# Comparison of the Hemodynamic Performance and Midterm Outcome of **Percutaneous versus Surgical** Stentless Bioprostheses for Aortic Stenosis with **Anticipated Patient Prosthesis Mismatch**

Schwartz Lorin MD[1], Finkelstein Arik MD[1], Banai Shmuel MD[1] , Keren Gadi MD[1], Kramer Amir MD[2], Uretzky Gideon MD[2] , Topilsky Yan, MD[1]

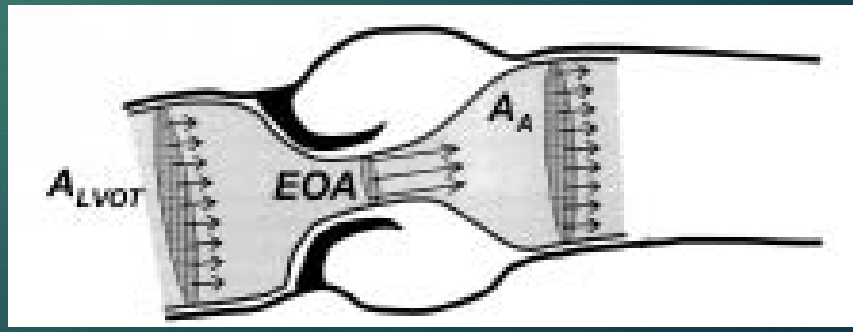
[1]Division of Cardiovascular Diseases Tel Aviv Medical Center
[2]Division of Cardiovascular Surgery, Tel Aviv Medical Center

# Disclosure

- None

# introduction

- Patient prosthetic mismatch (PPM)
  - Effective Orifice Area (EOA) of the implanted prosthesis is too small to body size area
  - Results in:
    - High post transplant gradient
    - Less regression of LVH
    - More cardiac events
    - Higher mortality



# Identification of PPM

- **Indexed EOA** = in vivo EOA/BSA ($cm^2/m^2$)
  - iOEA **< 0.85** $cm^2/m^2$ => **moderate** PPM
  - iOEA **< 0.65** $cm^2/m^2$ => **severe** PPM

- **Expected PPM -**
  - Step 1 – <u>the minimal acceptable EOA</u>

    Multiply known BSA by 0.85

    Player 1: 1.5 x0.85 = 1.275

    Player 2: 2.15 x0.85 = 1.82

| