

Echocardiographic guidance for HARPOON Beating-Heart Mitral Valve Repair

Andrzej Gackowski^{1*}, Michael N. D'Ambra², Paul Diprose³, Piotr Szymański⁴, Alison Duncan⁵, Krzysztof Bartus⁶, James S Gammie⁷

¹Dept. of Coronary Disease and Heart Failure, Jagiellonian University, Medical College, Noninvasive Cardiovascular Laboratory, John Paul II Hospital, Cracow, Poland. ²Dept. of Anesthesiology, University of Maryland, Baltimore, Maryland, USA. ³Cardiac Anaesthesia and Intensive Care, University Hospital Southampton, UK. ⁴Center for Postgraduate Medical Education and Clinical Cardiology Center, Central Clinical Hospital MSWiA, Warsaw, Poland. ⁵Heart Division, Royal Brompton Hospital, London, UK. ⁶Dept. of Cardiovascular Surgery and Transplantation, Jagiellonian University, Medical College, John Paul II Hospital, Cracow, Poland. ⁷Division of Cardiac Surgery, University of Maryland School of Medicine, Baltimore, MD, USA.

Sponsor: *This InSight paper was sponsored by Edwards Lifesciences SA, Switzerland*

Introduction

Conventional mitral valve (MV) surgery is the treatment of choice in patients with severe mitral regurgitation (MR) secondary to degenerative MV prolapse [1]. However, it is currently possible to treat MV prolapse without circulatory arrest and cardiopulmonary bypass [2-5].

HARPOON mitral repair is a procedure performed via puncture of the left ventricle (LV) with a low-profile valved introducer. The HARPOON device is inserted and precisely navigated towards the target. The prolapsed segment is punctured and an ePTFE cord forms a knot on atrial side of the prolapsed segment. The cord is externalized through the introducer.

After implantation of three or more knots, the cords are tensioned, and the coaptation is restored. The cords are then tied down on the epicardium over a felt pledget.

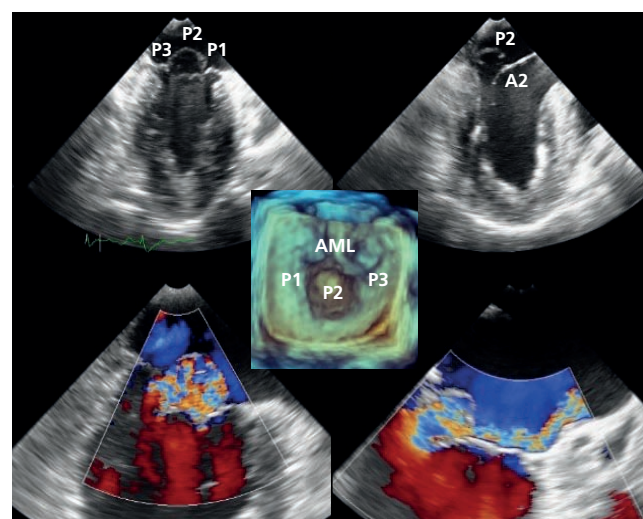
High quality echocardiography, is a crucial element of all steps of the HARPOON procedure including pre-screening and pre-procedural planning, selection of the thoracotomy site, puncture of the left ventricle (LV), navigation of the HARPOON device towards the target, implantation of a knot, optimal tensioning and tying down the cords, final evaluation and follow-up. This article summarizes the specific echocardiographic aspects of the HARPOON procedure, based on the initial experience of 60 procedures with up to 5 years follow-up [2-5].

Screening

TTE and particularly 3D TEE are used to identify those patients with suitable anatomy observed in multiple TEE planes (particularly in intercommisural, long axis and 3D views).

Although the HARPOON system can be used to implant the cords in any segment, the initial protocols were limited to patients with P2 prolapse.

The optimal anatomy suitable for the procedure includes an isolated P2 prolapse with anteriorly directed jet of severe MR and preserved concavity to enable device stabilization. The prolapse width should be sufficient to accept at least three knots.



* Corresponding author. E-mail: agackowski@gmail.com

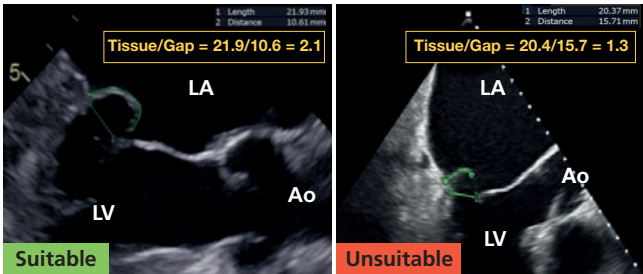
©The Author(s) 2021. Published by Oxford University Press on behalf of the European Society of Cardiology.

