|------|-----|---------|
| 2000 | 742 | 3.6     |
| 2001 | 1476| 7.1     |
| 2002 | 1744| 8.4     |
| 2003 | 1862| 9.0     |
| 2004 | 1934| 9.3     |
| 2005 | 2481| 12      |
| 2006 | 2812| 13.6    |
| 2007 | 3438| 16.6    |
| 2008 | 4212| 20.3    |
| Total| 20,620| 100   |

The ability of the ASGE indications to forecast relevant endoscopic diagnoses was evaluated by calculating the likelihood ratio (LR) (positive and negative), both globally and for each separate indication. The LR represents a measure of the odds of having a disease relative to the previous probability of the disease. The use of LR is advantageous over sensitivity and specificity because it is less likely to change with changes in the prevalence of a disorder (16,17). A test is useless if the LR is equal to 1; a test has greater value the more the positive LR is greater than 1 and the negative LR is less than 1.

To evaluate the association between appropriateness and the presence of clinically relevant endoscopic diagnoses, patients in whom an EGD was performed according to an ASGE indication were compared with those in whom an ASGE indication was absent. The extent of this association was expressed as the OR of finding a relevant diagnosis in patients with an appropriate indication compared with those with an inappropriate indication. The association was considered to be statistically significant if the 95% CI of the OR did not include the value 1.0. Calculation of the 99% CI was considered to be prudent because of the use of multiple tests for statistical assessments. A two-way correlation analysis between the indication and findings was performed. The extent of the association between these two variables was subsequently expressed as the OR of finding a relevant diagnosis in patients with an appropriate indication compared with those without an appropriate indication. The association was considered to be statistically significant if the 95% CI of the OR did not include the value 1.0.

The study period included a total of 20,620 patients, of whom 9031 (43.8%) were men and 11,589 (56.2%) were women. The mean (± SD) age of the participants was 58±17.8 years, with men being slightly younger (58.1±17.5 years) than the women (59.4±18.3 years). The data presented in Table 1 illustrate the increasing number of OAEs performed during the nine-year period.

The study protocol was approved by the Institutional Review Board of the Bnai Zion Medical Center.

RESULTS
The study period included a total of 20,620 patients, of whom 9031 (43.8%) were men and 11,589 (56.2%) were women. The mean (± SD) age of the participants was 58±17.8 years, with men being slightly younger (58.1±17.5 years) than the women (59.4±18.3 years). The data presented in Table 1 illustrate the increasing number of OAEs performed during the nine-year period.

All patients underwent standard monitoring with pulse oximetry and automated blood pressure cuff. The major complication rate was practically zero. There was one episode of transient gastrointestinal bleeding following random duodenal biopsies, a duodenal hematoma that led to hospitalization and diagnosis of a coagulation defect, and an episode of gastric perforation following argon ablation of a...
gastric angiodysplasia. There were no procedure-related mortalities. No reported cases required endotracheal intubation, or resulted in death or neurological sequelae. However, there were occasional instances of respiratory depression requiring assisted ventilation. The incidence rate of respiratory events requiring bag-mask ventilation was one in 515 procedures (40 cases total). Although the endoscopy unit is in close regular contact with the referring family physicians and clinics, it was theoretically possible that delayed complications occurred and were not included in the data.

All of the indications for endoscopy are summarized in Table 2. Indications for EGD were considered to be appropriate according to ASGE criteria in 17,346 (84.1%) of the cases. The main indications in this group were as follows: epigastric distress or dyspeptic symptoms in 5881 patients (28.5%) older than 45 years of age; 4066 patients (19.7%) were referred because of anemia; 1337 (6.5%) were referred to investigate melena or gastrointestinal blood loss; and 1240 procedures (6.0%) were performed to treat heartburn. The remaining 3274 (15.9%) examinations were considered to be inappropriate. The main inappropriate indication was dyspepsia in 1365 patients (6.6%) younger than 45 years of age without a previous therapy trial.

There were two notable indications: chest pain in 99 patients (0.5%) and positive occult blood (with normal colonoscopy) in 340 patients (1.6%), which led mostly to no relevant diseases. Endoscopic findings are summarized in Table 3. Endoscopy was normal in 7954 cases (38.57% of all endoscopies), 5670 (27.50%) of all the procedures yielded clinically relevant findings and the remaining 14,950 (72.50%) yielded no clinically relevant findings. The most frequent clinically relevant findings were esophagitis (977 patients [4.74%], esophageal varicos (991 patients [4.81%]) and gastric erosions (625 patients [3.03%]). From the not clinically relevant findings, hiatal hernia accounted for 14.46% of the findings, while nonerosive gastritis accounted for 14.16%.

