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May 19 - 24, 2007

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Saturday, May 19, 2007

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Sunday, May 20, 2007

Time	Session Info
8:00 AM-5:00 PM, Hall E (Washington Convention Center), <b>Esophagus</b>	
8:00 AM-5:00 PM	<b>S1291. Radiofrequency Ablation of Barrett's Esophagus Containing High-Grade Dysplasia</b> <u>J.J. Gondrie</u> ; F. Peters; W.L. Curvers; C. Sondermeijer; F.J. ten Kate; P. Fockens; J.J. Bergman
8:00-8:00 AM	<b>S1292. Long-term (2.5 year) Follow-up of the AIM-II Trial for Ablation of Barrett Esophagus: Results After Primary Circumferential Ablation Followed by Secondary Focal Ablation</b> <u>D.E. Fleischer</u> ; B.F. Overholt; V.K. Sharma; A. Reymunde; M.B. Kimmey; R. Chuttani; K. Chang; C.J. Lightdale; N. Santiago; D.K. Pleskow; P.J. Dean; K.K. Wang
8:00-8:00 AM	<b>S1335. Focal Ablation for Treatment of Dysplastic and Non-Dysplastic Barrett's Esophagus: Safety Profile and Initial Experience with the HALO<sup>90</sup> Device in 508 Cases</b> <u>R.I. Rothstein</u> ; K. Chang; B.F. Overholt; J.J. Bergman; N.J. Shaheen
8:00-8:00 AM	<b>S1336. HALO<sup>360</sup> Circumferential Ablation is Safe and Effective for the Treatment of Barrett's Esophagus and High-Grade Dysplasia: A U.S. Multi-Center Registry</b> <u>R.A. Ganz</u> ; B.F. Overholt; V.K. Sharma; M. Panjehpour; S.R. DeMeester; A. Bohorfoush; S.R. Freeman; V.E. Eysselein; F.G. Gress; M. Branch; K. Chang; V. Muthusamy; S.C. Pace; R.E. Pruitt; D.E. Fleischer; N.J. Shaheen; G. Triadafilopoulos
8:00-8:00 AM	<b>S1350. Optimizing the Technique for Circumferential Ablation of Barrett Esophagus Containing High-Grade Dysplasia Using the HALO360 System</b> <u>J.J. Gondrie</u> ; R.E. Pouw; C. Sondermeijer; W.D. Rosmolen; F. Peters; W.L. Curvers; F.J. ten Kate; K.K. Krishnadath; P. Fockens; J. Bergman
8:00-8:00 AM	<b>S1365. Circumferential Ablation of Barrett Esophagus with Low Grade Dysplasia: One and Two Year Follow-up of the AIM-LGD Trial</b> <u>V.K. Sharma</u> ; H. Kim; D. Musil; M.D. Crowell; P.J. Dean; D.E. Fleischer
8:00-8:00 AM	<b>S1349. Endoscopic Ablative Therapy is a Cost-Effective Management for Non-Dysplastic Barrett Esophagus</b> A. Das; <u>C.D. Wells</u> ; D.E. Fleischer; H.J. Kim; V.K. Sharma

Monday, May 21, 2007

Time	Session Info
8:30 AM-10:00 AM, 207 (Washington Convention Center), GERD and Barrett's Esophagus	
8:45-9:00 AM	<b>292. Radiofrequency ablation is more cost-effective than endoscopic surveillance or esophagectomy among patients with Barrett's esophagus and low-grade dysplasia</b> <u>J.M. Inadomi</u> ; R.D. Madanick; M. Somsouk; N.J. Shaheen

Tuesday, May 22, 2007

Time	Session Info
8:30 AM-10:00 AM, 145 (Washington Convention Center), Endoscopic Diagnosis and Treatment of Esophageal Cancer or High Grade Dysplasia	
9:06-9:18 AM	<b>612. Novel Combined Modality Therapy for Barrett's Esophagus Containing High-grade Dysplasia: Endoscopic Mucosal Resection Followed by Circumferential and Focal Ablation Using the HALO System</b> <u>R.E. Pouw</u> ; J.J. Gondrie; C. Sondermeijer; W. Rosmolen; F. Peters; W.L. Curvers; F.J. ten Kate; K.K. Krishnadath; P. Fockens; J.J. Bergman
9:30-9:42 AM	<b>614. Frequency Of Buried Barrett's Metaplasia After BÂRRX Ablation For Intestinal Metaplasia With Or Without Dysplasia</b> <u>J.C. Hernandez</u> ; F. Tsai; S. Reicher; D. Chung; B.V. Pham; J. Nieto; G. DiSibio; S. French; V.E. Eysselein

