Transcatheter Aortic Valve Replacement
From Fanciful Idea to the Greatest Leap Forward

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Charles Nicolle Hospital, University of Rouen, France

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Rutgers University, New Brunswick, USA, October 18, 2014
Disclosure Statement of Financial Interest

Within the past 12 months, I have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tr>
<td>• Consulting Fees/Honoraria</td>
<td>• Edwards Lifesciences</td>
</tr>
<tr>
<td>• Proctoring-Training activities/Honoraria</td>
<td>• Edwards Lifesciences</td>
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</tbody>
</table>
Rouen: since 1985, development of innovative technologies in the field of valvular disease

- 1985: Balloon Aortic Valvuloplasty
- 1997: Mitral Commissurotome
- 2002: Transcatheter Aortic Valve

« Don’t undertake a project unless it is manifestly important and nearly impossible » Edwin Land
1998- Dhaka, Bangladesh
Mitral Commissurotomy, with Zoltan
An eternal gratitude to my mentors

1977- Cedars Sinaï Medical Center, Los Angeles

Their legacy reside in the number of young cardiologists they have trained, inspired, and mentored.
An eternal gratitude to my mentors

Professor Brice Letac (1933-2002),
Past Chief of the Department of Cardiology, University of Rouen, France

A strong dedication to clinical research and innovative technologies
Interventional Technologies for Degenerative AS
An Unmet Clinical Need

Aortic Stenosis is the most frequent acquired valvular disease in adults: 5-7% of people > 65-y

Surgical AVR:
the standard of care for decades

Low mortality
Return to normal life expectancy

One third of patients are left untreated

Mortality:
> 80% at 3 years
Rouen, Sept 1985
F.I.M. – Balloon Aortic Valvuloplasty

In the 80s, age per-se was a contra-indication to AVR
In Rouen, 95% of our AVR patients were < 75 years

72 year-old woman

- Highly symptomatic:
  - Several daily syncopes
  - NYHA IV
  - CAD (angina / past-AMI)
- Declined for surgery X 3
  (age + CAD)

In the 80s, age per-se was a contra-indication to AVR
In Rouen, 95% of our AVR patients were < 75 years

20mm Balloon

A memorable reaction of the medical community!

Percutaneous transluminal valvuloplasty of acquired aortic stenosis in elderly patients: An alternative to valve replacement?

Alain Cribier
Nadir Saoudi
Jacques Berland

Thierry Savin
Paulo Rocha
Brice Letac

The Lancet, January 11, 1986

- Two years without symptom!
- Return to normal life
Enthusiastic response of the cardiologists worldwide

Rouen, 1986: First International Course on BAV with Live Demonstrations
Balloon Aortic Valvuloplasty in the 90s

- Thousands of cases performed worldwide
  - Impressive number of registries
    (including the US Mansfield and NHLBI registries)
  - Hemodynamic/symptomatic improvement
    and less rehospitalization
  - FDA approval in restricted indications

Important limitations

- Early valvular restenosis
- No beneficial effect on long term mortality

Solving these issues became a personal obsession

A Transcatheter Heart Valve?
First dreams of non-surgical valve replacement

Main objective: Aortic Insufficiency

1965: Davis catheter mounted valve

1971: Monopoulous (catheter-mounted aortic valve)
1976: Phillips (balloon-mounted valve)
1992: Matsubara (balloon-mounted valve)

Experimental devices
No human application
Transcatheter Valve: recent pioneers

- Hening Rud Andersen-

Experimental percutaneous heart valve

- Porcine valve in a self-made stent
- First implantation (pig model): 1989
- First publication: EHJ 1992
- Patent issued: 1995

No human application

- Philipp Bonhoeffer-

Percutaneous pulmonary valve

- Bovine jugular vein valve within a balloon expandable stent

2000: First human implantation in RV to PA conduit.

Large worldwide expansion in this indication: the Melody valve
Developing TAVI: an “unrealistic” project

“Implanting a valve prosthesis within the diseased calcific aortic valve, on the beating heart, using percutaneous catheter based techniques”

**Our Goal:** Improving the results of BAV – No restenosis

**Highly challenging**

- Valvular calcification
- Surrounding structures:
  - *Coronary arteries*
  - *Mitral valve*
  - *IV septum (His bundle)*

**Major clinical issues**

- Coronary occlusion
- Mitral valve injury
- Permanent AV block
- Stroke
- Aortic regurgitation
- Prosthesis migration
- Non lasting results
Birth of the concept of stented valve in AS

- A balloon expandable stent with high radial force might keep the valve open.
- A valvular structure would have to be attached within the stent.

