The Future of TAVR: Minimalist Fast Track

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Disclosures

- On the speaker’s bureau for: Endologix, Lombard Medical, TriVascular, Edwards
- Training courses for: W.L. Gore, Endologix, Volcano, TriVascular, Lombard Medical
**Prevailing TAVR Trends in the US**

- Hospital admission
- Primarily performed in the OR (3-6x higher cost than interventional room!)
- Done under **GA**, rather then local!
- TEE
- CVL, Foley catheter, NG tube, radial line, Pump team
- FA cutdown and surgical FA repair
- RR or ICU stay 24 hrs. (3x >cost than a step-down unit!)
- LOS >48 hrs

All of these measures increase the cost, morbidity and unnecessary expenditure of health care resources
We Have to Face the Reality!

- TAVR is maturing technology (13 yrs old)
- The incidence of vascular complications has decreased from 16% (22-24Fr) to 5% (14&16Fr)
- All other complications are rapidly declining (PVL, ruptures, CHB, CVA)
- EU operators have shown that TAVR can be safely done with current technology, conscious sedation and percutaneous approach
We Have to Face the Reality!

- TAVR devices cost $33,000-35,000
- TAVR will be targeted and scrutinized more than any other procedures, because of costly devices and high hospital expenditures!
How to reduce morbidity and the cost of TAVR while preserving good clinical outcome?

**Minimalist Approach**

*Percutaneous Femoral Artery Access and Repair, Local Anesthesia and Conscious Sedation*
Goals of Least Invasive TAVR Approach

- Avoid the risk of Surgery
- Avoid the risks of GA
- Shorten the hospital stay
- Reduce the cost
How to Reduce the COST of EVAR

- Performing **TAVR** in interventional room rather than in more expensive OR
- Reducing cost of post procedural care by admitting patients to CCU or an interventional floor rather than to more expensive CVRR
- Greater application of **MAC** and **PTVAR** rather than GA and surgical FA repair.
Where is the evidence?
First Successful Percutaneous AAA Repair With Local Anesthesia

Closure of Large Percutaneous Access Sites Using the Prostar XL Percutaneous Vascular Surgery Device

P. Clay Haas, DO; Zvonimir Krajcer, MD; and Edward B. Diethrich, MD*
Department of Cardiology, Texas Heart Institute and St. Luke’s Episcopal Hospital, Houston, Texas; and the *Arizona Heart Institute and Arizona Heart Institute Hospital, Phoenix, Arizona, USA

Purpose: To report early experience using a vascular closure device following endovascular aortic aneurysmal repair in which large-bore sheaths are used.

Technique: A 10F Prostar XL Percutaneous Vascular Surgery device is used to deploy sutures around sheath entry sites up to 16F. At the completion of the procedure, the sutures are tied with a sliding knot to ensure adequate hemostasis.

Conclusions: Maintaining the minimal invasiveness of the percutaneous approach to aortic endografting reduces patient discomfort and permits earlier ambulation and hospital discharge. Initial success seems to be maintained at 1 month, however, longer follow-up will be required.

J Endovasc Surg 1999;6:168-170

Key words: vascular closure devices, endovascular grafting, abdominal aortic aneurysms, technique

Prospective nonrandomized study of pts. who participated in PARTNER trial including:

- **Group I**: MAC (70 pts)
- **Group II**: GA (22 pts)
- FA perc. or cut-down
- **FA sheath**: 22F or 24F
- Pre-close: 1 Prostar XL or 2 ProGlides
- No difference between 2 groups in baseline characteristic, except MAC group has higher EuroSCORE (40.1±19.3 vs. 28.1±15.7, p=0.01) and more prior strokes (21 (30%) vs. 2 (9%), p=0.04)
Median Procedural Duration in Patients with MAC vs. General Anesthesia

P = .008

Minutes

MAC (N=70) 91

GA (N=22) 155
ICU Stay in Patients with MAC Vs. General Anesthesia

P = .07

MAC (N=70) 27 hours
GA (N=22) 72 hours
### Procedural Data and In-Hospital Outcome of Patients with Monitored Anesthesia Care Vs. General Anesthesia

<table>
<thead>
<tr>
<th>Variable</th>
<th>MAC (n=70)</th>
<th>GA (n=22)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perc. FA access</td>
<td>46 (66%)</td>
<td>7 (32%)</td>
<td>0.005</td>
</tr>
<tr>
<td>Mean decrease in Hgb</td>
<td>2.4±1.5</td>
<td>2.9±1.8</td>
<td>0.2</td>
</tr>
<tr>
<td>Mean increase in creatinine</td>
<td>0.18±0.49</td>
<td>0.59±0.6</td>
<td>0.004</td>
</tr>
<tr>
<td>Mean Increase in CKMB</td>
<td>5.6±8.7</td>
<td>6.8±6.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Hospital death</td>
<td>3 (4.2%)</td>
<td>4 (18.1%)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

