Large refractory colonic polyps: is it time to change our practice? A prospective study of the clinical and economic impact of a tertiary referral colonic mucosal resection and polypectomy service (with videos) 🎥

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Background: Patients who have large, difficult, colorectal lesions not readily amenable to endoscopic resection are often referred directly to surgery. The application of advanced polypectomy and endoscopic mucosal resection (EMR) techniques undertaken by a tertiary referral colonic mucosal resection and polypectomy service (TRCPS) is not often considered but may be superior to surgery.

Objective: To evaluate the safety, efficacy, and cost savings of a TRCPS for colorectal lesions.

Design: Prospective intention-to-treat analysis.

Setting: Tertiary academic referral center.

Patients: In a 21-month period ending in April 2008, consecutive patients with large or complex colorectal polyps referred by other specialist endoscopists were prospectively enrolled on an intention-to-treat basis.

Intervention: For sessile lesions, a standardized EMR approach was used. Pedunculated lesions were removed with or without pretreatment with an Endoloop procedure.

Main Outcome Measurements: Complete resection, complications, recurrence, and potential cost savings comparing actual outcome of the cohort with a hypothetical analysis of surgical management.

Results: This study included 174 patients (mean age 68 years) who were referred with 193 difficult polyps (186 laterally spreading, mean size 30 mm [range 10-80 mm]). We totally excised 173 laterally spreading lesions by EMR (115 piecemeal, 58 en bloc). Invasive adenocarcinoma was found in 6 lesions—5 treated successfully with EMR. Eleven patients were referred directly to surgery without an endoscopic attempt due to suspected invasive carcinoma. Seven >30-mm, pedunculated polyps were removed. There were no perforations. A total of 20 bed days was used because of endoscopic complications. Among all patients referred, 90% avoided the need for surgery. Excluding patients who were treated surgically for invasive cancer, the procedural success was 95% (157 of 168). By using Australian cost estimates applied to the entire group and compared with cost estimates assuming all patients had undergone surgery, we calculated the total medical cost savings was $6990 (U.S.) per patient, or a total savings of $1,216,231 (U.S.).

Limitation: Not a randomized trial.

Conclusions: Colonoscopic polypectomy performed by a TRCPS on large or difficult polyps is technically effective and safe. This approach results in major cost savings and avoids the potential complications of colonic surgery. This type of clinical pathway should be developed to enhance patient outcomes and reduce health care costs. (Gastrointest Endosc 2009;70:1128-36.)

Endoscopic polypectomy at the time of colonoscopy is a highly effective intervention in the prevention of colo-rectal cancer in both average- and high-risk patient groups.[1,2] The vast majority of polyps detected during colonoscopy are <10 mm and do not represent a significant challenge for an appropriately trained and skilled colonoscopist.[3] A small proportion of "difficult" polyps are not amenable to standard techniques of endoscopic resection, primarily large, sessile lesions >20 mm in diameter but also giant, pedunculated lesions. These polyps are uncommonly encountered in routine practice and represent a therapeutic challenge for individual endoscopists when they are detected. Issues of safety, incomplete resection, and recurrence mean that many patients are referred for surgical management in preference to endoscopic treatment.[4,5] However, the majority of these lesions are benign, and, thus, if endoscopic resection were a viable option, substantial cost savings and clinical gains might be anticipated. This study was undertaken to assess the clinical and economic impact of a tertiary referral colonic mucosal resection and polypectomy service (TRCPS).

METHODS

The study was approved by the human ethics and research committee. All patients referred for the management of difficult polyps gave informed consent and were enrolled prospectively on an intention-to-treat basis over a 21-month period ending in April 2008. Patients with previous incomplete resections performed at other institutions were also included. All polyps had been detected at a preceding colonoscopy by a specialist endoscopist[6] from outside of our service and were considered too difficult or hazardous to be removed on the basis of the endoscopists' skills or the resources available to them. All patient referrals included biopsy results, and only those without invasive malignancy were included in this study. The referring endoscopist was asked to advise us of the intended treatment plan for cases in which the TRCPS was unsuccessful.

