



ÖSTERREICHISCHE GESELLSCHAFT
FÜR THORAX- UND CARDIOVASCULÄRE CHIRURGIE
AUSTRIAN SOCIETY FOR THORACIC AND CARDIOVASCULAR SURGERY

***Recommendations concerning implementation of programs in
endovascular, catheter-based heart valve repair by the
Austrian Society of Thoracic and Cardiovascular Surgery***

Current situation:

After the successful application of catheter-based procedures for the treatment of coronary artery disease, congenital heart disease (e.g. atrial septal defects and aortic coarctation), and injuries and diseases of the thoracic aorta, current experimental and clinical studies have demonstrated that valvular heart disease may also be treated by endovascular means. Austria Vienna General Hospital is currently conducting a study on transapical implantation of aortic valve prostheses. Innsbruck Medical University is planning a study on mitral valve repair through the coronary sinus and a study on endovascular aortic valve repair. Further projects are planned at Graz Medical University and at the Landeskrankenhaus St. Pölten. In order to ensure adequate patient safety and a controlled implementation process of these procedures, the Austrian Society of Thoracic and Cardiovascular Surgery has made the following recommendations.

Recommendations:

1. Programs should be implemented on an interdisciplinary basis. Such a collaborative process has recently been suggested in a position paper by the STS, AATS, SCAI professional societies. [Vassiliades et al. JTCVS 2005].
2. Some early catastrophic outcomes in live case conferences and premature publication in the lay press have resulted in significant negative publicity for endovascular heart valve procedures. We therefore advise that endovascular approaches to heart valve intervention be evaluated initially at University hospitals, academic teaching hospitals or at centers with both adequately trained personnel and the complementary infrastructure to support these patients. It is only after these new procedures are rigorously tested in tertiary care centers should they then be transferred to more widespread clinical application.
3. Endovascular heart valve procedures should only be carried out at tertiary health care centers with a cardiac surgery program. The interventions (transvenous, transarterial, or transventricular) should be performed in a cardiac surgery operating room or preferably in a cath lab-OR suite). The secure safety net of a cardiac surgery OR equipped with full extracorporeal circulation technology should be generously leveraged in support of these procedures.

4. The Austrian Society for Thoracic and Cardiovascular Surgery regards catheter-based and endovascular procedures on the heart valves as an “operation” rather than a catheter-based intervention. The Society also recognizes cardiac surgeons to be the sub-specialists possessing the most complete, anatomical and functional knowledge of heart valve disease, the most long-term experience in the interventional treatment of serious heart valve conditions, and the only healthcare providers who can fully manage all possible heart valve complications. It is therefore logical that cardiac surgeons be the specialists to implant endovascular heart valve prostheses. However, the expertise of partners in cardiology is equally essential and should be an integral and active part of these highly collaborative programs. The Austrian Society of Thoracic and Cardiovascular Surgery recommends that regardless of access (transvenous, transarterial, or transventricular), there be an even share of procedural participation and responsibility between surgeon and cardiologist. To be clear, actions by the cardiac surgeon should not be restricted to vascular access and complication management but rather should also include the actual implantation of these devices. A qualified cardiac surgeon and cardiologist should be present and actively involved at every endovascular valve repair procedure. Further, each individual institution should clearly communicate the Society’s recommendation of equal participation between surgeon and cardiologist before embarking on an endovascular heart valve program. Postoperatively, these patients should initially be cared for in an intensive care unit or recovery room staffed by personnel experienced in the postoperative treatment of heart surgery patients.
5. The indications for endovascular, catheter-based heart valve procedures should be jointly established by heart surgeons and cardiologists. This principle should be followed during development and subsequent routine clinical application. Late postoperative treatment and patient follow up should be carried out in common outpatient departments.

Both specialities, heart surgery and cardiology, should undergo device specific training for each technology and there should be a special focus on adequate preclinical training on simulators, in dry- or wet-lab models, or in an animal model. Heart valve interventional programs should be planned and developed jointly.

6. A common heart surgery and cardiology program for the purposes of quality control with a corresponding common database should be established.
7. Cardiologists and cardiac surgeons who are not involved in endovascular programs of valve repair and who have no conflicts of interest, should review protocols submitted to local ethics committees in order to guarantee an objective view on ethical considerations and clinical outcomes.
8. On an interdisciplinary basis, care should be taken to ensure that adequate hospital reimbursement is obtained and that adequate physician honorarium is paid. Interdisciplinary share of reimbursement and honorarium should be the subject of pre-implementation discussions.

The Austrian Society of Thoracic and Cardiovascular Surgery takes a very proactive position towards the development of endovascular and catheter-based procedures in valve repair, supporting their implementation in Austria. Therefore, a working group for catheter-based and endovascular procedures in heart surgery has been formed. This working group will recruit partners from related medical disciplines in order to enable an interdisciplinary character of method development on a Society level.

The Austrian Society of Thoracic and Cardiovascular Surgery will convey the above recommendations to all Austrian hospitals with a cardiovascular angiography and cath-lab infrastructure. In addition, these recommendations will be conveyed to all related medical societies, physician chambers, hospital ethics committees, and medical industry, especially companies that are currently developing endovascular heart valve replacement devices. The Austrian Society of Thoracic and Cardiovascular Surgery is convinced that by adhering to these aforementioned recommendations, a safe, competent, and collegial implementation process of endovascular heart valve therapy will be possible.

Reference:

Vassiliades T et al. The clinical development of percutaneous heart valve technology. A position statement of the Society of Thoracic Surgeons, the American Association of Thoracic Surgery, and the Society for Cardiovascular Angiography and Interventions. Journal of Thorac Cardiovasc Surg 2005;29:970-6

Recommendations established by the Working group for endovascular and catheter-based procedures in cardiac surgery of the Austrian Society of Thoracic and Cardiovascular Surgery September 2006.

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