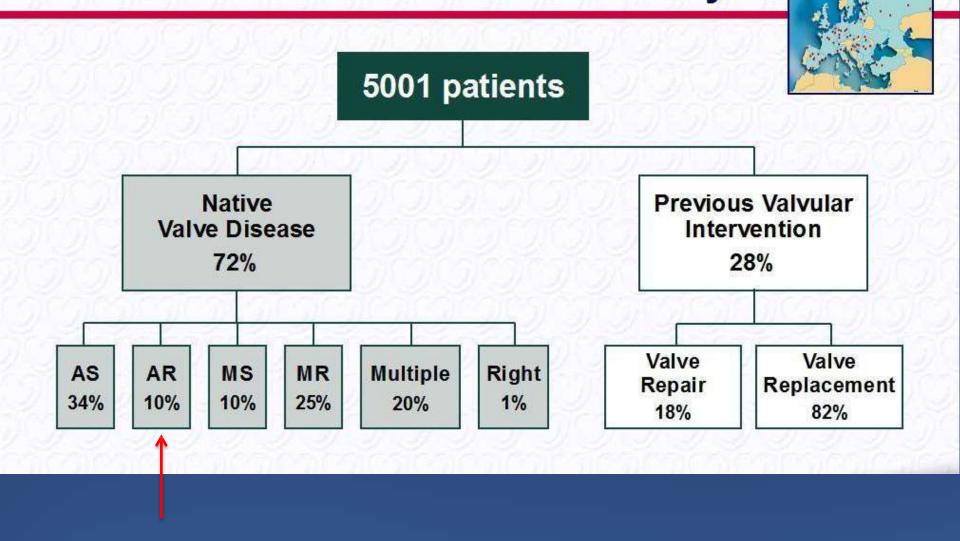
TAVR for Pure AR: International Registry Data and Technical Pearls

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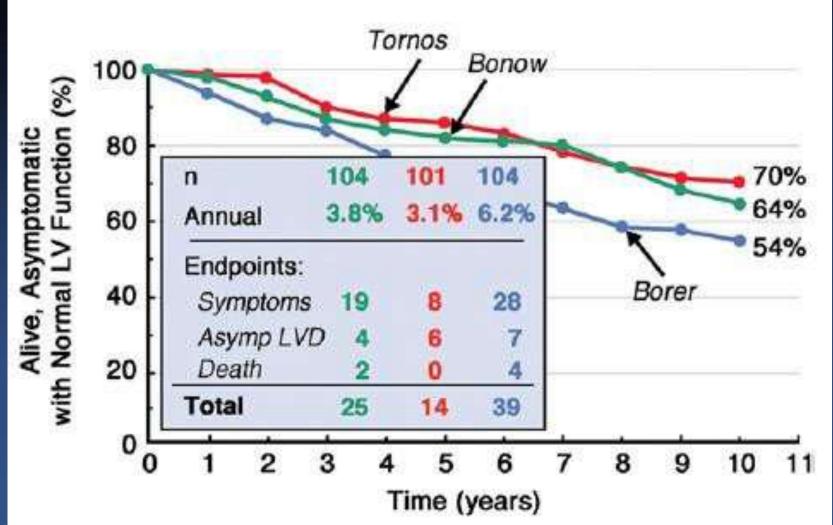