The diagnostic yields depicted in Table 3 were higher for ASGE indications: 4805 (23.30%) of the patients with clinically relevant findings had an appropriate ASGE indication compared with 865 (4.19%) without an appropriate ASGE indication (OR 1.173 [95% CI 1.076 to 1.278]; P<0.01). When comparing indication (ie, ASGE appropriate versus inappropriate), significant, clinically relevant findings were the following: esophageal varices (OR 1.556 [95% CI 1.271 to 1.904]; P<0.001), esophageal ulcer (OR 0.552 [95% CI 0.372 to 0.819]; P<0.01), gastric erosions (OR 1.488 [95% CI 1.160 to 1.910]; P<0.01), and gastric poly (OR 0.747 [95% CI 0.606 to 0.921]; P<0.01). Collective analysis of all clinically irrelevant findings yielded nonsignificant results; however, a detailed examination of the findings of a normal endoscopy (OR 0.862 [95% CI 0.799 to 0.930]; P<0.0001) and hiatal hernia (OR 1.363 [95% CI 1.215 to 1.530]; P<0.001) both yielded significant results.

Serious diagnoses such as esophageal malignancy were diagnosed in 284 patients (1.38%), of which 263 (1.28%) had an appropriate ASGE indication, while only 21 (0.10%) did not have an appropriate ASGE indication (OR 2.385 [95% CI 1.53 to 3.71]; P<0.001). With respect to gastric malignancy, the findings were similar: Of 440 patients (2.13%), 392 (1.90%) had an appropriate ASGE indication, while only 48 (0.23%) did not have an appropriate ASGE indication (OR 1.554 [95% CI 1.150 to 2.10]; P<0.01).

The positive and negative LRs for all ASGE indications are summarized in Table 2. As expected, the positive LR was greater than 2 for investigations of melena or hematemesis, and greater than 3 when following: esophageal varices (OR 1.556 [95% CI 1.271 to 1.904]; P<0.001). With respect to gastric malignancy, the findings were similar: Of 440 patients (2.13%), 392 (1.90%) had an appropriate ASGE indication, while only 48 (0.23%) did not have an appropriate ASGE indication (OR 1.554 [95% CI 1.150 to 2.10]; P<0.01).

The positive and negative LRs for all ASGE indications are summarized in Table 2. As expected, the positive LR was greater than 2 for investigations of melena or hematemesis, and greater than 3 when performing esophageal varices assessment. In contrast, the positive LR was less than 1 for indications such as dyspepsia (regardless of age), heartburn, weight loss and tissue biopsies.

**DISCUSSION**

OAE has been growing ever since its introduction 30 years ago (19), and is likely here to stay (20). It is more accessible, cost effective and safer than an endoscopy following a previous gastroenterologist consultation. The present study analyzed a substantial number of procedures and found a very low major complication rate, which
As noted, EGD was considered to be appropriate according to ASGE criteria in 84.1% of cases. Several studies (22-25) reported a substantial rate of inappropriateness of the indication for upper endoscopy, widely ranging from 5% to 61.7%. This broad variability may be, at least in part, due to the relatively low number of patients studied. Other studies show higher percentages and it clearly emphasizes the fact that general practitioners, which comprise the majority of physicians using the OA system, adhere to the ASGE guidelines. Moreover, it is an improvement over the 32% to 50% of referrals that was alluded to by Shekelle et al (33) and Shekelle (34) in two well-known articles discussing whether appropriateness criteria were ready for use in clinical practice. These reports were supportive of performing procedures that were not based solely on appropriateness criteria, and further stating that these criteria should not be the sole factor in the decision-making process.

The efficacy or diagnostic yield of an endoscopic procedure is usually defined according to its ability to detect a finding that is potentially relevant to patient care. In our study, only 4.19% of the procedures were performed for non-ASGE indications and found to be clinically relevant. Statistical analysis of the clinically relevant findings in both groups with and without an ASGE indication yielded very significant results (23.30% versus 4.19%, respectively; P<0.001). Other studies (14,27,28) showed that the frequency of endoscopies with positive findings that were performed for inappropriate indications range from 23% to 46%; however, not all of them were statistically significant (9).

A normal endoscopic finding occurred significantly less frequently when ASGE indications were present (P<0.001), which emphasizes one of the primary objectives of the ASGE indications – detecting significant abnormalities. Although a normal endoscopy was categorized as a clinically irrelevant finding, it may have changed the treatment course of a patient in some instances. Naji and Brunt (29) classified upper endoscopies as being either positive or negative, and helpful or unhelpful. In this study, 67% of the procedures with normal results assisted the caring physicians. Furthermore, a negative endoscopy in dyspeptic patients significantly reduced the number of specialist consultations and lessened the burden on the medical system. Other studies (30-32) have demonstrated a better quality of life and patient satisfaction for individuals with dyspepsia and a normal endoscopy.