Usual observation during BAV

Any calcified valve can be circularly opened by high pressure balloon inflation.

A challenging combination of balloon expandable frame and valve structure.
Validating the concept of stented valve

Optimal dimensions of the frame

Balloon expansion force, frame distortion, optimal dimensions, extraction force

- Circular stent opening
- High traction force to dislodge the stent

IV Septum (His bundle)
Diameter 23mm
Heigth: 14/16 mm
Coronary ostia
Mitral Valve
Confirmative cadaver study (2002)
Renu Virmani, MD, Washington DC

Traction force > 2kg to dislodge the stent

Circular Palmaz stent opening
1994: The drawing era
Conceiving a model of transcatheter valve

Uni-, Bi- or Tri-leaflet Valve?
A. Cribier, 1994

Polymer or Biologic Valve?

Stainless steel stent highly resistant to compression

Hand made model of stented valve

Crimped diameter: 8mm

JP Bessou, Cardiac Surgeon, Rouen, 1994
1994-1999: Search for a sponsor

Project submitted to all biomedical companies (including Medtronic and Edwards...)

Opinion of experts

- Technically impossible
- Clinically dangerous and irrelevant
- The most crazy project ever submitted

Forget it!
1999: Foundation of Percutaneous Valve Technologies, NJ, USA

Finding a partner

Stan Rowe
Alain Cribier
Stan Rabinovich
Martin Leon

ARAN R&D, Caesarea, Israel
1999: Percutaneous Valve Technologies
From prototypes to clinical application

Clinical requests to the engineers
Aran R&D, Caesarea, Israel

- A prosthesis made of a highly resistant frame
- Containing a uni-, bi-, or tri-leaflet valvular structure
- Able to be homogeneously compressed over a high pressure balloon, making possible its introduction into an introducer (femoral artery) of 7 to 9 mm in diameter
- Able to be enlarged by balloon inflation to an external diameter of 23mm without any damage to the frame and valvular structure
The issues of preclinical engineering
The "philosophy" of the transcatheter valve

Hemodynamic
- High EOA / Low gradient
- Proper coaptation of the leaflets
- Tissue deflection matching
- Minimized regurgitation / Leak

Safety
- Minimized interference with anatomy
- Enable low crimped profile
- Deploy and anchor safely, predictably

Durability
- Resistant Leaflet Tissue
- Uniform stress distribution on leaflets
- Leaflets resisting calcification
- Long term proven bovine pericardium

+ Animal testing on rabbits, sheep, pigs
Valve and frame: In-vitro testing
Inventing new tools for a new technology

**VALVE TESTS**

- Hemodynamics
- Pulse duplicator
- Accelerated Wear Tester
- Anticalcification
  - 20 weeks juvenile sheep implants

**FRAME TESTS**

- Durability
  - 200 million cycles \(\sim 5\) y
- Radial Force
- Oval crushing
- Finite Element Analysis
- Fatigue testing
1999-2000: Percutaneous Valve Technologies

First prototypes of stented-valve

- Different valve configurations, frame material and design
- Different leaflet design, material and attachment means

The «finalized» device

- Stainless steel stent
- 23mm in diameter
- External pet cuff (1/3)
- Tricuspid valve:
  - *Polyurethane*, then *bovine pericardium*

PVT Heart Valve

2000-2002

Animal implantations

- Crimping device
- Numed balloon
2000-2002 Percutaneous Valve Technologies

Animal experiment, CERA, Paris, France

- Sheep model -
Aortic valve, pulmonic valve
descending aorta

Acute and chronic studies

Implantation in native aortic valve

5-month follow-up: descending aorta

Lessons on:
- Vascular access
- Large size introducer sheath
- Delivery system
- Guidewire
- Most procedural aspects
- Anticoagulant regimen
2002, Rouen, F.I.M – TAVR
Moving from concept to clinical execution

57-y/o man, cardiogenic shock, LVEF 12%

Multiple comorbidities

Gradient: 11mmHg
EAO: 0.63cm²

LVEF 12%, no contractility reserve
Intra-LV thrombus
2002, Rouen, F.I.M – TAVR

From dream to reality

Oh! my God!
CHALLENGE:

Demonstrating the potential benefit of a disruptive technology on a subset of critically ill patients with life-threatening comorbidities.

