TAVR, Conduction Disturbances and Pacemakers

Overview and Recommendations

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TAVI and Pacemakers

- Background
- Factors Affecting Pacemaker Implantation
- Implant Best Practices
- Future Advancements
- Conclusions

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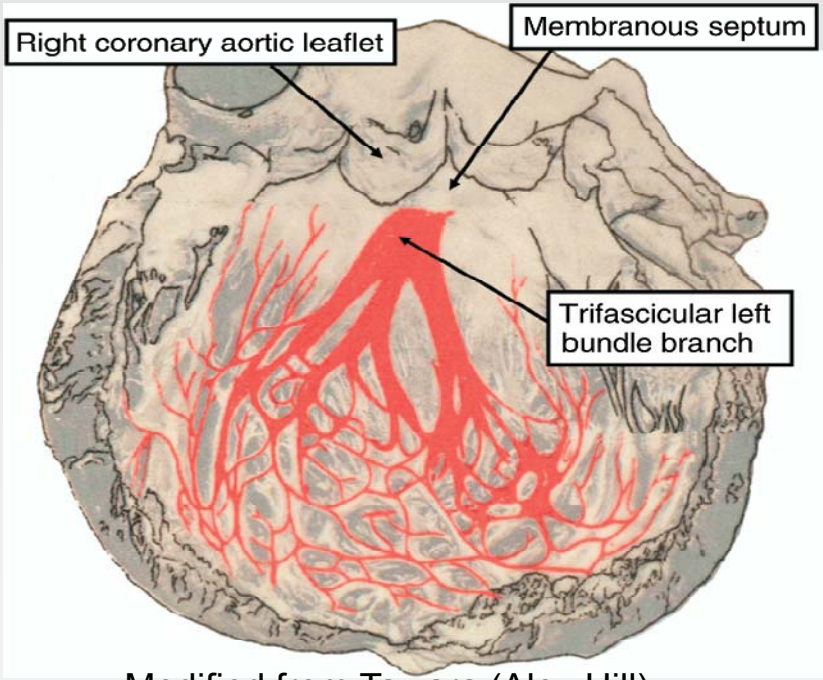
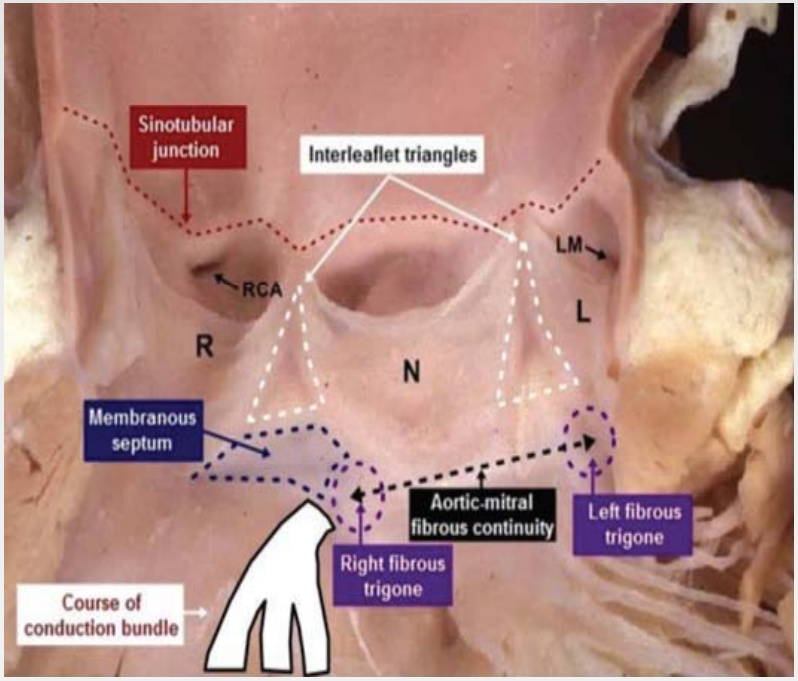
Background

Given the anatomical proximity of the aortic valve to the conduction system the occurrence of conduction abnormalities and the need for permanent pacemakers in patients undergoing SAVR or TAVR is not surprising



Modified from Tawara (Alex Hill)



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Aortic Valve Replacement and Conduction Disorders

Permanent pacemaker (PM) implantation rates with aortic valve replacement:

- **Surgical Aortic Valve Replacement** (SAVR): **7.2%[1] (Range: 3.2% - 8.5%)**
- **Transcatheter Aortic Valve Implantation** (TAVI): **15% [2] (Range: 0 – 47%)**