Wednesday, May 23, 2007

*You have nothing scheduled for this day*

Thursday, May 24, 2007

*You have nothing scheduled for this day*

Final ID: S1291

## Radiofrequency Ablation of Barrett's Esophagus Containing High-Grade Dysplasia

*J. J. Gondrie*<sup>1</sup>; *F. Peters*<sup>1</sup>; *W. L. Curvers*<sup>1</sup>; *C. Sondermeijer*<sup>1</sup>; *F. J. ten Kate*<sup>2</sup>; *P. Fockens*<sup>1</sup>; *J. J. Bergman*<sup>1</sup>;

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**Abstract Body** : Background: Circumferential balloon-based ablation of non-dysplastic Barrett's esophagus (BE) has been proven by others as safe and effective. This study assessed the efficacy and safety of ablation for BE with high-grade dysplasia (HGD) in patients with and without prior endoscopic resection (ER).

Methods: Eligible patients demonstrated BE with HGD on at least 2 prior EGDs. Visible abnormalities were resected with ER prior to ablation. Persistence of dysplasia was confirmed with biopsy after ER. Patients received esomeprazole 40 mg BID during study.

A balloon-based electrode (HALO360 System) was used for primary circumferential ablation (CA) and an endoscope-mounted electrode (HALO90 System) for secondary focal ablation (FA) of residual BE. Both systems (BÂRRX Medical, Sunnyvale, CA) use an electrode array that delivers a short burst of high power RF energy (40 W/cm<sup>2</sup>) at a preset energy density (12 J/cm<sup>2</sup>).

After primary CA, EGD was performed at 2 mo intervals with secondary ablation of residual BE using CA or FA, depending on extent of BE. Two mos after the last ablation, EGD with Lugol's and large cup biopsy (4Q/q 1cm) was performed. Histopathology was reviewed by a single pathologist. Primary endpoint: complete response dysplasia (CR-D), absence of dysplasia in all biopsies. Secondary endpoints: adverse events (AE); visible BE regression; complete response intestinal metaplasia (CR-IM), absence of IM in all biopsies.

Results: Twenty-three pts (17 men, median age 66 yrs, IQR 55-78) were treated (median BE length 7 cm, IQR 4-10). ER was performed in 13 patients: mucosal carcinoma (n=4), HGD (n=6) and LGD (n=3). Worst pathological grade of BE after ER and prior to RFA was LGD (n=3) and HGD (n=20).

Patients underwent a mean of 1.5 CA and 2.6 FA sessions. CR-D was achieved in 22/23 patients (96%) and CR-IM in 21/23 patients (92%). Patients with residual BE (n=2) have only small islands remaining (median BE regression: 99%). There were 3 AE's. Fever/chest pain (n=2) after CA, resolved with narcotics. An ER-related stenosis (n=1), resolved after 1 dilation. There were no thermally-mediated strictures. After a median additional follow-up of 6 mos and 2.1 endoscopies, no patient with CR-D has shown recurrence of dysplasia and no patient with CR-IM has shown recurrence of IM. None of the 521 biopsies of neosquamous mucosa contained subsquamous BE ("buried Barrett's").

Conclusions: Radiofrequency ablation of BE containing HGD is a safe and effective treatment, with a CR-D and CR-IM of 96% and 92%, respectively. Circumferential and focal ablation using the HALO devices can be safely performed after prior ER for endoscopically visible abnormalities.

**Long-term (2.5 year) Follow-up of the AIM-II Trial for Ablation of Barrett Esophagus: Results After Primary Circumferential Ablation Followed by Secondary Focal Ablation**

*D. E. Fleischer*<sup>1</sup>; *B. F. Overholt*<sup>2</sup>; *V. K. Sharma*<sup>1</sup>; *A. Reymunde*<sup>3</sup>; *M. B. Kimmey*<sup>4</sup>; *R. Chuttani*<sup>5</sup>; *K. Chang*<sup>6</sup>; *C. J. Lightdale*<sup>7</sup>; *N. Santiago*<sup>3</sup>; *D. K. Pleskow*<sup>5</sup>; *P. J. Dean*<sup>8</sup>; *K. K. Wang*<sup>9</sup>;

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8. GI Pathology, Memphis, TN, USA.
9. Mayo Clinic Rochester, Rochester, MN, USA.