2002-2005: The “heroic period” in Rouen

40 patients, I-REVIVE & RECAST trials


Equine Pericardium

Single size 23mm

4 Pts survived > 5 -y
1 Pt survived > 6.5 -y

with no symptom and optimal valve function
# Lessons

1. Feasibility of TAVR
2. Accuracy of valve placement
3. No THV embolization
4. No coronary occlusion
5. No MR
6. No AV - Block
7. Optimal valvular function
8. Excellent hemodynamics

8. *Paravalvular AR* > grade 2 in 25%

*(single size 23mm)*
Translation of post-mortem data (1993) to clinical practice

- Minimal risk of coronary occlusion
- Free access to LM / RCA on long term
- No MR on short and long term
- Pace-Makers required in < 10%
From 2004: Edwards LifeSciences

TAVI enters a new era

New valves, new delivery systems, new approaches

**Cribier-Edwards**
- 23mm size
- Equine pericardium
- 1/3 external coverage

**Edwards-SAPIEN**
- 23 & 26mm
- Treated bovine pericardium
- 50% external coverage

Vancouver, Canada
J. Webb

Leipzig, Germany
M. Mohr, T. Walther
M. Mack
TAVI enters a new era

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- 1/3 external coverage

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**RETROGRADE APPROACH**
- Transfemoral (RetroFlex catheter)
  - REVIVE (EU)
  - REVIVAL II
  - CAN Special Access
  - PARTNER (EU)
  - SOURCE (EU)

**ANTEGRADE APPROACH**
- Transapical (Ascendra catheter)
  - TRAVERCE (EU)
  - REVIVAL II
  - CAN Special Access
  - PARTNER (EU)
  - SOURCE (EU)

**PARTNER (US)**

Evidence based trial leading to FDA approval

+ Multiple national and international registries

From 2004: Edwards LifeSciences
Advanced Technology
Delivery system 3rd generation: RETROFLEX 3

RetroFlex 3

Nose cone
Sheath size: 22F (23mm), 24F (26mm)

2006-2009
All European registries
Including SOURCE Registry

2009
Pivotal randomized
PARTNER US Trial
PARTNER U.S. Randomized Pivotal Trial
The crucial milestone

Oct 2010: Martin Leon et al
June 2011: Craig Smith et al
March 2012: S. Khodali et al
May 2012: R. Makkar et al

N = 179
N = 358

Inoperable
Standard
Therapy

ASSESSMENT:
Transfemoral
Access
Not In Study

TF TAVR
1:1 Randomization
VS

Primary Endpoint: All-Cause Mortality (Superiority of TAVR)

TF TAVR
1:1 Randomization
VS

Primary Endpoint: All-Cause Mortality (Non-inferiority of TAVR)

N = 248
N = 104
N = 103
N = 244
N = 699

High Risk

ASSESSMENT:
Transfemoral (TF)
Transapical (TA)

1:1 Randomization
1:1 Randomization

Yes
No

Symptomatic Severe Aortic Stenosis

ASSESSMENT: High-Risk AVR Candidate

Total = 1,057 patients

PARTNER U.S. Randomized Pivotal Trial

The crucial milestone

Marked and long lasting functional improvement

TAVI: The treatment of choice in inoperable patients
Medtronic CoreValve vs SAVR
High Risk: US Pivotal Trial
Adams et al, New England Journal of Medicine, 2014
A long translational pathway
25 Years from BAV
18 Years from concept
10 Years from FIM

Oct 2011- FDA Approval:
Non Surgical Patients (PARTNER B)

Oct 2012- FDA Approval:
High Risks Patients (PARTNER A)

In Guidelines
Europe 2012: ESC / EACTS
USA 2014: AHA / ACC

F.I.M. Balloon Aortic Valvuloplasty

« Percutaneous Valve Technology » (prototypes)
Post-mortem studies of intra-valvular stenting

F.I.M. THV implantation

Feasibility Studies (antegrade)
Animal implantations (sheep)

Edwards Lifesciences TF & TA

Feasibility Studies

2004
2002
2002-03
2000
1999
1994
1985

A long translational pathway
25 Years from BAV
18 Years from concept
10 Years from FIM
TAVR: Where are we today?

