

Outcome of An Endoscopic Mucosal Resection Service for Large Sessile Colonic Polyps (≥ 20 mm) over A 9-Year Period: A Single Centre Experience and Analysis of Change over Time in A University Teaching Hospital

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ABSTRACT

AIM: To assess the clinical outcome of a service providing colonic endoscopic mucosal resection (EMR) of polyps ≥ 20 mm at University Hospital of Leicester NHS Trust and to assess changes over a 9-year period.

METHODS: Retrospective observational study, data were prospectively collected for all cases of sessile colonic polyps ≥ 20 mm that were removed via EMR by colonoscopists accredited by the Bowel Cancer Screening Programme (BCSP) between 2006 and

2014.

RESULTS: 569 lesions in 564 patients were assessed for EMR; 424 lesions were successfully excised via EMR. Recurrence/residual adenoma at the EMR site was found in 56 (17%) at the first surveillance endoscopy; endoscopically treated in 53/56 (95%) patients; 3/56 (5%) were referred for surgical resection. Complete eradication at second surveillance endoscopy; 269/292 patients (92%). Recurrence in 23 (8%) patients and the recurrent lesion was endoscopically resected in 22/23 patients. The overall complication rate was 17/424 (4%). There were no procedure-related deaths. Over a 9-year period, there was a consistent reduction in the number of patients with benign polyps not treated via EMR who were instead referred for surgical resection ($P = 0.003$). There were increases in the numbers of EMRs completed annually ($P = 0.001$), mean polyp size resected ($P = 0.024$) and level 3 and 4 polypectomies ($P < 0.001$). **CONCLUSIONS:** Endoscopic mucosa resection of large sessile polyps ≥ 20 mm by accredited Bowel Cancer Screening programme (BCSP) colonoscopists showed good quality of this EMR service over time.

Key words: Endoscopic Mucosal Resection; Endoscopic Polypectomy

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INTRODUCTION

Injection-assisted Endoscopic mucosal resection (EMR) is an established therapeutic procedure to remove large sessile or flat adenomatous lesions within the colon^[1]. Polyps that were previously

referred for surgical resection are now commonly removed endoscopically. The size, anatomical location and accessibility of a polyp relative to mucosal folds and flexures, determines the technical difficulty and risk of perforation and bleeding during removal^[2-6]. Five levels of competency to remove colorectal polyps have been proposed. These vary from level 0 where no lesions are removed, all referred to advance endoscopists to level 4 where large sessile lesions or other challenging polyps that may otherwise need removal surgically, are excised endoscopically^[7]. As an initiative to optimise patient outcome from endoscopic mucosal resection of benign colonic polyps at University Hospital of Leicester (UHL), it was decided that large sessile polyps identified by the medical and surgical endoscopic team would be referred for assessment and removal by accredited Bowel Cancer Screening Programme (BCSP) colonoscopists.

METHODS

A retrospective observational study of all patients referred for EMR of sessile colorectal polyps sized ≥ 20 mm over 9-year was conducted at University Hospital of Leicester NHS Trust. EMRs performed from January 2009 to December 2014 were included in the study. Follow up of all patients was completed in April 2016. Patients with underlying inflammatory bowel disease were excluded from the study. Patient demographics, resection technique, completeness of initial resection, recurrence rate at first surveillance endoscopy, level of polypectomy, histology, polyp eradication rate at second surveillance endoscopy and complication rates were compared between screening and non-screening group over 9-year period.