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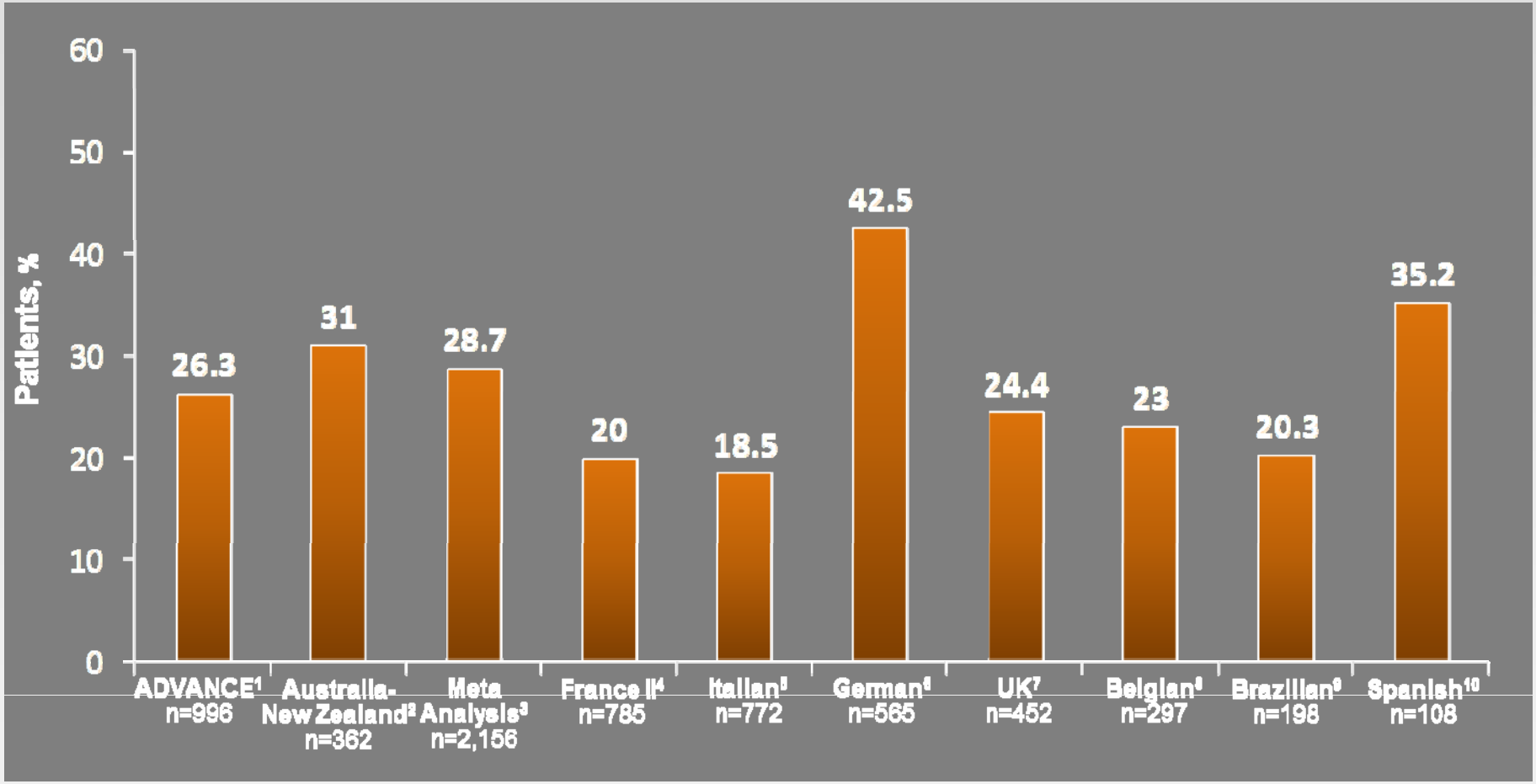
1. Bates MGD *Interact CardioVasc Thorac Surg* 2011;12:243-253. (Median)
2. Erkapic D. *J Cardiovasc Electrophysiol* ; November 2011 In Press (Crude Estimate).

CoreValve Pacemaker Implantation Rates Across Studies



1. Linke, A. Treatment of High Risk Aortic Stenosis Patients with Transcatheter Medtronic CoreValve Implantation. Presented at: ACC 2012. 2. Meredith I.T. 12 Month Results from ANZ CoreValve TAV Study. Presented at: TCT 2011. 3. Ruiz C.E. Weighted meta-analysis of CoreValve® Outcomes. Presented at: EuroPCR 2011 (analysis sponsored by Medtronic, Inc.). 4. Cribier A. FRANCE II Multicenter TAVR Registry. Presented at: TCT 2011. 5. Petronio AS. Italian Registry. Presented at: EuroPCR 2010. 6. Zahn R., et al. *European Heart Journal*. 2011; 32:198-204 . 7. Moat N.E., et al. *JACC*. 2011;58. 8. Bosmans J. Belgian TAVI Registry. Presented at: London Valves 2011. 9. Brito F.S. Brazilian Registry. Presented at TCT 2011. 10. Avanzas P, et al. *Rev Esp Cardiol*. 2010;63:141-148.

