

# Clinical Study of Short-Term Effect of Endoscopic Radiofrequency Ablation for Gastroesophageal Mucosal Lesions

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## Keywords:

Endoscopic radiofrequency ablation; Barrett's esophagus; Intraepithelial neoplasia; Atrophic gastritis; Intestinal metaplasia

## 1. Abstract

**1.1. Aims:** To investigate short-term effect and safety of endoscopic radiofrequency ablation (ERFA) for treatment of esophageal and gastric mucosal lesions.

**1.2. Methods:** Thirty-six patients with mucosal lesions of esophagus and stomach were prospectively enrolled who were treated with ERFA at Sir Run Run Shaw Hospital Affiliated to Medical College of Zhejiang University from September 2017 to January 2021. Histological controls were performed on the lesions before and 3 months after ERFA.

**1.3. Results:** The histological results showed that 3 months (6 months of 5 patients) after ERFA, the histological remission rate was 75.0% for Barrett's esophagus, 63.6% for esophageal squamous intraepithelial neoplasia with 100% for low-grade intraepithelial neoplasia, 66.7% for gastric mucosal low-grade intraepithelial neoplasia, and 72.0% for chronic atrophic gastritis with severe intestinal metaplasia compared to pre-ERFA. The major adverse effects all occurred in esophageal circumferential ERFA: including 3 cases of esophageal stricture and 1 case of bleeding with emergency endoscopic hemostasis.

**1.4. Conclusion:** The short-term effect and safety of ERFA in the treatment of gastroesophageal mucosal lesions, whether it is intestinal metaplasia or low-grade intraepithelial neoplasia, are worthy of recognition.

## 2. Introduction

Endoscopic Radiofrequency Ablation (ERFA) is a minimally invasive technique that applying radiofrequency ablation electrodes to flat

mucosal lesions in the gastrointestinal tract under the direct view of the endoscope, causing coagulation and necrosis of the cells to eliminate the lesions. In recent years, the treatment scope of ERFA has expanded from Barrett's Esophagus (BE) combined with dysplasia to superficial lesions such as early flat gastroesophageal cancer and its precancerous lesions, severe atrophic gastritis, and gastrointestinal capillary dilation [1-2]. ERFA is currently the first choice for the treatment of BE, which has been confirmed to safely and effectively induce squamous epithelial cell reversal [3]. For early esophageal squamous cell neoplasm, ERFA has application prospects, but large-scale, prospective studies still need to be further clarified. The use of ERFA for chronic atrophic gastritis (CAG) with severe intestinal metaplasia (IM) and low-grade intraepithelial neoplasia (LGIN) in the gastric mucosa has shown significant short-term clinical efficacy with few complications, but has not yet been fully clinically validated [4].

In this study, we prospectively followed up and analyzed the endoscopic manifestations and biopsy histology of esophageal and gastric mucosal lesions before and after treatment with ERFA, as to derive the short-term effect and safety of ERFA in the treatment of gastroesophageal mucosal lesions.

## 3. Methods

### 3.1. Case Inclusion

All cases that met the inclusion criteria undergoing ERFA by the center for gastrointestinal endoscopy at Sir Run Run Shaw Hospital from September 2017 to January 2021 were selected. Inclusion criteria: (1) 18 years of age or older; (2) diagnosis with one or more of

BE, esophageal squamous intraepithelial neoplasia, gastric mucosal LGIN and CAG with severe IM; (3) histology report at the lesion prior to ERFA treatment must be available. Exclusion criteria: (1) under 18 years of age; (2) diagnosis of gastrointestinal capillary dilatation such as gastric antral vascular ectasia; (3) diagnosis meeting the inclusion criteria but lack of histology report at the pre-ERFA treatment site. A total of 36 cases were actually included, 18 males and 18 females, with a mean age of  $58.38 \pm 10.61$  years.