Regarding upper gastrointestinal malignancies, findings in the present study showed that an endoscopy leading to a diagnosis of neoplasia occurred more frequently when adhering to ASGE guidelines. This was previously documented (16,26); however it contradicts the findings in the study conducted by Hassan et al (14) in 2007, who reported more malignancies in the group without an appropriate ASGE indication. From the total of 808 malignancies (284 esophageal, 440 gastric and 84 duodenal) in our study, 698 (86.38%) were reported more malignancies in the group without an appropriate ASGE indication. From the total of 808 malignancies (284 esophageal, 440 gastric and 84 duodenal) in our study, 698 (86.38%) were diagnosed in patients for whom the EGD was appropriate according to ASGE guidelines. In other words, if we were not ‘liberal’ in performing all endoscopies, except when contraindicated, 110 upper gastrointestinal malignancies would have been missed. This approach was alluded to by Shekelle et al (33) and Shekelle (34) in two well-known articles discussing whether appropriateness criteria were ready for use in clinical practice. These reports were supportive of performing procedures that were not based solely on appropriateness criteria, and further stating that these criteria should not be the sole factor in the decision-making process.

Except for the malignancies mentioned, without that same ‘liberal’ policy, 102 duodenal ulcers would have been missed, thus giving additional support to our policy.

### Table 3

| Finding | n (%) | ASGE indication, n (%) | OR | 95% CI | P |
|---------|-------|------------------------|----|--------|---|
| Clinically relevant | 5670 | 27.50 | 4805 (23.30) | 865 (4.19) | 1.173 | 1.076–1.278 | 0.000 |
| Esophageal varices | 991 | 4.81 | 882 (4.28) | 109 (0.53) | 1.556 | 1.271–1.904 | 0.000 |
| Esophagitis | 977 | 4.74 | 844 (4.09) | 133 (0.65) | 1.208 | 1.002–1.456 | 0.041 |
| Esophageal erosion(s) | 156 | 0.76 | 134 (0.65) | 22 (0.11) | 1.151 | 0.735–1.802 | 0.660 |
| Esophageal ulcer | 130 | 0.63 | 97 (0.47) | 33 (0.16) | 0.552 | 0.372–0.819 | 0.003 |
| Esophageal stenosis | 149 | 0.72 | 129 (0.63) | 20 (0.10) | 1.219 | 0.763–1.947 | 0.499 |
| Esophageal malignancy | 284 | 1.38 | 263 (1.28) | 21 (0.10) | 2.385 | 1.532–3.712 | 0.000 |
| Gastric ulcer | 502 | 2.43 | 423 (2.05) | 79 (0.38) | 1.011 | 0.793–1.288 | 1.000 |
| Gastric erosion(s) | 625 | 3.03 | 554 (2.69) | 71 (0.34) | 1.488 | 1.160–1.910 | 0.001 |
| Gastric malignancy | 440 | 2.13 | 392 (1.90) | 48 (0.23) | 1.554 | 1.150–2.100 | 0.004 |
| Gastric polyp | 564 | 2.74 | 451 (2.19) | 113 (0.55) | 0.747 | 0.606–0.921 | 0.008 |
| Duodenal ulcer | 612 | 2.97 | 510 (2.47) | 102 (0.49) | 0.942 | 0.759–1.169 | 0.575 |
| Duodenal angiodysplasia | 61 | 0.30 | 27 (0.13) | 34 (0.16) | 1.493 | 0.781–2.854 | 0.307 |
| Duodenal erosion(s) | 95 | 0.46 | 56 (0.27) | 39 (0.19) | 0.269 | 0.179–0.404 | 0.000 |
| Duodenal malignancy/polyp | 84 | 0.41 | 43 (0.21) | 41 (0.20) | 0.196 | 0.128–0.300 | 0.000 |
| Not clinically relevant | 14,950 | 72.50 | 12,541 (60.82) | 2409 (11.68) | 0.937 | 0.861–1.020 | 0.135 |
| Normal | 7954 | 38.57 | 6593 (31.97) | 1361 (6.60) | 0.862 | 0.799–0.930 | 0.000 |
| Hiatal hernia | 2983 | 14.47 | 2607 (12.64) | 376 (1.82) | 1.363 | 1.215–1.530 | 0.000 |
| Nonerosive gastritis | 2919 | 14.16 | 2433 (11.80) | 486 (2.36) | 0.936 | 0.842–1.040 | 0.219 |
| Nonerosive duodenitis | 924 | 4.48 | 756 (3.67) | 168 (0.81) | 0.842 | 0.711–1.000 | 0.053 |
| Esophagus: Other | 63 | 0.31 | 57 (0.28) | 6 (0.03) | 1.796 | 0.792–4.073 | 0.225 |
| Stomach: Other | 89 | 0.43 | 79 (0.38) | 10 (0.05) | 1.493 | 0.781–2.854 | 0.307 |
| Duodenum: Other | 18 | 0.09 | 16 (0.08) | 2 (0.01) | 1.51 | 0.387–5.900 | 0.756 |
| Total | 20,620 | 100.00 | 17,346 (84.12) | 3274 (15.88) | – | – | – |