An established clinical pathway was followed, with a member of the medical staff reviewing all referrals. Patients received detailed information regarding the rationale for, alternatives to, and potential benefits and complications of complex polypectomy. Direct consultation of referred patients was not routinely performed except in cases of substantial comorbidities, a potentially inappropriate referral, or at patient request. Treatment with antiplatelet agents was discontinued for 7 days prior to the procedure, except in the presence of a significant contraindication, such as a drug-eluting coronary stent. Warfarin therapy was managed in accordance with recognized guidelines and was discontinued for 4 doses prior to the procedure.[7]

Capsule Summary

What is already known on this topic

- Many patients with large, complicated polyps undergo surgery instead of endoscopic treatment because of fears of safety, incomplete resection, or recurrence.

What this study adds to our knowledge

- In 174 patients with 193 large or complex colonic polyps referred to a tertiary referral colonic mucosal resection and polypectomy service, 90% avoided the need for surgery, and the procedural success rate was 95%.

Colonoscopy was performed using Olympus 180 series pediatric, variable-stiffness colonoscopes (Olympus Optical, Japan, Tokyo) with narrow band imaging (NBI) capability. Two senior endoscopists (M. J. B. and S. J. W.) performed or directly supervised all procedures. The diameter of the polyp was estimated at the time of colonoscopy by reference to an open polypectomy snare placed adjacent to the polyp.

Technical success was defined as complete removal of all visible polyp tissue in a single treatment session. Bleeding was classified as immediate if it required additional measures over and above dilute adrenaline (1:10,000) injection. This type of bleeding was primarily managed by the placement of endoscopic clips (Resolution Clip, Boston Scientific, Natick, Mass; QuickClip, Olympus). Bleeding was classified as delayed if it occurred after discharge and was of a clinically significant level to require readmission.

Polypectomy was not attempted on frankly malignant lesions, in particular those with surface ulceration, effacement of surrounding mucosal folds, or fixed central depression. The endoscopist at his or her discretion could elect not to continue with the resection in the presence of a nonlifting sign. However, all of these cases were included in the final analysis as per the intention-to-treat protocol.

EMR procedures were performed on outpatients in the morning. After EMR, patients remained in a second-stage recovery area for 4 to 6 hours until medically cleared for discharge by the endoscopist. If there were clinical concerns, the patient was admitted for observation. On discharge, dietary instructions were for clear fluids overnight and to resume a normal diet the following day. We provided patients with written contact information and instructions regarding symptoms and potential problems.

EMR technique

The department's EMR technique has previously been described.[8] Key aspects are demonstrated in Videos 1 and 2 (available online at www.giejournal.org). The

Figure 1. A 60-mm granular laterally spreading tumor (Paris 0-IIa) involving the ileocecal valve. (**A**) Before, (**B**) during, and (**C**) after resection. The same tumor is shown in Video 1.

injection solution for EMR consisted of 1 mL of 0.4% indigo carmine and 1 mL of 1:10,000 adrenaline combined with 8 mL of normal saline solution. En bloc resection was attempted for lesions less than 25 mm. For lesions greater than 25 mm, sequential piecemeal EMR resection was performed (taking as few pieces as was safely possible), with emphasis placed on the inclusion of a small (1-3 mm) margin of normal tissue in the lateral margins (Fig. 1), analogous to surgical removal of cutaneous lesions.[9] Tissue was cleared in a systematic fashion from the point of first entry into the submucosal plane, working from the edge of the defect within the established plane (Fig. 2), similar to the technique used in surgical dissection.[10] For extensive lesions (greater than 40 mm or those that occupied more than 1 wall of the colon), injection and resection of each wall or a half segment (Fig. 3) were performed in turn to allow free access to tissue within potentially sharp angulations, enhance visualization, and minimize time for subsidence of the cushion due to fluid diffusion.

When recognition of the polypectomy site at colonoscopic follow-up was likely to be difficult—location on the proximal side of the fold or absence of nearby localizing landmarks (transverse or redundant, featureless colon)—the site was marked by a submucosal injection of sterile carbon particle suspension (Spot, GI Supply, Camp Hill, Penn) in the adjacent normal mucosa.

The dominant parts of large polyps resected piecemeal or those resected en bloc were flattened and fixed onto corkboard before pathological fixation. All specimens were analyzed by GI specialist pathologists. Lesions with high-grade dysplasia (HGD) or carcinoma were reviewed in conjunction with the investigators.

