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Endoscopic resection outcomes and predictors of failed en bloc endoscopic mucosal resection of colorectal polyps ≤ 20 mm among advanced endoscopy trainees

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ABSTRACT

Background and study aims En bloc endoscopic mucosal resection (EMR) is preferred over piecemeal resection for polyps ≤ 20 mm. Data on colorectal EMR training are limited. We aimed to evaluate the en bloc EMR rate of polyps ≤ 20 mm among advanced endoscopy trainees and to identify predictors of failed en bloc EMR.

Methods This was a multicenter prospective study evaluating trainee performance in EMR during advanced endoscopy fellowship. A logistic regression model was used to identify the number of procedures and lesion cut-off size associated with an en bloc EMR rate of ≥ 80 %. Multivariate analysis was performed to identify predictors of failed en bloc EMR.

Results Six trainees from six centers performed 189 colorectal EMRs, of which 104 (55 %) were for polyps ≤ 20 mm. Of these, 57.7 % (60/104) were resected en bloc. Trainees with ≥ 30 EMRs (OR 6.80; 95 % CI: 2.80–16.50; $P = 0.00001$) and lesions ≤ 17 mm (OR 4.56;95 CI:1.23–16.88; $P = 0.02$) were more likely to be associated with an en bloc EMR rate of ≥ 80 %. Independent predictors of failed en bloc EMR on multivariate analysis included: larger polyp size (OR:6.83;95 % CI:2.55–18.4; $P = 0.0001$), right colon location (OR:7.15; 95 % CI:1.31–38.9; $P = 0.02$), increased procedural difficulty (OR 2.99; 95 % CI:1.13–7.91; $P = 0.03$), and having performed < 30 EMRs (OR: 4.87; 95 %CI: 1.05–22.61; $P = 0.04$).

Conclusions In this pilot study, we demonstrated that a relatively low proportion of trainees achieved en bloc EMR for polyps ≤ 20 mm and identified procedure volume and lesion size thresholds for successful en bloc EMR and independent predictors for failed en bloc resection. These preliminary results support the need for future efforts to define EMR procedure competence thresholds during training.

Introduction

The removal of colorectal polyps during colonoscopy reduces the incidence of colorectal cancer (CRC) and cancer-related mortality [1, 2]. The effectiveness of this strategy is largely dependent on the completeness of the resection. Assurance of complete endoscopic resection is crucial to minimize metachronous neoplasia and post-colonoscopy CRC. In fact, it is estimated that incomplete removal of neoplastic polyps accounts for nearly one-third of interval CRC [3, 4]. From a technical standpoint, en bloc endoscopic resection of polyps is most desirable, as this approach procures a single specimen ideal for careful endoscopic and histological assessment of the deep and lateral resection margins [5]. Importantly, en bloc resection of colorectal polyps is associated with a significantly decreased risk of incomplete resection and local recurrence when compared with piecemeal removal [6]. Hence, en bloc endoscopic mucosal resection (EMR) is recommended over piecemeal EMR as an effective and safe approach for lesions up to 20 mm [7].

Yet a recent systematic review and meta-analysis confirmed that nearly 21 % of polyps between 10 and 20 mm are incompletely resected [8]. Factors associated with failed en bloc EMR of polyps ≤ 20 mm have not been fully elucidated. However, prior studies have suggested flat morphology and difficult polyp location as potential variables associated with failed en bloc EMR and incomplete resection [8–10]. Given that quality of colonoscopy and EMR are highly operator dependent, there is a need to focus our educational efforts on improving EMR performance to ensure best patient practices [11]. Nonetheless, studies on endoscopic training to improve EMR outcomes are limited. This multicenter pilot study aimed to prospectively evaluate the en bloc EMR resection rate for colorectal polyps ≤ 20 mm in size among advanced endoscopy trainees and to identify predictors of failed en bloc resection.