An impressive growth of procedures

France: 3000 TAVR / Y
Germany: 6000 TAVR / Y

Marked disparity of penetration in European countries

Courtesy of Mike Weinstein: J.P. Morgan
In 2014, Indications of TAVR are frozen in the past
ESC Guidelines 2012 / US experts Consensus 2012

Decision confirmed by a «Heart Team»

Cardiac Surgery On-site

High Risk Non operable Frailty

Anatomic Suitability

Potential Benefit

TAVR

Low and Intermediate Risk Patients Are Not Candidates to TAVR

PARTNER US:

**TAVR**: New technology, 1st generation devices (Edwards SAPIEN)
Early experience of teams

**SAVR**: Most experienced cardiac surgeons
Well established treatment for 50 years
How might the future of TAVR be anticipated?

- **2014**: “TAVR is indicated in patients who cannot be considered for SAVR”

  «TAVR is the default strategy for most AS patients: SAVR is indicated in patients who cannot be considered for TAVR»

How far are we from the exit?
Elements required to expand the indications to lower risk patients

**Done**
- Improved devices and strategies making TAVR SAFER, simpler
- Cost-effective

**Pending**
- Evidence-based trials in lower risk patients
  - PARTNER II: SAPIEN XT
  - SURTAVI: CoreValve

**Assessment of Valve + Platform durability on longterm**
- 5 Years

- **Evidence-based trials** in lower risk patients
  - PARTNER II: SAPIEN XT
  - SURTAVI: CoreValve
Addressing the issue of complications remains the priority

<table>
<thead>
<tr>
<th>Severe Vascular (3-16%)</th>
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<tbody>
<tr>
<td>- Lower size devices</td>
</tr>
<tr>
<td>- Improved closure devices</td>
</tr>
<tr>
<td>- Other approaches (<em>trans-aortic</em>)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Paravalvular AR (5% &gt; grade 2)</th>
</tr>
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<tbody>
<tr>
<td>- Better valve sizing and positioning</td>
</tr>
<tr>
<td><em>New imaging technologies</em></td>
</tr>
<tr>
<td>- New models of prosthesis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stroke (2-7%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Detection of high risk patient</td>
</tr>
<tr>
<td>- Embolic protection devices</td>
</tr>
<tr>
<td>- Modified anticoagulation strategy</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>AV Block (PM) (Edwards 3-12%, CoreValve 16-35%)</th>
</tr>
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<tbody>
<tr>
<td>- Positioning issue: new valves and delivery systems</td>
</tr>
</tbody>
</table>
Advanced valves / delivery systems, new technologies and new strategies have changed the world of TAVR.

- **Edwards SAPIEN**
  - **2005**
  - Sheath size: 24F
  - Valve size: 23, 26mm

- **SAPIEN XT**
  - **2009**
  - Sheath size: 18-20F
  - Valve size: 23, 26, 29mm

- **SAPIEN 3**
  - **2012**
  - Sheath size: 14-18F
  - Valve size: 20, 23, 26, 29mm

- **CoreValve**
  - **2006**
  - Sheath size: 21F
  - Valve size: 26, 29mm

- **Evolut™**
  - **2012**
  - Sheath size: 14F
  - Valve size: 23mm
Over 12 years, considerable impact of TAVI on biomedical industry

Imaging technologies, protection devices, closing devices ....
New strategies for TF-TAVI (> 75% of cases)

2 strategies

- Local anesthesia
  - Conscious Sedation

- General Anesthesia

From « maximalist » to « minimalist » approaches

The unique strategy in Rouen since 2002

Complications
Assessment of results
In-Cath Lab minimalist TF-TAVI approach in Rouen
Room Setting: SAPIEN XT - SAPIEN 3

« Near by », aware of the procedure, ready to come:

Anesthetist
Echocardiographer
Cardiac surgeon

Conscious sedation, local anesthesia
No TEE, Preclosing with ProStar XL 10F
Duration of the procedure: 45 min
Discharge at Day 1 to 3

A team of 6 in Cath Lab

Conversion to G.A., Heart Surgery, Vascular surgical repair < 1%
Trend to treat lower risk patients in most recent series

AVR: 65%

Low / Intermediate risk

<table>
<thead>
<tr>
<th>Log EuroScore</th>
<th>2007-2009</th>
<th>2010-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>FRANCE</td>
<td>25.6%</td>
<td>21.9%</td>
</tr>
<tr>
<td>SOURCE</td>
<td>25.8%</td>
<td>20.5%</td>
</tr>
<tr>
<td>ADVANCE</td>
<td>23.0%</td>
<td>19.2%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STS</th>
<th>2009</th>
<th>2011-13</th>
<th>2013</th>
<th>2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARTNER 1</td>
<td>11.8%</td>
<td></td>
<td></td>
<td>US CoreValve Pivotal 7.4%</td>
</tr>
<tr>
<td>Post Market US</td>
<td>7.0%</td>
<td></td>
<td>CHOICE</td>
<td>6.0%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>US CoreValve Pivotal 7.4%</td>
</tr>
</tbody>
</table>
TAVR: Higher Survival in Lower Risk Patients

