Feasibility, Safety and Efficacy of a Novel Pre-Shaped Nitinol Esophageal Deviator to Successfully Deflect the Esophagus and Ablate Left Atrium without Esophageal Temperature Rise during Atrial Fibrillation Ablation – The DEFLECT GUT study

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Short Title: Esophageal deviation during atrial fibrillation ablation

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Abstract

**Background:** Esophageal thermal injury is a feared complication of radiofrequency ablation (RFA) for atrial fibrillation (AF). Rise in luminal esophageal temperature (LET) limits the ability to deliver RF energy on posterior wall of LA.

**Objective:** The aim of this registry was to evaluate feasibility, safety and efficacy of a mechanical esophageal deviation (ED) tool during AF ablation.

**Methods:** We evaluated 687 patients who underwent RFA for AF. In 209 patients, EsoSure® was used to deflect esophagus away from ablation site. Propensity-score matching was performed to obtain 180 patients each in ED and non-ED arms. ED was used for LET rise seen in 61.7% (111/180) patients and was used if esophagus was in the line of ablation on fluoroscopy in 38.3% (69/180) patients.

**Results:** The mean deviation of trailing edge of esophagus with EsoSure® was 2.45 ± 0.9 cm (range: 1-4.5 cm). LET rise >1°C was significantly lower in ED than non-ED group (3% vs 79.4%, p<0.001). Mean LET rise (ED 0.34 ± 0.59 vs non-ED 1.66 ± 0.54, p<0.001). Intra-procedural success of PVAI, was slightly improved in ED arm than in non-ED arm without statistical significance. AF recurrence was lower in ED arm at 3-month, 6-month and 1-year follow-up than non-ED arm. No ED-related complications were noted.
Conclusions: Mechanical displacement of esophagus with EsoSure® appears to be feasible, safe and efficacious in enabling adequate RF energy delivery to posterior wall of LA without significant LET rise and obvious clinical signs of esophageal injury.

Key Words: Atrial Fibrillation; Atrio-Esophageal Fistula; Catheter Ablation; Esophageal Deviation; Esophageal Injury.

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
Introduction

Radiofrequency catheter ablation (RFA) is increasingly being performed for the management of atrial fibrillation (AF). One of the feared complications of this procedure is thermal esophageal injury and atrio-esophageal fistula (AEF) [1,2]. Esophageal injury of varying severity has been reported, anywhere between 2-48% [3-7]. Although the overall incidence of AEF is low (0.03-0.1%), it is associated with very high morbidity and mortality [2,8,9]. A rise in luminal esophageal temperature during the procedure has been identified as a surrogate marker for thermal injury [10-13]. Despite the limitations of this method [14-16], luminal esophageal temperature monitoring during AF-RFA is routinely performed in most centers across world. A rapid and significant rise in luminal esophageal temperature may indicate significant heating of esophageal tissue from adjacent RFA on left atrial (LA) posterior wall.

Typically, RFA is more tempered on posterior wall with lower power, shorter duration and lower contact force to minimize collateral damage to esophagus. If esophagus lies exactly posterior to target ablation site, frequent temperature rises limit ability to deliver adequate lesions, increase procedure time and potentially result in higher PV reconnections.

Mechanical deflection of esophagus away from ablation site may enable more effective RF lesion delivery while avoiding esophageal thermal injury. Previous attempts of esophageal displacement with transesophageal echocardiography (TEE) probe, endoscope and an endotracheal stylet placed in thoracic chest tube have been reported with modest but promising success [17-19]. However, their routine use has been limited due to their complexity, resource constraints and concerns about esophageal erosion with bulky heat-retaining probes. Recently, a novel pre-shaped nitinol esophageal retractor (EsoSure®) has been available for use in US for
esophageal deviation. Limited experience in animal models has suggested safety of esophageal
development with this device [20]. However, there are no clinical data available for EsoSure® use
for deflecting esophagus during AF-RFA to minimize esophageal injury. We performed a multi-
center study using a prospective registry involving 4 participating centers to evaluate safety and
efficacy of EsoSure® use during AF-RFA.