Surveillance colonoscopy and follow-up

Clinical follow-up was performed at 2 weeks, when results were communicated to the referring specialists and patients. The surveillance colonoscopy protocol was as follows: For patients who had undergone a technically successful and complete resection, with endoscopically clear margins and without HGD, colonoscopy at 12 months was recommended. For patients with HGD or a potentially incomplete resection, a procedure was scheduled in our unit at 3 months. When invasive malignancy was detected, surgical review was advised. At follow-up colonoscopy, the site of the EMR scar (Figs. 4 and 5), with or without the Spot tattoo, was visualized. Residual/recurrent adenoma was excised with a minisnare and, if necessary, ablated with argon plasma coagulation (APC). Submucosal injection was generally not performed to remove small, flat, residual tissue, because injection tends to elevate mucosa around the target, but not beneath it, creating a canyon effect and making subsequent resection difficult.

Economic analysis

Economic analysis was calculated by using the Australian National Cost Data Collection 2004-2005 (Commonwealth Department of Health and Ageing), with an indexation factor of 9.4% applied for increases to 2006-2007 (Commonwealth Department of Health Model). Costs were converted to U.S. dollars by using an exchange rate of $AU 1.00 = $U.S. 0.65. Analysis of endoscopic management included average cost of service and consumables. An outpatient-day-only polypectomy procedure was assigned a length-of-stay value of 1 day. No analysis was made of patient- or community-related financial or social costs, such as sick leave. Surgery was assigned depending on polyp location, with the least expensive cost code applied for each surgical procedure, assuming no catastrophic or severe complications. Unplanned admissions after polypectomy, as well as early (3 month) repeat colonoscopy, was factored into the cost of avoiding surgery. Current guidelines[11] advise postoperative colonoscopy at 12 months, so ongoing health care costs between the 2 arms were assumed to equilibrate at this point.

Statistical analysis

Descriptive statistical analyses were performed with statistical software (SPSS for Windows version 15, SPSS Inc,
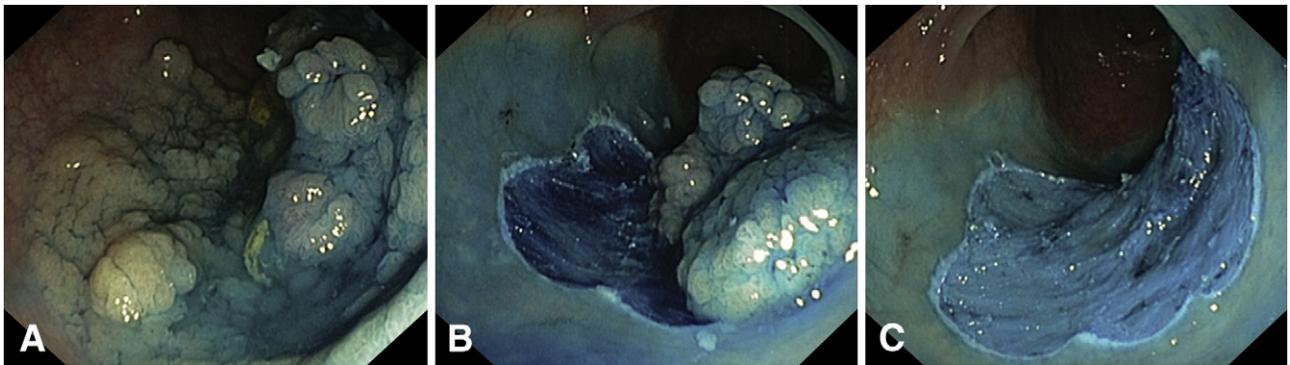
Figure 2. A 50-mm granular laterally spreading tumor (Paris 0-IIa + Is) in the proximal rectum. (**A**) Before, (**B**) during, and (**C**) after resection.
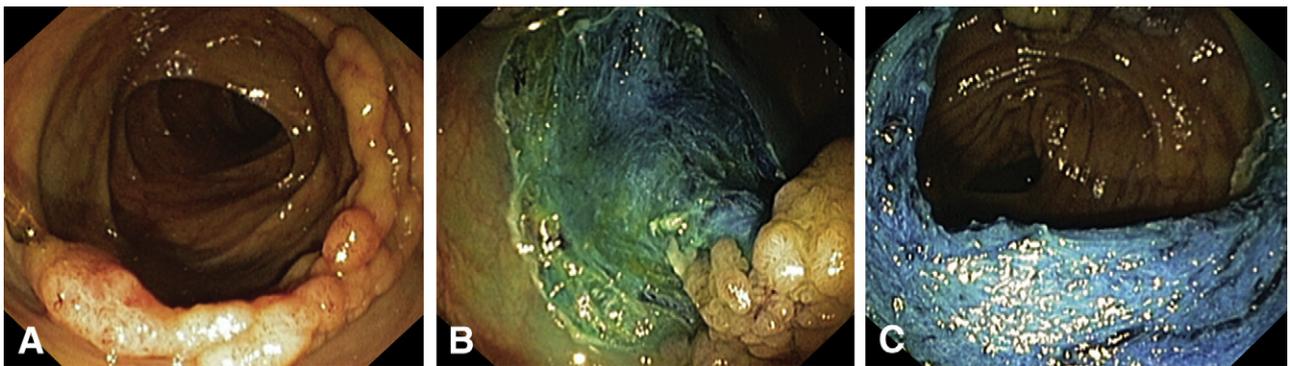