Methods

Study aims

The primary aims of this pilot study were to use an EMR structured assessment tool (EMR-STAT) to evaluate the en bloc EMR rate of polyps ≤ 20 mm in size among advanced endoscopy trainees and to identify predictors of failed en bloc resection using a logistic regression model. A secondary aim of this study was to determine the number of procedures and lesion size at which trainees achieved en bloc resection in at least 80 % of the cases.

Study subjects

This was a prospective multicenter study conducted at six tertiary care referral centers in the United States. The trainees from the participating centers (trainee 1 through 6) were enrolled in this study from July 2019 to July 2020. There were a total of 12 supervising endoscopists, two per institution. All trainees had completed either a 3-year gastroenterology fellowship in the United States (n = 5) or 2-year gastroenterology fellowship in Canada (n = 1). All participating trainees provided informed consent. The study was approved by the Human Research Protection Office or Institutional Review Board at each participating institution, with the University of Florida serving as the central coordinating center.

Study design

Structured data collection for colorectal EMR

The EMR structured assessment tool (EMR-STAT) was designed by both consensus opinion and review of the existing literature by expert endoscopists in colorectal EMR. The aim of this tool was to evaluate key concepts and core skills necessary for high-quality EMR as per the American Society of Gastrointestinal Endoscopy (ASGE) Practice Guidelines [12]. The EMR-STAT was developed as part of a recent study by our group to evaluate learning curves and competence in EMR among trainees during their AEF [13].

The EMR-STAT was shared with all the supervising endoscopists from the participating centers. All supervising endoscopists were interventional endoscopists with experience in colorectal EMR. The systematic evaluation process with this tool was explained, discussed and clarified by the principal investigator and all participating centers. The supervising endoscopists completed an EMR-STAT for each EMR performed by the AEF during his/her training.

The EMR-STAT included information regarding polyp characteristics (morphology, size, location), procedural complexity/difficulty, type of submucosal lift during EMR, total EMR procedure time, and type of EMR (en bloc vs. piecemeal).

The research team at the University of Florida collected the prospectively completed EMR-STAT forms from all centers. Data were de-identified and entered into a centralized electronic database at the end of the study.

Definitions

EMR was defined as either injection-assisted polypectomy (conventional EMR) or water immersion-assisted polypectomy (underwater EMR). Cases of snare polypectomy without prior submucosal lifting were not included in the study. En bloc EMR was defined as successful lesion removal as a single specimen with no endoscopically visible residual neoplastic tissue following resection. En bloc resection rate was defined as the proportion of cases of en bloc removal of colorectal polyps ≤ 20 mm in size. Polyp size was estimated in real-time by using a reference standard (i. e. open snare of known dimensions). A procedure was considered of increased complexity/difficulty if it met one or more of the following criteria as per the supervising endoscopist's assessment: difficult access/positioning for EMR, unfavorable lesion position in relationship to gravity (polyp on the dependent side), prior incomplete EMR attempt, tattoo identified at the base of the lesion, or non-lifting sign during EMR. Adverse events (AEs) were categorized according to the ASGE consensus criteria [14]. Total EMR procedure time included the interval between initiation of submucosal lifting to completion of the EMR. This included time required to remove/treat any residual adenoma, treatment of intraprocedural complications, and time for elective closure if applicable.

There are currently no guidelines on what constitutes an acceptable rate for en bloc EMR of polyps ≤ 20 mm. For our analysis, we decided examine factors such as number of procedures and lesion size on an arbitrarily chosen en bloc EMR of 80 %.

Statistical analysis

All variable and outcome distributions were summarized as percentages for categorical variables and means with standard deviation (SD) for all continuous variables. The Shapiro-Wilk test was utilized to determine normality. If variables were determined to follow a normal distribution, they were compared using an independent sample *t*-test. Non-parametric testing was performed on those that did not assume a normal distribution, including the two sample Wilcoxon rank-sum test. Dichotomous variables were evaluated in a univariate fashion using a Pearson's chi square test. If the sample size for a dichotomous variable was not sufficiently large enough, the Fisher's exact test was used. Multivariate analysis was performed to identify factor associated with failed en bloc EMR. Candidate variables for inclusion in the model included any variable significant at a $P \leq 0.1$ on univariate analysis. To assess trainee's procedural volume and lesion size on en bloc EMR rate, these variables were plotted against the primary endpoint (en bloc EMR) and fitted to a logistic regression model. We then used the model to identify the number of procedures or lesion size above which trainees achieved the desired outcome ≥ 80 % of the time. All statistical analyses were performed using SAS JMP for Macintosh OS, version 15.1 (SAS Institute Inc., Cary North Carolina, United States, 1989–2020).