Methods

Study Population

All patients who had EsoSure® device for esophageal deviation (EsoSure® group) use
during AF-RFA between January 2016 and August 2017 were included in study. EsoSure® was
used by operator when a) there was a luminal esophageal temperature rise (>1°C from baseline or
>38.5°C), or b) esophagus was lying exactly posterior to target site while ablating on the
posterior wall of LA. Patients with pre-existing esophageal stricture, esophageal varices, prior
esophageal dilatation and other intervention were excluded. Patients undergoing AF-RFA
without EsoSure® use between August 2015 and August 2017, served as a control group (non-
EsoSure® group).

Ablation Procedure

Patients underwent pulmonary vein antral isolation (PVAI) with a double transseptal
approach as described in detail elsewhere [21]. All ablations were performed under general
anesthesia on uninterrupted anticoagulation. LA was mapped using mapping catheter (Lasso®,
Biosense Webster, California or Advisor®, Abbott, Minnesota). Electrical isolation was
accomplished by ablating PV antra with 3.5 mm/4 mm open irrigated tip, contact force sensing catheter (ThermoCool SmartTouch® SF, Biosense Webster/TactiCath™, Abbott). All site monitored esophageal temperature by 9F single thermistor esophageal probe (ER 400-9; Smiths Medical, Ohio). It was adjusted dynamically along trailing edge of esophagus to approximate lesion delivery site as close as possible throughout the procedure.

The endpoint for PVAI was achievement of both entrance block and exit block. 20 mcg/min of isoproterenol was given for 15 minutes to identify non-PV triggers. For paroxysmal AF, only PVAI was performed. For persistent AF, additional ablations were done at the operator’s discretion.

**Ablation Parameters**

A maximum of 40W on anterior wall and 25 W for 20 seconds (contact force <15 gm) on posterior wall was used. Ablation was stopped if the luminal esophageal temperature increased rapidly up to 1°C from baseline or reached a maximum of 38.5°C. An esophagogram to define borders of esophagus was performed with light barium prior to EsoSure® insertion. In control group, ablation at that location was halted until luminal esophageal temperature returned to baseline. Strategy to deliver further lesions at that or adjacent sites were determined by operator based on factors such as proximity of esophagus, rapidity of luminal esophageal temperature rise and feasibility of lesion delivery.

**EsoSure® Device**
EsoSure® (Northeast Scientific Inc., Waterbury, CT) is a 0.052 inches diameter temperature programmed Nitinol stylet which is soft at room temperature and firm at body temperature (Figure 1a-c). It is inserted into lumen of standard 18-Fr Oro-Gastric tube (OGT) and assumes its temperature programmed “S” shaped curve. The esophagus has minimal anatomical restraints in the posterior mediastinum which enables the device to create an esophageal deviation behind LA. The stylet-OGT can be moved cranially-caudally to deviate different sections of esophagus. It can also be rotated to achieve posterior deviation of esophagus. It is a US Patented and FDA registered class I device under classification of a retractor. The ability of EsoSure® to retract esophagus was well appreciated in human cadaver and live human use (Supplemental video).

**Esophageal Deviation and Luminal Esophageal Temperature monitoring**

The EsoSure® was used in patients with a) temperature rise on the luminal esophageal temperature probe (>1°C from baseline or absolute temperature >38.5°C) while ablating on the posterior wall of LA or b) when esophagus was just posterior to the site of ablation on fluoroscopy. A step-by-step guide as outlined below was used at all participating sites while inserting EsoSure® (Supplemental Table-1). In brief, EsoSure® device was introduced into the lumen of OGT following light barium esophagogram. The OGT was primed with lubricant (1-2 cc of olive oil) injected through the lumen prior to insertion in order to facilitate smooth advancement of EsoSure® into OGT. Using fluoroscopy, EsoSure® stylet was adjusted to deviate esophagus away from the planned RF lesion delivery site (Figure-2). Esophageal temperature probe was adjusted to trailing edge of esophagus (as close as possible to RF lesion site). Subsequent manipulations of EsoSure® were performed as needed to keep esophagus away...
from ablation site. The goal was to achieve deflection of trailing edge of esophagus by at least 2 cm from ablation site. In cases with <2 cm deviation, we manipulated to achieve maximal possible deviation away from intended ablation. All manipulations were done under fluoroscopy and final position was confirmed with fluoroscopy with residual contrast in esophagus. In cases where EsoSure® stylet was inserted due to rising temperature, repeat ablation at same spot was performed after esophageal deviation. At the end of procedure, EsoSure® was withdrawn and suction was applied through OGT to remove residual barium from stomach and esophagus. Allied professionals scrubbing in case performed esophageal deviation after prior training with assistance from operator as needed.