**Abstract Body : Aims:** Any endoscopic method for ablation of Barrett esophagus (BE) must demonstrate high efficacy and long-term benefit. We assessed the long-term (2.5 year) follow-up results of ablation of non-dysplastic (BE) using primary circumferential ablation (CA) followed by secondary focal ablation (FA).

**Methods:** This study was conducted at 8 U.S. centers from May 2004 to Dec 2006. The CA device (HALO<sup>360</sup> System, BÂRRX Medical, Sunnyvale, CA) is a balloon-based ablation catheter and delivers a programmed amount of energy circumferentially to BE. The FA device (HALO<sup>90</sup> System) is an endoscope-mounted electrode. In previous reports, these devices ablate to the muscularis mucosae without stricture formation.

The AIM-II Trial included pts with BE (2-6 cm). CA was performed (10 J/cm<sup>2</sup> delivered 2x per session) and repeated at 4 months (if needed.) The trial was extended after 1 year follow-up to include FA for any visible BE (up to 2 sessions). Patients underwent EGD with 4Q/q2cm bx plus directed bx at 1, 3, 6, 12, 30 mo. All received esomeprazole 40 bid 1 month post-ablation and 40 qd thereafter.

Symptoms after CA and FA sessions (chest, throat, abdominal pain; odynophagia; dysphagia) were quantified using a 14-day diary (visual analog scale, VAS, 0-100). Primary outcome was histological complete response (CR), defined as all bx negative for IM at 12 and 30 mos. Pathology was read centrally (GI pathologist) in a blinded manner. T-test was used to compare procedure time, sedation requirement, and diary scores between CA and FA.

**Results:** 70 pts (52 men, mean age 55.7 yrs, range 26-79, mean BE 3.2 cm) were enrolled. Median procedure time for CA was 28 min (IQR 24-33). Median diary scores <20/100 for each symptom on day 1, and returned to 0/100 by day 5. At 12 mo (n=69; mean 1.5 sessions), CR for BE was achieved in 70% of pts. There were no strictures.

62 patients (89%) participated in the trial extension. Median procedure time for FA was 16 min (IQR 10-21), significantly shorter than CA (p<0.001). Median diary scores <20/100 for each symptoms day 1, and all returned to 0/100 by day 4, comparable to CA (p>0.05). At 30 mos (n=60, mean 1.7 sessions), CR for BE was achieved in 83% of pts (ITT 81%). Additional FA and follow-up biopsies pending. There were no strictures.

**Conclusion:** A sequential regimen of circumferential and focal ablation of BE results in complete elimination of BE in 83% of patients at 2.5 year follow-up (with additional ablation and follow-up pending in some pts). FA improves on the complete response achieved with CA alone, and is well tolerated by patients (shorter procedure times, less procedure medication, and comparable symptom scores vis-à-vis CA.)

**Focal Ablation for Treatment of Dysplastic and Non-Dysplastic Barrett's Esophagus: Safety Profile and Initial Experience with the HALO<sup>90</sup> Device in 508 Cases**

*R. I. Rothstein*<sup>1</sup>; *K. Chang*<sup>2</sup>; *B. F. Overholt*<sup>3</sup>; *J. J. Bergman*<sup>4</sup>; *N. J. Shaheen*<sup>5</sup>;

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**Abstract Body : Introduction:** Several modalities have been evaluated for focal treatment of Barrett esophagus (APC, MPEC, laser, EMR) and for wide-field ablation of BE (PDT, balloon-based ablation with HALO<sup>360</sup>).

**Aims:** Assess the initial safety experience associated with the HALO<sup>90</sup> focal ablation (FA) device for secondary treatment of residual BE after primary wide-field ablation, as well as for primary ablation of short segment BE.

**Methods:** The HALO<sup>90</sup> FA device (BARRX Medical, Sunnyvale, CA) fits on the tip of a gastroscope, preserving visualization. The upper surface is a 20x15 mm articulated platform covered by an electrode array. The device uses high power (40 W/cm<sup>2</sup>) and a pre-set energy density (12 J/cm<sup>2</sup>) to control ablation depth. Using the endoscope, the electrode is positioned at the target, deflected upward, and energy delivered.

