### Pacemakers for the TAVI patient: For whom? When?

Michael Glikson, MD, FESC, FACC Davidai Arrhythmia Center Sheba Medical Center Tel Hashomer, Israel

> 8th International Conference Acute Cardiac Care June 2013



### Disclosures

- Research grants from device companies (MDT, Biotronik, SJM)
- Speaker / proctor for MDT, BSCI, SJM, Biotronik







#### The Edwards Sapien (balloon expandable )

#### **Corevalve (self expanding)**









•Transfemoral •Transaxillary •Transaortic

Piazza Circ interv 2008



#### Incidence of Conduction Abnormalities Following Transfemoral TAVI

	New LBBB (%)	High degree AVB (%)
Core Valve	40 (30– 65) <sup>1,3,5</sup>	25(12 -44) <sup>1,3,5,4,8,9</sup>
Edwards	12 (6-18) <sup>1,7</sup>	5 (0-27) <sup>1,6,8,9</sup>

- 1. Nuis Eur Heart J 2010
- 2. Roten AJC 2010
- 3. Khawaja Circulation 2011
- \*Maier et al TCT 2010 Lowest incidence with more superior positioning
- 5. Guetta Glikson AJC 201<sup>2</sup>
- 6. Bates Int CV and thor Surg 2011
- 7. Godin Am J Cardiol 2010
- 3. Zahn EHJ 2011
- Khatri Ann Int Med 2013 (n= 16000)



### Anatomy of the Aortic Root



Figure 6. This image of the aortic root opened from the left ventricle shows the fibrous continuities between the interleaflet triangles, the fibrous trigones, and the membranous septum. A-M indicates aortic-mitral.



# Location of the Conduction System

#### 6 mm from bottom of NCC to emergence of LBB





### Depth of Implantation and LBBB





Piazza JACC INTERV 2008



#### Predictors of High Degree AVB with CoreValve - Baseline Parameters -

Class	Predictors	OR/HR	Ref
Preexisting CSD	RBBB	OR > 40	4,5
	LBBB+long PR		5
	Wide QRS	3.45	2
LVOT and AV anatomy	IVS hypertrophy	1.18	2
	NCC thickness		3
	<b>AV Calcifications</b>	1.5	2

1- Nuis et al Eur Heart J 2010; 2- Khawaja Circulation 2011; 3-Jilaihawi Am Heart J 2009 ; 4- Piazza JACC CV Int 2008 ; 5- Guetta ,Glikson AJC 2011; 6-Fraccaro AJC 2011

Sheba Medical Center Tel Hashomer

#### Predictors of High Degree AVB with CoreValve - Procedural Parameters -

Class	Parameter	OR/HR	Ref
Depth	Depth of Implantation > 6 mm	OR > 20	4,5
Size	Balloon : Annulus ratio >1.3		1
	Large prosthesis (29)	2.5	2

1- Nuis et al Eur Heart J 2010; 2- Khawaja Circulation 2011; 3-Jilaihawi Am Heart J 2007 ; 4- Piazza JACC CV Int 2008 ; 5- Guetta ,Glikson AJC 2011; 6-Fraccaro AJC 2011

Sheba Medical Center Tel Hashomer



### Course of AVB Over Time in CoreValve

- 40-80% occur during the procedure, 50% of which occur during balloon pre-dilatation<sup>2,3</sup>
- Later there are opposing processes of resolution of edema / inflammation vs. self expanding nature of CoreValve
  - Periprocedural AVB "resolved" (?) in 35% at discharge , 64% within  $\geq$  30 days <sup>1,2,3</sup>
  - 20-60% of HDAVB develop AFTER procedure most of them within 5 days
  - Few reports of late onset AV block after discharge <sup>5</sup>, few cases of late SCD
    - I Roten Am J Cardiol 2010
    - 2- Nuis Eur Heart J 2010
    - 3- Guetta & Glikson AJC 2011
    - 4- Piazza Eurointerv 2010
    - 5- Fraccaro Am J Cardiol 2011





#### Time to Development of High Degree AV Block n = 25/70

#### Predictors and Course of High-Degree Atrioventricular Block After Transcatheter Aortic Valve Implantation Using the CoreValve Revalving system