Figure 3. A 50-mm hemicircumferential granular laterally spreading tumor (Paris 0-IIa) in the distal transverse colon. (**A**) Before, (**B**) during, and (**C**) after resection.
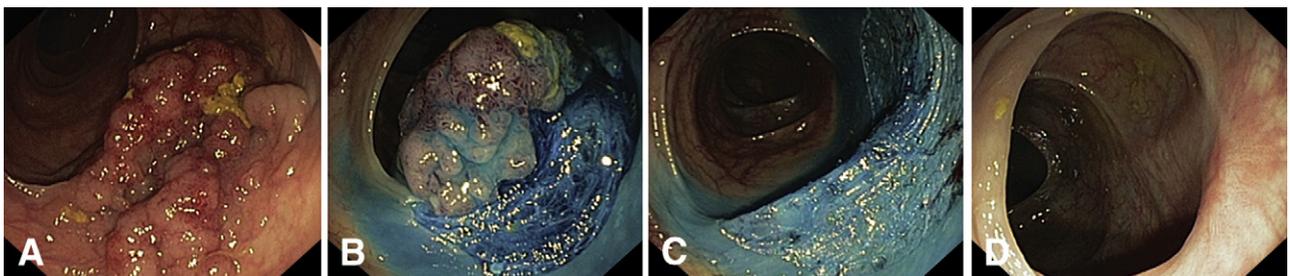

Figure 4. A 50-mm granular laterally spreading tumor (Paris 0-IIa + Is) of the midtransverse colon. (**A**) Before, (**B**) during, and (**C**) after resection. **D**, Follow-up at 3 months. The same tumor is shown in Video 2.

Chicago, Ill). Mean and median were calculated for continuous data. The Mann-Whitney test and *t* test were used to test for differences in continuous data, and a chi-square test or Kruskal-Wallis test was used for categorical data. Differences were considered significant if the 2-sided *P* value was <.05.

RESULTS

Between August 2006 and April 2008, a total of 3298 colonoscopies were performed in the department. The study included 174 patients (Table 1, Fig. 6) with 193 large or complex colonic polyps (186 sessile, median size 30 mm,

range 15-80 mm; 7 pedunculated, median size 40 mm, range 30-70 mm) who were referred specifically to the TRCPS by 52 specialist endoscopists. One hundred twelve of 186 sessile lesions were located at or beyond the hepatic flexure. All pedunculated lesions were in the left colon.