In 2006, 508 FA procedures for BE were performed in the U.S. and Netherlands with this device. 182 of the cases were performed under one of several IRB-approved trials for non-dysplastic BE, LGD-BE and HGD-BE. For the trial cases, treatment data (procedure time, sedation requirement) were collected and post-ablation symptoms were assessed (chest, throat, abdominal pain; odynophagia; dysphagia) using a standardized 14-day diary (visual analog scale, 0-100). For all cases, a monitoring system was used to detect adverse events.

**Results:** Of 182 trial cases, median procedure time was 20 min (IQR 14-32). Sedation: midazolam 7 mg (IQR 5-8), and either meperidine 75 mg (50-100) or fentanyl 100 mcg (IQR 75-175). One site used propofol as a single agent (median 410 mg, IQR 337-521.)

There were no perforations, mucosal lacerations, bleeds, or strictures. One patient (0.5% of trial cases) reported symptoms of esophageal spasm on day 1 and was admitted for pain control.

**Conclusions:** This represents the first report of the safety profile of this focal ablation device. Its use appears to be very well-tolerated, with post-ablative symptoms that were minor and short-lived, and an adverse event incidence of 0.5%. This technique may significantly complement wide-field ablative therapy for achieving the goal of complete BE ablation. Future studies are evaluating this device as primary therapy of short segment BE.

Patient Responses: Post Ablation Symptom Diary		
Post-ablation Symptom Queried	Day 1 Median VAS* (IQR) (n=156)	Day Median VAS Returned to Zero
Chest Pain	9 (0-20)	Day 4
Dysphagia	2 (0-40)	Day 2
Odynophagia	10 (0-45)	Day 4

Throat Pain	10 (0-36)	Day 3
Abdominal Pain	0 (0-0)	Day 1
* VAS (visual analog scale, 0-100) "100"= worst symptom severity "0"= absent symptom		

HALO<sup>360</sup> Circumferential Ablation is Safe and Effective for the Treatment of Barrett's Esophagus and High-Grade Dysplasia: A U.S. Multi-Center Registry

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**Abstract Body : Background:** Barrett esophagus (BE) containing high-grade dysplasia (HGD) is currently treated with esophagectomy or PDT entailing considerable morbidity and, in some cases, mortality. We report results from an ongoing U.S. registry assessing the safety and effectiveness of circumferential ablation (CA) using the HALO<sup>360</sup> System as an alternative endoscopic modality for patients with BE-HGD.

**Methods:** This registry involved 13 U.S. centers, each with a comprehensive Barrett's program. Evaluation for BE-HGD typically included one or more of the following; confirmation of HGD by 2 pathologists, CT, EUS, EMR for nodular disease, and bid PPI therapy.

The HALO<sup>360</sup> Ablation System (BARRX Medical, Sunnyvale, CA) is comprised of a sizing balloon, a balloon-based electrode, and an energy generator. The sizing balloon measures the inner diameter of the targeted esophagus using a pressure/volume system. Thereafter, circumferential ablation (CA) is performed using an ultra-short pulse of energy (300 W, 12 J/cm<sup>2</sup>), typically resulting in complete ablation to the muscularis mucosae and preservation of submucosa. Post-ablation, all patients continue to receive high-dose PPI therapy and continue surveillance, typically q 3 mo, with 4Q/1-2cm biopsies. Complete response (CR) for HGD is defined as no histologic evidence of HGD or cancer in any biopsy at FU. If HGD is present at FU, patients undergo further ablation.

**Results:** From Sept 2004 to Nov 2006, 85 pts with BE-HGD underwent circumferential ablation (75 male, mean age 67 yrs, IQR 59-76). Median baseline BE was 6.4 cm (IQR 3-9). Eight patients had focal EMR for nodule(s) prior to ablation. FU is available for 57 patients (mean 9.5 mos, range 1-27 mos) after a mean of 1.4 ablation sessions. Median surface area regression of BE was 100% (IQR 90-100). CR for HGD occurred in 88% of pts (53% normal squamous, 23% non-dysplastic IM, 9% HGD, 9% LGD, 4% indeterminate, 4% intramucosal cancer, IMC). Five (9%) with residual HGD will have repeat ablation. One patient developed focal IMC and is undergoing focal EMR. One patient had surgery for HGD/IMC. There was 1 stricture (1.1%) that resolved with dilation. One patient died from melanoma 1 year after ablation.