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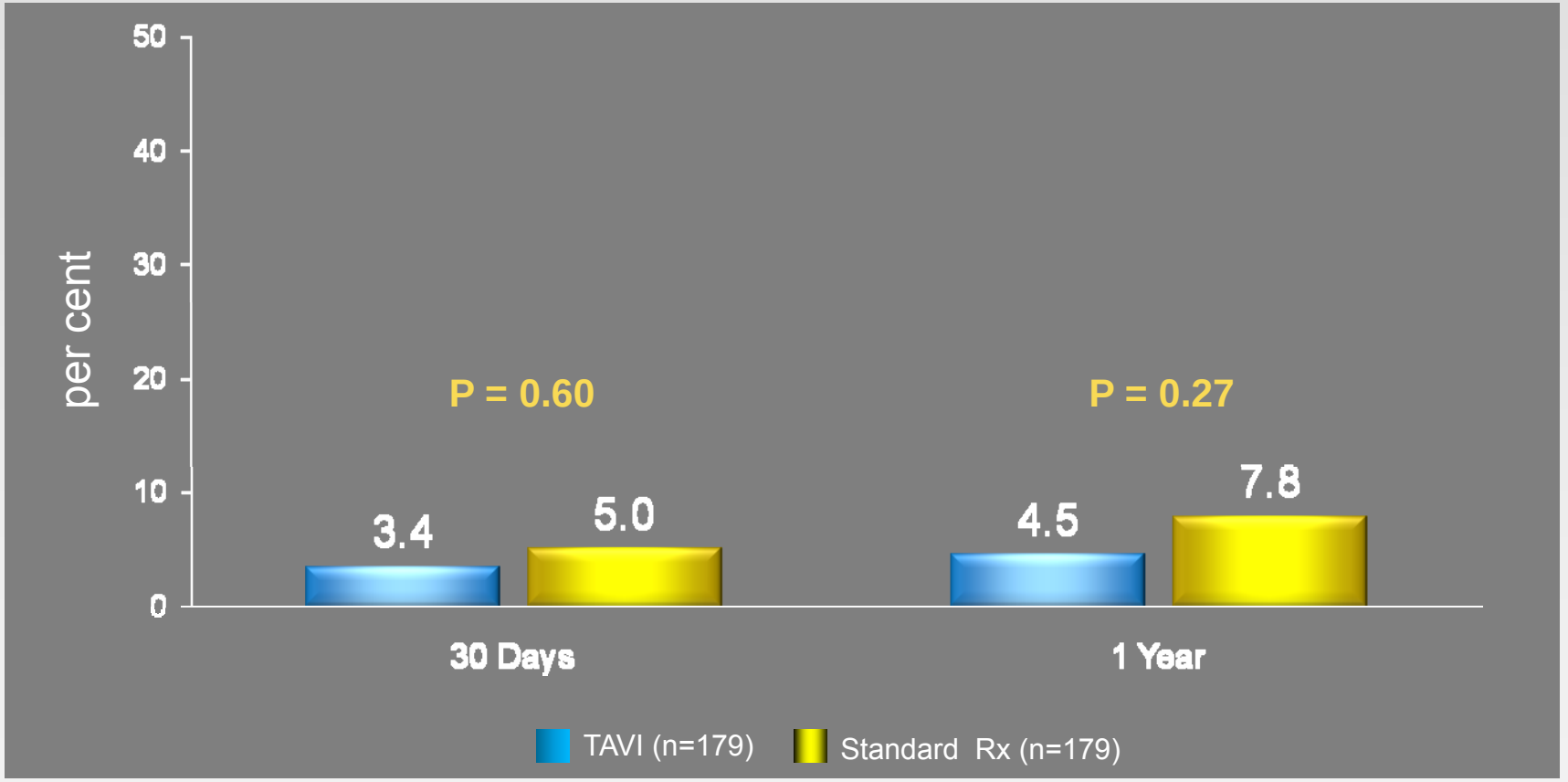
Partner Trial New Pacemakers at 30 Days and 1 Year



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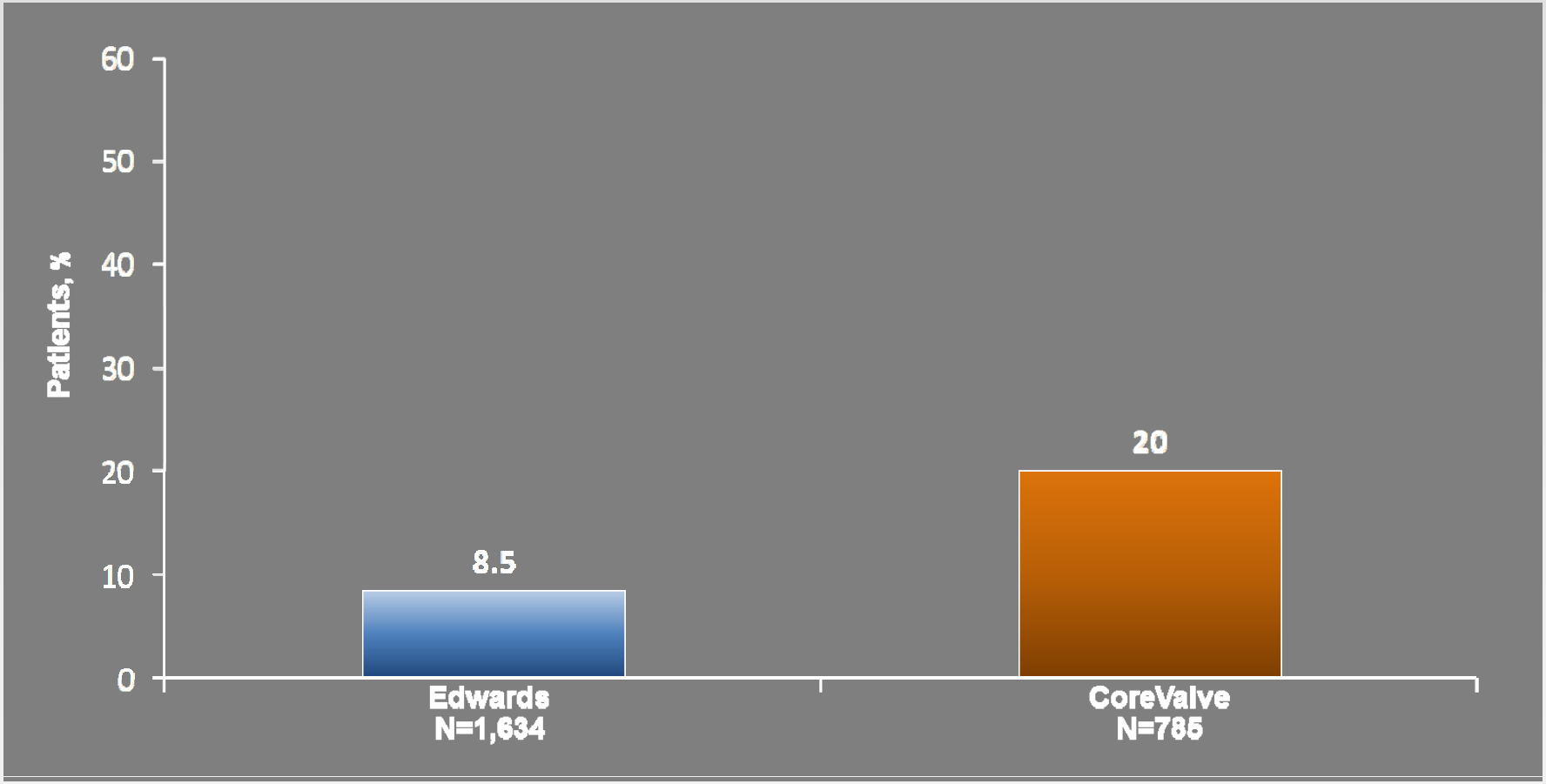
France II Registry[1]
New Permanent Pacemaker