Victor Guetta, MD<sup>a,\*</sup>, Gustavo Goldenberg, MD<sup>b</sup>, Amit Segev, MD<sup>a</sup>, Danny Dvir, MD<sup>b</sup>, Ran Kornowski, MD<sup>b</sup>, Arik Finckelstein, MD<sup>c</sup>, Ilan Hay<sup>a</sup>, Ilan Goldenberg, MD<sup>a</sup>, and Michael Glikson, MD<sup>a</sup>



AJC 2011



#### Periprocedural ECG Changes and Later Progression to HDAVB

- Periprocedural AVB is the strongest predictor of persistent AVB<sup>1</sup> (in our series ALL had permanent pacemakers implanted )
- New LBBB is a poor predictor of later HDAVB (6/33)<sup>2</sup>
- Of 39 cases with periprocedural worsening of conduction (other than HDAVB) only 8 progressed later to HDAVB<sup>2</sup>
- Of 15 patients with late HDAVB only 8 had demonstrated periprocedural conduction system changes <sup>2</sup>
- In patients with normal QRS both before and after TAVI, rate of later development of HDAVB was 0 – 13% <sup>1,2</sup>



**1**- Khawaja Circulation 2011 2-Guetta and Glikson 2011



### Permanent Pacing After TAVI

- Absolute indication :
  - New high degree AV block of any duration (early or immediate implantation )
  - Alternating BBB
- Relative indication :
  - Preexisting LBBB+ 1<sup>st</sup> degree AVB with any change ?
  - Preexisting RBBB with any change ?
  - New LBBB + 1<sup>st</sup> degree AV block ? ?
- Role of EPS ?
  - Prophylactic pacing ?
  - Early decision after procedure ?





#### Predictive Factors and Long-Term Clinical Consequences of Persistent Left Bundle Branch Block Following Transcatheter Aortic Valve Implantation With a Balloon-Expandable Valve

Marina Urena, MD,\* Michael Mok, MD,\* Vicenç Serra, MD,† Eric Dumont, MD,\* Luis Nombela-Franco, MD,\* Robert DeLarochellière, MD,\* Daniel Doyle, MD,\* Albert Igual, MD,† Eric Larose, MD,\* Ignacio Amat-Santos, MD,\* Mélanie Côté, MSc,\* Hug Cuéllar, MD,† Philippe Pibarot, PHD,\* Peter de Jaegere, MD, PHD,‡ François Philippon, MD,\* Bruno Garcia del Blanco, MD,† Josep Rodés-Cabau, MD\* *Quebec City, Quebec, Canada; Barcelona, Spain; and Rotterdam, the Netherlands* 

- 202 pt with no CSD implanted with Edwards Sapien TAVI
- 30% developed new LBBB which resolved later in 37% and 57% after 6 and 12 m
- New LBBB was associated with higher incidence of PPM for CAVB (20% vs 0.7%) as well as with syncope and CHF





### Effect of LBBB on Permanent Pacing and Mortality





# Monitoring After CoreValve TAVI

- In-hospital monitoring for 5 days
- 24-48 hours with temporary pacemaker
- 3 days for "low risk" patients ?
- Holter before discharge in borderline cases
- Role of pre discharge EPS ?





# Monitoring After Edwards Sapien TAVI

- Up to three days in hospital
- No need for temporary pacemaker if no change in conduction





#### **Preventive Measures**

- Use Edwards Sapien in RBBB
- High position of Corevalve
- Preventive permanent pacing before TAVI:
  - Absolute :
    - Preexisting indications for PPM (History of syncope, holter!)
  - Relative :
    - All patients with RBBB undergoing CoreValve implantation ?
    - All patients with preexisting LBBB + 1<sup>st</sup> degree AV block undergoing CoreValve implantation??