Upon receipt of a referral following discussion by the lower Gastrointestinal Multidisciplinary team (MDT) or a referral from medical or surgical colleagues (within UHL or Gibraltar), patients of advanced age with multiple co-morbidities underwent assessments and received explanations of the EMR procedure and the risks involved, specifically the risk of perforation requiring surgery. A referral letter was sent to the endoscopy unit to ensure the allocation of an appropriate amount of time on the endoscopy list for the EMR procedure to be performed. On the day of the procedure, the endoscopists met with the patients and obtained written informed consent. The lesions were removed via injection-assisted EMR technique. Complete snare resection was the main aim in each case. Minor residual not amenable to snare excision was subjected to argon plasma coagulation (set at 20-40W and 0.5-1L flow depending on location of the lesions) or hot biopsies. APC therapy was not used empirically to treat the margin prophylactically in cases in which complete excision was considered to have been achieved. Excised polyps were collected for histological analysis. Details regarding the EMR procedure and the immediate outcomes were immediately described by each endoscopists using the Unisoft endoscopy reporting tool. After the procedure, all complications, histological findings and outcomes at the time of follow-up endoscopy were recorded on the UHL EMR database. The Size, Morphology, Site and Access (SMSA) scoring system was used to grade the difficulty encountered during polypectomy^[8].

Four polyp levels (with increasing level of complexity) were identified based on the scoring system, Level 1 (4 - 5 points), Level 2 (6 - 9 points), Level 3 (10 - 12 points) and Level 4 (>12 points). If surveillance endoscopy showed recurrent or residual adenoma at the site of the EMR, this finding was recorded, and the lesion was treated with endoscopic resection.

Statistical analysis

Results for continuous variables were summarised as means (SD)

or as medians (IQR) for skewed data. Frequencies (%) were used to summarise categorical variables, and 95% CIs were calculated when relevant. Student's t-test was used to compare the distribution of continuous variables and difference between screening and non-screening group. All tests were two-sided and $P < 0.05$ was considered statistically significant. Time-trend analysis was used to examine the overall pattern of change in EMR service over time. Logarithmic transformations of independent variables were used in the time-trend analysis to improve data interpretation. Mean absolute percentage error (MAPE), mean absolute deviation (MAD) and mean squared deviation (MSD) were used to compare the fits of different smoothing methods in the time-trend models. A polynomial regression approach was used to control for multiple potential confounding factors in the time-trend analysis. Multivariate analysis and a best-fit multiple binary logistic regression model were used to assess risk factors associated with recurrent or residual adenoma at the time of the first surveillance endoscopy. Statistical analysis was performed using Minitab 17.

RESULTS

Patients demographics, lesion characteristics and EMR outcome

Over a 9-year period, 569 lesions in 564 patients were identified from the UHL EMR database. 424 lesions (138 in the screening group and 286 in the non-screening group) were successfully excised via EMR. The mean patient age was 68.7 years (SD 11 years), and 53% of the patients were male. Piecemeal EMR was performed in 381 (90%) successful EMR cases and 'En-bloc' in 43 (10%). The mean and median polyp sizes were 33 mm (SD 15 mm) and 30 mm (IQR 25 - 40), respectively.

EMR was not attempted in 70 patients; they were instead referred for surgical resection. Among these patients, 36 clearly harboured cancer. The remaining 34 patients were sent for surgical resection due to technical difficulties. These technically difficult lesions were located as follows: 4 within the appendiceal orifice, 2 within the Ileocaecal valve, 9 within a segment associated with diverticular disease, 2 unable to retain air, 1 within a haemorrhoid and 16 in an unstable position within the ascending colon or hepatic flexure).

There were 32 patients with incomplete resection based on the presence of a non-lifting sign; therefore, these patients were sent for surgical resection. Of these, 19 patients harboured deep invasive cancer and 13 patients harboured a benign polyp.

There were an additional 43 patients who were neither referred for surgery nor for EMR (declined surgery or EMR = 13, pseudo-polyps = 22, moved away = 8). All 43 of these patients were from the non-screening group. Those patients who declined surgery or EMR were offered computed tomography virtual colonogram (CTVC) as an alternative surveillance method and patients who had moved away were informed to arrange endoscopy follow-up via their new GP.