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/4.0/>), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

The ratio of the length of the prolapsing segment (tissue) to the distance between the free edge of the anterior leaflet and the base of the posterior leaflet (gap) is used.

Tissue/Gap ratio of at least 1.5 (ideally > 2.0) throughout the width of the P2 prolapse is needed to accept the patient for the procedure.

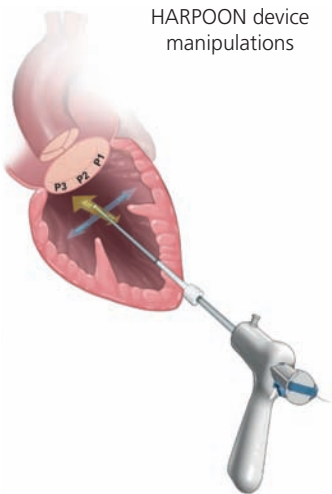
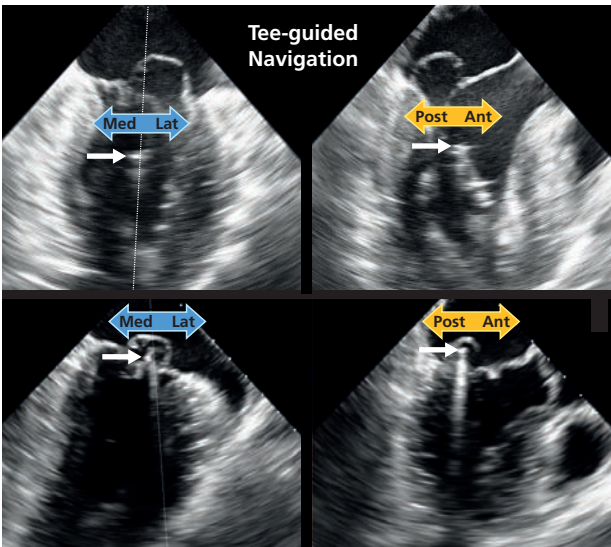
Pre-op planning and targeting is performed based on detailed 3D analysis.



Current exclusion criteria include prominent calcification in the prolapsed part of the valve, active endocarditis, leaflet perforation, and presence of contraindications to the performance of a TEE study.

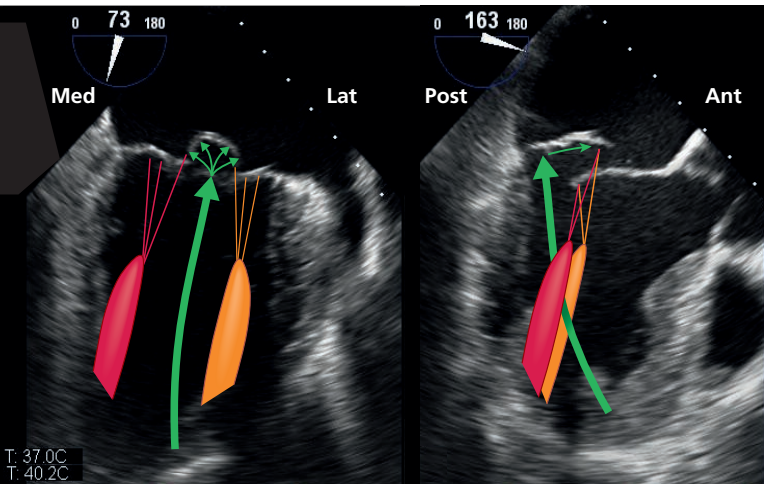
Procedural Communication and TEE Guidance

TTE is used to identify the optimal position for skin incision. The surgeon palpates the left ventricular (LV) wall with a finger at the planned entrance site which is visualized and confirmed on TEE. The puncture site is located approx 2cm basal and lateral from the LV apex, between the LAD and diagonal arteries. After placement of pledgeted purse-string sutures, the LV is punctured. A guidewire followed by a hemostatic introducer and the Harpoon device is then inserted into the LV under TEE control.