▶ **Table 1** Polyp and procedural characteristics of colorectal EMR cases performed by trainees (n = 189)

Polyp size; mean (interquartile range), mm	24.3 (15–30) mm
Paris Classification; n (%)	
▪ Ip	10 (5.3 %)
▪ Is	50 (26.5 %)
▪ IIa	76 (40.2 %)
▪ IIb	23 (12.2 %)
▪ IIa + IIc	16 (8.5 %)
▪ IIa + Is	5 (2.6 %)
▪ Other	9 (4.8 %)
Polyps with prior attempted EMR; n (%)	21 (11.1 %)
▪ Polyp location; n (%)	
▪ Proximal colon	145 (76.7 %)
▪ Distal colon	44 (23.3 %)
Type of submucosal lifting agent	
▪ Normal saline	88 (46.6 %)
▪ Viscous solution	74 (39.2 %)
▪ Underwater EMR	27 (14.3 %)
Procedure time; mean (interquartile range), min	22.6 (12–29) min

EMR, endoscopic mucosal resection.

Results

Six AEFs from six advanced endoscopy training programs participated in this study. A total of 189 EMRs were performed by the six AEFs during their 12-month fellowship (trainee 1, n = 45; trainee 2, n = 44; trainee 3, n = 54; trainee 4, n = 14, trainee 5, n = 8; and trainee 6, n = 24), with a mean of 31.5 EMRs per study site AEF. The mean polyp size was 24.3 mm (interquartile range [IQR]: 15–30 mm) (▶ **Table 1**). The most common polyp morphology based on the Paris classification system was IIa (40.2 %), followed by Is (26.5 %), IIb (12.2 %), and IIa + IIc (8.5%). Twenty one of the 189 polyps (11.1 %) had prior interventions (attempted/incomplete EMR). Normal saline (88/189; 46.6 %) was the most commonly utilized submucosal lifting solution. Most EMRs were performed in the proximal colon (145; 76.7 %) and the mean procedure time was 22.6 min (IQR: 12–29 min). There were no procedural AEs reported.

EMR for polyps ≤ 20 mm in size

Of the 189 EMRs performed, 104 cases were for colorectal polyps ≤ 20 mm. En bloc resection was achieved in 57.7 % (60/104), whereas piecemeal EMR was performed in the remaining 42.3 % (44/104). ▶ **Table 2** compares procedural and polyp characteristics between the en bloc EMR and piecemeal EMR groups for lesions ≤ 20 mm in size. When compared to the en bloc EMR group, polyps removed in piecemeal fashion were larger (mean size 18.6 ± 2 vs. 14.4 ± 4 mm; $P < 0.0001$) and associated with a longer procedural time (mean 20.8 ± 11 vs. 13.3 ± 12 minutes; $P = 0.001$). A higher proportion of polyps in the piecemeal EMR group were lateral spreading granular tumors (34.1 % vs 15 %; $P = 0.02$). When compared to polyps removed en bloc, polyps resected via piecemeal EMR were more frequently located in the right colon (96 % vs 73 %; $P = 0.003$). Overall, increased procedural difficulty was more commonly encountered in the piecemeal EMR group (30/44; 68.2 %) as compared to those removed by en bloc resection (26/60; 43 %) ($P = 0.01$). In both groups, challenging access and scope positioning was cited as the most common factor for increased procedural difficulty for both the en bloc EMR (10/60; 16.7 %) and piecemeal EMR (28/44; 63.6 %) groups.