Distribution of Valvular Heart Diseases in the Euro Heart Survey

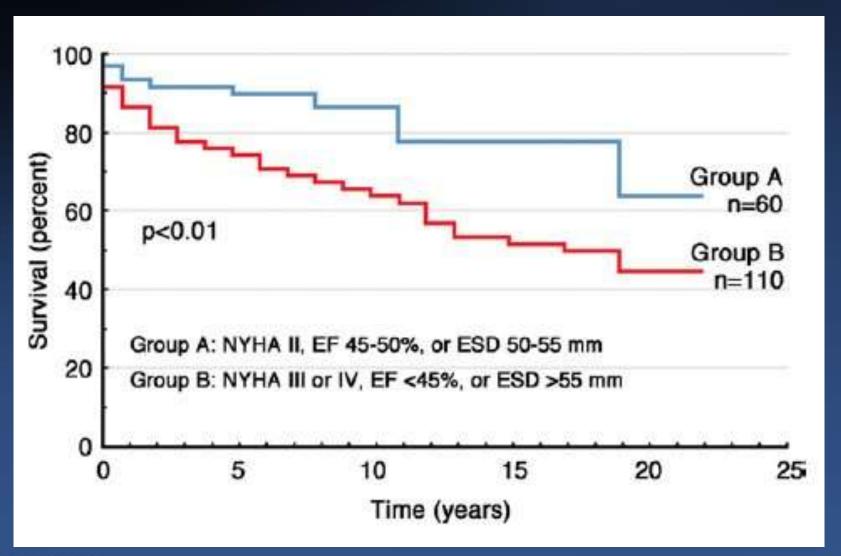


Third valvulopaty

Aortic regurgitation: Natural Hystory in Asymptomatic Patients

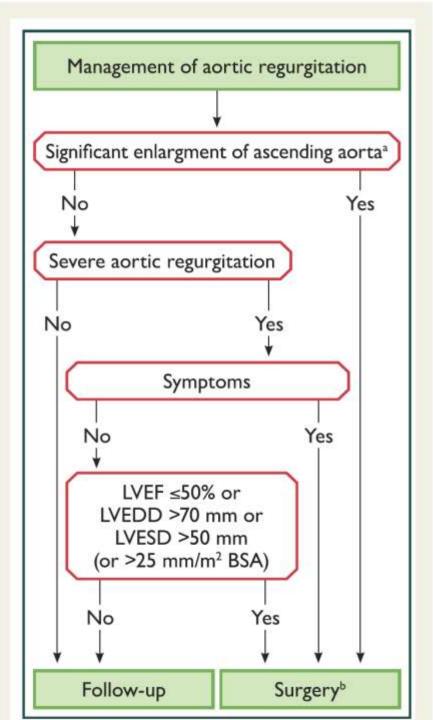


Survival after AVR for AR



Aortic regurgitation: Natural Hystory

| Asymptomatic | %/Y |
|--|-------|
| Normal LV function (~good prognosis) | |
| Progression to symptoms or LV dysfunction | < 6 |
| Progression to asymptomatic LV dysfunction | < 3.5 |
| 75% 5-year survival | < 0.2 |
| Sudden death | |
| Abnormal LV function | 25 |
| Progression to cardiac symptoms | 23 |
| Symptomatic (Poor prognosis) | > 10 |
| Mortality | |



Indications for surgery in (A) severe aortic regurgitation and (B) aortic root disease (irrespective of the severity of aortic regurgitation)

| Indications for surgery | Classa | Levelb | | |
|---|--------|--------|--|--|
| A. Severe aortic regurgitation | | | | |
| Surgery is indicated in symptomatic patients. ^{57,58,66,67} | ı | В | | |
| Surgery is indicated in asymptomatic patients with resting LVEF ≤50%. ^{57,58} | 1 | В | | |
| Surgery is indicated in patients undergoing CABG or surgery of the ascending aorta or of another valve. | 1 | С | | |
| Heart Team discussion is recommended in selected patients ^c in whom aortic valve repair may be a feasible alternative to valve replacement. | 1 | С | | |
| Surgery should be considered in asymptomatic patients with resting ejection fraction >50% with severe LV dilatation: LVEDD >70 mm or LVESD >50 mm (or LVESD >25 mm/m ² BSA in patients with small body size). ^{58,66} | lla | В | | |

Aortic regurgitation: Management

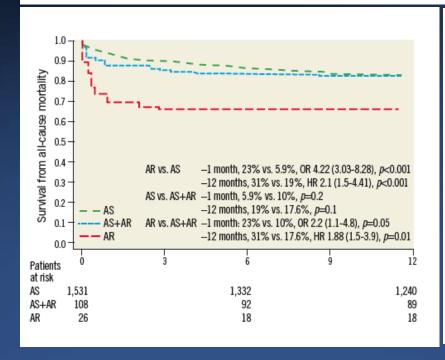
- Is there a place for TAVI or re-TAVI?
- Patients with severe aortic regurgitation and at high or extreme surgical risk for whom conventional surgical aortic valve replacement may be unsuitable and who might benefit from transcatheter-based therapy.
- Patients with severe aortic regurgitation following TAVI or AVR

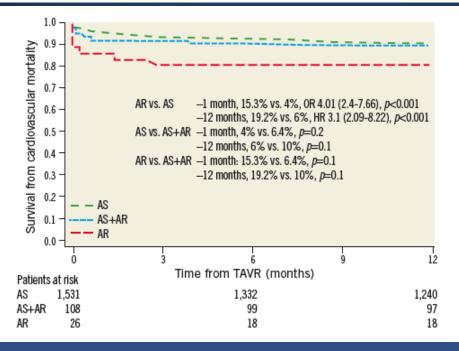
Still an off-label indication?



