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Safety of Prior Endoscopic Mucosal Resection in Patients Receiving Radiofrequency Ablation of Barrett's Esophagus

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Abstract

BACKGROUND & AIMS—Radiofrequency ablation (RFA) is safe and effective treatment for flat dysplasia associated with Barrett's esophagus (BE). However, there are limited data on the safety of RFA in patients who had prior endoscopic mucosal resection (EMR), which might increase the risk of complications. We compared complications and histologic outcomes between patients who had EMR before RFA and those who received only RFA.

METHODS—We performed a retrospective analysis of data collected from patients treated for BE, associated with dysplasia or intramucosal cancer, at the Mayo Clinic in Rochester, Minnesota, from 1998–2009. Patients were divided into groups that had RFA after EMR (group 1, n = 44) or only RFA (group 2, n = 46). We compared the incidence of complications (strictures, bleeding, and esophageal perforation) and histologic features (complete resolution of dysplasia and complete resolution of intestinal metaplasia [CR-IM]) between groups. Logistic regression analysis was performed to assess predictors of stricture formation.

RESULTS—Stricture rates were 14% in group 1 and 9% in group 2 (odds ratio, 1.53; 95% confidence interval [CI], 0.26–9.74). The rates of CR-IM were 43% in group 1 and 74% in group 2 (odds ratio, 0.33; 95% CI, 0.14–0.78). The rates of complete resolution of dysplasia were 76% in group 1 and 71% in group 2 (odds ratio, 1.28; 95% CI, 0.39–4.17). The adjusted odds ratio for CR-IM in group 1 (adjusting for age, segment length, and grade of dysplasia) was 0.50 (95% CI, 0.15–1.66).

CONCLUSIONS—Stricture rates among patients who receive only RFA are comparable to those of patients who had prior EMR. EMR appears safe to perform prior to RFA.

Keywords

Esophageal Neoplasms; Barrett's Esophagus; Ablation Techniques; Endoscopy

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Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Clinical Gastroenterology and Hepatology* at www.cghjournal.org, and at doi:10.1016/j.cgh.2011.10.030.

Conflicts of interest

This author discloses the following: Kenneth K. Wang receives research support from Barrx Medical. The remaining authors disclose no conflicts.

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A wide variety of endoscopic mucosal ablative techniques have been evaluated in an effort to define the role of ablative therapies in patients with Barrett's esophagus (BE) with or without dysplasia.¹ Endoscopic mucosal resection (EMR) is typically used to remove focal, nodular areas of dysplasia and neoplasia from the BE segment.^{2,3} However, this leaves the patient at potential risk of metachronous lesions during followup.⁴ To prevent this, EMR has been combined with ablative therapy such as radiofrequency ablation (RFA) to eradicate residual intestinal metaplasia.^{5,6}

However, RFA after EMR could theoretically result in an increase in the incidence of procedural complications; scarring of the esophagus and change in compliance of the esophageal wall after EMR might make the performance more challenging and potentially increase the risk of perforations, tears, and stricture formation.⁷

Currently available studies of complications in patients who have received RFA after EMR have been limited by small numbers, short segments of BE, and the absence of a comparison group.^{8,9}

We compared the complications and histologic outcomes of 2 cohorts of patients, those treated with RFA after EMR and those treated with RFA alone for BE and associated dysplasia.

Methods

Study Design

This was a retrospective cohort study in the Barrett's Esophagus Unit of the Mayo Clinic, Rochester and was approved by the Institutional Review Board of our institution. Data from a prospectively maintained database were obtained on consecutive patients with BE who were treated with RFA after EMR or RFA alone between 2000 and 2009. Patients who were treated with RFA included those with no dysplasia (as part of a clinical trial) or those treated for dysplasia as part of clinical practice. Patients who were treated with photodynamic therapy or with a history of stricture were excluded from this study because these have been shown to increase stricture formation after additional ablative therapy. Patients underwent four-quadrant biopsies every centimeter of the visible BE segment for dysplastic patients and every 2 cm for nondysplastic patients. For those enrolled in a study, max-capacity or jumbo forceps were used. For patients with high-grade dysplasia (HGD) and intramucosal carcinoma (IMC), baseline endoscopic ultrasound (EUS) and computed tomography (CT) (or positron emission tomography scans in those with IMC) of the chest and upper abdomen were obtained to exclude invasive and distant metastatic disease. Subsequently, RFA was performed at least 4 weeks after EMR to allow for mucosal healing if subsequent endoscopy demonstrated non-nodular disease.