**Conversion rate from MAC to GA was 10%, all elective**
COMPARISON OF A MINIMALIST APPROACH TRANSFEMORAL TAVR WITH STANDARD APPROACH TRANSFEMORAL TAVR IN A US CENTER

Vasilis C. Babaliaros; Chandan Devireddy; Stamatios Lerakis; Robert Leonardi; Sebastian Iturra; Kreton Mavromatis; Bradley Leshnower; Robert Guyton; Mihir Kanitkar; Patricia Keegan; Amy Simone; James Stewart; Iman Aziz; Nima Ghasemzadeh; Peter Block; Vinod Thourani

[+] Author Information

J Am Coll Cardiol. 2014;63(12_S):. doi:10.1016/S0735-1097(14)61718-6
Study Design

- All cases of elective TF TAVR, Percutaneous access and Edwards SAPIEN (22&24 Fr) were included
- Standard approach included Hybrid room and GA with surgical FA access and repair
- Minimalist approach with percutaneous approach, local anesthesia and conscious sedation in the cardiac catlab
- All variables defined with VARC-2
- Additional variables: ICU utilization, LOS & cost

Thourani, ACC 2014
## Procedural Details

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Minimalist Approach N=70</th>
<th>Standard Approach N=72</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Success</td>
<td>70 (100)</td>
<td>69 (96)</td>
<td>0.24</td>
</tr>
<tr>
<td>Proc. Mortality</td>
<td>0</td>
<td>3 (4)</td>
<td>0.24</td>
</tr>
<tr>
<td>2\textsuperscript{nd} Valve implanted</td>
<td>4 (6)</td>
<td>2 (3)</td>
<td>0.43</td>
</tr>
<tr>
<td>Postdilatation</td>
<td>27 (39)</td>
<td>16 (22)</td>
<td>0.06</td>
</tr>
<tr>
<td>Coronary obstruction</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
</tbody>
</table>
## Procedural Details

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Minimalist Approach N=70</th>
<th>Standard Approach N=72</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intubation</td>
<td>1 (1%)</td>
<td>72 (100%)</td>
<td>0.001</td>
</tr>
<tr>
<td>IABP</td>
<td>1 (1%)</td>
<td>2 (3%)</td>
<td>0.57</td>
</tr>
<tr>
<td>Conversion to SAVR</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>X ray time</td>
<td>29±10</td>
<td>32±11</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure time</td>
<td>93±32</td>
<td>125±46</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
## Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Minimalist Approach N=70</th>
<th>Standard Approach N=72</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU care</td>
<td>53 (75)</td>
<td>69 (100)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ICU time hrs</td>
<td>22 (2-8)</td>
<td>28 (23-48)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Procedure to discharge-days</td>
<td>3 (2-4)</td>
<td>5 (3-6.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospital Stay-days</td>
<td>4 (3-7)</td>
<td>6 (4-9)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Babaliaros....Thourani, ACC

Texas Heart Institute™
<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Minimalist Approach N=70</th>
<th>Standard Approach N=72</th>
<th>( P ) value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In-hospital Mortality</strong></td>
<td>0 (0)</td>
<td>3 (4.2)</td>
<td>0.24</td>
</tr>
<tr>
<td><strong>30 day Mortality</strong></td>
<td>0 (0)</td>
<td>4 (6)</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>30 day Stroke or TIA</strong></td>
<td>3 (2-4)</td>
<td>5 (3-6.5)</td>
<td>0.35</td>
</tr>
<tr>
<td><strong>Vascular complications</strong></td>
<td>3 (4)</td>
<td>8 (11)</td>
<td>0.30</td>
</tr>
<tr>
<td><strong>New LBBB</strong></td>
<td>4 (6)</td>
<td>5 (7)</td>
<td>0.71</td>
</tr>
<tr>
<td><strong>Vascular Surgery</strong></td>
<td>0 (0)</td>
<td>3 (4.2)</td>
<td>0.24</td>
</tr>
<tr>
<td><strong>Pacemaker</strong></td>
<td>2 (3)</td>
<td>4 (6)</td>
<td>0.44</td>
</tr>
</tbody>
</table>
TAVR Economics Will See Continued Improvement with Minimalist Approaches

Minimalist Experience at Emory University Hospital

<table>
<thead>
<tr>
<th>Standard Approach</th>
<th>Minimalist Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>► Hybrid operating room</td>
<td>► Cardiac catheterization lab</td>
</tr>
<tr>
<td>► General anesthesia</td>
<td>► Local anesthesia</td>
</tr>
<tr>
<td>► Intubation</td>
<td>► Minimal conscious sedation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>218 Minutes</th>
<th>Procedure Room Time</th>
<th>150 Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 Hours</td>
<td>Intensive Care Unit Time</td>
<td>22 Hours</td>
</tr>
<tr>
<td>5 Days</td>
<td>Length Of Stay</td>
<td>3 Days</td>
</tr>
<tr>
<td>$55.3K</td>
<td>Hospital Costs</td>
<td>$45.5K</td>
</tr>
</tbody>
</table>

