2017-Απόσταγμα βιβλιογραφίας για τις βαλβιδοπάθειες

Βλάσης Νινιός
Κλινική Άγιος Λουκάς
Θεσσαλονίκη 2018
Conflict of Interest

• Proctor for Mitraclip- Abbott
Epidemiology

- The association between traditional cardiovascular risk factors and incident, severe aortic stenosis (AS) was highlighted in a large unselected elderly population (1)
- In a population based prospective cohort with 1297 incident cases of AS during 15 years of follow-up overall obesity and abdominal adiposity were positively associated with incidence of AS (2)
- The prevalence of VHD in ESC member countries is approximately 13.3 million. Access to surgical and transcatheter heart valve treatment is better developed in high-income countries (3)
- Global age standardized mortality due to rheumatic Heart disease fell by 47.8% from 1990 to 2015. There were still more than 30 million cases of rheumatic heart disease and around 300 000 deaths in 2015 (4)

Aortic stenosis

• Echocardiography is the first-line imaging technique for the evaluation of patients with VHD
• other imaging modalities can be used to obtain complementary information
  • Aortic valve calcification detected by cardiac computed tomography (CT) can be used for low-flow, low-gradient AS
  • CT coronary angiography should be considered as an alternative to invasive angiography before valve surgery in patients with a low probability of coronary artery disease (1)

2017 ESC/EACTS Guidelines for the management of valvular heart disease

The Task Force for the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

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**Aortic stenosis- MSCT**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>Clinical criteria</td>
<td>• Typical symptoms without other explanation</td>
</tr>
<tr>
<td></td>
<td>• Elderly patient (&gt;70 years)</td>
</tr>
<tr>
<td>Qualitative imaging data</td>
<td>• LV hypertrophy (additional history of hypertension to be considered)</td>
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<tr>
<td></td>
<td>• Reduced LV longitudinal function without other explanation</td>
</tr>
<tr>
<td>Quantitative imaging data</td>
<td>• Mean gradient 30–40 mmHg</td>
</tr>
<tr>
<td></td>
<td>• AVA ≤0.8 cm²</td>
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<td></td>
<td>• Low flow (SVI &lt;35 mL/m²) confirmed by techniques other than standard Doppler technique</td>
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<tr>
<td></td>
<td>(LVOT measurement by 3D TOE or MSCT; CMR, invasive data)</td>
</tr>
<tr>
<td>Calcium score by MSCT³</td>
<td>• Calcium score by MSCT³</td>
</tr>
<tr>
<td></td>
<td>- Severe aortic stenosis very likely: men ≥3000; women ≥1600</td>
</tr>
<tr>
<td></td>
<td>- Severe aortic stenosis likely: men ≥2000; women ≥1200</td>
</tr>
<tr>
<td></td>
<td>- Severe aortic stenosis unlikely: men &lt;1600; women &lt;800</td>
</tr>
</tbody>
</table>

*AV = aortic valve area; CMR = cardiovascular magnetic resonance; LV = left ventricular; LVOT = left ventricular outflow tract; MSCT = multislice computed tomography; SVI = stroke volume index; TOE = transoesophageal echocardiography.

³Haemodynamics measured when the patient is normotensive.

⁴Values are given in arbitrary units using Agatston method for quantification of valve calcification.
Asymptomatic patients with AS

- EARLY TAVR and EVoLVeD trial

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Level</th>
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<tbody>
<tr>
<td>SAVR is indicated in asymptomatic patients with severe aortic stenosis and systolic LV dysfunction (LVEF &lt;50%) not due to another cause.</td>
<td>I C</td>
</tr>
<tr>
<td>SAVR is indicated in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing symptoms on exercise clearly related to aortic stenosis.</td>
<td>I C</td>
</tr>
<tr>
<td>SAVR should be considered in asymptomatic patients with severe aortic stenosis and an abnormal exercise test showing a decrease in blood pressure below baseline.</td>
<td>IIa C</td>
</tr>
</tbody>
</table>
| SAVR should be considered in asymptomatic patients with normal ejection fraction and none of the above-mentioned exercise test abnormalities if the surgical risk is low and one of the following findings is present:  
  - Very severe aortic stenosis defined by a $V_{max} >5.5$ m/s  
  - Severe valve calcification and a rate of $V_{max}$ progression $>0.3$ m/s/year  
  - Markedly elevated BNP levels (>threefold age- and sex-corrected normal range) confirmed by repeated measurements without other explanations  
  - Severe pulmonary hypertension (systolic pulmonary artery pressure at rest $>60$ mmHg confirmed by invasive measurement) without other explanation. | IIa C |
Moderate AS and LV dysfunction