Lange et al, JACC 2012

4 Quartiles 2007-10
420 Pts

Global Mortality
Log ES

1 vs 4 \( p < 0.03 \)

25
19
18
17

Wenaweser et al. EHJ 2013 286 Pts 2007-2011

Global Mortality

STS
Low vs High
\( p < 0.001 \)
\( > 8 \)
\(< 3 \)

CV Mortality

STS
Low vs High
\( p < 0.001 \)
\(< 3 \)


Global Mortality

Log ES

Low vs High
\( p < 0.001 \)

CV Mortality

Log ES

\( p < 0.001 \)

Lower risk Pts
Patients with risk factors not captured in Log ES
TAVR and SAVR: Similar Survival in Propensity-Matched Score Analysis

784 patients (Bern, Munich, Rotterdam)

Piazza et Al, JACC Cardiovascular Int 2013
# TAVR and SAVR: Complications in Propensity Matched Score Analysis

**The OBSERVANT Study**

D’Errigo et al, Int J Cardiol 2013

<table>
<thead>
<tr>
<th></th>
<th>TAVR (n=133)</th>
<th>SAVR (n=133)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log EuroScore</td>
<td>8.9 + 9.5%</td>
<td>9.4 + 10.4%</td>
<td>NS</td>
</tr>
<tr>
<td>30-D Mortality</td>
<td>3.8%</td>
<td>3.8%</td>
<td>NS</td>
</tr>
<tr>
<td>Stroke</td>
<td>0%</td>
<td>1.5%</td>
<td>NS</td>
</tr>
<tr>
<td>AMI</td>
<td>0.8%</td>
<td>0.8%</td>
<td>NS</td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>36.1%</td>
<td>49.6%</td>
<td>&lt; 0.02</td>
</tr>
<tr>
<td>Maj Vasc Compl</td>
<td>5.3%</td>
<td>0%</td>
<td>&lt; 0.007</td>
</tr>
<tr>
<td>PVL</td>
<td>39.2%</td>
<td>10.3%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>PPM</td>
<td>12% (65% CV)</td>
<td>0.8%</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>
Most frequent complications (PVL, Vascular) almost gone with new generation devices

Edw Sapien 3
*External cuff*

DF medical
*Repositionable, retrievable*

BS Sadra SJ Portico

Edw Centera
*Self seating features*

Accurate

Jena Valve
*Native leaflets incorporated*

Engager
2014: Last Generation Devices
A crucial step towards the future

The SAPIEN 3 Trial
Early Experience (Learning Curve)

N= 150, Age: 83.6, TF & TA
High and Intermediate Risk

<table>
<thead>
<tr>
<th>TF results</th>
<th>N= 96</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-D Mortality: 1.1%</td>
<td></td>
</tr>
<tr>
<td>Stroke: 1.0%</td>
<td></td>
</tr>
<tr>
<td>PVL moderate: 2.6%</td>
<td></td>
</tr>
<tr>
<td>Vascular complic: 5.2%</td>
<td></td>
</tr>
<tr>
<td>PPM: 12%</td>
<td></td>
</tr>
<tr>
<td>Preclosing: 96% TF</td>
<td></td>
</tr>
</tbody>
</table>

J. Webb, PCR 2014

TF > 80%
« Minimalist approach » Increasingly accepted
Evidence-based comparison of SAVR vs TAVI in intermediate risk patients

Edwards PARTNER 2 Trial

- Operable (STS ≥4)
  - Yes: ASSESSMENT: Transfemoral Access
    - Transfemoral (TF)
      - 1:1 Randomization
        - TF TAVR SAPIEN XT VS Surgical AVR
  - No: Transapical (TA)
    - 1:1 Randomization
      - TAVR: TA / TAO VS Surgical AVR

Primary Endpoint: All-Cause Mortality + Major Stroke at Two Years (Non-inferiority)

CoreValve® SURTAVI Trial

- STS Score ≥4% and ≤10%
  - Heart Team Evaluation
    - Randomization
      - N = ~2,500 patients
        - CoreValve
          - TAVI
            - TAVI + PCI
            - TAVI only
        - SAVR
          - SAVR + CABG
          - SAVR only