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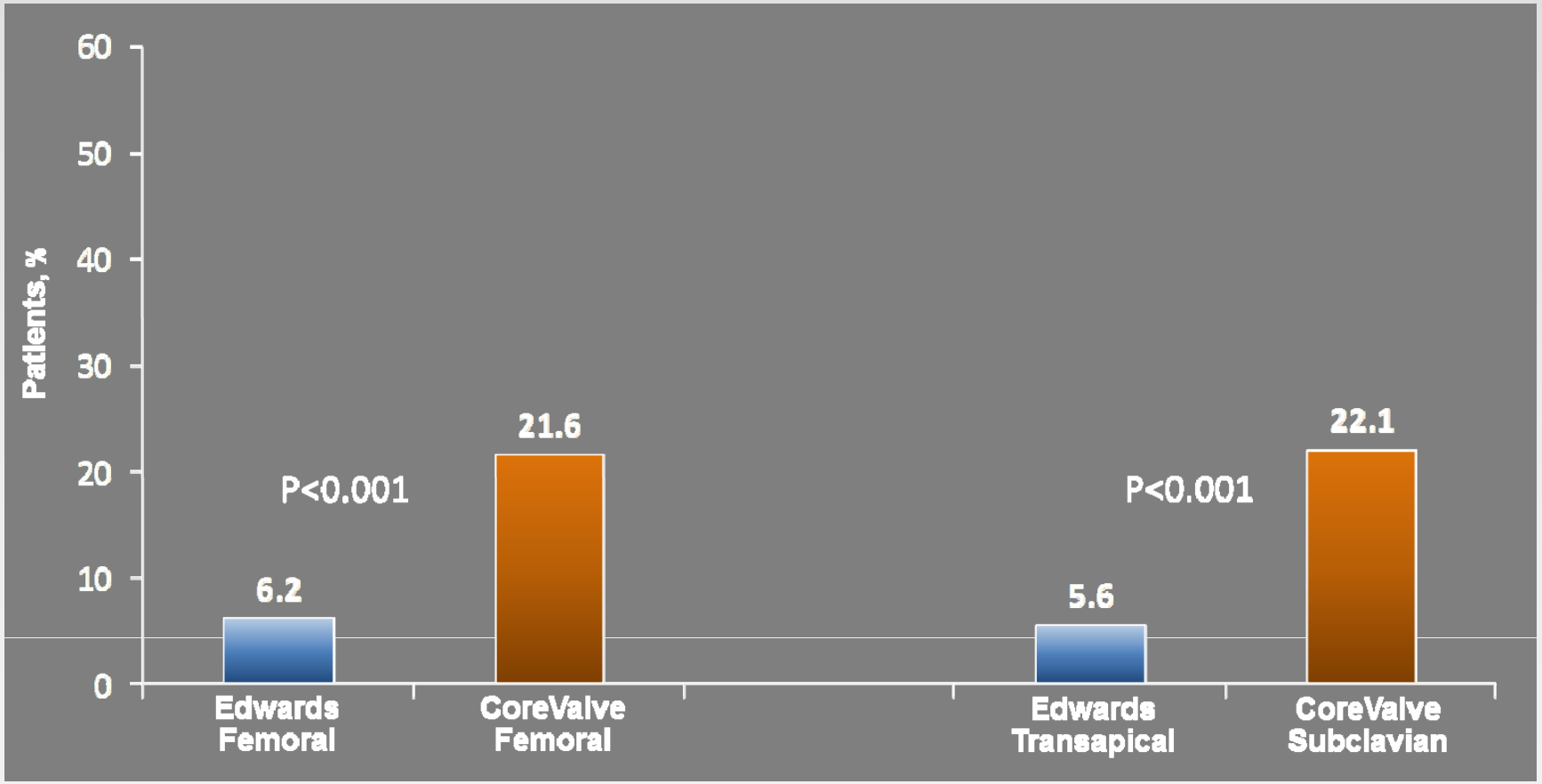
1. Cribier A. The FRANCE Multicenter TAVR Registry Experience. Presented at: TCT 2011.

UK Registry[1]
New Permanent Pacemaker



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1. Blackman D. UK TAVI: A Large Scale National Registry Comparing Transcatheter Aortic Valve Type & Access Route. Presented at: TCT 2011.