• Observational study demonstrated that patients with concomitant moderate AS and left ventricle systolic dysfunction are at high risk for clinical events (1)

• (TAVR)-UNLOAD trial

AS- FRAILTY SCORES

• Two studies demonstrated the utility of clinical scores for detecting frailty and predicting 1-year mortality after AVR in elderly patients (1,2)


The burden of mitral annular calcification is also associated with outcomes after TAVI (similar to AVR).

Severe mitral annular calcification was encountered in 10% of patients; this was an independent predictor of both overall mortality (HR 2.35, 95% CI 1.19–4.66) and permanent pacemaker implantation [odds ratio (OR) 2.83, 95% CI 1.08–7.47] following TAVI.

AVR: BIO vs Metallic

- AVR 50-69 Y. OLD: survival was higher in the group with mechanical prostheses (HR 1.34, 95% CI 1.09–1.66), and the risk of reoperation was lower (2)
- In a sub-analysis the benefit persisted in those aged 50–59 years, but not for those aged 60–69 years
- Long-term mortality benefit associated with a mechanical prosthesis, as compared with a biological prosthesis, persisted until 55 years of age among those AVR, and until 70 years of age among patients undergoing MVR (3)


Figure 1 Number of aortic valve replacements per year. Number of patients aged 50-69 years who had undergone aortic valve replacements with mechanical or bioprosthetic valves in Sweden between 1997 and 2013. From Glaser et al.13
## TAVR vs SAVR: Heart Team decision

<table>
<thead>
<tr>
<th>Clinical characteristics</th>
<th>Favours TAVI</th>
<th>Favours SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>STS/EuroSCORE II &lt;4% (logistic EuroSCORE I &lt;10%)</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>Presence of severe comorbidity (not adequately reflected by scores)</td>
<td>+</td>
<td></td>
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<tr>
<td>Age &lt;75 years</td>
<td></td>
<td>+</td>
</tr>
<tr>
<td>Age ≥75 years</td>
<td>+</td>
<td></td>
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<tr>
<td>Previous cardiac surgery</td>
<td>+</td>
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<tr>
<td>Frailty</td>
<td></td>
<td>+</td>
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<tr>
<td>Restricted mobility and conditions that may affect the rehabilitation process after the procedure</td>
<td>+</td>
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<tr>
<td>Suspection of endocarditis</td>
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<td>+</td>
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</table>

<table>
<thead>
<tr>
<th>Anatomical and technical aspects</th>
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</thead>
<tbody>
<tr>
<td>Favourable access for transfemoral TAVI</td>
<td>+</td>
</tr>
<tr>
<td>Unfavourable access (any) for TAVI</td>
<td></td>
</tr>
<tr>
<td>Sequelea of chest radiation</td>
<td>+</td>
</tr>
<tr>
<td>Porcelain aorta</td>
<td>+</td>
</tr>
<tr>
<td>Presence of intact coronary bypass grafts at risk when sternotomy is performed</td>
<td>+</td>
</tr>
<tr>
<td>Expected patient–prosthesis mismatch</td>
<td>+</td>
</tr>
<tr>
<td>Severe chest deformation or scoliosis</td>
<td>+</td>
</tr>
<tr>
<td>Short distance between coronary ostia and aortic valve annulus</td>
<td></td>
</tr>
<tr>
<td>Size of aortic valve annulus out of range for TAVI</td>
<td>+</td>
</tr>
<tr>
<td>Aortic root morphology unfavourable for TAVI</td>
<td>+</td>
</tr>
<tr>
<td>Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI</td>
<td>+</td>
</tr>
<tr>
<td>Presence of thrombi in aorta or LV</td>
<td>+</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe CAD requiring revascularization by CABG</td>
<td>+</td>
</tr>
<tr>
<td>Severe primary mitral valve disease, which could be treated surgically</td>
<td>+</td>
</tr>
<tr>
<td>Severe tricuspid valve disease</td>
<td>+</td>
</tr>
<tr>
<td>Aneurysm of the ascending aorta</td>
<td>+</td>
</tr>
<tr>
<td>Septal hypertrophy requiring myectomy</td>
<td>+</td>
</tr>
</tbody>
</table>

TAVR vs SAVR

• **SURTAVI** trial: 1746 patients intermediate risk

• **Results:** TAVI with self-expanding prosthesis was non-inferior to SAVR incidence of all-cause mortality and disabling stroke in 24 months (12.6% vs. 14.0%).