**Conclusion:** Circumferential ablation with the HALO<sup>360</sup> device is a safe and effective modality for ablation of BE-HGD and an attractive alternative to esophagectomy or PDT. This registry allows annual tracking of long-term safety and

efficacy related to this technique. Ablation can be repeated for residual BE or HGD using the present device or a new, related focal ablation device, with the potential to achieve 100% eradication of residual BE-HGD in this population.

**Optimizing the Technique for Circumferential Ablation of Barrett Esophagus Containing High-Grade Dysplasia Using the HALO360 System**

*J. J. Gondrie*<sup>1</sup>; *R. E. Pouw*<sup>1</sup>; *C. Sondermeijer*<sup>1</sup>; *W. D. Rosmolen*<sup>1</sup>; *F. Peters*<sup>1</sup>; *W. L. Curvers*<sup>1</sup>; *F. J. ten Kate*<sup>2</sup>; *K. K. Krishnadath*<sup>1</sup>; *P. Fockens*<sup>1</sup>; *J. Bergman*<sup>1</sup>;

1. Gastroenterology, Academic Medical Centre, Amsterdam, Netherlands.
2. Pathology, Academic Medical Centre, Amsterdam, Noord-Holland, Netherlands.

**Abstract Body** : Background: The optimal technique for applying circumferential ablation (CA) to Barrett esophagus (BE) containing high-grade dysplasia (HGD) using the HALO360 System (BÂRRX Medical, Sunnyvale, CA, USA) has evolved at our center over the past 2 years with increased case experience and availability of clinical trial results. Methods: We compared the efficacy of 2 CA techniques in 2 clinical trials (AMC-I and AMC-II) for BE-HGD. All CA sessions were performed with the HALO360 ablation catheter (40 W/cm2, 12 J/cm2). Patients received esomeprazole 40 mg BID.

AMC-I: 1% acetic acid, ablate proximal to distal, reposition using shaft cm markings. After first pass, reposition electrode, repeat ablation.

AMC-II: 1% acetylcysteine, ablate proximal to distal, reposition using visual landmarks. After first pass, remove and clean electrode, thoroughly suction coagulum from ablation zone, reintroduce catheter, repeat ablation.

Endpoints: procedure time, sedation, post-ablation symptom scores, and regression of BE 10 wks post-ablation (% surface area regression, reduction in “C” and “M” value of the Prague Classification).

Conclusions: There is a significant difference between the efficacy outcomes of the techniques. While AMC-II technique requires more procedure time, it results in superior BE regression results for M category (Prague) and surface area regression. It appears that cleaning the electrode and ablation zone after the first pass provides more assured eradication. A more assured regression after primary CA allows more optimal focal ablation of any residual BE and achievement of complete eradication for this patient population.

Results:			
	amc-I	amc-II	p-value
N	11	12	.
Time(min)	27 (25-34)	37 (33-51)	0.009
Regression C value	75% (0-100)	100 (89-100)	NS
Regression M value	14% (0-44)	100 (91-100)	<0.001
% surface area regression	90 (60-99)	99% (60-100)	0.035
Values are median (IQR)			

Final ID: S1365

## Circumferential Ablation of Barrett Esophagus with Low Grade Dysplasia: One and Two Year Follow-up of the AIM-LGD Trial

*V. K. Sharma*<sup>1</sup>; *H. Kim*<sup>1</sup>; *D. Musil*<sup>1</sup>; *M. D. Crowell*<sup>1</sup>; *P. J. Dean*<sup>2</sup>; *D. E. Fleischer*<sup>1</sup>;

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2. GI Pathology, Memphis, TN, USA.

**Abstract Body : Aims:** To assess the long term safety, tolerability and effectiveness outcomes of a combination of primary circumferential ablation (CA) followed by secondary focal ablation (FA) using the HALO Ablation System for Barrett esophagus (BE) with low-grade dysplasia (LGD).

**Methods:** This is an extension of the AIM-LGD Trial, which commenced in 06/2004. Inclusion required 2-6 cm BE-LGD on 2 biopsy sessions in the prior 2 years and independently confirmed by 2 pathologists. The CA device (HALO<sup>360</sup>, BÂRRX Medical, Sunnyvale, CA) is a balloon-based electrode, which delivers a pre-set amount of energy (12 J/cm<sup>2</sup>) at high power (40 W/cm<sup>2</sup>) to BE tissue. The FA device (HALO<sup>90</sup>) is an endoscope-mounted electrode.

