TREAT GASTRIC ANTRAL VASCULAR ECTASIA (GAVE) WITH BARRX™ RFA FOCAL CATHETERS

HELPFUL TREATMENT FOR ALL YOUR GAVE CASES

Hemostasis using the Barrx™ radiofrequency ablation system has been shown helpful at reducing symptoms and transfusion dependency for patients in multiple studies.1-3

ANOTHER THERAPEUTIC OPTION

With a larger ablative surface area than argon plasma coagulation (APC), Barrx™ RFA focal and channel RFA endoscopic catheters offer the clinician another thermo-coagulative device indicated for GAVE.4

AREA TREATED IN A SINGLE ENERGY APPLICATION

<table>
<thead>
<tr>
<th>Application</th>
<th>Treatment Surface Area</th>
<th>Electrode Dimensions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrx™ Ultra Long RFA Focal Catheter</td>
<td>520 mm²</td>
<td>13 mm X 40 mm</td>
</tr>
<tr>
<td>Barrx™ 90 RFA Focal Catheter</td>
<td>260 mm²</td>
<td>13 mm X 20 mm</td>
</tr>
<tr>
<td>Barrx™ 60 RFA Focal Catheter</td>
<td>150 mm²</td>
<td>10 mm X 15 mm</td>
</tr>
<tr>
<td>Barrx™ Channel RFA Endoscopic Catheter</td>
<td>117.75 mm²</td>
<td>7.5 mm X 15.7 mm</td>
</tr>
<tr>
<td>APC</td>
<td>12 mm²</td>
<td>n/a</td>
</tr>
</tbody>
</table>

Controlled depth of coagulation

Blood vessels associated with bleeding in GAVE are confined to the mucosa. Barrx™ RFA focal and channel RFA endoscopic catheters provide a uniform, superficial depth of ablation, reliably eliminating the ectatic vasculature while minimizing the likelihood of complications.5,6

Comparison of tissue ablation areas using Barrx™ ultra long RFA focal catheter, Barrx™ 90 RFA focal catheter, Barrx™ channel RFA endoscopic catheter and APC
CASE STUDY
Jose M Nieto DO FACP FACG
Chairman, Advanced Therapeutic Endoscopy Center, Borland Groover Clinic, Orlando, FL

BACKGROUND
A 63-year-old woman with a history of chronic renal insufficiency developed melena and anemia. Her hemoglobin was 5.9 g/dL and an upper endoscopy revealed gastric antral vascular ectasia. She was treated with argon plasma coagulation on three occasions over a seven-month period without good effect.

PROCEDURE AND RESULTS
The Barrx™ ultra long RFA focal catheter was used on three occasions over four months. The Barrx™ ultra long RFA focal catheter was mounted on the endoscope at the 12 o’clock position. Approximately half of the circumference of the affected antrum was treated with four energy applications per targeted site at settings of 12 J/cm². The ablation catheter was then removed and cleaned. For the second introduction, the catheter was mounted on the endoscope at the 6 o’clock position. Following one of the RF ablation sessions the patient experienced mild epigastric pain that resolved within one day. Complete resolution of bleeding was achieved and the patient has remained asymptomatic since her last RFA session with a hemoglobin of 11.2 g/dL. Follow-up is 12 months.

RESULTS FROM ADDITIONAL STUDIES
Radiofrequency ablation for refractory gastric antral vascular ectasia, McGorisk, 2013
A prospective study using RFA to treat 21 transfusion dependent GAVE patients who failed APC. On average, 1.9 RFA sessions were required and 86% of patients were rendered transfusion independent, which was maintained for the 6 month follow-up period. Mean hemoglobin increased from 7.8 to 10.2 in responders (n=18). Two adverse events occurred (minor acute bleeding and superficial ulceration); both resolved without intervention.

33 patients underwent 134 treatment sessions (89 APC and 45 HALO90) for GAVE. Hemoglobin levels at 4 weeks post-treatment when compared to pre-treatment baseline increased by 0.42g/dl with APC and 1.87g/dl with HALO90 (p <0.0001). Subgroup analysis for patients undergoing both treatments showed hemoglobin levels at 4 weeks rose by 0.19g/dl with APC and 1.85g/dl with HALO90 (p<0.0001). Mean endoscopic procedure time was 28.6 minutes for APC and 23.4 minutes for HALO90 (p<0.0001). Repeat ablations were required in 19 patients, of which 6 exclusively underwent APC. The other 13 patients had an average of 4.3 APC sessions and 3.4 HALO90 sessions and were 5.5 times more likely to have HALO90 as the last treatment than APC. Mean duration between retreatments was 92 days with APC vs. 138 days with HALO90 (p= 0.02). The authors concluded, “Overall, HALO90 ablation seems to be a better modality to treat GAVE lesions than APC.”

Endoscopic mucosal ablation for the treatment of gastric antral vascular ectasia with the HALO90 system, Gross, 2008
Six patients (four of whom had failed APC) underwent endoscopic mucosal ablation of antral lesions (mean procedure time 29 minutes; mean treatments 1.7). The mean hemoglobin level improved from 8.6 to 10.2 g/dl (mean two months after the last ablation). Five of six patients (83%) were rendered transfusion independent. ‘Device now called Barrx™ 90 RFA focal catheter

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner. Rx only.

Risk Information: The following are transient side effects that may be expected after treatment: chest pain, difficulty swallowing, painful swallowing, throat pain and/or fever. Complications observed at a very low frequency include: mucosal laceration, minor and major acute bleeding, stricture, perforation, cardiac arrhythmia, pleural effusion, aspiration, and infection. Potential complications that have not been observed include: death. Please refer to the product user manual or medtronic.com/gi for detailed information.

References:

US130326a © 2016 Medtronic. All rights reserved. Medtronic, Medtronic logo and Further, Together are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.