Lower PM Rates with CoreValve are Possible

PM Rate	Study Examples
12%	**Maier 2010[1]** • 132 CoreValve patients (excluded 16 patients with PM indications at baseline) • Only patients with complete AV block and/or symptomatic bradycardia received PM • Aimed for more superior positioning of the CoreValve device within the left ventricular outflow tract (LVOT) to mitigate conduction problems
14%	**Munoz-Garcia 2011[2]** • 181 CoreValve patients • Traditional delivery system (n=124) and AccuTrak™ delivery system (n=57) • 34.6% PM implants with Traditional Delivery System vs. AccuTrak 14% (P<0.001) • Depth of implant less in the LVOT for AccuTrak patients than patients receiving traditional delivery system (mean: 9.6 mm vs. 6.5 mm, P<0.007)
12%	**Grube 2011[3]** • 60 CoreValve patients • No use of balloon pre-dilation

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1. Maier TCT 2010 Presentation.
2. Munoz-Garcia 2011 EuroPCR Presentation.
3. Grube E. *JACC Cardiovascular Interv* 2011;4(7):751-757.

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Factors Influencing Conduction Disturbances

Patient History

- Age
- Poor LVEF
- Preoperative AR
- Previous MI
- Pre-existing conduction disorders / RBBB[1,2,3,4]
- Pulmonary hypertension
- Landing zone calcification [5]

Patient Anatomy

- Narrow LVOT[6]
- Location of the AV node
- Length and configuration of the membranous septum
- Septal wall thickness[7]

1. Erkapic D. J Cardiovascular Electrophysiol November 2011; In Press. 2. Fraccaro C. Am J Cardiol 2011;107:747-754. 3. Munoz-Garcia AJ. Rev Esp Cardiol 2010;63(12):1444-1451. 4. Calvi V. J Interv Card Electrophysiol November 2011, In Press. 5. Latsios G. Catheterization and Cardiovascular Interventions 2010;76:431-439. 6. Bain J. Am Heart J 2010;159:497-503. 7. Jilaihawi H. Am Heart J 2009;157:860-866.

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Pre-existing RBBB Conduction Disorders

Many studies have validated the presence of right bundle branch block (RBBB) before TAVI is a significant pre-procedure predictor for the development of complete atrioventricular (AV) block and subsequent PM

1.358 Odds Ratio (p=0.02) RBBB significant predictor of PM	Erkapic 2011[1]: Meta analysis of 5,258 TAVI patients
6.132 Odds Ratio (p=0.046) RBBB significant predictor of PM	Fraccaro 2011[2]: 70 CoreValve patients
47.6% PM rate with RBBB and 10% PM rate without RBBB (p=0.01)	Munoz-Garcia 2010[3]: 65 CoreValve patients
28.8% PM rate with RBBB and 2.7% PM rate without RBBB (p<0.0001)	Calvi 2011[4]: 181 CoreValve patients

1. Erkapic D. *J Cardiovascular Electrophysiol* November 2011; In Press.
2. Fraccaro C. *Am J Cardiol* 2011;107:747-754.
3. Munoz-Garcia AJ. *Rev Esp Cardiol* 2010;63(12):1444-1451
4. Calvi V. *J Interv Card Electrophysiol* November 2011; In Press.

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TAVI Procedural Factors

Pre-Deployment[1,2, 3]

- BAV balloon type and size
- BAV balloon size
- Wire stiffness and location
- Balloon: Annulus ratio
- BAV balloon over-dilation
- Valve and annulus ratio

Deployment[1,4,5,6,7,8]

- Depth of implant
- Positioning of balloon catheter and valve
- Process and timing of repositioning

1. Piazza N. J Am Coll Cardiol Interv 2008;1:310-316. 2. Nuis RJ EuroPCR Presentation 2011: Timing and Potential Mechanisms of New Conduction Abnormalities During Implantation of a Medtronic CoreValve in Patients with Aortic Stenosis. 3. Bonan R. Presentation. Need further reference.4. Giannini. 5. Munoz-Garcia AJ. Rev Esp Cardiol 2010:63(12):1444-1451. 6. Fraccaro C. Am J Cardiol 2011;107:747-754. 7. Valera C. *Rev* Esp Cardiol 2011;64(12):1202-1206. 8. Saia F. Catheter Cardiovasc Interv. 2012 ;79(2):315-321.

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Balloon Aortic Valvuloplasty (BAV)

BAV Impact on Conduction Disorders Prior to TAVI	
46% New conduction abnormalities during BAV procedure	**Nuis**[1]: 65 CoreValve patients. The timing and mechanism of new conduction abnormalities were identified during the TAVI procedure. These abnormalities were not necessarily associated with PM implants.
1.5% PM rate associated with BAV[2] 8.5% New conduction abnormality with BAV	**Laynez** [2]: 271 BAV patients. The ratio of balloon size to the left ventricular outflow tract diameter was associated with conduction disturbances (over sizing caused conduction disturbances).
9% PM rate associated with BAV[3]	**Baan**[3]**:** 34 CoreValve patients. Incidence of complete heart block and need for PM were identified after BAV and after the TAVI procedure.
16.1% Absolute increased PM rate with BAV	**Grube**[4]: 60 CoreValve patients PM rate: 11.7% without BAV and 27.8% with BAV

1. Nuis R. Eur Heart J. 2011;32(16):2067-2074.
2. Laynex .Am J Cardiiol 2011;108:1311-1315.
3. Baan J. Am Heart J 2010;159:497-503.
4. Grube E . JACC Cardiovasc Interv 2011;4(7):751-757.

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Depth of Implant

Odds Ratio Results	Study Examples
1.17 OR (p=0.003)	**Giannini**[1]: 275 CoreValve patients. Depth of prosthesis implantation was an independent predictor of PM implant.
1.15 OR (p=0.001)	**Munoz-Garcia**[2]: 181 CoreValve patients. Depth of prosthesis implantation was an independent predictor of PM implant.
1.21 OR (p=0.039)	**Fraccaro**[3]: 70 CoreValve patients: Depth of prosthesis implantation was an independent predictor of PM implant.
1.12 OR (p=0.03)	**Valera**[4] 26 CoreValve patients. Depth of prosthesis implantation was the **only** independent predictor of PM implant
1.37 OR	**Saia**[5]: 73 CoreValve patients. Distance between non-coronary cusp and the distal edge of the prosthesis was independent predictor of PM implant.