CA was performed at baseline and again at 4 months if needed. After 12 month EGD with biopsy for the primary 1 year endpoint, FA was performed for any visible mucosal abnormality (max 1 session). Patients received lansoprazole 30 mg bid throughout study.

Symptoms of chest, throat and abdominal pain, odynophagia, dysphagia were quantified for 14 days after each ablation session using a diary (visual analog scale, 0-100 mm). Patients underwent EGD with 4Q/1cm biopsies at 1, 3, 6, 12, 24 mo. Pathology review was blinded. Complete Response (CR) is defined as all biopsies negative for BE-LGD or BE (% pts with CR for each endpoint).

**Results:** Ten patients (9 men, mean age 56 years, range 26-79) with BE-LGD (median 4 cm, range 3-6) were treated with CA. Sedation: midazolam (median 5 mg), meperidine (median 50 mg). Median procedure time 47 min. Diary results after CA; all median scores <20/100 on day 1 and all completely resolved by day 5. There was one mild self-limited bleed. At 1 year, CR-BE was 80% and CR-LGD was 100%.

After 1 year, all patients had complete resolution of visible BE, except for irregular z-line in all. Nine of 10 patients underwent FA of irregular z-line (median procedure time 11 min). Sedation: midazolam (median 5 mg), meperidine (median 50 mg). Diary results after FA were similar to those after CA; all median scores <20/100 on day 1 and all completely resolved by day 6. There were no adverse events. Histological outcomes at 2 years are available for 5 patients; CR-BE 100%, CR-LGD 100%. There were no strictures or buried glands at 12 or 24 months.

**Conclusion:** A combined regimen of primary circumferential ablation and secondary focal ablation using the HALO System appears to safely and effectively eradicate BE and LGD at 1 and 2 year follow-up. Such an intervention could have implications for management and surveillance strategies for LGD. A randomized, sham-controlled trial is underway to confirm the results of this pilot trial.

**Endoscopic Ablative Therapy is a Cost-Effective Management for Non-Dysplastic Barrett Esophagus**

*C. D. Wells*<sup>2</sup>; *A. Das*<sup>2</sup>; *D. E. Fleischer*<sup>2</sup>; *H. J. Kim*<sup>2</sup>; *V. K. Sharma*<sup>2</sup>;

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3. Pathology, Mayo Clinic, Scottsdale, AZ, USA.

**Abstract Body** : Background: Advances have been made in the development of safe and effective ablative therapies for non-dysplastic Barrett esophagus (NDBE), although the cost-effectiveness (CE) of such a management strategy remains controversial. We performed a CE analysis to identify the determinants of CE of EAT in NDBE.

Methods: Using a Markov model, we evaluated 3 competing strategies in a hypothetical 50-year old cohort with NDBE over the lifetime of the cohort with a third party payer’s perspective. Strategy I: natural history of NDBE without surveillance or intervention. Strategy II: surveillance per ASGE guidelines. Strategy III: Endoscopic ablative therapy, up to 3 sessions (modeled after the HALO ablation system, BARRX Medical, Sunnyvale, CA). The model was biased against ablative therapy with a conservative estimate of histological complete response (CR) of NDBE at 50% and the model allowed for continued surveillance even after CR. Also, all potential complications were accounted for and an incomplete histological response after ablation was presumed to have same risk of progression as NDBE. Transitional probabilities, appropriately discounted cost estimates and utility values to estimate quality adjusted life-years (QALY) were obtained from published information.

Results: The results of the baseline analysis are shown in the table. In a Monte Carlo analysis using ablation, incremental average net health benefit ratio was achieved with a threshold willingness to pay of \$40,000 or higher. Compared to the Strategy I, the relative risk of developing cancer in the strategy III were 0.59 (95% CI, 0.55-0.64), respectively & NNT for preventing cancer were 16 (95% CI, 14-19). The threshold values of the determinants of the CE of ablation were age at entry into the model <55 years, total cost of ablation < \$11,300 and with > 45% achieving CR of NDBE. The incremental cost-effectiveness ratio (ICER) of strategy III over strategy II is < \$50,000 if cost of ablation falls below \$ 7,450 (baseline estimate \$10,000) or if the probability of CR increases to 0.66 (baseline estimate 0.5). Conclusions: Patient age, cost of ablation, and CR associated with ablation are critical determinants of its CE. Within a range of these parameters, ablation for NDBE is a CE strategy, in this model, by currently accepted standards.