CoreValve implantation for severe aortic regurgitation: a multicentre registry

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Native aortic regurgitation and TAVI

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CLINICAL RESEARCH

Interventional Cardiology

Transcatheter Aortic Valve Implantation for Pure Severe Native Aortic Valve Regurgitation

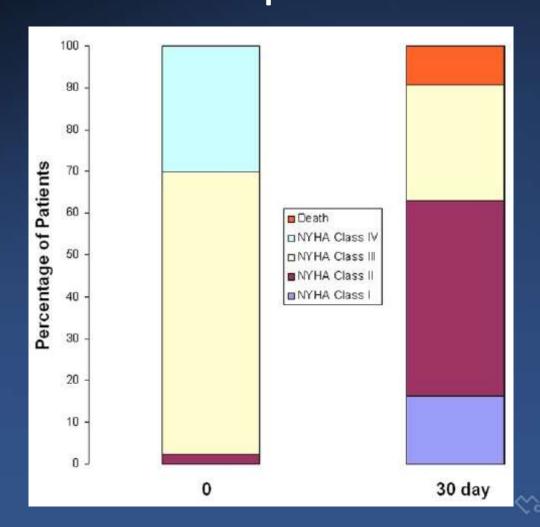
David A. Roy, MD,* Ulrich Schaefer, MD, PhD,† Victor Guetta, MD,‡ David Hildick-Smith, MD,§ Helge Möllmann, MD,|| Nicholas Dumonteil, MD,¶ Thomas Modine, MD,# Johan Bosmans, MD,** Anna Sonia Petronio, MD,†† Neil Moat, MBBS, MS,‡‡ Axel Linke, MD,§§ Cesar Moris, MD,||| Didier Champagnac, MD,¶¶ Radoslaw Parma, MD, PhD,## Andrzej Ochala, MD,## Diego Medvedofsky, MD,‡ Tiffany Patterson, MD,‡‡ Felix Woitek, MD,§§ Marjan Jahangiri, MD,* Jean-Claude Laborde, MD,* Stephen J. Brecker, MD*



Native aortic regurgitation and TAVI 43 patients

Clinical and Safety Outcomes According to VARC

| Mortality | |
|-------------------------------|-------------|
| 30-day all-cause | 4 (9.3%) |
| 30-day cardiovascular | 1 (2.3%) |
| 12 month all-cause | 6/28 (21.4) |
| 12-month cardiovascular | 3/28 (10.7) |
| Major stroke (30 days) | 2 (4.7) |
| Major bleeding | 8 (18.6) |
| Acute kidney injury (stage 3) | 2 (4.7) |
| Myocardial infarction | 0 |
| Access site complications | 6 (14.0) |
| Major | 3 (7.0) |
| Minor | 3 (7.0) |
| VARC procedure success | 32 (74.4) |



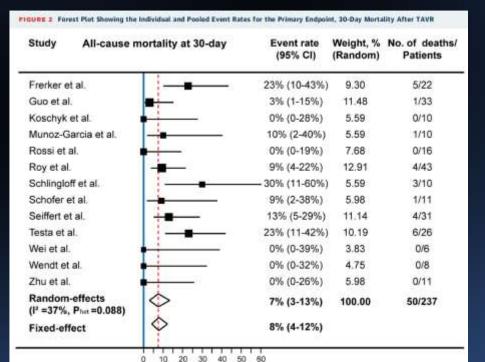
Native aortic regurgitation and TAVI

Transcatheter Aortic Valve Replacement for the Treatment of Pure Native Aortic Valve Regurgitation

A Systematic Review

Anna Franzone, MD, a Raffaele Piccolo, MD, George C.M. Siontis, MD, Jonas Lanz, MD, Stefan Stortecky, MD, Fabien Praz, MD, Eva Roost, MD, René Vollenbroich, MD, MPP, Stephan Windecker, MD, Thomas Pilgrim, MD





Event rate, %

FIGURE 3 Meta-Analysis of Secondary Endpoints

| Endpoint | No. of Studies | No. of Events/Patients | Event rate (95% Ci) | | | | | P |
|-------------------------------|-------------------|---------------------------|------------------------|---|------|-----------|----------|-----|
| Myocardial infarction | 13 | 0/237 | 0% | | | | | 0% |
| Stroke or TIA | 13 | 2/2/37 | 0% (0-1%) | 4 | | | | 0% |
| Acute kidney injury (Stage 3) | 12 | 20/211 | 7% (2-15%) | + | | 4 | | 54% |
| Major bleeding | 13 | 15/237 | 2% (0-7%) | | 4 | | | 41% |
| Major vascular complication | 13 | 12/237 | 3% (1-7%) | 1 | -1 | | | 0% |
| PPM implantation | 13 | 34/237 | 11% (5-19%) | | | -1 | | 50% |
| Moderate or severe AR | 12 | 41/215 | 9% (0-28%) | | | | \dashv | 90% |
| | | | | 0 | 10 | 20 | 30 | |
| | | | | | Even | t rate, % | | |