**Data collection**

Demographics, clinical, procedural and complications data were collected prospectively. **Efficacy endpoints:** 1) successful esophageal deviation ≥2 cm on fluoroscopy 2) Acute PVAI 3) Procedure time saved by moving esophagus 4) Number of sudden rapid luminal esophageal temperature rises per case. 4) 3-month, 6-month and 12-month atrial arrhythmia recurrences. **Safety endpoints:** 1) Symptoms of potential complications related to esophageal injury (dysphagia, odynophagia, early satiety, chest pain, melena, fever, chills, and stroke like symptoms) -collected prospectively with 1-week phone call; and 1-month and 3-month clinic visits. 2) Non-esophageal complications.

**Statistical analysis**
The protocol was approved by Institutional Review Board at each site. Categorical and continuous variables were compared using chi-square/Fisher’s exact test and students t-test respectively.

Potential confounding factors adjusted for in the multivariable analyses included age, gender, type of AF, CHADS\textsubscript{2}VA\textsubscript{2}Sc score and gastroesophageal reflux disease (GERD). We estimated a propensity score by fitting a logistic-regression model that adjusted for these items above. One-to-one pair matching between groups was performed by nearest-neighbor matching without replacement, with use of caliper width equal to 0.2 of standard deviation of logit of propensity score. Covariate balances before and after matching were checked by comparison of standardized mean differences. A standardized mean difference of less than 10.0% was considered to indicate a negligible imbalance between groups.

A p<0.05 (2-sided) was considered statistically significant. All analyses were performed with IBM SPSS 24.0 (SPSS Inc., Chicago, IL).

**Results**

Our study consisted of 687 patients who underwent AF-RFA. Out of these, 209 patients underwent EsoSure® use. Rest of 478 patients didn’t undergo EsoSure® use. Mean age in EsoSure® group was 63.8 years, while it was 63.5 years in non-EsoSure® group. Males were higher in non-EsoSure® group, but statistically not significant (69.9% vs 63.6%, p=0.13).

Baseline characteristics are shown in Table 1. Propensity-score matching yielded 180 patients who underwent EsoSure® use to 180 patients who didn’t undergo EsoSure® use. Propensity-
score matching improved the covariate balance considerably (Table-1). For the entire analysis the matched groups were used.

**Esophageal deviation and luminal esophageal temperature measurements:**

Esophageal deviation was used for luminal esophageal temperature rise in 111 (61.7%) patients early on and for close proximity of esophagus to ablation site in 69 (38.3%) patients later in registry. Esophageal deviation was used primarily for left sided PVs in 133 (74%) patients, right sided PVs in 38 (21%) patients and posterior wall in 9 (5%) patients. There was no statistical difference in location of esophagus between groups. Mean time duration for esophagogram assessment, and EsoSure® placement and manipulation was 8±6 minutes. It was reduced to 5±2 minutes in last 50 cases. The additional fluoroscopy time with esophageal deviation process was 76±20 seconds. The mean displacement of trailing edge of esophagus was 2.45±0.9 cm on fluoroscopy (range of 1.0-4.5 cm). In 36 (17%) patients, the maximum esophageal deviation was <2 cm. None of the clinical characteristics were predictive of deviation <2 cm.