En bloc resection rate of polyps stratified by trainees' procedure volume and lesion size

A logistic regression model was used to identify the number of procedures and lesion size above which trainees achieved the desired outcome, defined as an en bloc resection ≥ 80 % of the time. Based on this model, trainees with at least 30 EMRs were identified as more likely to successfully achieve en bloc EMR of polyps ≤ 20 mm in size as compared to those with less than 30 procedures (OR 6.80; 95 % CI: 2.80–16.50; $P = 0.00001$) (▶ **Fig.1a**). With regards to lesion size, en bloc EMR was achieved in 80 % of the cases for lesions ≤ 17 mm as compared to those > 17 mm (OR 4.56; 95 % CI: 1.23–16.88; $P = 0.02$) (▶ **Fig.1b**).

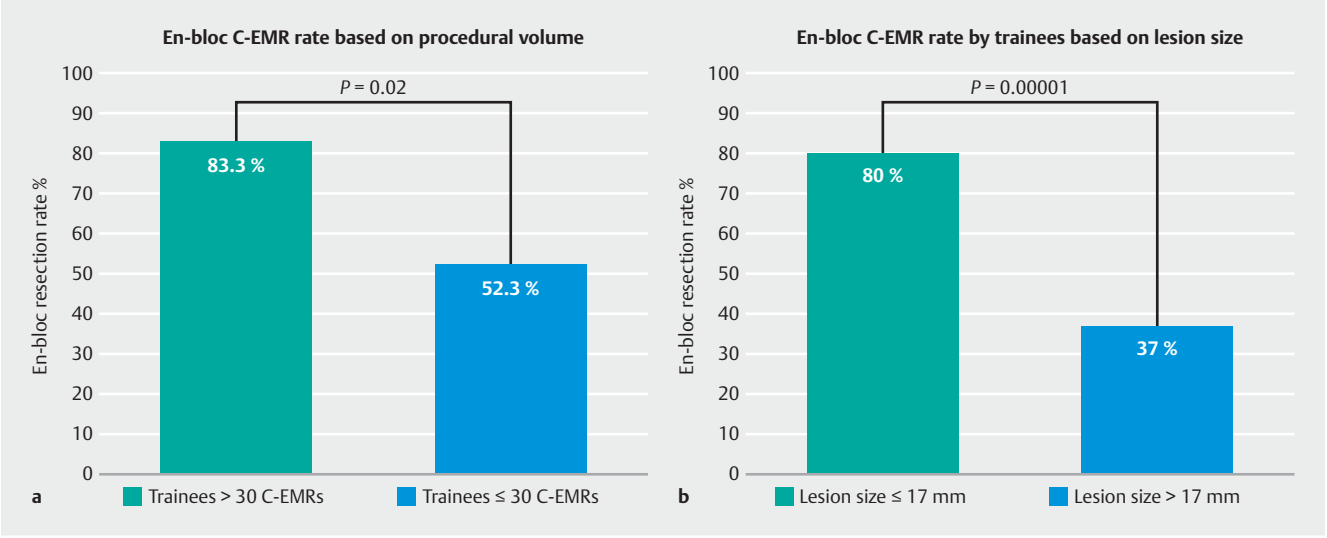
▶ **Table 2** Comparison of procedural and polyp characteristics between en bloc EMR and piecemeal EMR for lesions ≤ 20 mm.