Size distribution among the sessile lesions was 15 to 19 mm in 26 patients, 20 to 29 mm in 58 patients, 30 to 39 mm in 45 patients, 40 to 49 mm in 25 patients, and 50 mm or greater in 19 patients. One hundred seventy-three sessile lesions were totally excised by EMR (115 piecemeal, 58 en bloc). Endoscopic margins were clear after EMR alone in 157 polyps. APC was also required in 14 patients. Two patients required a second colonoscopy and EMR for successful treatment. In en
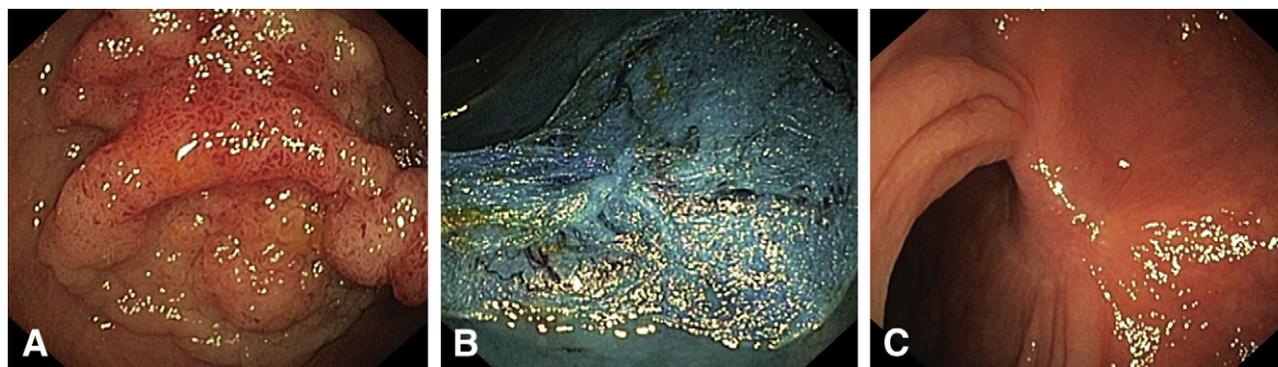
Figure 5. A 50-mm granular laterally spreading tumor (Paris 0-IIa + Is) at hepatic flexure. (**A**) Before and (**B**) after resection. **C**, Follow-up at 3 months.

TABLE 1. Patient characteristics and polyp distribution

Patient characteristic		No. (%)
Age (y)	67 ± 14.8 (SD)	
Sex		
Male		87
Female		87
ASA score	1	83 (48)
	2	54 (31)
	3	36 (20.4)
	4	1 (0.6)
Anticoagulant use	Nil	89 (51)
	Aspirin	54 (31)
	Clopidogrel	15 (9)
	Aspirin + clopidogrel	5 (3)
	Warfarin	11 (6)
Location of polyp (n = 193)	Ileocecal valve	5 (3)
	Cecum	40 (20)
	Ascending colon	54 (28)
	Hepatic flexure	12 (6)
	Transverse colon	25 (13)
	Splenic flexure	4 (2)
	Descending colon	15 (8)
	Sigmoid colon	21 (11)
	Rectum	17 (9)

ASA, American Society of Anesthesiologists score; *SD,* standard deviation.

bloc EMR cases, the mean histologic specimen size was 18 mm (range 10-32 mm), whereas for piecemeal EMR procedures, the mean size of the largest piece was 17 mm (range 5-35 mm). All 7 pedunculated lesions were re-moved successfully, with 4 requiring prior Endoloop (Olympus, Japan) placement.

Histologic results for resected polyps follow: tubulovillous 60%, tubular adenoma 17%, sessile serrated adenoma 13%, hyperplastic 3%, hamartoma 1%, and carcinoid 0.5%. As shown in Table 2, adenocarcinoma was found in 5.5% of patients (intramucosal in 3 patients and submucosal in 6 patients). HGD was present in 35% of tubulovillous polyps and 25% of tubular adenomas. One patient had a sessile serrated adenoma, and one had a hyperplastic polyp. Five patients with sessile lesions and submucosal invasion on histology subsequently underwent surgery; only 1 had residual cancer in the surgical specimen. Four patients declined to have surgery.

Twelve patients referred to the TRCPS for polypectomy did not have EMR performed (Table 3). Eleven of those patients were referred directly to surgery. Surgical specimens revealed 6 of 8 patients with invasive adenocarcinoma (T1N0) in those predicted or suspected to have invasive malignancy.

Significant primary bleeding was successfully controlled in 10 patients (hemoclips alone in 8 patients and combined with epinephrine in 2 patients). Clinically significant delayed bleeding occurred in 7 (3.7%) patients. Two underwent endoscopic (hemoclip) intervention, and 1 of those also required angiographic embolization for bleeding control. All 7 cases of delayed bleeding arose after right colonic (hepatic flexure and beyond) EMR, and this location was significantly associated with bleeding ($P = .027$). No other factors on multivariate analysis, such as polyp morphology, histology, size, or concomitant antiplatelet therapy, had a significant association with bleeding.

