Aortic Stenosis

- **Etiology**
  - Congenital (bicuspid, unicuspid)
  - Rheumatic (mixed AS/AR)
  - Calcific/Degenerative (risk factors – age, male, current smoking, HTN, high LDL and Lp(a), renal insufficiency, hypercalcemia)

AS is present in ~25% of adults over 65 years of age
Aortic Stenosis

• Classification of Severity

– **Mild** (area 1.5 cm\(^2\), mean gradient <25 mmHg, jet velocity <3.0 m/sec)
– **Moderate** (area 1.0-1.5 cm\(^2\), mean gradient 25-40 mmHg, jet velocity 3.0-4.0 m/sec)
– **Severe** (area <1.0 cm\(^2\), mean gradient >40 mmHg, jet velocity >4.0 m/sec)

NOTE: Do not rely on single number; Account for BSA; Symptoms predominate

~1/3 of patients with severe symptomatic aortic stenosis do not undergo AVR

Poor Prognosis

5 year survival of breast cancer, lung cancer, prostate cancer, ovarian cancer and severe inoperable aortic stenosis
The Edwards SAPIEN transcatheter heart valve is offered in two sizes, 23 mm and 26 mm, and accommodates an annular size range of 18 mm to 25 mm.
PARTNER Study Design

Symptomatic Severe Aortic Stenosis

**ASSESSMENT:** High-Risk AVR Candidate
3,105 Total Patients Screened

<table>
<thead>
<tr>
<th>N = 699</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inoperable</td>
<td>N = 358</td>
</tr>
</tbody>
</table>

2 Parallel Trials: Individually Powered

**Primary Endpoint:** All-Cause Mortality at 1 Year

HR [95% CI] = 0.93 [0.71, 1.22]

P (log rank) = 0.62

Leon et al, NEJM 2010; 363:1597-1607

Inoperable PARTNER Cohort
Primary Endpoint: All-Cause Mortality

HR [95% CI] = 0.54 [0.38, 0.78]

P (log rank) < 0.0001

Leon et al, NEJM 2010; 363:1597-1607
### Neurological Events at 30 Days and 1 Year

**All Patients (N=699)**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>30 Days</th>
<th>1 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TAVR (N = 348)</td>
<td>AVR (N = 351)</td>
</tr>
<tr>
<td>All Stroke or TIA – no. (%)</td>
<td>19 (5.5)</td>
<td>8 (2.4)</td>
</tr>
<tr>
<td>TIA – no. (%)</td>
<td>3 (0.9)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>All Stroke – no. (%)</td>
<td>16 (4.6)</td>
<td>8 (2.4)</td>
</tr>
<tr>
<td>Major Stroke – no. (%)</td>
<td>13 (3.8)</td>
<td>7 (2.0)</td>
</tr>
<tr>
<td>Minor Stroke – no. (%)</td>
<td>3 (0.9)</td>
<td>1 (0.3)</td>
</tr>
<tr>
<td>Death/maj stroke – no. (%)</td>
<td>24 (6.9)</td>
<td>28 (8.2)</td>
</tr>
</tbody>
</table>

### Major Vascular Complications

**AT Population**

![Bar chart showing major vascular complications]( Courtesy of Sandeep Nathan, MD)

### Major Bleeding

**AT Population**

![Bar chart showing major bleeding]( Courtesy of Sandeep Nathan, MD)

*Major bleeding is defined as any episode of major internal or external bleeding that caused death, hospitalization, or permanent injury, e.g., visceral or retroperitoneal bleeding of greater than 3 units RBCs within a 30-day period, pericardial effusion, open wounds, or vascular procedure for repair or reintervention.*

**TAVR Vascular Complications**

![Pie chart showing TAVR vascular complications]( Courtesy of Sandeep Nathan, MD)

*JACC 2012; 1043-1052*
Assessing Appropriate Vascular Access

- Vessel diameters must be a minimum of:
  - ≥ 7 mm for a 23 mm valve (requires a 22F RetroFlex 3 sheath)
  - ≥ 8 mm for a 26 mm valve (requires a 24F RetroFlex 3 sheath)

JACC 2012; 1043-1052

TAVR: Present & future

- Edwards Sapien THV (1st generation) 22/24 Fr with RetroFlex 3 delivery system
- Edwards Sapien XT (2nd generation) 18/19 Fr with NovoFlex delivery system
- Medtronic CoreValve
  - Transfemoral or subclavian delivery
  - Repositionable, self-expanding system
  - Perhaps greater need for pacing afterwards
- Medtronic CoreValve™
- Boston Scientific Lotus self-exp valve (Sadra Lotus)
- JenaValve
- St. Jude Medical Portico valve

- Medtronic Engager TA valve (Ventor Embracer)

TAVR Vascular Complications

<table>
<thead>
<tr>
<th>Time in Months Since Procedure</th>
<th>No Major VC</th>
<th>No Major VC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>355</td>
<td>37</td>
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<tr>
<td>1</td>
<td>318</td>
<td>261</td>
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<tr>
<td>3</td>
<td>291</td>
<td>273</td>
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<td></td>
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</tr>
<tr>
<td>12</td>
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</tbody>
</table>

Number at risk

Major VC: 04

Log-Rank p = 0.067

Death (%)
91 year old with severe AS requiring a 26 mm Edwards valve (TAVR)
Requires a 24F RetroFlex 3 sheath
Right groin access

Up and around angio of the left side and advancement of pigtail to the left common femoral artery for optimal TAVR access
→ Preclose with 3 Perclose Devices

Advanced a 300 cm Steel Core wire to the left SFA via a crossover sheath

Successful TAVR with 26 mm valve under rapid pacing of 180 beats/min to induce cardiac standstill
Advanced a 10mm x 4cm Charger balloon to the left external iliac over the Steel Core wire and Perclosed the 3 Preclose devices. Then Inflated the balloon to 1 atm for 5 mins at the femoral head.

Future of TAVR – it’s very bright!

1. Lower profile devices
2. Repositionable devices
3. Retrievable devices
4. Paravalvular leak
5. Delivery system options
6. Eliminate need for pacing
7. Embolic protection

Question 1: Is TAVR FDA approved for use in Bicuspid Aortic Valve Stenosis?

1. Yes
2. No

Impact of Total AR on Mortality (AT)
TAVR Patients
Question 2: Is TAVR FDA approved for use as treatment for Aortic Valve Regurgitation?

1. Yes
2. No

Thank You