LAmbre LAA Occluder Updates

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Characteristics

1. Two parts: LA Cover and Umbrella. "An Umbrella in LA Appendage"

2. Double-membrane design: A distal membrane to seal the appendage if that in the cover fail to do so.

3. TiN-coated LA cover with recessed hub to promote faster endothelialization and to reduce delayed thrombus formation.

4. Specially-designed umbrella (8 frames + PET membrane + 8 hooks) for multiple recapture and repositioning; only smaller sheaths (8-10Fr, Sizes 16-36mm) required.
Partial deployment of umbrella at proximal LAA
Anchoring Mechanisms

3 Anchoring Mechanisms:
- 8 small hooks
- Stenting effect of the over-sized umbrella
- 8 individual frames (trapped in trabeculations)
Two Specifications

Standard
- 16-36mm
- Cover 4-6mm larger

Special
- 16-26mm
- Cover 12-14mm larger
- Suitable for:
  - multiple lobes with restrictive septum
  - Small LAA with large opening
-> Opening up the umbrella at proximal LAA (active roll-in of stabilizing hooks)
-> Distal positioning of delivery catheter is not required!
-> Less demanding on catheter alignment in perpendicular to ostial axis!

## Comparisons with Current LAA occluders

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<thead>
<tr>
<th></th>
<th>WATCHMAN</th>
<th>ACP</th>
<th>LAmbre</th>
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<tbody>
<tr>
<td><strong>Device Design</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leak</td>
<td>More likely</td>
<td>Less likely</td>
<td>Less likely</td>
</tr>
<tr>
<td>Dependence on LAA depth</td>
<td>YES</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Delivery Sheath</td>
<td>14 Fr</td>
<td>9-13 Fr (13)</td>
<td>8-10 (9)</td>
</tr>
<tr>
<td><strong>Procedural control</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deep seating of delivery catheter</td>
<td>Required</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>Backward bounce of the device</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recapture and Repositioning</td>
<td>Limited</td>
<td>Limited</td>
<td>Full</td>
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Clinical Studies Updates Sept 2014

- 192 human implants were then performed successfully (184/184 attempts, 100% implant success)
  - 60: 2 German Centers for CE study (Nov 2013 – June 2014)
Transcatheter Left Atrial Appendage Closure with Lifetech LAmbre Device: Early Asian Experience

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2. Fuwai Hospital, Beijing, China
3. Renmin Hospital of Wuhan University, China
4. Hanoi Heart Hospital, Vietnam
5. Binawaluya Hospital, Indonesia
6. Shanghai Tenth People’s Hospital of Cardiology, China
Oct 2012 – June 2014

6 Asian Centers: Hanoi (n=2), Jakarta (n=18), Beijing (n=4), Wuhan (n=7), Hong Kong (n=3), Shanghai (n=32)

Inclusion: Stable NVAF patients with $\text{CHA2DS2-VASc} \geq 2$

Exclusion: LAA thrombus, NO anatomical exclusion criteria

Feasibility: Stable device placement without significant leak (>3mm peri-device leak)

Safety: A composite of CV death, device embolization, stroke, systemic embolism, MI, pericardial effusion/cardiac tamponade, major bleeding requiring intervention/transfusion, & need for CV surgery 7 days within the procedure
66 NVAF patients; Aged 67±10; 50% Male (n=33)

CHA2DS2-VASc: 3.8±1.4; HAS-BLED: 2.4±1.2

Procedure: General anesthesia/Deep sedation (n=61), Local anesthesia (n=6); Fluoroscopic +/- TEE guidance

Procedural time (min): 63±21; Fluoro. time(min): 12±4

Landing zone diameter(mm): 22.2±4.8; Device size (mm): 26.7±4.5

Standard device (n=62), special device (n=4)

Feasibility: Successful device implantation 100% ; Significant Peri-device leakage (color-Doppler width>3mm): 1 (4mm leak)

Safety (7-day events): 2 air-embolism, 1 mild pericardial effusion, no stroke or device embolization, no transfusion needed
Severe procedural-related complications compared with other 2 devices

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<tr>
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<th>PROTECT-AF</th>
<th>ACP Retrospective European Registry</th>
<th>LAmbre Global Registry</th>
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<tbody>
<tr>
<td>No of patients (time of follow-up)</td>
<td>463 (7 days within procedure)</td>
<td>143 (&lt;24 hour or upon discharge)</td>
<td>#192 (7 days within procedure)</td>
</tr>
<tr>
<td>Implantation success</td>
<td>401/463 (91%)</td>
<td>132/137 (96%), not attempted in 6</td>
<td>192/192 (100%)</td>
</tr>
<tr>
<td>Serious pericardial effusion</td>
<td>22 (4.8%)</td>
<td>5 (3.5%)</td>
<td>*2 (1.0%)</td>
</tr>
<tr>
<td>Procedural stroke</td>
<td>5 (1.1%)</td>
<td>3 (2.1%)</td>
<td>1 (0.5%)</td>
</tr>
<tr>
<td>Device embolization</td>
<td>3 (0.6%)</td>
<td>2 (1.4%)</td>
<td>0 (0%)</td>
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</table>

#the only exclusion criteria was the presence of LAA thrombus, no other anatomical exclusion criteria (i.e. patients with small, large or shallow LAA all included)
*1 due to stiff guidewire perforation of LAA during procedure, another due to delayed effusion 7 days after implantation
Case 1 - Routine Case
Case 2- Large Appendage

TEE 135 Degree

RAO Caudal Projection

34mm

35mm
Large Appendage – 36mm device, 10 Fr sheath
LAA angiogram by a 10 mm pigtail shows a very shallow appendage
Special type of L Ambre was used

Aggressive tug test at the end confirmed device stability
Conclusions

- Our preliminary human experience in Asia suggested LAA occlusion with LAmbre device is feasible in various LAA anatomies with no serious peri-procedural events.
- Main advantages of this device include small delivery system, ease of use and the ability to be fully retrievable and repositionable during implantation.
- Human trials with this novel device are underway in Asia/Europe to evaluate its long-term safety and efficacy.