Eleven of 173 (6.4%) outpatients required overnight admission. Two patients developed postprocedural abdominal pain with transient features of peritonism. Four patients were admitted with localized pain only—all were discharged the next day. There were no perforations.

To date, 105 of an eligible 112 (94%) patients have undergone a scheduled follow-up colonoscopy (45 at 3 months, 60 at 12 months). Eleven (10.5%) have had minor
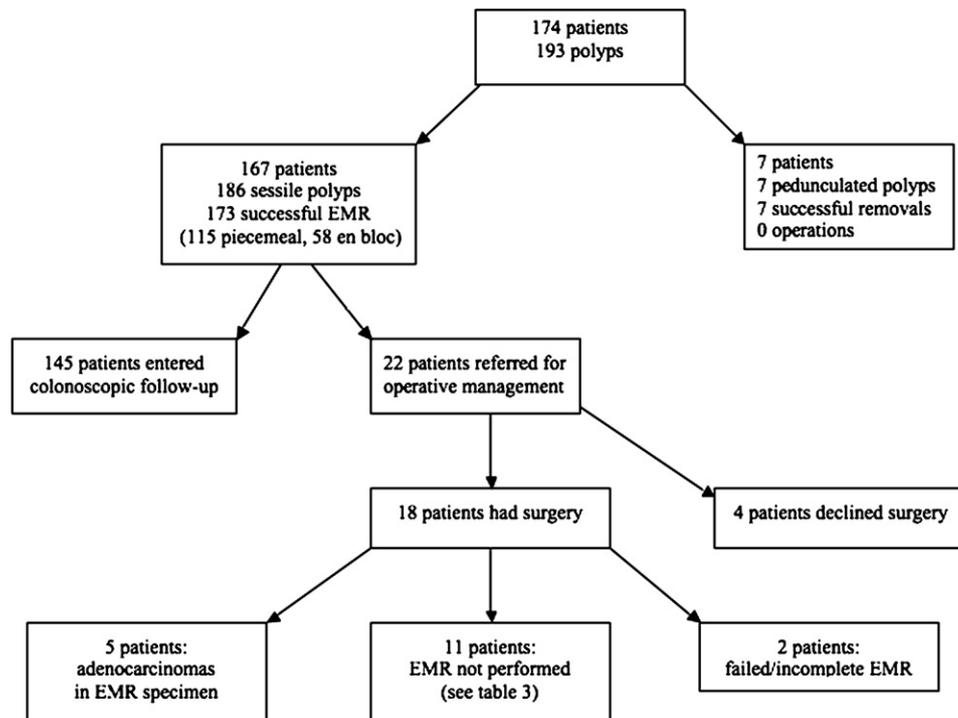
Figure 6. Flow chart of all patient outcomes.

TABLE 2. Histologic analysis of polyps			
	Adenocarcinoma	HGD	LGD
No.	9	43	141
Mean size (mm), (range)	25 (20-40)	33.6 (15-60)	27.8 (15-80)
Location			
Right colon	5	21	86
Left colon	4	23	55

HGD, High-grade dysplasia; *LGD,* low-grade dysplasia.

recurrent or residual adenoma found at the previous EMR site, all of whom have had resection with or without APC ablation. Recurrence was observed in 2 of 35 (6%) en bloc resections, compared with 9 of 67 (13.4%) piecemeal resections ($P = .33$). No invasive malignancies were found.

Surgical intervention was the intended treatment plan by the referring specialists in 173 of 174 patients in the advent of TRCPS failure. Continued colonoscopic follow-up was planned for 1 patient with hyperplastic polyposis.

Economic analysis was performed in 2 steps to assess the fiscal impact of a TRCPS approach. The first analysis assessed the actual cost of the observed outcome of the TRCPS cohort (Table 4), $2051 (U.S.) per patient. The second analysis assessed the hypothetical situation of 173 pa-

tients having surgical management (Table 5), $9041 (U.S.) per patient. Mature Australian health cost data are not available for laparoscopic colectomy procedures. Comparing the 2 techniques (Table 6), the TRCPS model represents an overall saving of $1,216,231 (U.S.) in the 174 patients, a mean cost savings of $6990 per patient and a reduction in length of stay of 6.7 days per patient.