Out of the 424 patients who received successful EMR, 328 (77%) had undergone their first surveillance endoscopy mean 7 months (SD 6 months). A total of 96 patients were ineligible for a first surveillance endoscopy (23 of these patients had a co-morbidity that increased the risk of procedure, 37 decided not to undergo a repeat procedure, 4 patients moved away and 32 patients deceased due to medical conditions). Patients who declined follow-up endoscopy were offered CTVC as an alternative. Patients who moved away were informed to arrange a follow-up endoscopy via their new GP.

Of the 328 patients who underwent an initial surveillance endoscopy, recurrent/residual adenoma was absent in 272/328 patients (83%, 95% CI 0.78 to 0.86). Recurrence was observed in

56/328 patients (17%, 95% CI 1.29 - 2.90). Of these, 53/56 (95%) recurrent lesions were endoscopically resected. The remaining 3 patients were referred for surgical resection (2 patients with a cancerous lesion and 1 patient with a benign polyp showing a non-lifting sign).

Complete eradication at the second surveillance endoscopy (mean 16 months, SD 8 months) was observed in 269/292 patients (92%, 95% CI 8.69 to 9.43). Recurrence was found in 23/292

patients (8%, 95% CI 0.58 to 1.30). Of these 23 patients, 22 (96%) were treated endoscopically. Resection was impossible in 1 patient due to underlying fibrosis, and this patient continues to be under surveillance.

A total of 36 patients were ineligible for second surveillance endoscopy (19 patients declined further procedures, 12 patients passed away due to medical conditions, 5 patients had a co-morbidity that increased the risk of procedure).

Table 1 Univariate analysis comparing the screening and non-screening groups.

	Screening group	Non-screening group	95% CI	P values
Total number of EMRs N = 424	138	286		
Gender				
Male	93	176		
Female	45	110		
Mean age (years)	66 (range 60 - 74, SD 4)	70 (range 25 - 91, SD 12)		
Mean polyp size (mm)	28 (range 20 - 65, SD 8)	34 (range 20 - 100, SD 13)	(-17.65, 0.76)	0.01
Histology				
Sessile serrated adenoma	9	113	(-19.67, -3.44)	0.04
Tubular adenoma	36	47		
Tubular villous adenoma	77	78		
Villous adenoma	14	47		
pT1 adenocarcinoma	2	1		
EMRs not attempted; patients referred for surgical resection (cancer) N= 36	19 (53%)	17 (47%)	(-1.68, 2.12)	0.87
EMRs not attempted; patients referred for surgical resection (Technical difficulty) N = 34	5 (15%)	29 (85%)	(-3.88, 1.45)	<0.05
Incomplete EMRs referred for surgical resection (Cancer) N = 19	8 (42%)	11 (58%)	(-1.62, 0.95)	0.589
Incomplete EMRs referred for surgical resection (Benign polyps) N = 13	6 (46%)	7 (54%)	(-1.27, 1.05)	0.84
Ineligible for first surveillance endoscopy N = 96	2 (2%)	94 (98%)	(-20.76, -2.24)	0.018
Recurrent/Residual adenoma at the time of the first surveillance endoscopy N = 56	12 (21%)	44 (79%)	(-5.44, -1.67)	<0.001
Ineligible for the second surveillance endoscopy N = 36	0	36 (100%)	(-7.25, -1.75)	0.003
No recurrent/residual adenoma at the time of the second surveillance endoscopy N = 266	136	130	(-10.69, 12.02)	0.9
Level of polypectomy				
Level 2 (N = 128)	65 (51%)	63 (49%)	(-4.34, 4.79)	0.85
Level 3 (N = 189)	73 (39%)	116 (61%)	(-13.45, 3.89)	0.025
Level 4 (N = 107)	50 (47%)	57 (53%)	(-5.65, 4.09)	0.45

Table 2 Time-trend analysis over a 9-year period using polynomial best-fit regression model.