Temperature rise >1°C was significantly higher in Non-EsoSure® than EsoSure® group (79.4% vs 3%, p<0.001). 3% EsoSure® group had esophageal deviation of 1 cm from the trailing edge with associated esophageal temperature rise. Non-EsoSure® group had a higher Δ luminal esophageal temperature rise (1.66 ± 0.54 vs 0.34 ± 0.59, p<0.001) than EsoSure® group (Table-2). Total procedure time was significantly lower in EsoSure® than non-EsoSure® group (182 ± 36 minutes vs 206 ± 32 minutes, p<0.001). There was no statistical difference in mean fluoroscopy and RF ablation times.
Among the 111 (61.7%) patients in whom EsoSure® was used due to increase in luminal esophageal temperature, the mean peak difference in luminal esophageal temperature was 1.3±0.2°C prior to EsoSure® use and 0.2±0.1°C after EsoSure® use (p<0.001). In the remaining 69 (38.3%) patients esophagus was moved without waiting for temperature elevation if it was within the line of ablation. In 97% (174/180) patients the peak difference in luminal esophageal temperature was <0.5 °C after using EsoSure®.

**Ablation Efficacy endpoints:**

There was no difference in intra-procedural PVAI rates between the groups [EsoSure®:179/180 (99.4%) vs. non-EsoSure®:174/180 (96.7%), p=0.12]. However, AF recurrence was significantly higher in non-EsoSure® at 3-month, 6-month and 12-month (Table-2).

**Safety endpoints:**

No patients were lost to follow-up. There was no difference in overall complications between cohorts (3.8% vs 3.8%, p=1.0) (Table-3). Major and minor complications of the procedure in EsoSure® group occurred in 7 (3.8%) of the patients. Two patients developed pericardial effusion, of which one didn’t require intervention and the other needed cardiac surgery. No patients had TIA, stroke or death. Eight patients (4.4%) complained of “sore-throat” immediately post procedure which subsided within 3-days. At subsequent follow-ups, none of the patients had symptoms suggestive of esophageal injury or had incidence of gastro-esophageal (atrio-esophageal fistula, symptomatic esophageal ulcerations, symptomatic gastric dysmotility) complications.
Discussion

Major findings: This is the first observational study to date evaluating the feasibility, safety and efficacy of EsoSure®, an esophageal deviation tool, during AF-RFA. In our multi-center study, we noted that mechanical displacement of esophagus with EsoSure® is not only feasible but effective in displacing esophagus and enabling successful delivery of RF energy to achieve ablation end-points without significant luminal esophageal temperature rise. Clinically, there were no safety issues noted.

Esophageal injury leading to AEF is one of the rare but dreaded complications of AF ablation procedures [1,2,8]. Intra-procedural luminal esophageal temperature measurement and subsequent modification of ablation lesion locations and energy delivery settings became standard practice. Often RF ablation is halted after luminal esophageal temperature rise for esophagus to cool down and subsequently use lower energy and/or briefer applications at site of interest prolonging procedure times. Luminal esophageal temperature may rise again during repeat energy application needing re-cooling of esophagus. Repeated on-off, low efficiency ablation could lead to sub-optimal lesion formation and in turn result in non-durable lesions and increase in arrhythmia recurrence. Moreover, acceptable upper limit of luminal esophageal temperature rise is not standardized and varies significantly across operators and institutions.

Very low incidence of AEF makes it very difficult to come up with an optimal cut-off luminal esophageal temperature. The interference of luminal esophageal temperature rise during RF ablation during index ablation procedure may persist during a ‘re-do’ ablation procedure also. [22] Other approaches such as esophageal cooling, although conceptually viable, haven’t been tested rigorously in clinical practice[23,24]. Therefore, mechanical displacement of esophagus
from the desired ablation site is a very useful alternative and in vast majority of cases can
become an important part of workflow, if performed safely and effectively.

