HARPOON
Beating Heart Mitral Valve Repair System

Dr. Paolo Denti - San Raffaele Hospital, Milan, Italy
Potential conflicts of interest

Dr. Paolo Denti, San Raffaele Hospital, Milan, Italy

Consultant: Edwards Lifesciences, Abbott, 4Tech, Neovasc and InnovHeart
An innovative new procedure that transforms surgical correction of severe degenerative MR

HARPOON Mitral Valve Repair System

- Simple, minimally-invasive, beating-heart, off pump repair
- Echo-guided chordal placement
- Real-time confirmation of results

Hemostatic Introducer
Minimizes blood loss

Low-Profile Delivery System
9 Fr shafted instrument

Secure Anchoring
Self-forming ePTFE knot
HARPOON Device Overview

21-Gauge Needle
with pre-wounded ePTFE suture in preformed knot configuration

Hemostatic Introducer
to reduce blood loss and improve tactile feedback

Delivery System
with a low profile (3 mm, 9 Fr) to deliver device to the valve

Proprietary Anchor
with an ePTFE suture as the only element left in the heart
The HARPOON procedure accesses the beating heart via a small incision on the left side of the chest without cardiopulmonary bypass or cardiac arrest.
The target zone for introducer insertion is approximately 2 to 4 cm basal from the true apex of the left ventricle, at the level of the base of the papillary muscles, between the LAD and the diagonal.
3 Delivery System Insertion & Navigation

The Delivery System is inserted into the heart via the Introducer, and using TEE guidance, is navigated to the target on the MV leaflet.
The proper positioning of the tip of the HARPOON Delivery System, which stabilizes the mitral leaflet, is confirmed with echocardiography.
The operator activates the HARPOON Delivery System by depressing the plunger on the device.

A needle tightly wrapped with the preformed ePTFE bulky knot, is rapidly advanced through the leaflet and withdrawn.

The bulky knot is deployed on the atrial surface of the targeted mitral valve leaflet.
Delivery System Removal

The Delivery System is removed from the introducer. The ePTFE cord pairs that secure the knot pass through the introducer and are ready to be tied.

If necessary, this procedure can be repeated multiple times via the same Introducer valve. The introducer is designed to hold up to four (4) ePTFE cords.
Once the appropriate number of knots has been inserted, the introducer is removed and the purse string suture is tightened.

According to the TRACER study (Gammie at al. JACC 2018)
An average of three (3) pairs of ePTFE cords were implanted in patients successfully treated by using the HARPOON device.
All ePTFE cords are progressively tensioned using TEE. When the sutures are properly tensioned, it restores the natural area of coaptation between the posterior and anterior leaflets and eliminates mitral regurgitation.
Once the optimal length of the cords has been confirmed under echo-guidance, the free-end of all sutures are secured to the outside surface of the heart, using a stiff pledget.
HARPOON Beating Heart Mitral Valve Repair System

Case Video
S.S., female patient, 77-years old

2004 echocardiographic diagnosis of mitral prolapse
Hypertension and hyperlipidemia

June 2017 TEE
• P2 flail/prolapse in myxomatous valvular disease
• Left atrium dilatation (AP 44mm)
• Left ventricle EDD 59mm, ESV 25ml, LVEF 70%
• PAPs 76mmHg

July 2017 left heart cath: LAD proximal stenosis
<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>EuroSCORE</td>
<td>1.43%</td>
</tr>
<tr>
<td>STS-score</td>
<td></td>
</tr>
<tr>
<td>Risk of Mortality</td>
<td>1.26%</td>
</tr>
<tr>
<td>Morbidity or Mortality</td>
<td>11.67%</td>
</tr>
<tr>
<td>DSW Infection</td>
<td>0.18%</td>
</tr>
<tr>
<td>Long Length of Stay</td>
<td>4.94%</td>
</tr>
<tr>
<td>Permanent Stroke</td>
<td>1.94%</td>
</tr>
<tr>
<td>Prolonged Ventilation</td>
<td>5.94%</td>
</tr>
<tr>
<td>Renal Failure</td>
<td>2.18%</td>
</tr>
<tr>
<td>Reoperation</td>
<td>6.34%</td>
</tr>
<tr>
<td>Short Length of Stay</td>
<td>35.71%</td>
</tr>
</tbody>
</table>
Pre-operative vs. Post HARPOON procedure
Pre-operative vs. Post HARPOON procedure
Conclusions

- HARPOON MVRS enables echo-guided beating heart anchoring of ePTFE artificial cords
- It is a truly minimally invasive procedure (9 Fr delivery system) which is performed without the need of cardiopulmonary bypass, and sternotomy
- Procedural traumatism and bleeding are limited
- It allows for real-time confirmation of the intra-operative results
- It does not preclude future intervention as leaflets are preserved