variables	Trend analysis	Mean absolute percentage error (MAPE)	Mean absolute deviation (MAD)	Mean square deviation (MSD)	Adjusted R2	S-value	P value
Number of patients identified for EMR	S-curve trend model	3.83	0.147	0.042	0.9	69.34	< 0.001
Number of EMRs completed	S-curve trend model	5.96	0.197	0.055	0.98	222.19	0.001
Number of sessile serrated adenomas resected	Quadratic trend model	29.5	0.486	0.343	0.88	31.6	0.001
Mean polyp size (mm)	S-curve trend model	2.98	0.097	0.017	0.61	7.37	0.024
Recurrence at the time of first surveillance endoscopy	Quadratic trend model	28.14	0.376	0.150	0.23	3.32	0.111
Number of Adenomas resected	S-curve trend model	12.7	0.266	0.13	0.92	45.57	< 0.001
Level 2 polypectomy	S-curve trend model	11.07	0.188	0.053	0.98	361.33	< 0.001
Level 3 polypectomy	Linear tend model	10.58	0.224	0.074	0.97	131.99	< 0.001
Level 4 polypectomy	Quadratic trend model	11.79	0.196	0.058	0.93	54.78	< 0.001
EMRs not performed; patients referred for surgical resection (benign polyps)	Quadratic trend model	6.028	0.053	0.004	0.82	18.74	0.003
Complete eradication at the time of first surveillance endoscopy	S-curve trend model	14.08	0.245	0.144	0.8	17.2	0.003

Differences between Screening and Non-screening group

The results of univariate analysis comparing the screening and non-screening groups are summarised in Table 1. Three cases of adenocarcinoma (pT1) were identified between 206 and 2014. In these three cases, the lesion was removed via EMR in 2006, 2009 and 2013; afterwards complete clearance with no evidence of local invasion, lymphadenopathy or metastasis was observed based on evaluation of resected colonic tissue or subsequent imaging. None of the polyps removed were known to be cancers prior to EMR, all were thought to be adenomas.

Changes over 9-years

Overall the time-trends suggested an increase in resection of sessile serrated adenoma, level 3 and 4 polypectomies over time, with corresponding reductions in the number of patients with benign polyps referred for surgical resection. The results of time-trend analysis of the changes over 9-years are summarised in Table 2.

Risk factors for early recurrence or residual adenoma

The results of multiple logistic regression analysis are summarised in Table 3.

The hospital patient administration system was used to determine the 30-day readmission rate following EMR and notes were reviewed to establish the cause of re-admission. Complications were classified as immediate perforation, immediate peri-procedural bleeding that required therapy (e.g. adrenaline or endoclips), delayed bleeding that required re-admission, post-polypectomy syndrome leading to re-admission, delayed perforation leading to re-admission, and death. The overall complication rate was 17/424 (4%). In 2013, there was one immediate perforation (0.2%) in a patient post EMR 80 mm caecal villous adenoma. In this case, the perforation site was sealed with endoclips. The patient was admitted for 7 days and treated with intravenous antibiotics. Surgical intervention was not required, and the patient was discharged with no further complications. Delayed bleeding occurred in 2 cases (0.5%) in 2013 and 2014; these patients required therapeutic intervention with endoclips and admission to a ward for 3-days of observation. There were 14 (3.3%) patients with

Table 3 Multivariate analysis using best-fit multiple logistic regression model to identify risk factors associated with recurrence at the EMR site during first surveillance endoscopy.