This study was an observational study, informed consent was not required. The study was conducted according to the Declaration of Helsinki and was approved by the ethics committee of Sir Run Run Shaw Hospital. (Ethical approval number: 20210330-38)

### 3.2. Endoscopic Radiofrequency Ablation

Patients underwent routine upper gastrointestinal endoscopy preoperative preparation. After endoscopic examination, magnification endoscopy (ME) + narrow band imaging (NBI) was used to determine the size and extent of the lesion, iodine staining was used to mark the lightly stained area for esophageal squamous intraepithelial neoplasia. Depending on the degree of radiofrequency ablation electrode fit, the treatment area may be elevated with injection or not. The electrode was placed on the lesion for cauterization. The ablation energy density of esophageal mucosal lesions was set to 10/12J, and the gastric mucosal lesions were set to 12/15J. The surface of the lesion was coagulated and turned white after cautery. The coagulated necrotic tissue was removed or not before the next cautery. Each esophageal lesion was cauterized 2-3 times and each gastric lesion was cauterized 2-5 times.

All primary ablations were performed by Gastroscopy Olympus (Japan) GIF-Q260J or GIF-HQ290 and radiofrequency ablation equipment, which consisted of BARRX™ radiofrequency ablation generator (Covidien llc, USA) and accessories including circumferential ablation catheters (BARRX™ 360 and BARRX™ 360 Express) and focal ablation catheters [including 13 mm x 20 mm (BARRX™ 90), 10 mm x 15 mm (BARRX™ 60)].

Fasting and intravenous proton pump inhibitor (PPI) were used on the day after operation. Fluid for 1 day and semi-fluid for 3 days post-operatively, avoiding strenuous activity. Oral PPI and gastric mucosal protector were given for 2 months after treatment.

### 3.3. Follow-Up and Outcome Measures

Patients underwent follow-up endoscopy with ME including Lugol staining or (and) NBI at 3 months after initial ERFA, and biopsies were obtained from the original treatment site. The primary outcome was the comparison of the histological findings of the treatment site biopsy at 3 months post-ERFA with the pre-ERFA histology: (1) histological remission: the level of intraepithelial neoplasia or IM at the lesion decreased or disappeared; (2) histological non-remission: the grade of intraepithelial neoplasia or IM at the lesion did not decrease or even progressed. The secondary outcome was the comparison

of the endoscopic performance at 3 months after ERFA with that before treatment: (1) endoscopic remission: the abnormal changes at the lesion were reduced or disappeared under the endoscope; (2) endoscopic non-remission: no significant change in abnormal endoscopic changes at the lesion or new abnormal changes.

### 3.4. Statistical Analysis

Statistical analysis was performed using the SPSS statistical package, version 25.0 (Chicago, Illinois, USA). Categorical variables were expressed as numbers (percentage) and compared using *Chi-square* test or *Fisher's* exact probability. Continuous variables were expressed as mean  $\pm$  standard deviation (SD). All reported *P*-values were two-sided, and the *P*-values  $< 0.05$  were considered statistically significant.

## 4. Results

Note on the timing of outcome follow-up: histological findings of endoscopic follow-up at 3 months after ERFA were statistically determined in 31 patients, at 6 months in 5 patients (2 patients of esophageal squamous intraepithelial neoplasia, 3 patients of gastric mucosal LGIN and CAG with severe IM), as shown in (Table 1). In addition: esophageal mucosal lesions were counted by number of cases, gastric mucosal lesions were counted by number of ERFA treated lesions with histological findings. Two patients had both esophageal and gastric radiofrequency treatment.

A total of 15 cases of esophageal lesions were treated, including 4 cases of BE and 11 cases of squamous esophageal intraepithelial neoplasia. Three patients with a pre-ERFA pathological diagnosis of BE recovered to squamous epithelium and IM disappeared. One patient still reported columnar epithelial mucosa in the lower esophagus, thus with a histological remission rate of 75.0% in BE. Four patients with a pre-ERFA pathological diagnosis of squamous LGIN reverted to squamous epithelial histology at follow-up. Three of the seven patients with high-grade intraepithelial neoplasia (HGIN) achieved histological remission, two of which did not report any dysplasia and one of which converted to LGIN. Other 4 cases with unremitting histology were followed up with remedial ESD, and histology of the ESD specimens revealed: 2 cases of HGIN, 1 case of squamous cell carcinoma in situ and 1 case of intermediate differentiated squamous cell carcinoma. The histological remission rate of esophageal squamous intraepithelial neoplasia was 63.6%, including 100% for LGIN and 42.9% for HGIN.