Endoscopic Interventions: Group 1 (Radiofrequency Ablation After Endoscopic Mucosal Resection)

Endoscopic mucosal resection—All patients with visible or nodular lesions underwent initial EMR. Beginning in April 2000, EMR was performed by using a commercially available EMR cap (EMR-001; Olympus America Inc, Center Valley, PA).^{10,11} Since 2004, EMR was also performed by using the Duette multiband mucosectomy device (Cook Ireland, Limerick, Ireland) by using previously described techniques.¹²

Radiofrequency ablation—RFA was performed in group 1 patients after visible nodular lesions had been removed by using EMR. For patients with circumferential BE, treatment was achieved by using the circumferential ablation device (HALO 360; BARRX Medical,

Sunnyvale, CA) and the HALO 90 for focal lesions as described previously.⁸ Circumferential RFA was performed in a standard fashion by using a sizing catheter to size the distal esophagus, followed by ablation with a treatment catheter as guided by measurements of esophageal diameter. Patients returned for subsequent assessment and ablation (with the focal ablation catheter) every 10–12 weeks. Patients underwent focal RFA until there was no evidence of intestinal metaplasia on esophageal and gastroesophageal junction biopsies or a maximum of 5 RFA sessions. Residual intestinal metaplasia persisting beyond 5 RFA treatments was treated by using EMR (for dysplastic BE) or multipolar electrocoagulation for intestinal metaplasia at the junction with a 7F Gold probe.

Endoscopic Interventions: Group 2

All patients who received RFA without prior EMR for treatment of dysplastic and nondysplastic BE were identified as above. Patients treated for nondysplastic BE were part of ongoing clinical trials.

Histologic assessment—Biopsies were obtained in a four-quadrant fashion in the area of the pre-ablation BE segment and from the gastroesophageal junction before and during ablation. Histopathology assessment was performed according to the protocol in our BE unit as previously described.¹⁰ Histologic grading was the most advanced grade in the sample specimen at that endoscopic session. Dysplasia was confirmed by 2 gastrointestinal pathologists. IMC was diagnosed once there was invasion through the basement membrane into lamina propria or into muscularis mucosae.

Patient Flow and Follow-up

All patients were placed on twice a day proton pump inhibitor therapy after EMR and/or RFA. They were carefully educated regarding EMR, RFA, and possible immediate and delayed complications and were encouraged to call into the BE unit with complications. Their calls were routed to the performing endoscopist, who would take the necessary measures and document appropriately. Patients with nondysplastic BE who had RFA were treated and then biopsied as part of a study. If they had achieved complete resolution of intestinal metaplasia (CR-IM), they were followed with surveillance endoscopies yearly. Patients with low-grade dysplasia (LGD) and HGD/IMC were treated every 10–12 weeks. After they achieved CR-IM, they had surveillance endoscopies on a 6-month and 3-month basis, respectively. After patients had achieved CR-IM for 1 year, surveillance was changed to yearly.

Outcome Variables

The primary end points were complications in groups including stricture formation after RFA (with or without preceding EMR), bleeding or esophageal wall perforation, and chest pain. We defined strictures after RFA as symptomatic dysphagia with endoscopically visible narrowing of the esophagus lumen; bleeding as hemodynamically significant hemorrhage after procedure (characterized by a drop in systolic blood pressure, the need for hospitalization or blood transfusions); and perforation as a transmural tear of the esophageal wall. Pain was assessed by the physician or nurse practitioner at 2-month visit after RFA. Patients were also instructed to call in with any unusual symptoms. Secondary end points were histologic response to treatment. Complete response was defined as all biopsies negative for intestinal metaplasia (CR-IM) or dysplasia (CRD) at last available follow-up.

Statistical Analysis

Data management and statistical analysis were performed by using JMP software (version 6.0; SAS Institute Inc, Cary, NC). Continuous data were compared by using the 2-sample *t*

test or the Wilcoxon rank sum test, depending on the data normality. Categorical data were compared by using the χ^2 test (or the Fisher exact test when necessary because of small sample size). Logistic regression was used for univariate and multivariate modeling. Model parameters were estimated by the maximum likelihood method. From these estimated, odds ratios with 95% confidence intervals (CIs) were computed.