Characteristics	En bloc EMR (n = 60)	Piecemeal EMR (n = 44)	*P* value
Polyp size, mean mm (standard deviation)	14.4 ± 5	18.6 ± 2	< 0.0001
Procedure time; mean (standard deviation)	13.3 ± 12	20.8 ± 11	0.001
Paris Classification; n (%)			
▪ Ip	2 (3 %)	1 (2 %)	1.00
▪ Is	20 (33 %)	10 (23 %)	0.28
▪ IIa	27 (45 %)	21 (48 %)	0.84
▪ IIb	8 (13 %)	6 (14 %)	1.00
▪ IIc	0	1 (2.3 %)	1.00
▪ IIa + IIc	3 (5 %)	4 (9.1 %)	0.45
▪ IIa + Is	0	0	1.00
▪ Not available	0	1 (2 %)	
Lateral spreading tumor; n (%)			
▪ Granular	9 (15 %)	15 (34 %)	0.02
▪ Non-granular	21 (35 %)	8 (18 %)	
Polyp location; n (%)			
▪ Right colon	44 (73 %)	42 (96 %)	0.003
▪ Ileocecal valve	0	3 (7 %)	
▪ Appendix	2 (3 %)	2 (5 %)	
▪ Cecum	12 (20 %)	8 (18 %)	
▪ Ascending colon	14 (23 %)	9 (20 %)	
▪ Hepatic flexure	5 (8 %)	9 (20 %)	
▪ Transverse	11 (18 %)	11 (25 %)	
▪ Left colon	16 (27 %)	2 (5 %)	
▪ Splenic flexure	0	0	
▪ Descending colon	8 (13 %)	2 (5 %)	
▪ Sigmoid	4 (7 %)	0	
▪ Rectum	4 (7 %)	0	
Procedural difficulty; n (%)	26 (43 %)	30 (68 %)	0.01
▪ Difficult access/positioning	10 (17 %)	28 (64 %)	
▪ Polyp on dependent side	6 (10 %)	3 (7 %)	
▪ Prior EMR attempt	6 (10 %)	8(18 %)	
▪ Tattoo at base of polyp	7 (12 %)	6 (14 %)	
▪ Non-lifting sign	4 (7 %)	4 (9 %)	

EMR, endoscopic mucosal resection.

Predictors of failed en bloc EMR for polyps ≤ 20 mm

On univariate analysis, potential risk factors for failed en bloc EMR included: increasing polyp size, trainees with < 30 EMR cases, polyps located in the right colon, polyps categorized as lateral spreading granular tumors, those deemed to be of higher procedural difficulty as assessed by the supervising endoscopist (▶ **Table 3**). On multivariate analysis, larger polyp size (OR:6.83; 95 % CI: 2.55–18.4; *P* = 0.0001), trainees with < 30 EMR cases (OR: 4.87; 95 % CI: 1.05–22.64; *P* = 0.04), right colon location (OR:7.15; 95 % CI:1.31–38.9; *P* = 0.02), increased procedural difficulty (OR:2.99; 95 % CI:1.13–7.91; *P* = 0.03) were



▶ **Fig. 1** En bloc EMR rate for polyps stratified by **a** trainee procedure volume and **b** lesion size.

identified as independent predictors of failed en bloc EMR of lesions ≤ 20 mm in size (▶ **Table 3**).

Discussion

En bloc EMR is preferred over piecemeal EMR of colorectal polyps up to 20 mm in size as the latter is associated with a higher risk of incomplete removal and local recurrence [6]. Hence, high quality EMR is a critical skill to acquire during endoscopic training to ensure best outcomes in clinical practice. In this prospective multicenter pilot study, we demonstrated that en bloc resection rate for colorectal polyps ≤ 20 mm was relatively low among trainees during their advanced endoscopy fellowship but improved with increased number of EMR cases.

The potential limitations of piecemeal EMR include the risk of incomplete resection requiring more frequent surveillance intervals, repeated endoscopic resection attempts, and post-colonoscopy CRC [4, 6, 12]. In fact, prior studies have suggested that incomplete resection of colorectal polyps is prevalent and may be responsible for nearly one-third of interval CRCs [4, 15]. Despite these well-recognized consequences of suboptimal EMR, there is a scarcity of data on EMR performance during endoscopic training. Using a pilot assessment tool during EMR training, we recently demonstrated that a relatively low proportion of advanced endoscopy trainees achieved competence on key cognitive and technical aspects of EMR during their fellowship [13]. These preliminary findings are supported by the current study, which showed that en bloc resection of polyps ≤ 20 mm was only achieved in 57.7 % of the cases. Our results emphasize the often underrecognized steep learning curve of EMR. Substantial training and experience are a prerequisite for optimal performance of EMR, including securing adequate resection margins. Indeed, a study evaluating colorectal polyp resection outcomes among trainees demonstrated that less than half (45.2 %) of the lesions were completely removed based on histological margin assessment [16]. Likewise, even in the hands of expert endoscopists, an unexpectedly high number of 100 EMR procedures has been reported as necessary to consistently achieve a complete resection rate above 75 % [17]. Yet EMR technique and quality, particularly for polyps ≤ 20 mm, have traditionally garnered less attention than other metrics such as adenoma detection rate and cecal intubation,

