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Radiofrequency ablation of symptomatic cervical inlet patch using a through-the-scope device: a pilot study

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Background and Aims: The cervical inlet patch (CIP) is an area of heterotopic gastric mucosa at the proximal esophagus, which can secrete both acid and mucus. Attributable symptoms include chronic globus sensation and sore throat. Previous studies have demonstrated improvement in symptoms after ablation using argon plasma coagulation. Our aim was to assess a through-the-scope radiofrequency ablation (RFA) catheter for ablation of symptomatic CIP.

Methods: Ten patients with endoscopically and histologically proven CIP and symptoms of globus or sore throat were included in the study. An ablation protocol of 3 ablations at 12 J/cm², without removal of coagulated tissue between ablations, was used. A maximum of 2 RFA sessions, 3 months apart, was allowed. A visual analog score was completed at baseline, 6 weeks (on proton pump inhibitor), 3 months (off proton pump inhibitor), and 12 months after treatment.

Results: Mean patient age was 56 years (± 3 years, standard error of the mean), 60% were men, and 80% were white. Barrett's esophagus was present in 50%. The mean number of CIPs was 2 (range, 1-4) with a median surface area of 2 cm² (range, .5-14). After a median of 2 treatments, 80% achieved complete endoscopic and histologic resolution, with a mean follow-up of 14 months (range, 12-17). Globus, sore throat, and cough significantly improved from baseline ($P < .05$). No strictures or buried glands were identified.

Conclusions: This prospective pilot study demonstrates that RFA using a through-the-scope device is safe and effective for treating patients with symptomatic CIP. One-year follow-up data suggest the effect is durable.

The cervical inlet patch (CIP) is a congenital anomaly of the esophagus consisting of heterotopic gastric mucosa because of the incomplete transformation from columnar to squamous epithelium during embryonic development.^{1,2}

Abbreviations: APC, argon plasma coagulation; CIP, cervical inlet patch; CR-CIP, complete reversal of cervical inlet patch; PPI, proton pump inhibitor; RFA, radiofrequency ablation; VAS, visual analog scale.

DISCLOSURE: The following author disclosed financial relationships relevant to this publication: J. M. Dunn: Educational grant recipient from Medtronic and Aquilant Endoscopy. All other authors disclosed no financial relationships relevant to this publication.

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0016-5107/\$36.00

<http://dx.doi.org/10.1016/j.gie.2016.06.037>

Received March 4, 2016. Accepted June 17, 2016.

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Prevalence varies from .1% to 14% in endoscopic studies.³ It is often missed, with studies demonstrating higher pickup rates when endoscopists were made aware of the entity.^{4,5}

An attributable symptom is chronic globus sensation, estimated at 6.7 per 100,000 of primary care consultations and 4% of otolaryngology clinics.^{6,7} Several studies have described a link between chronic globus sensation and CIP.⁸ Other presenting symptoms of CIP may include post-nasal drip, sore throat, cough, and excessive throat clearing.⁹

Despite studies demonstrating acid production from the CIP, the use of proton pump inhibitors (PPIs) is often ineffective.^{10,11} Symptomatic improvement after ablation with argon plasma coagulation (APC) has been shown.^{12,13}

Radiofrequency ablation (RFA) may be advantageous for this indication. The primary aims of this study were to assess the efficacy and safety of RFA for symptomatic CIP. Secondary aims were to measure the effect of ablation on esophageal physiology.

METHODS

This was a prospective 10-patient pilot study at a single site (Guy's & St. Thomas' Hospitals). All patients had

TABLE 1. Patient demographics

Patient No.	Age (y)	Sex	Ethnicity	Number of CIPs	Area of patches (cm ²)	Dominant symptom	Barrett's esophagus*
1	58	M	White	3	14	Globus	C0M1
2	66	F	White	2	1.5	Hoarseness	No
3	51	M	White	1	1	Sore throat	C3M4
4	63	M	White	2	2	Hoarseness	C1M2
5	63	F	White	1	.5	Hoarseness	C0M2
6	61	F	White	1	2	Hoarseness	No
7	58	M	White	4	4	Hoarseness	C0M1
8	62	M	White	1	2	Sore throat	No
9	48	M	Afro-Caribbean	2	2	Cough	No
10	33	F	Asian-Indian	2	1.5	Hoarseness	No

CIP, Cervical inlet patch.

*Prague classification.

TABLE 2. Study outcomes (endoscopic, pH measurement)

Patient no.	No. of ablations, first treatment	No. of ablations, second treatment	Follow-up (mo)	Final outcome	Histology	pH-metry before ablation	pH-metry after ablation
1	43	19	16	90% resolution	Squamocolumnar, no IM	Positive	Negative
2	6	3	17	No residual patch	Squamous	Negative	n/a
3	3	0	14	No residual patch	Squamous	Positive	Equivocal
4	9	9	13	95% resolution	Squamocolumnar, no IM	Positive	Positive (improved)
5	3	3	12	No residual patch	Squamous	Positive	Patient refused
6	6	6	12	No residual patch	Squamous	Positive	Negative
7	18	12	15	No residual patch	Squamous	Negative	n/a
8	9	3	15	No residual patch	Squamous	Negative	n/a
9	9	6	15	No residual patch	Squamous	Positive	Patient refused
10	12	0	12	No residual patch	Squamous	Negative	n/a

IM, Intestinal metaplasia; n/a, not applicable.

undergone endoscopy and biopsy sampling confirming the presence of CIP. Otolaryngologist review, with direct laryngoscopy, was undertaken before enrollment. All patients had at least 6 weeks of high-dose PPIs (omeprazole 20 mg twice a day) and remained symptomatic, as characterized by globus sensation, cough, sore throat, or hoarseness. A further interview was then arranged to assess that inclusion criteria were met, before informed consent. Ethics approval for the study was obtained (REC number 13/LO/1386). High-resolution manometry and dual pH/impedance nasal-catheter test (A.A., G.S.) was performed at baseline and 3 months after completion of therapy to assess the relationship between treatment response and acid suppression.

Treatment

One endoscopist experienced in RFA performed all procedures (J.M.D.), with the patient under conscious sedation with fentanyl (25-100 µg) and midazolam (2-5 mg).

Characteristics of CIP were documented using high-definition white-light endoscopy and narrow-band imaging (Olympus, Tokyo, Japan).

A through-the-scope RFA device (Barrx TTS, Medtronic, Minneapolis, Minn) was used for treatment in all cases, with an energy density setting of 12 J/cm². The mucosa was washed with *N*-acetyl cysteine using a spray catheter, followed by application of the RFA device using narrow-band imaging. After 3 energy deliveries were applied, the probe was inspected and, when necessary, removed from the endoscope and the electrode surface cleaned. This was repeated until the entire visible CIP was treated. Patients were discharged on omeprazole 20 mg bid for 2 months.

Symptom assessment and follow-up

Follow-up endoscopy was scheduled 3 months after first RFA treatment. If there was endoscopic evidence of CIP, then a further treatment with RFA was allowed. A final endoscopy was undertaken at 12 months after the first

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