• **Surgery** was associated with higher rates of acute kidney injury, atrial fibrillation, and transfusion requirements.

• **TAVI** had higher rates of residual aortic regurgitation (AR) and need for pacemaker implantation.

TAVR vs SAVR in real-life

- 9464 propensity-matched intermediate- and high-risk U.S. patients who underwent TAVI or SAVR, there were similar rates of death, stroke, and days alive and out-of-hospital to 1 year, but TAVI patients were more likely to be discharged home.

TAVR in Tricuspid vs Bicuspid AV

• In a multi-centre registry, 561 patients with bicuspid AS and 4546 patients with tricuspid AS were compared after propensity score matching, assembling 546 pairs of patients with similar baseline characteristics

• treatment in bicuspid AS was associated with a similar prognosis, but a lower device success rate.

TAVI valve-in-valve

• TAVI for bioprosthetic aortic valve failure has been associated with a relatively low complication rates and mortality, improved haemodynamics, and excellent functional and quality-of-life outcomes

Long-term (mean follow-up 6.6 years) survival after surgery is similar to an age and sex-matched population (1).
TAVI in AR

• Newer generation TAVI systems has improved the outcome with fewer patients needing a second valve (10%) and having significant residual AR (3%)

Echocardiography is essential to establish the diagnosis of secondary mitral regurgitation. In secondary mitral regurgitation, lower thresholds have been proposed to define severe mitral regurgitation compared with primary mitral regurgitation [20 mm$^2$ for effective regurgitant orifice area (EROA) and 30 mL for regurgitant volume], owing to their association with prognosis. However, it is unclear if prognosis is independently affected by mitral regurgitation compared with LV dysfunction. So far, no survival benefit has been confirmed for reduction of secondary mitral regurgitation.

From the 2017 ESC VHD guidelines...
MR-Quantification

• Integration of **echocardiography-derived** Doppler mitral flow and **CT-derived** cross-sectional mitral anatomical regurgitant orifice area to calculate mitral regurgitant volume

• In 73 patients undergoing TAVI, who also had either primary or secondary MR, this approach resulted in reclassification of MR from severe to non-severe in 10% and from non-severe to severe in 14% of the patients

Secondary MR

MV surgery in patients with moderate secondary MR undergoing CABG is NO longer recommended

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery is indicated in patients with severe secondary mitral regurgitation undergoing CABG and LVEF &gt;30%.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Surgery should be considered in symptomatic patients with severe secondary mitral regurgitation, LVEF &lt;30% but with an option for revascularization and evidence of myocardial viability.</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF &gt;30% who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>
Secondary MR

- Review of 397 patients: there was less recurrence of MR (relative risk (RR) 0.43, 95% CI 0.27–0.66; P= 0.0002), and more positive remodelling of the left ventricle in the group with the combined intervention as compared to those treated with just annuloplasty.

Primary MR-DMR

• The Mitral Regurgitation International Database (MIDA) mortality risk score
• Integrated various clinical and echocardiographic parameters endorsed by guidelines
• 3666 consecutive patients (age 66 ± 14 years; 70% males; follow-up 7.8 ± 5.0 years) with pure, isolated, DMR

Primary MR-DMR: Repair better than Replacement


- The operative mortality was lower in the MV repair group (0.2% vs. 4.4%, P< 0.001) and 20-year survival was better (41% vs. 24%, P< 0.001).
Transcatheter MV repair: edge-to-edge repair

• Dominated by the Mitraclip treatment
• Improvement in symptoms
• ? Prognosis- several trials on the way
  • COAPT (NCT01626079)
  • French MITRA-FR (NCT01920698)
  • RESHAPEHF2 (NCT02444338)
  • MATTERHORN (NCT02371512).
The recruitment goal of 420 patients is coming closer and closer!