282 **Current data on esophageal deviation:**

Owing to minimal attachments to mediastinal structures, esophagus can be moved away
from posterior wall of LA (Figure-3) with a deviating tool like EsoSure® but can quickly move
back to its approximate original location once the deviator is removed. Esophageal displacement
using a TEE probe by Mateos et al was found to be effective with average esophageal
displacement of 5.9±0.8 cm, sufficient to provide effective lesions without esophagus
overlapping[18]. However, it needs an additional procedure, and an experienced operator to
manipulate the probe. In addition, TEE probe is bulkier, significantly stiffer and could potentially
act as a heat retainer contributing to both mechanical and thermal esophageal injury. Similarly,
endoscope and an endotracheal stylet through a thoracic tube have been used to a limited extent
and faced logistic challenges, insufficient deviation and safety concerns[17,19,25].

Our study shows that mechanical displacement of esophagus using EsoSure® is
technically feasible and clinically safe. The most common complaint was transient symptom of
“sore throat” seen in 8(4.4%) patients, which can be related to endotracheal intubation. It
resolved within 3-days in all cases without any clinical sequelae. With esophageal temperature
probe lined up along trailing edge of esophagus, we did not notice any significant temperature
elevation (>0.5°C) in almost all patients while delivering effective lesions. We did not perform a
routine post-procedural endoscopy to evaluate for possible esophageal lesions with device use.
However, limited data from animal studies with endoscopy suggested safety of device [20].
These evidences, in addition to our clinical experience, are reassuring that we don’t routinely perform endoscopy. However, further prospective studies with post-procedural endoscopy will be needed for a definitive objective evidence.

Another notable finding of this study is that we were able to mobilize esophagus from the original location in most of the cases. Average displacement was 2.45±0.9 cm, that is consistent with previous clinical studies and possibly similar to natural physiological migration [17,19,26]. This displacement distance is sufficient enough to deflect esophagus from the area of ablation, which decreases risk of luminal esophageal temperature and possibly esophageal injury as its consequence. Displacement in our study is considerably less than 5.9±0.8 cm shown with TEE probe[18]. This in part adds to safety profile of device. Extreme esophageal displacement is unlikely going to be seen by this device due to its shallow and smooth deviation curves. Unlike TEE probe, EsoSure® is a Nitinol stylet that sits in the OGT creating gentle displacement in an arc mimicking physiologic migration without dramatic stress on esophagus. The spherical tip of the stylet further helps improve the safety profile of the device by preventing inadvertent puncture of OGT. It is important to note that we did not use the device in patients with prior esophageal interventions including fundoplication surgeries and esophageal dilations. The safety of this device in this subgroup of patients is currently unknown.

In our study, intra-procedural efficacy measured as acute PVAI was similar in both arms. This was associated with significantly longer procedure time for non-EsoSure® arm without statistical differences in fluoroscopy or RF time. Brief lesions resulting in rapid rise in luminal esophageal temperature and subsequent wait time for luminal esophageal temperature to return to

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nadir may account for this finding. AF recurrences at 3-month, 6-month and 12-month were significantly higher in non-EsoSure® arm. These findings of similarities in acute PVAI with higher recurrence rate at subsequent follow-ups in non-EsoSure® arm can be hypothesized due to repeated delivery of non-permanent lesions resulting in local tissue edema and inflammation, which may result in acute achievement of PVAI, but subsequent reconnection at later point of time. At this moment, we don’t have definitive data to support whether esophageal deviation can result in good lesion formation and aid durable PVI. However, subsequent studies comprising patients undergoing a re-do ablation may help us understand this phenomenon.

In summary, esophageal deviation with EsoSure® device during AF ablation appears to be safe and effective in enabling effective lesion delivery to the LA without significant rise in luminal esophageal temperature. This adds to the existing armamentarium of tools to minimize esophageal injury during AF ablation. A prospective trial to further validate our findings and also to correlate with post-procedural endoscopic findings is the next step.