1.Giannini 2011 EurPCR presentation.
2. Munoz-Garcia AJ. *Rev Esp Cardiol* 2010:63(12):1444-1451.
3. Fraccaro C. *Am J Cardiol* 2011;107:747-754.
4. Valera
5. Saia F. *Catheter Cardiovasc Interv.* 2012 ;79(2):315-321.

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Valve Procedural Differences

- CoreValve frame height 50mm. Although there is control over positioning during deployment, if the valve extends further into the LVOT, it may cause conduction disorders.[1-5]
- The Edwards SAPIEN XT valve -17mm alothough positioning dependent on stability by pacing during balloon expansion, the frame height potentially minimises valve depth options.

1.Giannini 2011 EurPCR presentation.
2. Munoz-Garcia AJ. *Rev Esp Cardiol* 2010:63(12):1444-1451.
3. Fraccaro C. *Am J Cardiol* 2011;107:747-754.
4. Valera
5. Saia F. *Catheter Cardiovasc Interv.* 2012 ;79(2):315-321.

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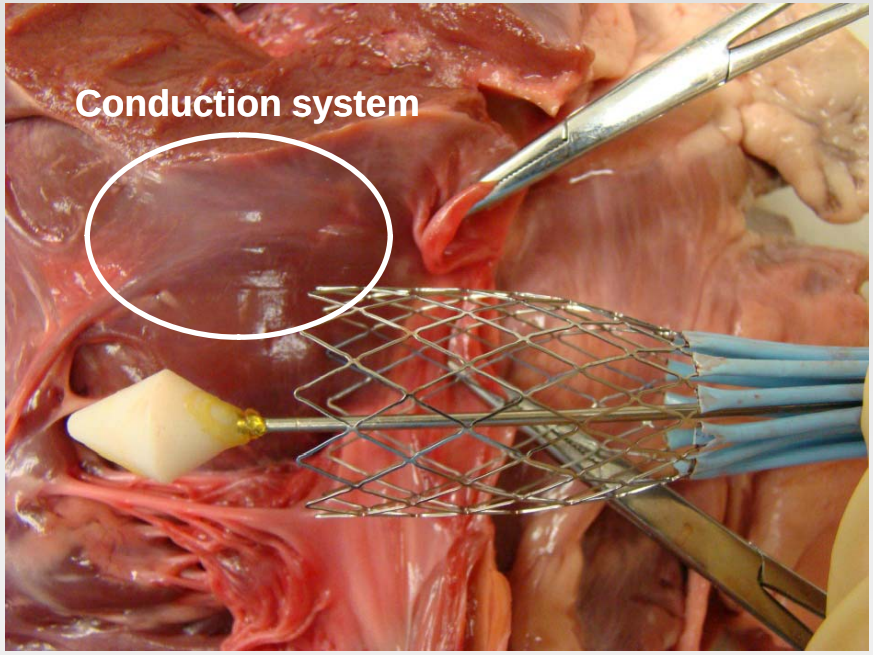
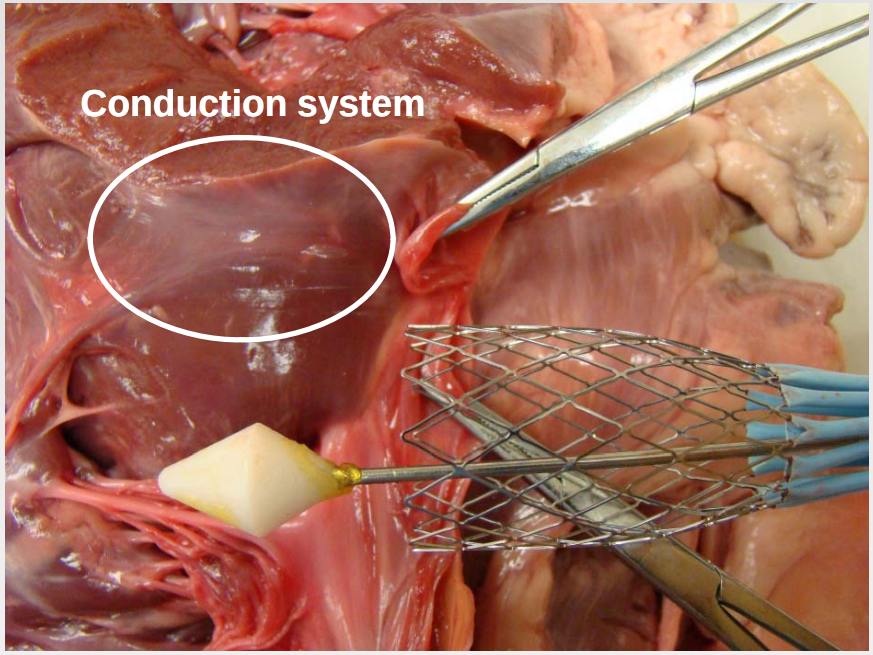
Depth of CoreValve Implant and Proximity of Aortic Valve to Conduction System



15 mm past annulus



5 mm past annulus

Images from porcine heart.