Results

A total of 90 patients were analyzed, 44 patients who had undergone RFA after EMR (group 1) and 46 patients who had only RFA (group 2). The baseline characteristics of these patients are summarized in Table 1. As is evident from Table 1, patients in group 1 were older and had longer BE segments. In addition, they were more likely to have HGD and IMC. Thirty-three subjects in group 1 (75%) and 38 subjects in group 2 (82%) were treated with circumferential (Halo 360) ablation, followed by focal ablation (Halo 90), with the remainder being treated with only focal ablation ($P = .78$).

Group 1 (Radiofrequency Ablation After Endoscopic Mucosal Resection)

The 44 patients in this group underwent a total of 92 EMR sessions. Seventy-five percent of EMRs were performed by using the Olympus EMR cap and 25% by using the Duette multiband device. The median number of EMR procedures was 2 (interquartile range [IQR], 1–2.3). The highest number in a single patient was 11. No circumferential EMRs were performed. Patients in this group underwent a total of 95 RFA sessions, median number 2 (IQR, 2–3). The maximum number of RFA sessions in this group was 5. The median time interval between EMR and first RFA was 2.8 months (IQR, 2–4.1). The median length of follow-up in group 1 was 20.5 months (IQR, 15–34.5 months).

Six patients (13.6%) developed strictures that presented with dysphagia to solid foods. They were treated successfully by using endoscopic dilation with a median of 2 dilations and complete resolution of dysphagia. Four strictures occurred with the cap method (4 of 33, 12%), compared with 2 in the multi-band method (2 of 11, 18%). These proportions were not statistically different ($P = .44$). Strictures occurred at a median of 3 weeks (IQR, 2.5–6) after RFA. Two strictures occurred after the first RFA treatment and 4 after the second RFA treatment. Histologic outcomes in this group are detailed in Table 2 with a breakdown in Table 3. Note that the 2 patients with nondysplastic BE underwent prior EMR because of nodular disease seen on pretreatment endoscopy. They both had one EMR session each and achieved CR-IM. In total, 41 patients (93%) either achieved CR-IM/CR-D or downgraded to a lower level of dysplasia: CR-IM 43%, CRD 76%, and an additional 20% downgraded. Of the remaining (3 patients with HGD), 2 remained unchanged. The last patient had received prior RFA. After the second RFA treatment, surveillance biopsies showed IMC. Imaging including positron emission tomography/CT as well as EUS did not show evidence of invasive or metastatic disease. The patient underwent subsequent EMR, which confirmed the diagnosis of malignancy but showed negative margins of resection. He is currently dysplasia-free.

A total of 3 patients reported significant postprocedure pain (all after circumferential ablation). On a subsequent appointment, one of the patients reported that he had chest pain for about 2 weeks after an RFA procedure. It resolved uneventfully with extra-strength Tylenol taken 500 mg twice a day and 2% viscous lidocaine slurry before meals. A second patient described chest pain for 2 days after an RFA procedure that resolved completely with Tylenol and viscous lidocaine. The third patient had postprocedure pain necessitating an emergency department visit the day after an RFA procedure. Work-up including a chest x-ray and electrocardiogram was nonrevealing. His pain also resolved with symptomatic

treatment. Treatment was completed successfully in all patients in the outpatient setting, with no procedure-related bleeding or esophageal perforation.

Group 2 (Radiofrequency Ablation Alone)

The 46 patients in this group underwent a total of 107 RFA sessions. The highest number in a single patient was 5. The median number of treatment sessions was 2 (IQR, 1–3). This was not statistically different between the 2 groups. The median length of follow-up for this group was 32 months (IQR, 15–58 months). Four patients (8.7%) developed strictures that were treated successfully by using endoscopic dilation with a median of 2 dilations. Strictures developed after a median time interval of 4 weeks (IQR, 3–5.5) after RFA; 3 developed after 2 RFA treatments, and 1 developed after the first RFA treatment. There has been no documented progression of disease in this group. Two patients reported significant postprocedure chest pain (both after circumferential ablation). One of the patients had persistent pain for 7 days after RFA. His symptoms resolved on treatment with viscous lidocaine and Tylenol elixir. The other patient mentioned that he had postprocedure throat pain at a subsequent visit. Patients did not have any procedure-related bleeding or perforation.