Babaliaros, V et al. “Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) vs. Hybrid Operating Room (Standard Approach)”. JACC 2014.
Feasibility and Safety of Early Discharge After Transfemoral Transcatheter Aortic Valve Implantation With the Edwards SAPIEN-XT Prosthesis

Eric Durand, MD, PhD\textsuperscript{a,}\textsuperscript{*}, Hélène Eltchaninoff, MD\textsuperscript{a}, Alexandre Canville, MD\textsuperscript{a}, Najime Bouhzam, MD\textsuperscript{a}, Matthieu Godin, MD\textsuperscript{a}, Christophe Tron, MD\textsuperscript{a}, Carlos Rodriguez, MD\textsuperscript{a}, Pierre-Yves Litzler, MD\textsuperscript{b}, Fabrice Bauer, MD, PhD\textsuperscript{a}, and Alain Cribier, MD\textsuperscript{a}

There is currently no consensus on the duration of hospitalization required after transfemoral transcatheter aortic valve implantation (TAVI). We report the feasibility and safety of early discharge after TAVI with the Edwards SAPIEN-XT prosthesis. From 2009 to 2013, 337 patients underwent transfemoral TAVI with the Edwards SAPIEN-XT prosthesis using local anesthesia and were discharged home either early (≤3 days, Early Discharge group, n = 121) or after 3 days (Late Discharge group, n = 216). The primary end point of the study combined death and rehospitalization from discharge to 30-day follow-up. Patients in the Early Discharge group were less symptomatic (New York Heart Association class ≥III: 64.5% vs 75.5%, p = 0.01) and had less renal failure (creatinine: 102.1 ± 41.0 vs 113.3 ± 58.9 μmol/L, p = 0.04), atrial fibrillation (33.1% vs 46.3%, p = 0.02), and previous balloon aortic valvuloplasty (11.6% vs 23.1%, p = 0.01) and were more likely to have a pacemaker before TAVI (16.5% vs 8.3%, p = 0.02). Pre-existing pacemaker (p = 0.05) and the absence of acute kidney injury (p = 0.02) were independent predictors of an early discharge, whereas previous balloon aortic valvuloplasty (p = 0.03) and post-TAVI blood transfusions (p = 0.002) were independent predictors of late discharge. The primary end point occurred in 4 patients (3.3%) in the Early Discharge group and in 11 patients (5.1%) in the Late Discharge group (p = 0.58). In conclusion, the results of our study suggest that early discharge after transfemoral TAVI using the Edwards SAPIEN-XT prosthesis is feasible and safe in selected patients. © 2015 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/). (Am J Cardiol 2015;115:1116–1122)
Key Milestones Before Starting a Least Invasive TAVR

- **Expertise in percutaneous approach and the use of SMCD**

- **Extensive TAVR experience by the TAVR TEAM (> 300 cases)**

- **More sophisticated understanding of TAVR sizing**

- **Transition from TEE to TTE**

- **Increased experience of Cathlab staff**
Indications and Contraindications for Least Invasive TAVR

- Eligibility confirmed by the Heart Team

- Suboptimal Vascular Access
- Morbid Obesity
- Low coronary arteries
- Barriers to emergent intubation
- Chronic pain
- Inappropriate mental status

General anesthesia, TEE, Case done in hybrid OR, ICU admission post TAVR

- Yes

Conscious sedation or MAC, TTE, Case done in hybrid OR or cath lab, ICU vs Floor admission post TAVR & next day discharge

- NO
Least Invasive TAVR Protocol

Screening
Plan for success
- Suitable for TAVR with Edwards Sapien 3 Valve system
- Suitable for Pre-Close
- Suitable for local anesthesia & conscious sedation or MAC
- No anatomic contraindications
- No comorbidities requiring extended hospitalization

During Procedure
Minimize complications
- Same day admission
- Procedure performed in Hybrid OR or Cathlab
- TF TAVR
- Percutaneous access
- Local/regional anesthesia
- Conscious sedation or MAC
- No Foley, no NG tube, no radial line, no central line
- No beta blocker 12 hrs before
- Plavix load

Post Procedure
Minimize hospital stay & reduce expense
- No ICU if not required
- Early ambulation & diet
- PT/OT/SS
- Next day discharge
Conclusions

• Minimalist TAVR can be performed safely and effective
• Minimal mortality and morbidity
• ICU can be eliminated
• Overall LOS should be reduced
• Significant cost saving can be anticipated
• Should only be performed by experienced TAVR team