

Actual endoscopic versus predicted surgical mortality for treatment of advanced mucosal neoplasia of the colon

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Background: EMR of advanced mucosal neoplasia (AMN) (ie, sessile or laterally spreading lesions of ≥ 20 mm) of the colon has become an increasingly popular alternative to surgical resection. However, data regarding safety and mortality of EMR in comparison to surgery are limited.

Objective: To compare actual endoscopic with predicted surgical mortality.

Design: Prospective, observational, multicenter cohort study.

Setting: Academic, high-volume, tertiary-care referral center.

Patients: Consecutive patients referred for EMR.

Intervention: EMR.

Main Outcome Measurements: To predict hypothetical surgical mortality, the Association of Coloproctology of Great Britain and Ireland score, composed of physiological and surgical components, was calculated for each patient. Predicted surgical mortality was then compared with actual outcomes of EMR. The results were validated by an unselected subcohort by using the Colorectal Physiologic and Operative Severity Score for Enumeration of Mortality and Morbidity.

Results: Among 1050 patients with AMN treated by EMR, including patients with a predicted mortality rate of greater than 5% (13.8% of cohort), no deaths occurred within 30 days after the procedure. The predicted surgical mortality rate was 3.3% with the Association of Coloproctology of Great Britain and Ireland score ($P < .0001$). This suggests a significant advantage of EMR over surgery. The results were validated by using the Colorectal Physiologic and Operative Severity Score for Enumeration of Mortality and Morbidity in 390 patients predicting a surgical mortality rate of 3.2% ($P = .0003$).

Limitations: Nonrandomized study.

Conclusion: In this large multicenter study of EMR for colonic AMN, the predicted surgical mortality rate was significantly higher than the actual endoscopic mortality rate. Given that endoscopic therapy is less morbid and less expensive than surgery and can be performed as an outpatient treatment, it should be considered as the first line of treatment for most patients with these lesions. (Gastrointest Endosc 2014;80:668-76.)

(footnotes appear on last page of article)



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Colorectal cancer (CRC) is the second most common cancer and cause of cancer death in Australia and the United States.^{1,2} In the majority of cases, it develops by the well-established adenoma-carcinoma sequence, allowing a therapeutic window to intervene. More than 85% of colonic polyps are small (< 10 mm) and are easily treated by endoscopic polypectomy. Modeling against historical

controls has clearly shown that colonoscopic polypectomy substantially reduces the incidence and mortality of CRC.^{3,4} With widespread CRC screening, increasing numbers of advanced mucosal neoplasias (AMNs) (ie, large [≥ 20 mm] sessile polyps or laterally spreading tumors), are detected. These are premalignant and have an even stronger association with CRC than conventional polyps and therefore require therapy.⁵ Endoscopic resection of AMNs is technically challenging, time-consuming, and potentially hazardous. Thus, traditionally, surgery has been the standard of care and remains the most common treatment today.⁶⁻⁸ For example, in a recent report by the French CRC screening program, 9.3% of all individuals with a diagnosis of benign colonic adenoma underwent surgical resection.⁸ Colorectal surgery, however, is associated with significant peri- and postsurgical morbidity and mortality, particularly in these often elderly patients with multiple comorbidities.^{9,10} Over the past decade, EMR via ambulatory colonoscopy has become an increasingly used and viable therapeutic option (Figs. 1 and 2).¹¹⁻¹⁵ Prospective studies have clearly shown the efficacy and safety of EMR for AMNs in an outpatient setting.^{12,14,15} Consequently, EMR has become established as an effective and safe therapy. Thus, it may not be ethically appropriate or logistically possible to perform a randomized, controlled trial against surgery. The best evidence in this context may therefore only come from modeling outcomes.^{3,4}

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) score and the Colorectal Physiologic and Operative Severity Score for Enumeration of Mortality and Morbidity (CR-POSSUM) were both developed and validated as dedicated user-friendly scoring systems to predict postoperative mortality in CRC (ACPGBI) or colorectal surgery (CR-POSSUM).^{16,17} Both combine measures of physiological health and operative severity with cancer stage to predict postoperative mortality.^{16,17} Numerous studies have confirmed the reliability of both scoring systems to predict 30-day mortality.¹⁷⁻²³

The aim of the current study was to examine the safety of EMR versus surgery for AMNs by comparing actual endoscopic mortality with predicted surgical mortality in a large, prospective, multicenter cohort.

METHODS

Study design and patient selection

This study was part of a prospective, observational study of all patients referred for EMR of colonic AMNs 20 mm or larger at 7 Australian academic endoscopy units.¹² Ethics approval was obtained by institutional review board approval for each participating center, and all patients gave written informed consent. Consecutive patients were enrolled from July 2008 to April 2012.

A detailed description of the study protocol, including adverse events, was previously published.¹² In brief, all

Take-home Message

- EMR for advanced mucosal neoplasia of the colon is safe and likely superior to surgery in terms of mortality, not only in healthy patients, but also in elderly patients with significant cardiac or renal disease.
- These results provide strong evidence that EMR, and not surgery, should be considered as the first line of treatment in the management of large colonic lesions.

patients were referred to a tertiary hospital for EMR after a previous colonoscopy by a nationally accredited consultant endoscopist had identified an advanced but ostensibly noninvasive lesion.¹¹ Patients were reviewed by the investigators immediately before the procedure, and clinical follow-up was obtained at 14 days and subsequent intervals of 4 and 12 months. Endoscopic follow-up was obtained at intervals of 4 and 12 months. All authors had access to the study data and reviewed and approved the final manuscript.

The EMR procedure was performed as previously described,^{11,12,24} unless there were features strongly suggestive of submucosal invasion, in which case, biopsy specimens were taken and surgical review was recommended. Patients with histological features of invasive malignancy in the EMR specimen were also referred for surgical review, and if they were unwilling or medically too unwell to have surgery, surveillance was offered.

Association of Coloproctology of Great Britain and Ireland score

The ACPGBI consists of 2 physiological and 3 operative variables (Table 1). Mortality is then calculated based on the following formula¹⁶: $\text{Log}_e^{R/(1-R)} = -4.859 + \text{total score}$.

Data collection for ACPGBI

Age and American Society of Anesthesiologists (ASA) grade were recorded prospectively per study protocol. The equivalent surgery was considered successful resection, as this would be the likely result of colorectal surgery of AMNs. The cancer stage was considered Dukes stage A and operative urgency elective. ASA grade was missing in 11 of 1061 patients, leaving 1050 patients with complete data for analysis.

Colorectal Physiologic and Operative Severity Score for Enumeration of Mortality and Morbidity

The CR-POSSUM includes 6 physiological and 5 operative variables (Table 2). Mortality is then calculated based on the following formula¹⁷: $\text{Log}_e^{R/(1-R)} = -9.167 + (0.338 \times \text{physiological score}) + (0.308 \times \text{operative score})$.

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