Comparison of Outcomes in Groups 1 and 2

The odds ratio of stricture formation in group 1 compared with group 2 was 1.55 (95% CI, 0.46–5.64), as detailed in Table 4. Multivariate analysis was not performed because of the limited number of noted complications. Histologic outcomes are detailed in Tables 2 and 5. The odds ratio of reaching CR-D in group 1 compared with group 2 was 1.28 (95% CI, 0.39 – 4.17) and of reaching CR-IM was 0.33 (95% CI, 0.14 – 0.78). However, after adjusting for age, length of Barrett's segment, and dysplasia grade in the 2 groups, the adjusted odds ratio of CR-IM was 0.50 (95% CI, 0.15–1.66), with a *P* value of .39. Hence, there was no statistically significant difference in terms of the likelihood of achieving CR-IM between the 2 groups.

Discussion

Endoscopic therapy of BE-associated neoplasia has been shown to be highly effective.^{8,11–15} In our study, we compared complication rates and histologic outcomes between patients who had RFA after EMR for treatment of BE and associated dysplasia and those who had RFA alone. Rates of complications were comparable between the 2 groups. In regards to histologic outcomes, CRD was similar in both groups. CR-IM was initially higher in group 2, but after adjusting for age, Barrett's segment length, and dysplasia grade, there was no statistically significant difference.

EMR is an important component of endoscopic ablative therapy of esophageal neoplasia in BE; it is a tissue acquiring technique.⁶ EMR enables proper patient selection on the basis of the histologic assessment of the resection specimen.^{14–19} Because EMR results in removal of focal lesions, further ablative therapy in the form of RFA can then be used to remove the remaining areas of dysplasia or metaplasia. RFA has been advocated for the treatment of BE with flat areas of dysplasia (85% clearance of dysplasia and 77% for intestinal metaplasia after 1 year) with minimal esophageal stenosis (6%).³ Therefore, a combination of both techniques seems the ideal treatment modality for early Barrett's neoplasia.

In our study, the lack of procedure-related bleeding or perforations in either of our 2 groups should be interpreted with caution. Because our procedures were performed by experienced personnel; experience in the community might be different. A recent study by Pouw et al⁹ reported a stricture rate of 9% in patients who had RFA after EMR. All had prior EMR, and

2 patients had undergone 2 EMR sessions. Our study is also different because we had a comparison group and did not exclude even the longest segments of BE. The study by Chennat et al⁶ reported a stricture rate of 37%. The patients in that study all had undergone between 1 and 4 EMR sessions. In our EMR + RFA group, we report a 13.6% stricture rate. The study by Shaheen et al⁸ in which patients were treated with RFA for eradication of dysplasia resulted in a stricture rate of 6%. Our stricture rate in this study for the RFA group is 8.7%. In our study, 83% of this group underwent treatment with both HALO 360 and 90 and overall had longer BE segments (8 cm was the upper limit of the BE segment in the study by Shaheen et al). This might account for the higher rate of stricture formation in our study.

In group 1, the CR-IM rate was lower than that in a recent previous study.⁹ There are several possible explanations for this. Ours is the largest study to date of its kind (including patients who underwent RFA, with and without preceding EMR). We included patients with very long segment BE and patients with HGD who had visible nodules requiring EMR and IMC (this is distinct from the randomized controlled trial,⁸ which included only few subjects needing EMR), which is likely to reflect more aggressive biology and might lead to decreased rate of response.²⁰ Furthermore, we systematically biopsy the gastroesophageal junction and do not place subjects in the CR-IM category until all esophageal and gastroesophageal junction biopsies are negative for intestinal metaplasia. Of the 57% of subjects not in CR-IM at the end of follow-up in this study, 25% had intestinal metaplasia only at the junction. These patients were subsequently treated with multipolar electrocoagulation at the gastroesophageal junction, and 80% have reached CR-IM by our definition.