Thank you for your contribution to this in 2017!

**Recruitment Overview:**

<table>
<thead>
<tr>
<th>Study site</th>
<th>Site activation</th>
<th>Randomized patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>RS05 - Thessaloniki</td>
<td>26JAN2016</td>
<td>84</td>
</tr>
<tr>
<td>RS04 - Athen</td>
<td>1DEC2015</td>
<td>69</td>
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<tr>
<td>RS07 - Zabrze</td>
<td>02JUN2016</td>
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<td>RS08 - Katowice</td>
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<td>RS06 - Wroclaw</td>
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</tr>
<tr>
<td>RS11 - Lisbon</td>
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<tr>
<td>RS12 - Krakow</td>
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<td>RS09 - Brescia</td>
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<tr>
<td>RS01 - Gütingen</td>
<td>22MAR2015</td>
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<tr>
<td>RS10 - Leon</td>
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<td>RS14 - Copenhagen</td>
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<td>RS02 - Heidelberg</td>
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<td>RS13 - VN de Gaia</td>
<td>12SEP2016</td>
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<tr>
<td>RS03 - Mainz</td>
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<tr>
<td>RS15 - Odense</td>
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<td>RS16 - Barcelona</td>
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<td>RS18 - Catersa</td>
<td>24SEP2017</td>
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<tr>
<td><strong>Total</strong></td>
<td></td>
<td><strong>304</strong></td>
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</table>
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<tr>
<td>Level</td>
<td>Evidence</td>
<td>Recommendation</td>
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<td>IIb</td>
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<td>When revascularization is not indicated, surgery may be considered in patients with severe secondary mitral regurgitation and LVEF &gt;30% who remain symptomatic despite optimal medical management (including CRT if indicated) and have a low surgical risk.</td>
</tr>
</tbody>
</table>

When revascularization is not indicated and surgical risk is not low, a percutaneous edge-to-edge procedure may be considered in patients with severe secondary mitral regurgitation and LVEF >30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have a suitable valve morphology by echocardiography, avoiding futility.

In patients with severe secondary mitral regurgitation and LVEF <30% who remain symptomatic despite optimal medical management (including CRT if indicated) and who have no option for revascularization, the Heart Team may consider a percutaneous edge-to-edge procedure or valve surgery after careful evaluation for a ventricular assist device or heart transplant according to individual patient characteristics.
Transcatheter MV repair: edge-to-edge repair

• First-in-man study on the Edwards PASCAL system in compassionate cases with symptomatic, severe functional, degenerative, or mixed MR has been reported

• 22/23 patients had residual Mr of Grade 2 or less

Transcatheter Mitral Valve Replacement (TMVR)

- Multicenter registry
- Valve-in-valve (VIV)- 176 patients
- Valve-in-Ring (VIR)- 72 patients
- Valve-in-MAC (Mitral Annular Calcification)

- Technical and device success rates were acceptable, at 92.3% (VIV) and 85.5% (VIR).
- VIR treatment had lower technical and device success, and was associated with more MR, life-threatening bleeding, acute kidney injury, and higher mortality

TMVR in non-calcified native valves

• 30 selected patients with primarily functional MR and high surgical risk
• Transapical implantation of the Tendyne valve
• Successful implantation in 28 patients with no acute deaths
• 30 days one patient had mild MR. The remaining patients had no residual MR
• 75% of the patients reported mild or no symptoms

Tricuspid Regurgitation

• Meta-analysis of 15 studies and 2840 patients
• Benefit of TV repair during surgery for left heart valve disease
• Reduced cardiac mortality (OR 0.38, 95% CI 0.25–0.58).

Percutaneous transcatheter TV therapy

• Systematic approach to define those patients suitable for transcatheter TV devices based on evaluation of the TV annulus geometry, right ventricle, vena cava dimensions, and spatial relationships between the TV and the right coronary artery using CT

Mitraclip for TR

- 64 consecutive patients deemed unsuitable for surgery
- The MitraClip device was successfully implanted in the TV in 97% of the cases
- TR was reduced by at least one grade in 91% of the patients with no intra-procedural deaths
- Functional class and 6-min walking distance improved significantly
  
Anticoagulation for Prosthetic Valves

• Factor Xa inhibition may have an advantage by influencing both the extrinsic and contact activation coagulation pathways with minimal antagonism of existing thrombin needed to maintain haemostasis.