# PPM by Tertiles Sheba MC 9/2008 – 6/2011





### **Temporary Pacing in TAVI**

- Initial experience with relatively high rate of complications, mainly perforations (ASA, Plavix)
- Prolonged temporary pacing associated with infections, perforations and dislocations
- Balance between risk of development of HDAVB and the risks of prolonged temporary pacing
- Practical approach :
  - Inserted via RIJV for stability
  - Use balloon tipped pacing catheters semi filled with saline to decrease risk of perforation \*
  - Temporary pacemaker left in for 48 hours in most patients
  - Early permanent pacing when indicated



\* Some use screw-in leads for stability



#### Incidence, Management, and Outcomes of Cardiac Tamponade During Transcatheter Aortic Valve Implantation

#### A Single-Center Study

Ahmed Rezq, MD,\*†‡ Sandeep Basavarajaiah, MD,\*† Azeem Latib, MD,\*† Kensuke Takagi, MD,\*†§ Tasuku Hasegawa, MD,\*† Filippo Figini, MD,\* Micaela Cioni, MD,|| Annalisa Franco, MD,¶ Matteo Montorfano, MD,\* Alaide Chieffo, MD,\* Francesco Maisano, MD,|| Nicola Corvaja, MD,# Ottavio Alfieri, MD,|| Antonio Colombo, MD\*†

- 4.3% tamponade in TAVI (17/389)
- 53% of tamponades were due to temporary pacemaker wires (screw in > passive), nearly all occurred on the table
- None of the pacemaker related tamponades was fatal





#### CLINICAL RESEARCH

#### Interventional Cardiology

#### Impact of Permanent Pacemaker Implantation on Clinical Outcome Among Patients Undergoing Transcatheter Aortic Valve Implantation

Lutz Buellesfeld, MD,\* Stefan Stortecky, MD,\* Dik Heg, PHD,† Sven Hausen, MD,‡ Ralf Mueller, MD,§ Peter Wenaweser, MD,\* Thomas Pilgrim, MD,\* Steffen Gloekler, MD,\* Ahmed A. Khattab, MD,\* Christoph Huber, MD,\* Thierry Carrel, MD,\* Balthasar Eberle, MD,|| Bernhard Meier, MD,\* Peter Boekstegers, MD,§ Peter Jüni, MD,† Ulrich Gerckens, MD,¶ Eberhard Grube, MD,‡ Stephan Windecker, MD\*†

Bern, Switzerland; and Bonn and Siegburg, Germany



The blue line represents outcomes of patients with permanent pacemaker implantation before TAVI, the red line represents patients with the need for permanent pacemaker implantation after TAVI, and the green line represents patients without permanent pacemaker implantation. Cl – confidence interval; HR – hazard ratio; other abbreviations as in Figure 1.



N= 98/353



#### Costs and complications of new PM

 Significantly prolongs the in-hospital length of stay, thus significantly increasing the TAVI related costs \*

	No complications	Complications	New PPI
Mean LOS (days)	8	14	18

\* Nuis RJ et Al.. Catheter Cardiovasc Interv. 2011 Sep 1;78(3):457-67

### Conclusions

- High degree AV block is a common consequence of TAVI, especially of the CoreValve type
- Its strongest predictors are preexisting RBBB and low valve position
- Temporary pacing for 48 hours and monitoring for 5 days is indicated in all patients following CoreValve TAVI
- With increased operator experience, new tools and high implant position, lower incidence of HDAVB is anticipated











#### NYHA functional class and LV function









#### LV function

LVEF (%)



Solid line represents the group of patients with new conduction defects after TAVI; dashed line represents the group of patients without new conduction defects.

Hoffmann R et Al. Impact of a New Conduction Defect After Transcatheter Aortic Valve Implantation on Left Ventricular Function. J Am Coll Cardiol Intv 2012;5:1257–63

#### QOL in patients with implantable devices



Outcome from the IQL (Icelandic Quality of Life Questionnaire): No significant differences were observed between ICD patients and pacemaker carriers on any of the 12 domains of the IQL. Comparisons with normal population values (age band 50–69 years) are shown.

Leosdottir M, Sigurdsson E, Reimarsdottir G, et al. Health-related quality of life of patients with implantable cardioverter defibrillators compared with that of pacemaker recipients. Europace 2006;8:168–74

# Mortality in octa- and nona-genarian patients with permanent pacemaker



Independent predictors	Ρ	Hazard Ratio (95% CI)
CHF	<0.001	2.6 (1.7 to 4.0)
COPD	<0.001	4.0 (2.1 to 7.6)
Older age	0.002	1.1 (1.0 to 1.1)
Syncope	0.005	1.8 (1.2 to 2.7)
Cancer	0.021	1.9 (1.1 to 3.3)
High-degree AV block	0.028	1.5 (1.0 to 2.2)

Shen WK. Ann Intern Med. 1996 Sep 15;125(6):476-80