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TAVI and Pacemaker Clinical Practices

Potential Lower Threshold for PM Implant with TAVI

- Temporary epicardial pacing used after SAVR allows time for conductive tissue to recover
- With TAVI, concerns about infection may prompt physicians to early pacemaker implantation
- Lack of knowledge about evolution of new onset conduction bradycardia and left bundle branch block and their prognostic impact[1,2]
- Variable and unknown pacing practices with TAVI patients[1,2,3]

Potential Economic Factors

- May be financial advantageous to implant a pacemaker rather than hospitalizing the patient for watchful waiting (reduce length of stay)[4]

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1. Rubin JM. *Circ Cardiovasc Interv*. 2011 :4(3):280-286
2. Erkapic D. *J Cardiovasc Electrophysiol* November 2011 In Press.
3. Avanzas P. *Rev Esp Cardiol* 2010;63(2):141-148.
4. Maier RM

ESC Pacing Guidelines for Acquired AV Block

1. **Third- or second-degree (Mobitz I or II) atrioventricular block: (i) after catheter ablation of the atrioventricular junction (ii) after valve surgery when the block is not expected to resolve (Class I) C Evidence**
2. **Chronic symptomatic third- or second-degree (Mobitz I or II) atrioventricular block (Class I) C Evidence**
3. **Asymptomatic third- or second-degree (Mobitz I or II) atrioventricular block (Class IIa) C Evidence**
4. **Symptomatic prolonged first-degree atrioventricular block (Class IIa) C Evidence**
5. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Kearns–Sayre syndrome, etc.) with third- or second-degree atrioventricular block (Class I) B Evidence
6. Neuromuscular diseases (e.g. myotonic muscular dystrophy, Kearns–Sayre syndrome, etc.) with first-degree atrioventricular block (Class IIb) B Evidence

Vahanian A. *European Heart Journal* 2007;28:2256-2295.

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TAVI and Pacemakers

- It is not known how uniformly these pacemaker guidelines are followed for TAVI patients.
- Many published TAVI studies do not identify the reasons for pacemaker implants.[1]
- The most common published reasons for implanting pacemakers in TAVI patients are for AV block II or III.[1]

Erkapic D. *J Cardiovasc Electrophysiol* November 2011; In Press.

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Implant Best Practices to Reduce Conduction Disturbances

Pre-Procedure	Intra-Procedure	Post-Procedure
♥ Assess pre-existing need for pacemaker and implant prior to TAVI if needed: ♥ RBBB ♥ LBBB + LAD ♥ Assess calcifications/ annulus size (MSCT) ♥ Assess septal wall thickness	♥ RIJ or LIJ temporary pacing wire access enables early patient mobility ♥ Cautiously advance guidewire to avoid septum ♥ Carefully consider valvuloplasty balloon selection: ♥ Undersize ♥ Shorter length ♥ Reduce depth of implant to < 6 mm ♥ Use AccuTrak System	♥ Continuous ECG monitoring until discharge ♥ Temporary pacemaker for 48 to 72 hours ♥ Use guidelines to determine need for pacemaker

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Assess Need for Pacemaker Prior to TAVI

- **Clinical practices vary and strongly influence pre-TAVI PM rates**
- **Proactively treating patients who have pacemaker needs prior to the TAVI procedure could reduce post-TAVI PM rates**

Study	Pre-TAVI PM Rate
PARTNER B Trial[1]	22.9%
UK Registry[2]	8%
Italian Registry[3]	6.3%

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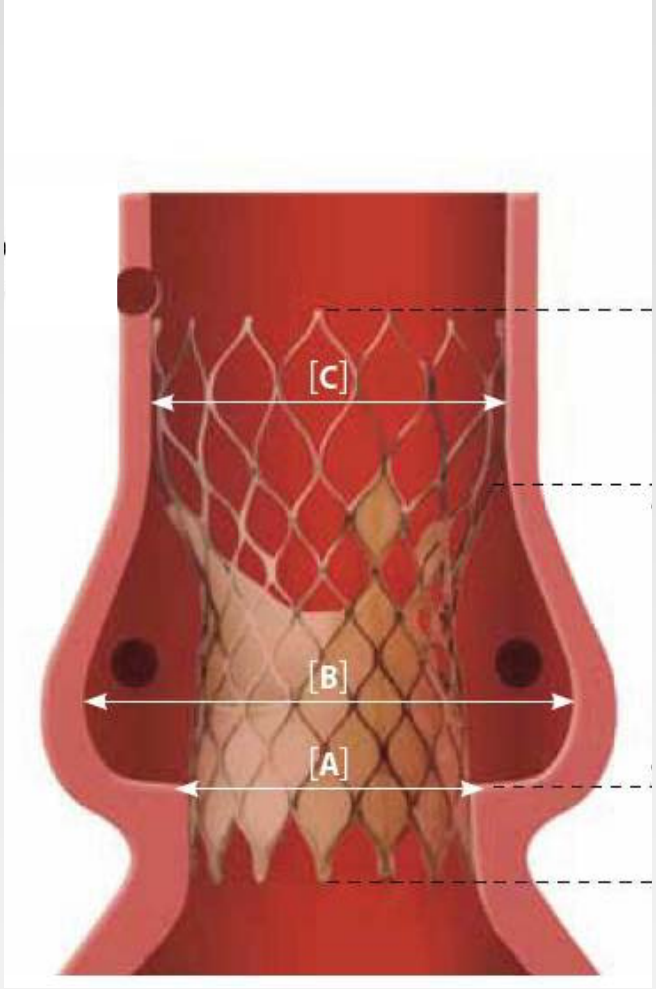
1. Smith CR. *N Engl J Med* 2011;364(23):2187-2198.
2. Khawaja MZ. Circulaltion 2011;123(9):951-960.
3. Tamburino C. *Circulation* 2011;123(3):299-308.