DISCUSSION

This study describes a single-center experience in the endoscopic treatment of a large cohort of patients with large and difficult polyps, accrued in a tertiary referral setting and enrolled on an intention-to-treat basis. Large studies of such lesions are relatively uncommon requiring either multicenter involvement, long study periods, or retrospective analysis to accumulate significant numbers.[12-16] In addition, the lack of an intention-to-treat methodology in the majority of these series means that an accurate assessment of the technical efficacy for EMR cannot be made from the existing literature.[13-15] Overhiser and Rex[17] demonstrated the increased procedural costs associated with the endoscopic removal of large (>20 mm) colorectal polyps; however, they did not take into account the costs of surveillance nor comparison with surgical management.

The current series demonstrates that a TRCPS can safely remove the majority of large, sessile, refractory, or difficult polyps referred by other specialist endoscopists

TABLE 3. Characteristics of polyps when EMR was not performed (n = 12)

Patient no.	Age/sex	Location	Reason	Prior attempt	Surgical specimen histology
1	74/M	C	Cancer predicted	N	Adenocarcinoma
2	82/M	C	Cancer predicted	Y	Adenocarcinoma
3	85/F	S	Technically impossible	N	TVA, LGD
4	77/M	AC	Cancer predicted	N	Adenocarcinoma
5	68/M	R	Poor lifting, cancer predicted	Y	TVA, LGD
6	66/F	DC	Cancer predicted	N	Adenocarcinoma
7	56/F	DC	Cancer predicted	N	Adenocarcinoma
8	58/F	C	Withdrew consent	N	TVA, LGD
9	71/M	HF	Polyp not present	N	N/A
10	67/M	S	Cancer predicted	Y	Adenocarcinoma
11	45/F	TC	Cancer predicted	N	TVA, LGD
12	65/F	TC	Multiple polyps, hyperplastic polyposis	N	Hyperplastic polyps

M, Male; *C,* cecum; *N,* no; *Y,* yes; *F,* female; *S,* sigmoid colon; *TVA,* tubulovillous adenoma; *LGD,* low-grade dysplasia; *AC,* ascending colon; *R,* rectum; *DC,* descending colon; *HF,* hepatic flexure; *TC,* transverse colon.

TABLE 4. Total cost* and length of stay for TRCPS cohort

Cost incurred	No.	Cost per procedure	Total cost	Average length of stay (days)	Total days
Colonoscopy	174	$818	$142,332	1.0	174
Abdominoperitoneal resection	0	$10,496	$0	10.2	0
Anterior resection	6	$10,496	$62,976	10.2	61.2
Extended right hemicolectomy	3	$8404	$25,212	8.5	25.5
Right hemicolectomy	9	$8404	$75,636	8.5	76.5
+ Overnight stay (days)	20	$650	$13,000	1.0	20.0
+ Angiographic embolization	1	$975	$975	1.0	1.0
+ Repeat colonoscopy at 3 months	45	$818	$36,810	1.0	45.0
Total cost of TRCPS arm (174 patients)		$356,941	**Total length of stay (174 patients)**		403.2
Per-patient cost		$2051 ± 2057 (SD)	**Average length of stay per patient**		2.3 ± 2.3 (SD)

TRCPS, Tertiary referral colonoscopic polypectomy service; *SD,* standard deviation.
*U.S. dollars.

on an outpatient basis. The concentration of difficult cases within a specialist center is a critical factor in achieving such outcomes. Individual endoscopists in community or hospital-based practice encounter such lesions infrequently. Considering all patients referred, 156 patients (89%) were successfully treated with this strategy, and 151 (87%) have so far avoided an unnecessary operation. Only a small proportion (3.4%) of patients was inappropriately referred and later confirmed to have invasive cancer at surgery. They all had early stage malignancy, and it is unlikely that referral for consideration of endoscopic treatment compromised their outcomes. Among the 9

TABLE 5. Total cost* and length of stay for TRCPS cohort all undergoing surgery

Cost incurred	No.	Cost per procedure	Total cost	Average length of stay (days)	Total days
Abdominoperitoneal resection	2	$10,496	$20,992	10.2	20.4
Anterior resection	51	$10,496	$535,296	10.2	520.2
Extended right hemicolectomy	25	$8404	$210,100	8.5	212.5
Right hemicolectomy	96	$8404	$806,784	8.5	816.0
Total cost of surgery arm (173 patients)		$1,573,172	**Total length of stay (173 patients)**		1,569.1
Per-patient cost		$9041	**Average length of stay per patient**		9.0

TRCPS, Tertiary referral colonoscopic polypectomy service.
*U.S. dollars.