Native aortic regurgitation and TAVI

Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation



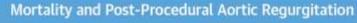
Sung-Han Yoon, MD, a Tobias Schmidt, MD, b Sabine Bleiziffer, MD, Niklas Schofer, MD, d Claudia Fiorina, MD, Antonio J. Munoz-Garcia, MD, Ermela Yzeiraj, MD, Ignacio J. Amat-Santos, MD, Didier Tchetche, MD, Christian Jung, MD, Buntaro Fujita, MD, Antonio Mangieri, MD, Marcus-Andre Deutsch, MD, Antonio Mangieri, MD, Marcus-Andre Deutsch, MD, Antonio MD, Boliara Deuschl, MD, Shingo Kuwata, MD, Chiara De Biase, MD, Timothy Williams, MD, Abhijeet Dhoble, MD, Won-Keun Kim, MD, Chiara De Biase, MD, Timothy Williams, MD, Antonio Miceli, MD, Cristina Giannini, MD, Guiherme F. Attizzani, MD, William K.F. Kong, MD, Enrique Gutierrez-Ibanes, MD, Victor Alfonso Jimenez Diaz, MD, Harindra C. Wijeysundera, MD, Hidehiro Kaneko, MD, Tarun Chakravarty, MD, Moody Makar, MD, Horst Sievert, MD, Christian Hengstenberg, MD, Md Bernard D. Prendergast, MD, Flavien Vincent, MD, Mohamed Abdel-Wahab, MD, Luis Nombela-Franco, MD, Miriam Silaschi, MD, Giuseppe Tarantini, MD, Christian Butter, MD, Stephan M. Ensminger, MD, David Hildick-Smith, MD, Anna Sonia Petronio, MD, Wei-Hsian Yin, MD, Karl-Heinz Kuck, MD, Antonio Colombo, MD, Saibal Kar, MD, Cesar Moris, MD, Victoria Delgado, MD, Francesco Maisano, MD, Fabian Nietlispach, MD, Michael J. Mack, MD, Dachim Schofer, MD, Ulrich Schaefer, MD, Jeroen J. Bax, MD, Christian Frerker, MD, Azeem Latib, MD, Raj R. Makkar, MD

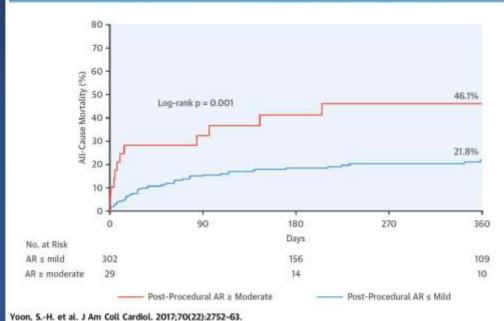
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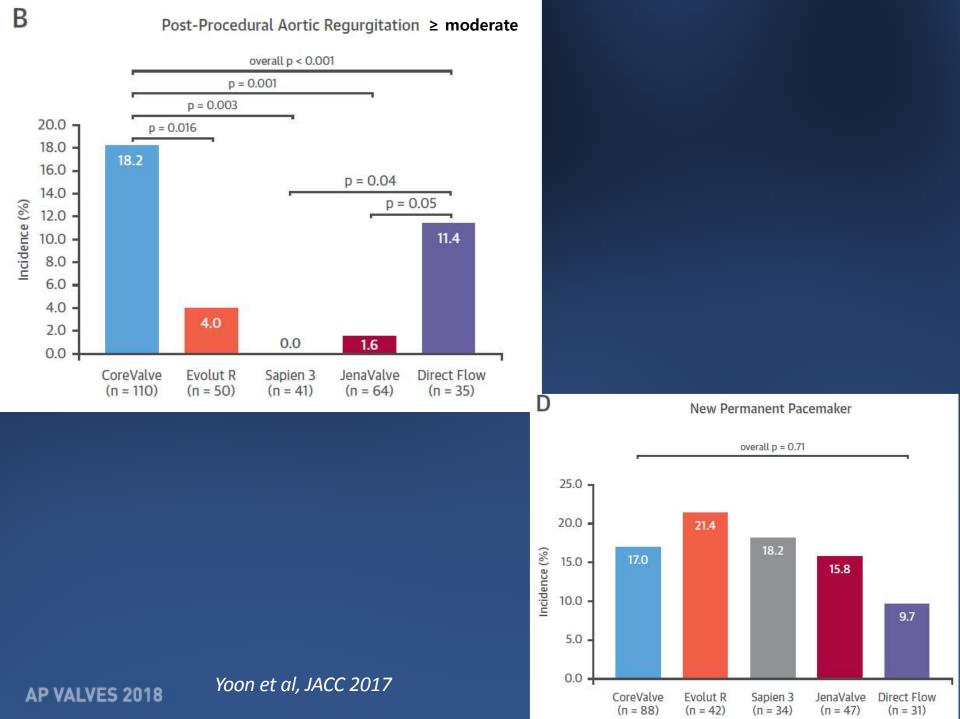
Outcomes According to Devices