A total of 23 cases of gastric lesions were treated, including 15 foci of LGIN and 50 foci of CAG with severe IM, of which 14 foci of LGIN combined with IM and 12 were severe IM. Ten of the fifteen foci with pre-ERFA pathology diagnosed existing LGIN were returned no any dysplasia on follow-up histology. Other 5 foci showed LGIN on pre- and post-treatment histology. The histological remission rate for LGIN in the gastric mucosa was 66.7%. Of the 50 foci with pre-ERFA pathologically diagnosed CAG with severe IM, 36 lesions achieved histological remission after ERFA, with 23 lesions converting to moderate IM, 11 to mild IM and 2 to disappearance

of IM. Other 14 lesions were treated with ERFA without remission of IM. The histological remission rate for CAG with severe IM was 72.0%.

The ERFA efficacy analysis on the lesion characteristics and the radiofrequency regimen was performed for gastric mucosal LGIN lesions and CAG with severe IM lesions, as shown in Table 2-5. The results showed that different radiofrequency energy had statistical significance on the histological remission of severe IM lesions, 15]

was more likely to achieve histological remission than 12J ( $P < 0.05$ ). Endoscopic remission correlated with histological remission regardless of whether the lesion was LGIN or CAG with severe IM ( $P < 0.05$ ). The differences in the characteristics of the lesion itself (lesion location, lesion morphology, whether it was combined with IM or LGIN) and other radiofrequency treatment parameters (electrode type, cautery times, with or without intermediate clean, with or without injection elevation) were not statistically significant ( $P \geq 0.05$ ).

**Table 1:** Histological and endoscopic imaging follow-up results of 36 patients undergoing ERFA from 2017.09 to 2021.01.

Pathological diagnosis before ERFA				Follow-up results after ERFA			
	Number of cases (foci)	Histological remission	Histology non-remission	Histological remission rate	Endoscopic remission	Endoscopy non-remission	Endoscopic remission rate
Barrett esophagus	4	3	1	75.00%	3	1	75.00%
Esophageal squamous intraepithelial neoplasia	11	7	4	63.60%	8	3	72.70%
LGIN	4	4	0	100%	3	1	75.00%
HGIN	7	3	4	42.90%	5	2	71.40%
Gastric mucosal LGIN	15	10	5	66.70%	7	8	46.70%
CAG with severe IM	50	36	14	72.00%	36	14	72.00%

LGIN: Low-grade intraepithelial neoplasia; HGIN: High-grade intraepithelial neoplasia; CAG: Chronic atrophic gastritis; IM: Intestinal metaplasia

**Table 2:** Histological remission results of gastric LGIN lesions with different characteristics

Lesion characteristics	Histological remission ( $n=10$ )	Histology non-remission	$\chi^2$	$P$
		( $n=5$ )		
Lesion site			0.696	0.87
Gastric angle	3	1		
Gastric antrum	5	2		
Gastric corpus	1	1		
Junction	1	1		
Lesion morphology			6.000	0.050
II-a	6	3		
II-b	4	0		
Others	0	2		
With IM			Fisher	1
Yes	9	5		
No	1	0		
Endoscopic remission			Fisher	0.026
Yes	7	0		
No	3	5		

Others : 0-I and II-a+ II-c; IM: Intestinal metaplasia

**Table 3:** Histological remission results of gastric LGIN lesions with different radiofrequency regimens

Radiofrequency regimens	Histological remission ( $n=10$ )	Histology non-remission ( $n=5$ )	$\chi^2$	$P$
Electrode			Fisher	0.333
BARRX™ 90	0	1		
BARRX™ 60	10	4		
Energy density			Fisher	1.000
15J, 57W	5	2		
12J, 57W	5	3		
Ablation times			0	1.000
2 times	4	2		
3 times	2	1		
4-5 times	4	2		
Intermediate clean			Fisher	1.000
Yes	5	2		
No	5	3		
Injection elevation			Fisher	0.329
Yes	7	2		
No	3	3		

**Table 4:** Histological remission results of severe intestinal metaplasia lesions with different characteristics

Lesion characteristics	Histological remission (n=36)	Histology non-remission (n=14)	$\chi^2$	P
Lesion site			0.574	0.751
Gastric angle	12	4		
Gastric antrum	15	5		
Gastric corpus	9	5		
Lesion morphology			0.574	0.449
II-a	9	5		
II-b	27	9		
With LGIN			0.07	0.791
Yes	9	3		
No	27	11		
Endoscopic remission				
Yes	32	4	18.191	0.000
No	4	10		