The strengths of our study include uniformity of technique, endoscopic expertise in the management of BE neoplasia, and careful standardized assessment and follow-up. Patients with BE segments of all lengths and nodularity requiring EMR were included, potentially increasing external validity. Limitations include both groups were dissimilar with respect to age and histologic grade at baseline. This is understandable because patients undergoing EMR are more likely to have higher grades of dysplasia and to be older. A prospective randomized trial is unlikely to be performed because EMR cannot be justified in patients without a visible lesion, which is more common with higher grades of dysplasia. Second, the varying lengths of follow-up for each patient did not allow for a uniformity of end points. Third, there is the possibility of a type II error. Although our results indicate similar complication rates, this might be due to lack of statistical power. This is reflected in the wide confidence intervals of estimates as seen in Table 2. These results should be confirmed in larger adequately powered studies, which are likely to require large sample sizes.

In conclusion, in this retrospective cohort study comparing complications and histologic outcomes in patients treated for BE, there was no difference in the rate of complications between those who had received prior EMR and those treated with RFA alone. In addition, despite longer BE lengths in the EMR group, the rate of CRD was similar.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations used in this paper

BE	Barrett's esophagus
CI	confidence interval
CR-D	complete resolution of dysplasia
CR-IM	complete resolution of intestinal metaplasia
CT	computed tomography
EMR	endoscopic mucosal resection
EUS	endoscopic ultrasound
HGD	high-grade dysplasia
IMC	intramucosal carcinoma
IQR	inter-quartile range
LGD	low-grade dysplasia
RFA	radiofrequency ablation

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Table 1

Comparison of Baseline Characteristics in the 2 Treatment Groups

Variables	Variables	Group 1 (RFA after EMR) (N = 44)	Group 2 (RFA) (N = 46)	P value
Age (y)	Mean, range	66.7 ± 1.3, 47–90	59.6 ± 1.5, 33–78	.001
Sex, n (%)	Female	3 (6.8)	6 (12.8)	.34
	Male	41 (93.2)	41 (87.2)	
Length of BE (cm)	Mean ± SEM, range	6.9 ± 0.5, 1–15	4.5 ± 0.5, 1–18	.001
Histology, n (%)	No dysplasia	2 (4.5)	25 (54.3)	(Trend) = .01
	LGD	3 (6.8)	13 (28.3)	
	HGD	35 (79.5)	8 (17.3)	
	IMC	4 (9.1)	0 (0)	

SEM, standard error of mean.

Table 2

Comparison of Outcomes (Strictures and Histology) in the 2 Treatment Groups

Outcome	Group 1 (RFA after EMR) (N = 44)	Group 2 (RFA) (N = 46)	P value
Stricture (%) (95% CI)	6 (13.6) (8–27)	4 (8.7) (6–21)	.456
CR-IM (%) (95% CI)	19/44 (43.1) (35–55)	34/46 (73.9) (60–91)	.006
CRD (%) (95% CI)	32/42 (76.1) (66–88)	15/21 (71.4) (62–89)	.920
Progression (%) (95% CI)	1/44 (2.3) (1–9)	0/46 (0)	.304

Table 3

Breakdown of Initial and Final Pathology for Group 1

Initial histology	Final histology results			
	HGD	LGD	CRD	CR-IM
IMC (n = 4)	1	1	1	1
HGD (n = 35)	2	7	11	15
LGD (n = 3)	0	0	2	1
BE (n = 2)	0	0	0	2

Table 4

Univariate Predictors of Stricture Formation

Variable	Odds ratio (95% CI)	P value
Age	0.99 (0.93–1.05)	.76
Gender	0.00 (0.00–1.48)	.09
BE length	1.12 (0.95–1.32)	.14
Histology		
LGD vs nondysplastic	0.60 (0.08–3.08)	.55
HGD vs nondysplastic	1.07 (0.27–4.23)	.92
EMR	1.55 (0.45–5.46)	.48
EMR number	0.94 (0.46–1.51)	.53
Halo 90 only for RFA	0.9 (0.4–1.5)	.60

Table 5

Breakdown of Initial and Final Pathology for Group 2

Initial histology	Final histology results			
	LGD	BE	CRD	CR-IM
HGD (n = 8)	1	0	0	7
LGD (n = 13)	2	0	3	8
BE (n = 25)	0	6	0	19