Feasibility of Circumferential Pulmonary Vein Isolation Using a Novel Endoscopic Ablation System

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Disclosures

- None
Background

- Pulmonary vein isolation is an established treatment option for paroxysmal atrial fibrillation
- It remains a challenge to achieve continuous transmural lesions using established ablation energies and systems
- Commonly used ablation systems may be associated with severe complications

→ Demanding new energy sources and new catheter designs
Aim of the Study

- Feasibility of PVI using a novel endoscopic ablation system
- Pattern of PVI
- Assess system-related complications
  - PV-stenosis
  - Incidence and quality of esophageal thermal lesions
  - Phrenic nerve injury
The Endoscopic Ablation System
Technical Features

• Non-steerable compliant balloon with max. diameter of 32mm

• Filled and flushed with D₂O

• Contains a 980nm laser optic and a 2F fiberoptic endoscope

• Variable power settings (5.5W–18W, 20-30 sec)
Variable Balloon Size - LIPV

- small
- medium
- large
Methods

“CROSSTALK”

LSPV

LIPV

TP
EAS
CS
LASSO
TS
Circumferential PVI

"CROSSTALK"

LSPV

LIPV
Simultaneous Isolation of LPVs

LSPV
post.

LIPV

Lasso
ant.

Laser
Wide Area Circumferential Ablation - RPVs
Inclusion Criteria

• Drug-refractory Paroxysmal Atrial Fibrillation
• Age: 18 - 70 years
• LA-diameter < 50 mm
• PV-diameter ≤ 32 mm
• LVEF > 30 %
• Valvular dysfunction < II°
• No previous PVI attempt
Diagnostics and Treatment

- **Pre-procedural:**
  - MRI or multislice-CT

- **Post-procedural:**
  - MRI or multislice-CT 3 months post ablation
  - Endoscopy 2 days post ablation

- **Post-procedural treatment:**
  - Continuation of previously ineffective antiarrhythmics
  - PPI for 6 Weeks
Periprocedural Safety Aspects

• Esophageal temperature probe using a temperature cut-off of 38.5 °C
  (→ Reddy et al. Circulation 2009)

• Phrenic-nerve pacing while ablating the RPV
## Results

### Demographics:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Ptn. (n)</td>
<td>40</td>
</tr>
<tr>
<td>Age [yrs]</td>
<td>57 ± 9</td>
</tr>
<tr>
<td>History of PAF [yrs]</td>
<td>5 ± 5</td>
</tr>
<tr>
<td>Number of AADs</td>
<td>1 ± 1</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>20 (50)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>22 (55)</td>
</tr>
<tr>
<td>LA size [mm]</td>
<td>42 ± 4</td>
</tr>
</tbody>
</table>
# Acute Success

<table>
<thead>
<tr>
<th></th>
<th>Simultaneous Isolation</th>
<th>Separate Isolation</th>
<th>Failed Isolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>LPVs, n (%)</td>
<td>18/40 (45)</td>
<td>22/40 (55)</td>
<td>0</td>
</tr>
<tr>
<td>RPVs, n (%)</td>
<td>6/40 (15)</td>
<td>33/40 (83)</td>
<td>1/40 (2.5)</td>
</tr>
</tbody>
</table>
## Number of Laser Applications

<table>
<thead>
<tr>
<th></th>
<th>No. of applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSPV</td>
<td>37±19</td>
</tr>
<tr>
<td>RIPV</td>
<td>32±12</td>
</tr>
<tr>
<td>LSPV</td>
<td>46±19</td>
</tr>
<tr>
<td>LIPV</td>
<td>37±19</td>
</tr>
<tr>
<td>LCPV</td>
<td>55±17</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Fluoroscopy Time [min]</td>
<td>30 ± 17</td>
</tr>
<tr>
<td>Procedure Time [min]</td>
<td>240 ± 62</td>
</tr>
</tbody>
</table>
Procedure Times

![Procedure Times Graph]

The graph above represents the procedure times over a period of 40 days. The y-axis indicates the time duration, ranging from 0 to 400 units, while the x-axis represents the days from 1 to 40.

The data shows fluctuations in procedure times, with noticeable peaks and troughs. The trend appears to decrease overall, suggesting improvements or changes in the procedure over time.

Key observations:
- Day 7 shows a significant increase compared to previous days.
- Day 11 and Day 30 exhibit lower procedure times.
- There are minor fluctuations on days 13, 18, and 27, indicating possible adjustments or external factors affecting the procedure times.

This graph is useful for identifying patterns, understanding trends, and making informed decisions regarding procedural improvements.
**Endoscopical Findings**

- **Postinterventional Gastroscopy**
  - in 37/40 patients
  - 2 ± 1 days post ablation

<table>
<thead>
<tr>
<th>Lesion Type</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No thermal lesions</td>
<td>30/37 (81)</td>
</tr>
<tr>
<td>Minimal thermal lesions</td>
<td>3/37 (8)</td>
</tr>
<tr>
<td>Esophageal ulceration</td>
<td>4/37 (11)</td>
</tr>
</tbody>
</table>

- **All thermal lesions resolved during repeat endoscopy 6 ± 1 days after initial endoscopy**
Correlation Temperature and Endoscopical Findings

- no lesion
- minimal lesion
- ulceration

Max $T_{eso}$ [°C]

$p < 0.05$
## Complications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phrenic Nerve Palsy</td>
<td>1</td>
<td>2.5%</td>
</tr>
<tr>
<td>Pericardial Effusion/Tamponade</td>
<td>2</td>
<td>5%</td>
</tr>
<tr>
<td>PV-Stenosis</td>
<td>0</td>
<td></td>
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<tr>
<td>Pneumothorax</td>
<td>0</td>
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Conclusions

• Circumferential PVI using the novel endoscopically-guided ablation system is feasible in the majority of LPVs and a minority of RPVs

• Complication-rate comparable to established systems

• Continuous monitoring of temperature increase in the esophagus may minimize potential collateral damage