Randomization

Operable (STS ≥4)

Evidence-based comparison of SAVR vs TAVI in intermediate risk patients

Edwards PARTNER 2 Trial

- Operable (STS ≥4)
  - Yes: ASSESSMENT: Transfemoral Access
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            - TAVI only
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          - SAVR + CABG
          - SAVR only

Randomization
Expansion of TAVR - New Indications: V-in-V

Global Valve-in Valve Registry
Dvir et al Circulation 2012

- Feasible but technically more demanding
- Perfect knowledge of the surgical bioprosthesis
- Procedural risks different from regular TAVR
- Good short and mid term results

<table>
<thead>
<tr>
<th></th>
<th>TOTAL (n=202)</th>
<th>Corevalve (n=124)</th>
<th>Edwards (n=78)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malposition</td>
<td>15,3%</td>
<td>16,9%</td>
<td>12,8%</td>
<td>NS</td>
</tr>
<tr>
<td>Coron Occlusion</td>
<td>3,5%</td>
<td>3,2%</td>
<td>3,8%</td>
<td>NS</td>
</tr>
<tr>
<td>Pacemaker</td>
<td>7,4%</td>
<td>8,9%</td>
<td>5,1%</td>
<td>NS</td>
</tr>
<tr>
<td>30-Day Mortality</td>
<td>8,4%</td>
<td>7,3%</td>
<td>10,3%</td>
<td>NS</td>
</tr>
<tr>
<td>Mean Gradient</td>
<td>15,9+/-8,6</td>
<td>13,9+/-7,5</td>
<td>19,2+/-9,2</td>
<td>&lt;0,0001</td>
</tr>
<tr>
<td>AR (&gt;2)</td>
<td>5%</td>
<td>6,5%</td>
<td>2,6%</td>
<td>NS</td>
</tr>
</tbody>
</table>
Expansion of TAVR - New Indications: AR

Very early experience

Two models of prosthesis with native valve incorporated

JenaValve

Helio Sapien
Degenerescence of the valve prothesis is not an issue in the elderly population

- A very few cases of valvular degenerescence reported so far
- No case in our 12 years of experience
Rouen, May 13th, 2012, 10th year FIM-TAVI Celebration
Nearly 600 attendees from 50 countries

83 y/o patient
8 years post – TAVR
Normal valve function
Normal life
Costs of device + procedure: the main limitation for a worldwide expansion of TAVI

Hopes for the future
- Amortized costs of R&D, increased number of TAVI
- Concurrent devices
- Cost effective procedures (less resources, short hospitalization)

$45,485 \pm 14,397$

$55,377 \pm 22,587$

V. Babaliaros
Emory Hospital,
Atlanta, USA
ACC 2014
Final thoughts

In 2014, the future is close

- Results of TAVR in lower risk patients are better and comparable in many aspects to SAVR.
- Current data with newest TAVR systems and minimalist strategies justify the use of TAVR in elderly low risk patients suitable for TF access (>80%). Patients and relatives should be fairly informed of the alternative treatments and associated to the heart team decision.
- The missing long term data on durability (10 years) is not a limitation for the elderly population (Valve-in-Valve).
- The upcoming evidence-based results on intermediate risk patients will have enormous consequences on the future of TAVR.
In 2014, TAVI is now recognized a medical breakthrough

- A disruptive technology which can be largely applied
- Addressing an important unmet clinical need for a common disease
- A benefit demonstrated by rigorous evidence-based evaluation
- Durable impact on the pattern of medical practice

TAVR has saved the life and improved thousands of patients who otherwise would have been left untreated with a catastrophic outcome
FROM BAV TO TAVR
A Long Bumpy Road

Feelings
- Cardiologists
- Surgeons

- Enthusiasm
- Satisfaction
- Depression

BAV
Restenosis
Concept of TAVR (Autopsy)
No sponsor TAVR program rejected

TAVR
FIM
Prototypes (Animals)
Transseptal series
Feasibility series

Edwards
CoreValve
TF, TA, SC

New THVs
FDA
TAVR expansion
PARTNER US
Postmarket studies
My dream TAVI team in Rouen

Pr J.P. Bessou
Cardiac Surgeon

Pr Helene Eltchaninoff
Interventional Cardiologist

Have you seen that in many places?
Thank You very much!

12 YEARS!

Transcatheter Aortic Valve Implantation