Limitations and Future directions

The current study has all the inherent limitations of an observational registry. We did not perform endoscopic evaluations in these patients to assess if esophageal lesions were minimized or avoided. Nevertheless, there was no clinical occurrence of any major esophageal injury related complications in our study, which should be considered as a positive finding and should provide impetus to further studies evaluating esophageal displacement strategies. Endoscopic evaluation of esophagus post ablation with esophageal deviation may help confirm the improved safety attributed to use of this device. A prospective randomized control trial with and without
esophageal deviation assessing the anatomic and functional integrity of the upper gastrointestinal system and acute successful PVI and long-term arrhythmia freedom may help us understand its true utility. Whether esophageal deviation helps in preventing esophageal fistula cannot be assessed by this small study. However, posterior wall ablation can be done effectively improving the acute PVI success without significant luminal esophageal temperature rise which is a marker for esophageal injury. We should also consider adding these data points to the NCDR AF ablation registry to be able to assess the impact of esophageal deviation on the outcomes of esophageal injury going forwards.

**Conclusion**

Esophageal deviation using EsoSure® is feasible, safe and efficacious during RFA for AF in patients in whom luminal esophageal temperature rise prevents delivering effective RF lesion or in patients where esophagus is directly posterior to the intended ablation site. Future randomized studies with a protocol-based endoscopic evaluation may give definitive evidence of safety and efficacy.
References


**Table 1: Baseline Characteristics of the unmatched and matched cohorts.**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Entire Cohort</th>
<th>Propensity Score Matched Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EsoSure® (n=209)</td>
<td>Non-EsoSure® (n=478)</td>
</tr>
<tr>
<td>Age (mean ± SD, years)</td>
<td>63.8 ± 9.9</td>
<td>63.5 ± 11.3</td>
</tr>
<tr>
<td>Males (%)</td>
<td>133(63.6%)</td>
<td>334(69.9%)</td>
</tr>
<tr>
<td>Body Mass Index (mean ± SD, kg/m²)</td>
<td>31 ± 7</td>
<td>32 ± 6</td>
</tr>
<tr>
<td>Paroxysmal Atrial Fibrillation (%)</td>
<td>135(64.6%)</td>
<td>253(52.9%)</td>
</tr>
<tr>
<td>CHA₂DS₂-VASc (mean ± SD)</td>
<td>2.3 ± 1.4</td>
<td>2.4 ± 1.5</td>
</tr>
<tr>
<td>Gastro Esophageal Reflux Disease (%)</td>
<td>55(26.3%)</td>
<td>231(48.3%)</td>
</tr>
<tr>
<td>Hiatal Hernia</td>
<td>22(10.5%)</td>
<td>62(13%)</td>
</tr>
<tr>
<td>Prior Atrial Fibrillation ablation</td>
<td>74(35.4%)</td>
<td>187(39.1%)</td>
</tr>
<tr>
<td>Left Ventricular Ejection Fraction (%)</td>
<td>54 ± 10</td>
<td>55 ± 10</td>
</tr>
<tr>
<td>Left Atrial Volume (mean ± SD, in cc)</td>
<td>133 ± 47</td>
<td>131 ± 44</td>
</tr>
<tr>
<td>Primary Left atrial locations prompting esophageal displacement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Left sided veins' antra</td>
<td>142(68%)</td>
<td>339(71%)</td>
</tr>
<tr>
<td>Right sided veins' antra</td>
<td>53(25%)</td>
<td>116(24%)</td>
</tr>
<tr>
<td>Posterior wall</td>
<td>14(7%)</td>
<td>23(5%)</td>
</tr>
<tr>
<td>Esophageal Displacement (mean ± SD)</td>
<td>2.61 ± 1 cm</td>
<td>NA</td>
</tr>
</tbody>
</table>
Table 2: Differences in efficacy endpoints between EsoSure® and non-EsoSure® groups