Risk factors for recurrent/residual adenoma	Odd ratio (OR)	P Value
Lesion size (mm)		
20	0.70 (0.31, 1.63)	0.41
21 - 30	1.13 (1.50, 4.69)	0.012
31 - 40	3.18 (2.85, 16.55)	0.03
> 40	5.74 (1.47, 22.34)	0.012
Prophylactic endoclips post EMR	1.04 (0.42, 2.59)	0.92
Argon plasma coagulation use (APC)	0.27 (0.07, 0.98)	0.047
Hot biopsy use	0.75 (0.32, 1.73)	0.012
Splenic flexure	0.07 (0.01, 0.90)	0.041
Caecum	11.13 (1.56, 79.37)	0.016

post-polypectomy pain syndrome requiring admission for intravenous administration of fluid and antibiotics. The mean polyp size in those 14 patients was 37 mm (SD 20 mm). No surgical intervention required for those patients and there were no procedure-related deaths.

DISCUSSION

The UHL EMR data for large sessile polyps ≥ 20 mm presented in this manuscript demonstrate that over a 9-year period, the number of EMR procedures performed increased by tenfold and the appearance of recurrent/residual adenomatous tissue reduced from 33% of cases in the first year to 7.4% of cases in the ninth year. This result was supported by an overall serious complication rate of 4%. There were no deaths or operative intervention required in any of these patients. In our case series, more patients in the non-screening group were referred for surgical resection due to technical difficulty ($P < 0.05$), were ineligible for follow-up endoscopy due to underlying co-morbidities, ($P = 0.018$) and showed recurrent/ residual adenoma at the EMR site at the time of the first surveillance endoscopy ($P < 0.001$). There were also more patients in the non-screening group

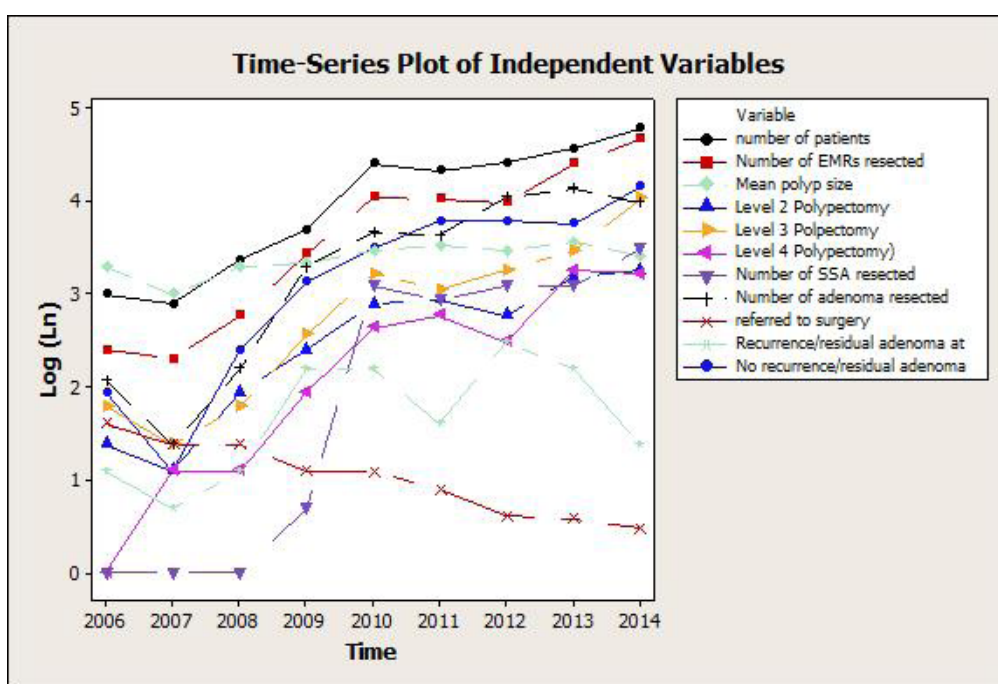


Figure 1 Scatter plot showing log-transformed values for independent variables over time since 2006.

receiving level 3 polypectomy ($P = 0.025$), having a larger polyp size ($P = 0.01$) and receiving resection of sessile serrated adenoma ($P = 0.04$). The increased prevalence of sessile serrated adenoma in the non-screening group (mean age 70 years old) was comparable to the findings of a recent retrospective case-control study of 499 Chinese patients with serrated polyps warranting careful endoscopic examinations^[9].