ASGE American Society for Gastrointestinal Endoscopy
Similar to several other studies (9,25,26,35), the most common inappropriate indication was dyspepsia in patients 45 years of age or younger who received no adequate treatment and experienced no alarm symptoms. Similar indication frequencies were reported in a large American national endoscopic database (36), in which EGD was most commonly performed to evaluate dyspepsia and/or abdominal pain (23.7%), dysphagia (20%), symptoms of gastroesophageal reflux without dysphagia (17%) and suspected upper gastrointestinal bleeding (16.3%).

Endoscopic examination of the upper gastrointestinal tract in fecal occult blood test (FOBT)-positive individuals reveals mostly benign disease, with an equal prevalence in colonoscopy-negative and colonoscopy-positive patients. These types of endoscopies have a very low diagnostic yield for significant lesions, not only from a therapeutic standpoint, but also for the detection of malignant lesions (37). Our findings support what is already known – that performing routine upper endoscopy in FOBT-positive individuals is not indicated and should be undertaken only for appropriate symptoms (38), especially in patients with anemia (39,40).

Our study showed that most findings were not clinically relevant when gastroscopy was performed for chest pain. The literature reports that gastroesophageal reflux disease (GERD) and dysmotility are the most frequent causes of esophageal chest pain. Additional available data regarding the prevalence of esophageal and upper gut findings in patients with noncardiac chest pain showed that a normal upper endoscopy was noted in 44.1%, 28.6% had a hiatal hernia, 19.4% had erosive esophagitis, 4.4% had Barrett’s esophagus and 3.6% had stricture/stenosis (41). We agree with the European Expert Panel who believed that endoscopy is appropriate, but not crucial, for patients with noncardiac chest pain who underwent a previous cardiac workup and whose symptoms were unresponsive to GERD treatment. Conversely, in the absence of a previous cardiac workup, endoscopy is inappropriate (42).

Study limitations
Indications for OAE were based on information provided from the referral forms; consequently, appropriateness was possibly underestimated. Furthermore, we did not include histological analysis of normal mucosa, which could lead to a diagnosis of celiac disease and, therefore, clinical relevance.

Appendix 1 of the ASGE guidelines (43) provides examples (ie, including, but not limited to) of acceptable indications for OAE. For gastroscopy, they included the following: dyspepsia that is poorly responsive to proton pump inhibitor trial, chronic GERD to rule out Barrett’s esophagus and positive guaiac-based FOBT (for patients with negative colonoscopy results).

Major complication rates were extremely low. However, despite our regular meetings and monthly follow-up reports, it is theoretically possible that delayed complications occurred and were not reported to us by the referring physicians and, therefore, not included in our data. The two complications documented in the present study concur with those reported in previous studies (44,45). The low incidence rate of respiratory depression of slightly below one in 500 procedures documented in the present study was comparable with incidence rates reported in the literature. Reports from nonanaesthesia endoscopy specialists working in three separate centres documented incidence rates of respiratory events requiring bag-mask ventilation that ranged from slightly below one in 500 to slightly below one in 1000 cases (46).

CONCLUSION
We reported our substantial experience with more than 20,000 endoscopic procedures, referred to us in an OA model over a nine-year period. As shown, this referral system is growing annually. It is more efficient, less costly and safer than endoscopy requiring previous consultation. Education programs for the referring physicians must be implemented to maximize the potential of this system to assist them in providing proper medical care before and after the procedure.

The results show that the ASGE guidelines are a good tool to enable the comparison of different centres with respect to procedure results and indications. However, using these guidelines as the sole determinant for performing endoscopies is not advisable because many clinically relevant diagnoses may be overlooked. Successful implementation of an OA system requires ongoing assistance to the general practitioners as to the appropriate indications for gastrointestinal endoscopy.

KEY RESULTS AND MESSAGES
- Single-centre, nine-year experience with more than 20,000 OAE procedures.
- OAE is a very safe, much less expensive and less time-consuming system.
- The most common indications in the ASGE-appropriate group were dyspepsia in patients older than 45 years of age and in those with anemia.
- The most common indication in the non-ASGE-appropriate group was dyspepsia in patients younger than 45 years of age who had not previously undergone a therapy trial.
- The most common findings were hiatal hernia and nonerosive gastritis.
- Strict adherence to the ASGE guidelines would have missed many malignancies and duodenal ulcers.
- We suggest a ‘liberal’ policy in performing all open-access upper gastrointestinal endoscopies unless a contraindication is present.
- We stress the importance of close, regular contact between the OAE unit and referring family physicians.

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