▶ **Table 3** Predictors of failed en bloc EMR of polyps ≤ 20 mm.

Variable	Univariate analysis			Multivariate analysis		
	Odds ratio	95 % CI	*P* value	Odds ratio	95 % CI	*P* value
Lateral spreading granular tumor	2.93	1.14–7.53	0.02	1.81	0.61–5.36	0.29
Right colon location	7.64	1.65–35.25	0.003	7.15	1.31–38.91	0.02
Increasing polyp size	6.80	2.80–16.50	<0.00001	6.84	2.55–18.38	0.0001
Increased procedural difficulty	4.56	1.23–16.88	0.012	2.99	1.13–7.91	0.03
Trainees with < 30 EMR cases	4.56	1.23–16.88	0.02	4.87	1.05–22.64	0.04

EMR, endoscopic mucosal resection.

possibly because it is more difficult to study [11]. However, given that most high-risk adenomas are 10 to 20 mm and how commonly these are encountered by endoscopists in clinical practice, this is an important field that deserves further attention [18]

Our study provides knowledge on potential predictors of failed en bloc EMR during training. Polyp size, particularly those larger than 17 mm, was identified as an independent predictor of failed en bloc EMR. Furthermore, when compared to polyps in the left colon, right-sided polyps were less likely to be removed en bloc. The higher failed en bloc resection rate in the right colon could be presumptively attributed to the higher prevalence of sessile serrated polyps in the proximal colon with their characteristic flat morphology and undiscernible borders [11, 19]. In addition to polyp characteristics, prior data have also shown that location in the right colon is an independent predictor of incomplete resection, perhaps due to the deeper haustral clefts in this side of the colon or difficulty in scope manipulation [20]. Not surprisingly, we identified increased procedural difficulty, primarily attributed to access and positioning of the colonoscope, as an independent predictor of failed en bloc resection. Our findings are consistent with the literature and have direct implications during EMR training. Scope positioning and stabilization with precise tip control are fundamental requirements for a successful procedure and should be an important target for future educational efforts [21]. Given the higher rate of failed en bloc resection of polyps in the right colon, initial training of gastroenterology fellows on en bloc EMR techniques may preferentially include smaller left colon lesions that are readily accessible. Furthermore, despite the many benefits of submucosal injection, attention to the technique and amount of injectate should be placed during training, as excessive submucosal injection increases submucosal tissue tension and lesion size, potentially hindering en bloc resection [22]. In part, this may potentially account for why lesions > 17 mm were significantly more challenging to resect en bloc by trainees in this study. Furthermore, considering the high rate of failed en bloc EMR for polyps ≤ 20 mm reported in this study, additional points of emphasis during training should include careful inspection of the post-resection margins and how to effectively use adjunct techniques (i. e. trimming of resection margins with cold snare, margin thermal ablation) to reduce the risk of incomplete resection and recurrence [23].