Strategy	Cost(\$)	QALY gained	ICER (\$/QALY)
I	2611	18.057	-
II	13,348	18.349	36,776 (vs. strategy I)
III	22,442	18.480	46,882 (vs. strategy I) 69,270 (vs. strategy II)

Final ID: 292

## Radiofrequency ablation is more cost-effective than endoscopic surveillance or esophagectomy among patients with Barrett's esophagus and low-grade dysplasia

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**Abstract Body: Background/Aim:** Management of patients with Barrett's esophagus (BE) with low-grade dysplasia (LGD) is controversial. Strategies include endoscopic surveillance, esophagectomy, or radiofrequency ablation (RFA). The aim of this study was to compare the incremental cost-effectiveness between these competing strategies.

**Methods:** A mathematical model was created to simulate the natural history of a cohort of patients with BE and LGD from age 50 to 80 years or death using a third-party payer perspective. Interventions included annual endoscopic surveillance with esophagectomy for cancer (SURV), immediate esophagectomy (ESOPH), or ablation using RFA with surveillance depending on whether there was residual LGD (1-year intervals) or no dysplasia (3-year intervals).

Outcomes included the incremental cost-effectiveness ratio (ICER) comparing total direct costs and quality adjusted life years (QALYs) between competing strategies, and a sensitivity analysis identifying the thresholds at which the preference for strategies changed. Diagnostic error was incorporated. Utilities were based on existing literature, as was the efficacy of ablation therapy (residual LGD=30%; BE without dysplasia=10%, no BE=60%). RFA was modeled using a combination of the BÂRRX Halo 360 device, a circumferential ablation balloon catheter, with follow-up treatment using the Halo 90 device, a treatment device for focal disease, as necessary. Complications of endoscopy and surgery were included, as were increased rates of stricture and perforation in the ablation arm. **Results:**

Compared to the natural history of LGD (total direct costs \$615, 14.34 QALYs), the ICER of SURV (\$8081, 15.25 QALYs) was \$8200 per QALY gained. However, the ICER for RFA (\$10457, 16.14 QALYs) was lower: \$2670 per QALY gained over SURV, thus RFA was preferred to SURV based on extended dominance. ESOPH (\$39720, 14.84 QALYs) was more expensive and less effective (dominated) than SURV and RFA. Using more conservative estimates, assuming that no complete ablation of metaplasia was achieved, RFA remained the preferred strategy if the proportion of patients with residual LGD after ablation was 0% (willingness to pay [WTP] \$50000 per QALY) or <40% (WTP \$100000 per QALY); otherwise SURV was optimal. These results were robust to variation in other variables. **Conclusions:** Our base case suggests that RFA therapy may be the most cost-effective option in patients with BE and LGD. If the effectiveness of RFA is substantially lower than current estimates, however, surveillance may be preferred.

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## Novel Combined Modality Therapy for Barrett's Esophagus Containing High-grade Dysplasia: Endoscopic Mucosal Resection Followed by Circumferential and Focal Ablation Using the HALO System

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**Abstract Body** : Background: Endoscopic mucosal resection (EMR) allows for removal of high-grade dysplasia (HGD) and early mucosal cancer (EMC) in Barrett's esophagus (BE) with histological verification of resection margins. Focal EMR, however, is associated with recurrent lesions in non-resected areas, while radical EMR is associated with a significant incidence of stricture formation. Ablative therapy with PDT or APC may allow for treatment of the remaining BE after EMR, but is associated with residual BE and dysplasia, "buried Barrett's", and stricture formation. A newer ablative therapy (HALO System) may be successful in eliminating residual BE with dysplasia after focal EMR.

Aims: Assess the safety and efficacy of focal EMR followed by ablation using the HALO System in patients with BE containing HGD or EMC.

Methods: To be eligible, patients had BE <10 cm, visible abnormalities with HGD or EMC, and no signs of submucosal infiltration or lymphnode metastases on endoscopy or EUS. EMR was performed with cap technique or multi-band mucosectomy (MBM) device. Circumferential ablation (CA) was performed with the balloon-based HALO360 System (BÂRRX Medical, Sunnyvale, CA, USA) and secondary focal ablation (FA) with the endoscope-mounted HALO90 System. Six weeks after EMR, CA was performed, followed every 2 months by CA or FA sessions until endoscopically clear of BE. Two months after the last ablation, EGD with lugol's staining and large cup biopsy (4Q/1 cm) was performed. Histopathology was reviewed by a single pathologist.