LGIN : Low-grade intraepithelial neoplasia

**Table 5:** Histological remission results of severe intestinal metaplasia lesions with different radiofrequency schemes

Radiofrequency regimens	Histological remission (n=36)	Histology non-remission (n=14)	$\chi^2$	P
Electrode			0.019	0.889
BARRXTM 90	3	1		
BARRXTM 60	33	13		
Energy density			8.14	0.004
15J, 57W	33	8		
12J, 57W	3	6		
Ablation times			1.838	0.399
2 times	13	8		
3 times	11	3		
4-5 times	12	3		
Intermediate clean			0.066	0.797
Yes	14	6		
No	22	8		
Injection elevation			0.031	0.860
Yes	19	7		
No	17	7		

The major adverse effects all occurred after the circumferential ERFA. A total of 4 patients underwent esophageal circum-ERFA, 3 cases had esophageal stenosis, and 1 case had bleeding with emergency endoscopic hemostasis. The incidence of adverse reactions to circumferential ablation was 100%. Of 3 cases of esophageal stenosis, 1 case gradually relieved after treatment with glucocorticoids, and no discomfort such as dysphagia in 3-month follow-up; 1 case received an esophageal stent, and no obvious dysphagia when removed after 3-month stent placement; 1 case has undergone 3 sessions of water bladder dilatation already, the symptoms of discomfort have alleviated. The case of bleeding after ERFA with emergency endoscopic hemostasis was a patient with alcoholic liver cirrhosis and gastroesophageal varices. The bleeding occurred after in taking an apple on the third day post-ERFA. Gastroesophageal varicosis rupture bleeding caused by mechanical damage cannot be ruled out. The remaining 32 patients who underwent focal ablation, regardless of whether the lesion was in the stomach or (and) the esophagus, 25 patients (78.1%) experienced varying degrees of chest tightness, heartburn, upper abdominal discomfort, nausea or vomiting on the day after ERFA, but these discomfort all relieved itself within 3-7 days after treatment.

## 5. Discussion

This is a prospective observational clinical study of the short-term efficacy of ERFA in the treatment of gastroesophageal mucosal lesions. The main finding is that the histological remission rate was 75.0% for BE, 63.6% for esophageal squamous intraepithelial neoplasia with 100% for LGIN and 42.9% for HGIN, 66.7% for gastric mucosal LGIN and 72.0% for CAG with severe IM by comparing the histology of same-site biopsy specimens before ERFA with those at 3 or 6 months after treatment. The major adverse effects all occurred after circum-ERFA including 3 cases of esophageal stricture and 1 case of bleeding with emergency endoscopic hemostasis. The above suggests that the short-term effect and safety of ERFA in the treatment of gastroesophageal mucosal lesions, whether IM or LGIN, are positive.

In 4 patients with BE, 3 flat lesions obtained both endoscopic remission and histological remission after a single session of ERFA treatment. One lesion with localized elevation did not remit on either endoscopic manifestation or histology, which was considered to be related to the lesion itself.

For esophageal squamous intraepithelial neoplasia, the results of previous clinical studies have shown that the complete remission rate for early-stage esophageal squamous carcinoma and its precancerous lesions is 75% to 100% more than 6 months after ERFA [5-13]. The histological remission rate for esophageal squamous intraepithelial neoplasia in this study (63.6%) was lower than these results, which may be related to the study protocol of a single-session ERFA and a short-term 3-month follow-up. In this study, all 4 patients with basic LGIN achieved histological remission after ERFA, while 4 of 7 patients with basic HGIN did not. In these 4 patients, the "pink color sign" was observed with NBI showing a "silvery white sign" under endoscope before ablation and 2 subsequent ESD specimens were histologically upgraded compared with pre-ERFA. This may indicate that the underlying lesion is more likely to resolve of LGIN with radiofrequency treatment, and LGIN is more reasonable as an indication of ERFA. Whereas HGIN lesions are prone to inadequate histological grading due to the limitations of the sampling biopsy operation itself. Continuation of the standard radiofrequency treatment protocol for BE is not sufficient for these more aggressive lesions. To increase the ablation efficacy for HGIN lesions, whether it is possible to improve the radiofrequency treatment regimen, such as increasing cautery times or increasing the cauterization energy remains to be further studied.