Throughout the 9-year period, the time-series trend analysis showed increasing number of patients identified for EMR annually, with corresponding increases in the number of successful EMRs performed annually ($P = 0.001$), the mean polyp size resected ($P = 0.024$), the number of sessile serrated adenomas resected ($P = 0.001$) and the numbers of level 2, 3 and 4 polypectomies performed ($P < 0.001$). There was a reduction in the number of EMRs not performed for benign polyps in patients who were referred for surgical resection ($P = 0.003$).

Recurrent/residual adenoma at the EMR site at the time of the first surveillance endoscopy did not show a statistically significant difference based on time trend analysis over this 9-year period ($P = 0.111$). The risk factors identified for recurrent/residual adenoma at the time of the first surveillance endoscopy in our case series were polyp size of > 20 mm, use of APC and hot biopsies and location of the polyps at the splenic flexure or the caecum. Routine prophylactic use of endoclips after EMR resection was not associated with an early recurrence or residual adenoma. A total of 95% of adenoma recurrence or residual adenoma at the first surveillance endoscopy were managed with endoscopic resection. Recurrent or residual adenomatous tissue is more difficult to remove after a previous attempt at polypectomy due to fibrosis; hence clearance in the first EMR attempt is recommended^[10]. These results were comparable to those of the large Australian Colonic EMR (ACE) study^[11]. The results of time-trend analysis using best-fit models is shown in Figure 1. No other time series trend analysis for EMR service has been reported in the literature for comparison to our results.

The optimal timing of surveillance endoscopy following EMR of large sessile polyps ≥ 20 mm has not been established. Guidelines from the British Society of Gastroenterology and the US multi-task force recommend follow-up at 3 - 6 months following piecemeal EMR of large polyps^[12,13,14]. However, in most cases as observed in our case series, the rate of recurrent/residual adenoma at the EMR site was low. This finding suggests that 7 months may be sufficient time in most cases for recurrent/residual adenoma to become apparent but to remain small, and thus, easily treatable via endoscopic resection. Further study of a large number of patients would be required to demonstrate the superiority of an alternative schedule for these procedures. We have taken initiatives within our endoscopy unit to ensure all patients who underwent EMR for large sessile polyps to receive surveillance endoscopy within the recommended time frame.

There are limitations to our study. This single-centre retrospective observational design of our study has inherent potential for bias that was not limited by specific exclusion criteria. While the results at 16-months post EMR for all cases followed up to date are very encouraging, it would be ideal to have follow-up data over 3 - 5years to further assess the long-term outcomes of EMR. Confounding factors related to the time-series trend analysis of EMR outcome, such as changes in the sociodemographic characteristics, age structure and ethnic composition of the population have not been considered in our study.

Key performance indicators such as rates of surgery for management of large sessile polyps, time to the first surveillance

endoscopy, recurrent/residual adenoma at the time of the first surveillance endoscopy, complication rates and careful assessment and counselling of patients with multiple co-morbidities for EMRs are useful for determining the outcomes of EMR service provided over time^[15]. A nationwide EMR auditing or database entry for large sessile polyps ≥ 20 mm is needed to monitor EMR service outcomes over time and to help form further recommendations.

DECLARATIONS

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Endoscopy Department, University Hospital of Leicester NHS Trust, UK; Dr Dennis Nyuk Fung Lim – data collection, study design, statistical analysis, drafting and revision of manuscript. Dr Peter Wurm, Dr Richard Robinson, Dr John DeCaestecker – critical review of manuscript. Ms Allison Moore – Clinical Research Nurse, University Hospital of Leicester NHS Trust, UK data collection. All authors reviewed and provided final approval of the manuscript

Conflicts of interest

Ethical approval was not required. Approval was obtained from the audit committee at UHL.

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