Results: 13 pts (9 men, mean age 59±10 yr, median BE length 7(5-10)cm) underwent EMR (n=7 cap, n=6 MBM).

There were 7 en-bloc and 6 piecemeal resections (median 2.5/pt). One patient had acute bleeding after EMR, treated with a hemoclip. Resection specimens: EMC(n=4), HGD(n=6), LGD(n=3); all with clear vertical margin. Remaining BE after EMR: HGD (n=11), LGD (n=2).

Complete histological and endoscopic elimination of dysplasia and IM occurred in 12/13 patients (92%) after 1.5 CA and 2.5 FA sessions (mean/patient). None of the 284 biopsies obtained from neosquamous mucosa contained subsquamous BE. One patient developed a stenosis at the site of the EMR after a procedure in which CA was combined with a 2nd EMR for a new focal lesion. The stenosis resolved with 1 dilation.

Conclusions: Patients with BE containing HGD or EMC can be effectively treated with this combined modality therapy of focal EMR followed by ablation of the remaining BE using the HALO System. A complete response rate for IM and dysplasia of 92% was achieved and there was no ablation-related stenosis. These results compare favorably with other regimens, such as radical EMR, PDT, or APC.

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**Frequency Of Buried Barrett's Metaplasia After BÂRRX Ablation For Intestinal Metaplasia With Or Without Dysplasia**

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**Abstract Body :** Aims: Radiofrequency ablation is a rapidly evolving therapeutic modality for Barrett's esophagus (BE). Buried Barrett's metaplasia (BBM) is a well known complication of all endoscopic ablative therapies for BE. The aim of this study is to assess the frequency of BBM following BÂRRX radiofrequency ablation of BE. Methods: Prospective trial in patients with histologically confirmed >1 cm BE, including short and long segment BE (SSBE/LSBE). Patients with nondysplastic BE (ND) and BE with low or high grade dysplasia (LGD/HGD) are included. Patients in the ND group receive 2 ablations at 10J/cm<sup>2</sup> and patients in the LGD or HGD group receive 12J/cm<sup>2</sup> during each treatment. All patients receive lansoprazole 30 mg bid. Assessment for buried Barrett's metaplasia is performed via 3 & 12-mo follow-up EGD with 4-quadrant bx every 1 cm from the original BE region. Patients in whom all bx are negative are deemed to have complete response (CR). Patients with BBM on 3-mo bx (or overt residual/superficial BE) return at 6 mo for repeat treatment. Endpoints at one year evaluation include CR, BBM, residual/superficial BE, and loss to follow-up for any reason (patients with BBM at 3-mo will be followed as a subgroup). Results: 18 of 50 planned patients have undergone initial ablation. 15 patients (8 male, mean age 59 years, 8 ND, 2 LGD, 8 LSBE, mean BE length 5.7 cm, range 1 to 11 cm) have completed 3-mo evaluation. 3-mo follow-up is pending for the other 3 patients. Of the 15 who have completed 3-mo follow-up, 2 (13%; both in the ND group; 1 LSBE, 1 SSBE) had buried Barrett's metaplasia and will undergo second tx at 6-mo. Of the remaining 13 patients, 8 were completely free of Barrett's metaplasia at 3-mo. Conclusions: The finding of buried Barrett's metaplasia after any therapeutic intervention for BE is concerning due to the potential for malignant transformation under the healing neosquamous epithelium that would no longer be endoscopically detectable. To date, this is the first trial to detect evidence of buried Barrett's metaplasia following BÂRRX ablation. However, our preliminary data suggests that it occurs at lower rates (13%) compared to other BE ablative therapies (14.8-51.1%), which may be due in part to the more circumferential and uniform depth of radiofrequency ablation delivered by the BÂRRX device. Nonetheless, even the possibility of buried Barrett's metaplasia after ablation of BE should necessitate diligent follow-up surveillance biopsies to detect the presence of buried Barrett's metaplasia and repeated ablation as necessary. Long term data on patients with buried Barrett's metaplasia and planned repeat ablation is pending.