Gastric cancer is an important cancer worldwide, intestinal gastric cancer is the main subtype which progresses from normal mucosa through chronic gastritis, multifocal atrophic gastritis, IM, intraepithelial neoplasia and adenocarcinoma. In the practical application of the gastric cancer screening process, up to 30% of lesion states such as chronic atrophic gastritis and intraepithelial neoplasia are confirmed by endoscopy and pathological biopsy [14]. whether ERFA can make the IM and LGIN a long-term remission, thereby reducing the incidence of gastric adenocarcinoma has only been reported in cases [15]. In this study, the histological remission rates of LGIN and CAG with severe IM in the gastric mucosa were 66.7% and 72.0%, respectively. Despite the short follow-up period, we believe that ERFA has some value when applied to LGIN and CAG with severe IM, and it is worthwhile to further explore the best radiofrequency regimen for efficacy under the condition of ensuring safety. The results of the effect analysis showed that different radiofrequency energies (12J, 15J) had statistical significance for the histological remission of severe IM lesions ( $P < 0.05$ ). Due to the large time span of cases enrollment in this study, the past gastric mucosal lesion therapy continued the BE radiofrequency parameters, the currently recognized energy for gastric lesions in China is 15J. The results of this study also confirms that 15J has a higher short-term histological remission rate than 12J for gastric mucosal lesions.

In 2 lesions with pre-ERFA and 3-month post-ERFA pathology showing LGIN in the gastric mucosa, 1 case had histology not suggestive of intraepithelial neoplasia at the 9-month endoscopic fol-

low-up and the other case progressed to HGIN at the 6-month follow-up. Intraepithelial neoplasia is a definite precancerous lesion and non-invasive change. It has been reported in the literature that most cases of HGIN are actually concurrently cancerous [16]. Therefore, active follow-up and scientific surveillance of LGIN patients have become an effective way to prevent gastric cancer. Previous studies have shown that 38%-75% of LGINs regress spontaneously, 19%-50% persist, and 23% of non-relieving LGIN cases progress to malignancy within 10-48 months [17]. One Netherland study reported a 0.6% probability of progression to gastric adenocarcinoma in the LGIN population in a 5-year follow-up study [18]. Therefore, these patients with LGIN of the gastric mucosa are recommended to have endoscopic follow-up at least every 6 months and ERFA treatment can be repeated according to individual circumstances.

Some lesions with CAG with severe IM achieved histological remission at the first endoscopic follow-up but progressed again to severe IM status at the 6/9-month follow-up, presumably related to uncontrolled risk factors or subsequent discontinuation of PPI and gastric mucosal protective agents. The annual incidence of gastric cancer in patients with CAG with IM has been reported to be 0.25%. A meta-analysis of 21 studies investigating the risk of gastric cancer in patients with IM from 1985 to 2016 showed a higher risk of gastric cancer in patients with IM (OR = 3.58) [19]. Annual endoscopic follow-up of patients with multifocal atrophy with severe IM is therefore necessary, and the effectiveness of ERFA in treating atrophic gastritis with severe IM needs further study.

The greatest advantage of ERFA over endoscopic resection is that it is easy and safe to perform. However, the incidence of adverse effects after circum-ERFA in this study was 100%, including 75% of esophageal strictures. Further studies are needed to determine whether early postoperative pharmacological prophylaxis such as glucocorticoids or other intraoperative interventions can be used to reduce strictures in patients treated with circum-ERFA.

This study has several limitations. First, as a single-center study, selection and information bias could not be completely excluded and there were differences in the level of different endoscopists. Secondly, although some patients had a calibration biopsy prior to treatment, in cases where no definitive biopsy was taken there were errors in the site of the lesion when pathology specimens were obtained. Third, with the small number of patients currently treated with ERFA and the short follow-up period, many analyses of efficacy-related factors yielded negative results, and it was not possible to conclude that radiofrequency treatment improved the prognosis of esophageal LGIN, gastric mucosal LGIN and CAG with severe IM.

## 6. Conclusion

The short-term efficacy and safety of ERFA for the treatment of gastroesophageal mucosal lesions whether IM or LGIN is positive. It is explicit that ERFA can relieve BE and reduce the incidence of esophageal adenocarcinoma. However, to clarify the long-term

remission effect of ERFA for esophageal LGIN, gastric mucosal LGIN and CAG with severe IM requires expanding patient numbers and further follow-up of patients.

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