TABLE 6. Cost* and length of stay comparisons between actual TRCPS cohort outcome and hypothetical all surgery outcome

	TRCPS cohort	All surgery arm	Difference
Total cost for cohort	$356,941	$1,573,172	$1,216,231
Total cost per patient	$2051	$9041	$6990
Total length of stay for cohort (days)	403.2	1569.1	1165.9
Average length of stay per patient (days)	2.3	9.0	6.7

TRCPS, Tertiary referral colonoscopic polypectomy service.
*U.S. dollars.

patients who were found to have cancer after endoscopic treatment, 4 declined intervention after surgical review, reflecting a combination of the patient's preference, comorbidities, and the small risk that a cure had not been achieved. Only 1 of the 5 treated surgically had residual malignancy (T1N0). Ultimately, only 6 patients with benign disease could not be treated endoscopically.

The recurrence rate of 10.5% in this study is comparable with that of other studies of EMR and higher than early reports of colonic endoscopic submucosal dissection.[18] However, in the present study and as others have described,[14] recurrent/residual neoplasia is usually minor, benign, and easily treated. No malignancy was detected in this large cohort at follow-up. There was an observed nonsignificant trend to higher recurrence in piecemeal EMR in this study, consistent with previous studies.[19,20] A limitation of this study is the short surveillance period, with only 70% of patients having reached the timeframe for the scheduled surveillance colonoscopy.

Bleeding arose from the proximal ascending colon or cecum in all cases, and this association was highly significant ($P = .027$). No other potential factor on multivariate analysis was found to be relevant. This is the first such study to identify lesion location, specifically the very proximal colon, as a risk factor for post-EMR bleeding and may reflect a relative difference in the anatomical structure and associated submucosal vasculature of the plane of resection (deep submucosal layer). This aspect merits further prospective study.

Surgery in this cohort, who are often elderly with significant comorbidity, even if performed laparoscopically, carries significant risks and substantial costs.[21] In the Colon Cancer Laproscopic or Open Resection (COLOR) trial, the cost of laparoscopic and open colonic resections, including productivity loss, was found to be €11,660 and €9814, respectively.[22] In Australia, the health care cost of open colectomy is $10,496 (U.S.), rising to $18,519 (U.S.) in the event of a serious complication, without including productivity loss.[23] In this study, the vast majority of patients were able to resume their normal activities the following day. Only 6% required overnight hospital admission, and a further 4% were admitted for between 1 and 4 days with post-EMR bleeding. There were no perforations, and there was no associated mortality. In a recent Australian prospective observational study conducted in 3 tertiary referral centers, the investigators found a 28%

complication rate and a mortality rate of 5% in 58 patients over the age of 70 who underwent elective or emergency colonic surgery.[24] Similar surgical outcomes have been reported from large studies in the United States.[25] Adjusted 28-day mortality was between 4.5% and 5.6% for patients undergoing colectomy, and this appeared to be largely independent of operator or hospital volume.[26]

With the advent of worldwide national bowel cancer screening programs,[27] the role of a TRCPS model assumes even greater significance. Recent data suggest that up to 10% of patients with benign adenomas detected by colonoscopy after a positive fecal occult blood test will be treated surgically.[28] The current study lacks the strength of a prospective randomized trial to conclusively prove the clinical and economic superiority of endoscopic treatment over surgery, but in light of the safety and efficacy of EMR and other polypectomy techniques[29] and the current data, we believe it would now be unethical to embark on such a trial.

In conclusion, we have shown that colonoscopic polypectomy performed by a TRCPS on outpatients with large sessile or difficult colonic polyps is cost effective and safe. This approach results in major cost savings and avoids the protracted recovery and potential complications of colonic surgery in the majority of patients. This type of clinical pathway should be developed to enhance patient outcomes and reduce health care costs.

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