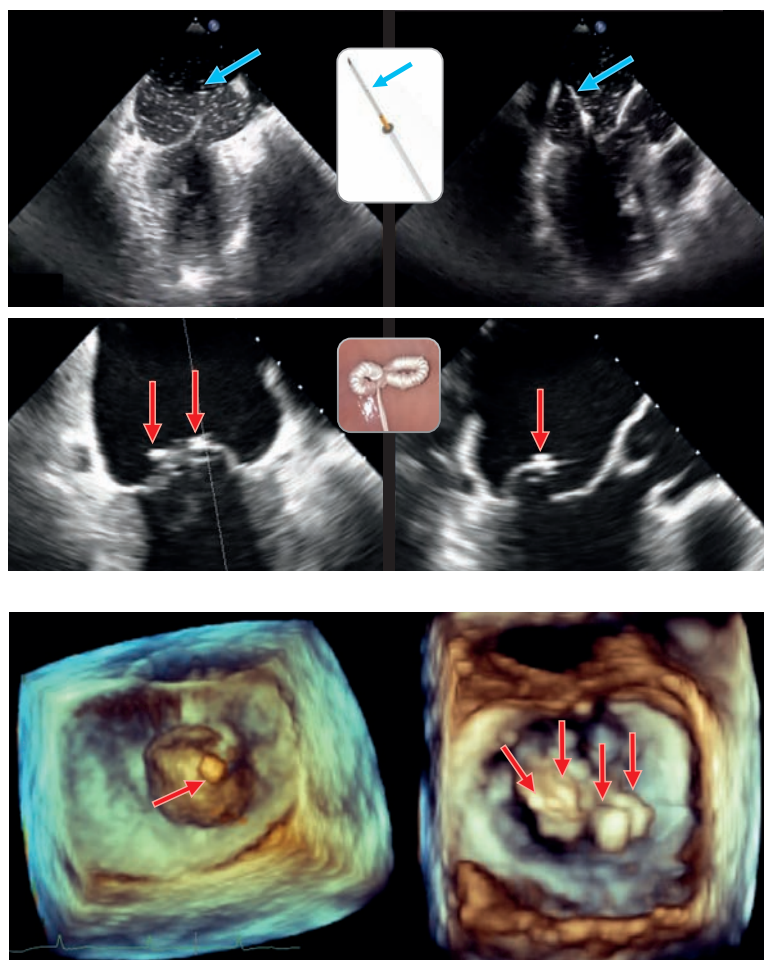
The characteristic artifact of the HARPOON device tip (white arrow) is used for navigation. Precise manipulations of the xPlane orthogonal TEE imaging planes (intercommisural and long-axis), crossing at the device tip are necessary. Blind manipulation of the device should be avoided. A specific “directional vocabulary” has

been developed for communication between the echocardiographer and the surgeon (i.e. *anterior, posterior, medial, lateral, advance, stop, deploy*, etc.). A specific simulation training for both physicians is performed prior to the procedure to ensure synchronized and perfect collaboration.



The device is navigated stepwise between papillary muscles reaching the base of the P2 segment without the risk of entanglement in native chords (thick green arrow). The device is then stabilized on the leaflet and gradually moved towards the pre-specified target approximately 4mm from the free edge of the prolapsed leaflet (thin green arrows). It is essential to avoid the “no fly zones” located anteriorly and close to the commissures. In case the position of the device is lost it is withdrawn to the level of papillary muscles and re-advanced towards the leaflet.

Anchoring the cords



Prior to knot deployment, orthogonal biplane imaging must demonstrate optimal HARPOON device positioning (approx. 4mm from the free edge) with the P2 scallop constantly tenting on the device tip throughout cardiac cycle. The plunger is pushed and the prolapsing MV segment is punctured with a needle wrapped with a coil of ePTFE (blue arrows) which forms a knot on the atrial surface of the leaflet.

After deployment, the device with the pair of cords is withdrawn. The knot formed on the leaflet is observed and recorded in both 2D and 3D views to assess knot positions (red arrows).

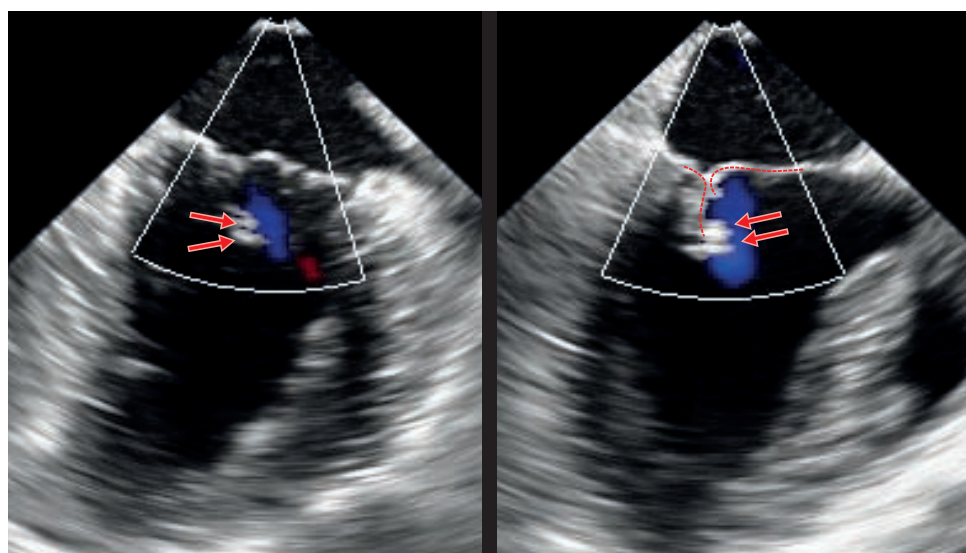
The procedure is repeated until all the pre-planned number of knots (at least 3) are evenly distributed close along the leaflet free edge.