Yoon et al, JACC 2017



Technical Challenging in TAVI for aortic regurgitation

Morphological Features of Aortic Valve Stenosis or Regurgitation

Calcific Aortic Valve Stenosis

1- Nodular calcific deposits on aortic side





Aortic Valve Regurgitation

- 1- Minimal or absent cusp calcification
- 2- Dilated aortic root
- 3- Frequent coexistence of dilated ascending aorta





Technical Challenges of TAVR in Aortic Valve Regurgitation

Suboptimal Fluoroscopic Visualization of the Native Valve

Insufficient Anchoring and Sealing of the Transcatheter Device

Risk of Misplacement and Migration of the Device Risk of Residual Valvular Regurgitation



Tips and Tricks

- Suboptimal fluoroscopic visualization of cuspid us e two pigtails as reference
- Insufficient anchoring due to lack of calcifications use repositionable and retrievable devices. Considering pacing during implant
- Risk of residual valvular regurgitation and use device with perianular skirt

oversize the valve



| B Device | | Design; Delivery Access | Features |
|----------|---|--|---|
| | ACURATE (Symetis) | Self-expandable nitinol stent; Transapical Transfemoral | Self-positioning at supra-annular level; fixed in a waistlike manner, thereby covering the aortic annulus (hourglass design); tactile feedback reducing the risk of malpositioning; possibility of partial resheating |
| | JenaValve* (JenaValve Technology) | Self-expandable nitinol stent; Transapical | Feeler-guiding positioning and clip fixation mechanism of the native aortic valve leaflet; retrievable and repositionable |
| | CoreValve Revalving System (Medtronic) | Self-expandable nitinol frame; Transfemoral | The lower portion of the prosthesis has high radial force to expand and exclude the native leaflets and to avoid recoil; the middle portion is constrained to avoid the coronary arteries and the upper portion is flared to center and fix the stent frame firmly in the ascending aorta and to provide longitudinal stability and coaxial positioning |
| | Direct Flow (Direct Flow Medical) | Non-metallic framework and two inflatable rings; Transfemoral | Peculiar anchoring mechanisms (inflatable rings) not requiring calcium for sealing; repositionability and retrievability; functional during positioning (ensures hemodynamic stability); fully retrievable |
| | Engager** (Medtronic) | Self-expandable nitinol stent; Transapical | Trapping of valve leaflets in order to stabilize the sytem and to avoid coronary ostia occlusion |
| | Helio dock** (Edwards Lifesciences) | Self-expandable nitinol stent; Transfemoral | The dock is fixed inside the aortic root and assists in annular fixation of a standard balloon-expandable SAPIEN XT transcatheter heart valve by incorporating and entrapping the native cusps |
| | CoreValve Evolute R** (Medtronic) | Self-expandable; Transfemoral | Recapturability and repositionability; supra-annular position |
| | J-Valve (JieCheng Medical Technology) | Self-expandable nitinol stent; Transapical | Featured by three U-shape anatomically oriented devices-graspers- which facilitate 'self-positioning' during implantation and provide extra-radial fixation by embracing the native valve leaflets (clip mechanism). The two stages releasing design facilitates accurate position |
| | Lotus** (Boston Scientific) | Nitinol frame with an Adaptive SeaITM Technology; Transfemoral | Mechanically deployed with possibility to retrieve and reposition; early functional during deployment |

Conclusions

- Preliminary experiences (registries) are available for the use of TAVI in patients with severe aortic regurgitation at high risk for surgery.
- TAVI represents a valid option for the treatment of para- valvular regurgitation and intra-prosthetic regurgitation as a valve-in-valve procedure.
- New generation and repositioning devices are able to limit residual AR following TAVI.
- Ad hoc studies are necessary to evaluate outcome of new generation devices and to consider TAVI as a frontline treatment option for high risk patients with native severe AR.

Thanks for your attention