We acknowledge the limitations of the current study. Firstly, even though the study was performed at six different training centers, the overall low number of EMRs, specifically for lesions ≤ 20 mm, limits the generalizability of our results. The main focus of most advanced endoscopy fellowships remains on endoscopic retrograde cholangiopancreatography and endoscopic ultrasound, which may account for the wide variation and low number of EMRs reported by the trainees in this study. However, rather than a limitation of study design, the low case volume may reflect the status of EMR training among advanced endoscopy fellowships in the United States and raises the question of whether comprehensive EMR training can be achieved during this period. It is reassuring that our preliminary data suggest that performance improved significantly after 30 EMR cases; yet, these results should be interpreted with caution given the relatively low number of trainees involved in this study. Nonetheless, it should be noted that all trainees had already completed general gastronterology fellowship with hands-on EMR as part of their curricula. Given how common colorectal polyps ≤ 20 mm are routinely encountered, future studies evaluating performance among general gastroenterology trainees may shed further light on the preparedness of categorical gastroenterologists in the management of these lesions and their readiness for independent practice. We also recognize that the low en bloc resection rate could have been skewed by the higher complexity of the polyps included in this study, as these were lesions referred for EMR to advanced endoscopists. Furthermore, we did not include outcomes of polyps removed by conventional snare polypectomy without prior lifting via submucosal injection or water immersion, which is an accepted strategy for the resection of many lesions ≤ 20 mm. Because there are no current guidelines on what constitutes an acceptable en bloc resection rate for polyps ≤ 20 mm, this was arbitrarily set at a threshold of 80 % in this study. It should be noted that a recent randomized controlled trial comparing underwater EMR with conventional EMR demonstrated that en bloc resection rates of polyps ≤ 20 mm ranged between 65 % and 94 %, even in the hands of expert endoscopists [24]. Hence, it is not surprising that the en bloc resection rate by trainees in this study was lower at 57 % and perhaps a lower threshold may have been more appropriate. Irrespective of that, additional studies are needed to determine what is the most appropriate benchmark threshold for this outcome during fellowship training. In addition, we acknowledge that some potentially relevant variables (i. e. type and size of snares, use of electrocautery and settings) were not documented as part of the EMR-STAT. The goal was to have data collected in real time by the supervising endoscopists without delaying fellow training and clinical care. Future studies are needed to develop a comprehensive yet pragmatic data collection tool that can be widely adopted for EMR training assessment. Lastly, we acknowledge that interobserver and intraobserver variability among supervising endoscopists, differences in experience and training styles, and variations in EMR techniques were not accounted for in this study. Nonetheless, we speculate that the impact of these factors was somewhat mitigated by the a priori consensus definition of outcomes and standardized prospective data collection among the participating centers.

Conclusions

In summary, this study demonstrated that a relatively low proportion of trainees achieved en bloc resection during EMR for colorectal polyps ≤ 20 mm during their 12-month advanced endoscopy fellowship; albeit this appeared to improve with procedural volume. Larger polyp size, location in the right colon, and increased procedural difficulty were additional independent predictors of failed en bloc EMR. Our preliminary data provide a potential blueprint for future large-scale studies focused on identifying EMR technique quality indicators that

may help guide the formulation of competence criteria guidelines by professional gastroenterology societies.

Competing interests

Dr. Yang is a consultant for Boston Scientific, Lumendi, and Steris Endoscopy. Dr. Draganov is a consultant for Boston Scientific, Olympus America, Cook Medical, Microtech, Steris Endoscopy, Merit, Lumendi, and Fujifilm. Dr. Wallace is a consultant for Virgo Inc, Cosmo/Aries Pharmaceuticals, Anx Robotica (2019), Covidien, GI Supply, Endokey, Endostart, Microtech, and Boston Scientific; has stock options with Virgo Inc; and receives research grants from Fujifilm, Boston Scientific, Olympus America, Medtronic, Ninepoint Medical, and Cosmo/Aries Pharmaceuticals. Dr. Gomez is a consultant for Olympus America. Dr. Bucobo is a consultant for Cook Medical. Dr. Trindade is a consultant for Pentax Medical and Olympus America and receives research support from Ninepoint Medical. Dr. Kumta is a consultant for Apollo Endosurgery, Boston Scientific, Gyrus ACMI Inc, GLG consulting, and Olympus. Dr. DiMaio is a consultant and teacher for Boston Scientific and Medtronic and a speaker for AbbVie. Dr. Pohl receives research grants from Steris and Cosmo/Aries Pharmaceuticals.

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