Tensioning and final evaluation

The cords are simultaneously pulled with equally distributed tension, to reposition the prolapsed leaflet segment towards the LV under continuous biplane imaging. The knots should ultimately

be positioned on P2 segment below the coaptation point, maximizing coaptation length. Color Doppler is used to confirm elimination of mitral regurgitation (video 1).

If pre-tensioning demonstrates a satisfactory result and no more knots are needed, the cords are released, the introducer removed, and the LV apical insertion point closed. The optimal tensioning is again tested stepwise with careful TEE analysis. The optimal tension should allow good coaptation without residual Prolapse and without over-tensioning. Constant tension of cords should be avoided. A moderate decrease of the antero-posterior (AP) annular systolic diameter is usually observed both acutely and in follow-up.



The final result is documented with TEE undertaking a thorough assessment of the entire coaptation length. Follow-up TTE is

performed after extubation, prior to discharge, at 3, 6, 12 months, and then annually post-procedure (video 2).

Conclusion

The HARPOON procedure has been shown to be a safe and effective mitral valve repair option in carefully selected patients [4-6]. It requires extensive use of expert 2D and 3D TEE echocardiography. The echocardiographer and surgical team should undergo pre-procedural HARPOON training. Simulators are used to attain competence in synchronized HARPOON device and echo

probe motion, this is vital to ensure excellent communication allowing safe and precise navigation.
The HARPOON procedure is now being further evaluated in the RESTORE, REPLICATE and ASCEND trials.

Corresponding author name:	Professor Andrzej Gackowski Jagiellonian University Medical College, John Paul II Hospital, Krakow, Poland – agackowski@gmail.com
InSight title:	An imaging driven procedure: HARPOON Beating Heart Mitral Valve Repair System
DOI:	10.1093/ehjci/jeab044
OXFORD ACADEMIC	© The Author(s) 2021. Published by Oxford University Press on behalf of the European Society of Cardiology. This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http://creativecommons.org/licenses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com
ESC European Society of Cardiology	

References

- David T.E., et al. Chordal replacement with polytetrafluoroethylene sutures for mitral valve repair: a 25-year experience. *J Thorac Cardiovasc Surg.* 2013; **45**: 1563–1569.
- Colli A, et al. Transapical off-pump mitral valve repair with Neochord implantation: early clinical results. *Int J Cardiol.* 2016; **204**: 23–28.

- Gammie J.S., et al. Transapical beating-heart mitral valve repair with an expanded polytetrafluoroethylene cordal implantation device: initial clinical experience. *Circulation.* 2016; **134**: 189–197.
- Gammie J.S., et al. Beating-heart mitral valve repair using a novel ePTFE cordal implantation device: prospective trial. *J Am Coll Cardiol.* 2018; **71**: 25–36.
- Gammie JS, et al. Safety and performance of a novel transventricular beating heart mitral valve repair system: 1-year outcomes *Eur J Cardiothoracic Surg.* 2021; **59**: 199–206.

Conflict of Interest Statement:

Andrzej Gackowski: was an investigator for the Harpoon 'Tracer Trial' and is a consultant for Edwards Lifesciences. **Michael N. D'Ambra:** was a consultant for Harpoon Medical but does not report current COI. **Paul Diprose:** was an investigator for the Harpoon 'Tracer Trial' and is a consultant for Edwards Lifesciences. **Piotr Szymanski:** was an investigator for the Harpoon 'Tracer Trial'. He is a proctor for edge-to-edge procedures and a member of the speakers' bureau for [Abbott CV]. Does not report other COI. **Alison Duncan:** was an investigator for the Harpoon 'Tracer Trial'. **Krzysztof Bartus:** was an investigator for the Harpoon 'Tracer Trial' and is a consultant for Edwards Lifesciences. **James Gammie:** was a founder of Harpoon Medical and is a consultant of Edwards Lifesciences.