• In a porcine model with aortic heterotopic valves, short-term, intravenous apixaban treatment was associated with a reduced weight of valve thrombus as compared to warfarin and no bleeding events occurred in the apixaban group.

Antiplatelet therapy post TAVI

- Meta-analysis of four studies including 640 patients
- No benefit of dual over single antiplatelet therapy regarding the risk of stroke or mortality
- Increased frequency of major and lethal bleeding events during the first 30 days after intervention

Leaflet thrombosis post TAVR and SAVR

- Leaflet thickening and reduced leaflet motion on CT
  - hypo-attenuating leaflet thickening (HALT)
  - hypo-attenuation affecting motion (HAM)
- HAM may be more common after TAVI (13%) than after SAVR (4%) (1).
- Stent frame underexpansion increases the risk
- Post-dilatation of self expanding transcatheter heart valves and supra-annular valve position seemed to reduce the occurrence of this phenomenon (2)


The ongoing trials on antithrombotic therapy after TAVI

• ARTE (NCT01559298),
• ATLANTIS (NCT02664649)
• AUREA (NCT01642134)
• AVATAR (NCT02735902)
• GALILEO (NCT02556203)
• POPULAR-TAVI (NCT02247128)
Pregnancy and AS

- The Registry on Pregnancy and Cardiac Disease (ROPAC)
- Pregnant women with severe AS, defined as a peak gradient \( \geq 64 \text{mmHg} \),
- 35.3% were hospitalized because of cardiac reasons compared with 12.9% of the women with moderate AS \((P = 0.02)\)

Mechanical prosthesis and Pregnancy

A meta-analysis of 18 studies with 800 pregnancies evaluated four different antithrombotic regimes
  - VKA,
  - low molecular weight heparin (LMWH),
  - LMWH+VKA
  - unfractionated heparin+VKA

VKA is preferred from a maternal perspective.

Dose-adjusted LMWH throughout the pregnancy was associated with a lower foetal risk when compared to other regimes, but the foetal risk was similar to risk in the group taken a dose of VKA < 5mg/day (HR 0.9, 95% CI 0.3–2.4).

The teratogen effect by VKA seems to be dose-dependent

Imaging in Infective endocarditis (TEE vs CT)

- Small imaging study (n=49) of patients with both native and prosthetic valve IE
- Preoperative TOE and CT findings were compared to those at surgery
- No difference in the diagnostic sensitivity of the two methods
- TOE identified numerically more vegetations, leaflet perforation, and paravalvular leakage

Infective Endocarditis Incidence

• In a population-based cohort study of 138 867 patients with a prosthetic valve (median follow-up 1.7 years) the incidence rate of oral streptococcal IE was 93.7/100 000 patient-years.

• No increased rate of IE was found within three months of exposure to invasive dental procedure, but in a case crossover analysis a dental procedure was more frequent in IE periods (5.1% vs. 3.2%, OR 1.66; 95% CI 1.05–2.63; P = 0.03).

• CONCOR registry, including patients with congenital heart disease, the incidence of IE was 1.33 cases/1000 patient-years

• Prosthetic valves were associated with an increased risk of IE (HR 5.48, 95% CI 3.58–8.38) compared with no prosthetic valves


• In a registry-based observational study of both biological and mechanical aortic prostheses (mean follow-up 6.2 years), the incidence of prosthetic valve IE was 0.57%/person-year; the risk was highest during the first year after surgery

• Risk higher in Bioprosthesis

• Value of Antibiotic prophylaxis in patients with prosthetic valves

Conclusions

• Expansion of TAVI indication to lower risk groups
• Value in treating asymptomatic AS
• Value in multimodality imaging for VHD
• Repair over replacement in DMR
• Questionable value of Surgical valve intervention in Secondary MR
• Transcatheter repair comes into maturity (Mittraclip) with new therapies on the way
• Eagerly awaiting the RCTs for secondary MR
• Expanding transcatheter therapies for TR as we pay more attention to this entity discovering new patient profiles