<table>
<thead>
<tr>
<th>Efficacy endpoint</th>
<th>EsoSure® (n=180)</th>
<th>Non-EsoSure® (n=180)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Change in esophageal temperature</td>
<td>0.34±0.59</td>
<td>1.66±0.54</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Esophageal temperature rise</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1.0°C(cases)</td>
<td>6(3%)</td>
<td>143(79.4%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total Procedure Time (minutes)</td>
<td>182±36</td>
<td>206±32</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total Radiofrequency Duration (minutes)</td>
<td>62±21</td>
<td>65±26</td>
<td>0.22</td>
</tr>
<tr>
<td>Total Fluoroscopy Time (minutes)</td>
<td>34.5±13.7</td>
<td>33.1±13.2</td>
<td>0.32</td>
</tr>
<tr>
<td>Acute Pulmonary Vein Isolation</td>
<td>179(99.4%)</td>
<td>174(96.7)</td>
<td>0.12</td>
</tr>
<tr>
<td>AF recurrence at 3-months</td>
<td>29(16.1%)</td>
<td>51(28.3%)</td>
<td>0.008</td>
</tr>
<tr>
<td>AF recurrence at 6-months</td>
<td>37(20.6%)</td>
<td>55(30.6%)</td>
<td>0.04</td>
</tr>
<tr>
<td>AF recurrence at 12-months</td>
<td>42(23.3%)</td>
<td>60(33.3%)</td>
<td>0.05</td>
</tr>
</tbody>
</table>
Table 3: Differences in safety endpoints between EsoSure® and non-EsoSure®
groups

<table>
<thead>
<tr>
<th>Efficacy endpoint</th>
<th>EsoSure® (n=180)</th>
<th>Non-EsoSure® (n=180)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI symptoms</td>
<td>8(4.4%)</td>
<td>9(5.0%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Major bleeding complications</td>
<td>2(1.1%)</td>
<td>3(1.6%)</td>
<td>1.0</td>
</tr>
<tr>
<td>Minor bleeding complications</td>
<td>5(2.7%)</td>
<td>4(2.2%)</td>
<td>1.0</td>
</tr>
<tr>
<td>TIA/Stroke</td>
<td>0</td>
<td>0</td>
<td>NA</td>
</tr>
</tbody>
</table>
**Figure-1a-c: Features of EsoSure® Device.** Figure-1a shows minimal and malleable curves at room temperature. Figure-1b shows exaggerated and firm curves at body temperature. Figure-1c shows additional features of device. Ball at the tip prevents inadvertent puncture of OGT.

**Figure-2: Esophageal deviation with EsoSure® (AP-view).** Figure-2a: Pre-EsoSure® esophagogram demonstrates exact relationship of trailing edge of esophagus in relation to intended lesion delivery site indicated by position of ablation catheter. Temperature probe in esophagus showing baseline position of esophagus in relation to lasso at ostium of right superior pulmonary vein and ablation catheter in left superior pulmonary vein. Note that catheter tip is in proximity of trailing edge of esophagus in this view near left sided veins. Figure-2b: EsoSure® placed in OGT to deviate esophagus from intended site of lesion delivery. The deviation trailing edge of esophagus from lesion delivery site was 1.8 cm.

**Figure-3: Possible deflection courses for esophagus at displacement with EsoSure®.** This illustration on a CT scan image shows possible courses an esophagus can take on deflection with EsoSure®. The most common courses are right and left posterior-lateral which are best appreciated in LAO and RAO views respectively.
Fig. 1a - EsoSure stylet at room temperature. Stylet curve is malleable and minimal.

Fig. 1b - EsoSure stylet at body temperature. Stylet curve is firm and exaggerated.

Fig. 1c
- All on tip prevents OG tube puncture.
- Larger primary curve is on distal end of stylet.
- Smaller secondary curve is proximal.
- .052 dia. Nitinol shaft is shorter than the distance to the OG tube’s proximal hole.
- Spongy plug occludes end of OG tube.
- Markings on handle indicate direction of primary curve during insertion.
- Clip secures handle to pillow or sheet.
4 Deflection Courses

**Left Lateral**: Where the esophagus slides between the aorta and the left atrium. Best in AP view. Infrequent.

**Left Posterior-Lateral**: Where the esophagus slides between the aorta and the vertebrae. Best visualized in LAO view. Frequent.

**Right Lateral**: Esophagus slides between the right lung and left atrium. Best in AP view. Infrequent.

**Right Posterior-Lateral**: Where the esophagus slides between the right lung and right side of the vertebrae. Best in RAO view. Frequent.