Depth of Implant Recommendation



Distance of the lower edge of the non-coronary cusp to the valve inflow edge should be < 6 mm[1]

Valve should be implanted in a superior location within the LVOT

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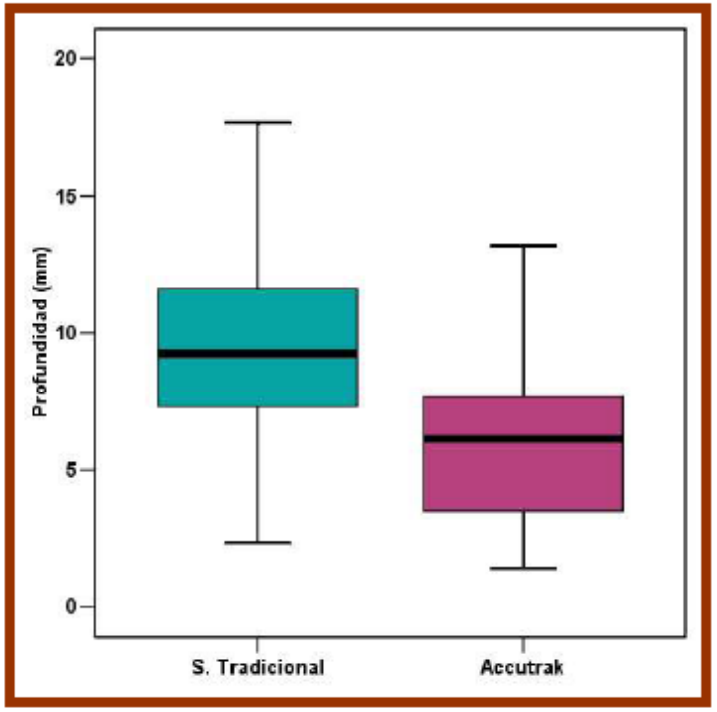
AccuTrak Study Results[1]

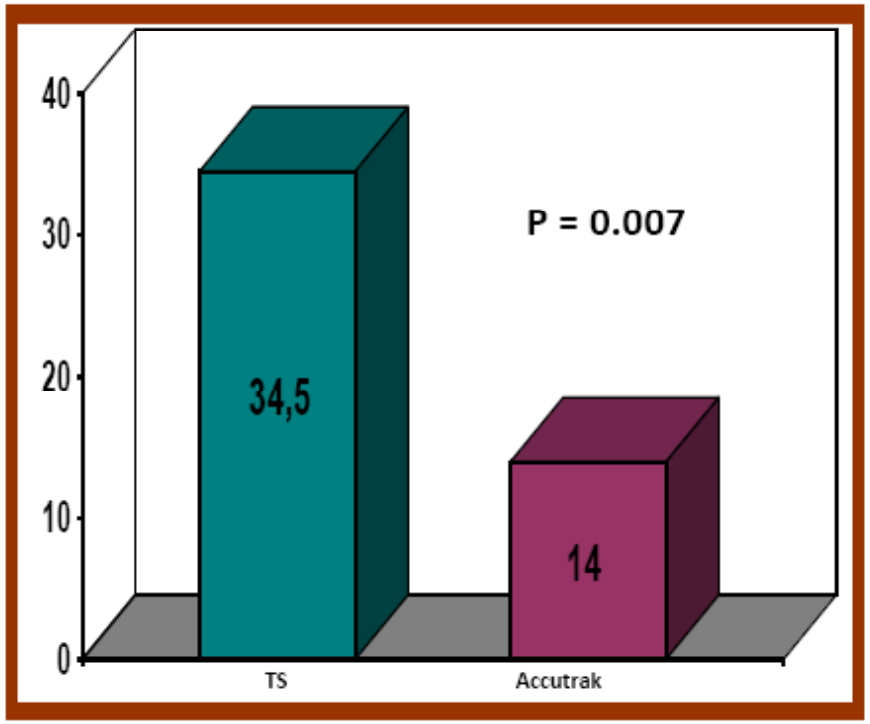
Conclusion: AccuTrack System helped reduce the depth of the valve implant and lower the pacemaker implant rate

Depth of implantation



9.6 ±3.1 mm vs. 6.5 ±3.1; p < 0.001

Pacemaker (%)



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1. Munoz-Garcia PCR 2011

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Future Advancements in TAVI Technology

- Improved stability
- Improved control and ergonomics
- Refinements in valve sizing
- Full repositionability

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Conclusions

- Given the anatomical proximity of the aortic valve to the conduction system, pacemaker implants are a known complication of aortic valve replacement procedures.
- There are some differences between the currently available technologies with respect to the PPM requirement
- Depth into the LVOT may cause conduction disorders and increase the PM rate.[1-5] CoreValve PM rate (25.8%)[6] has been reduced when the depth of implant is kept under 6 mm and the AccuTrak delivery system is used optimize the position and depth of the valve (12% to 14%)[7,8,9].

1. Giannini 2011 EurPCR presentation. 2. Munoz-Garcia AJ. *Rev Esp Cardiol* 2010:63(12):1444-1451. 3. Fraccaro C. *Am J Cardiol* 2011;107:747-754. 4. Valera C. *Rev Esp Cardiol* 2011;64:1202-1206. 5. Erkapic D. *J Cardiovasc Electrophysiol* November 2011. In Press. 6. Saia F. . *Catheter Cardiovasc Interv.* 2012 ;79(2):315-321. 7. Maier TCT 2010 Presentation. 8. Munoz-Garcia 2011 EuroPCR Presentation. 9. Grube E. *JACC Cardiovascular Interv* 2011;4(7):751-757

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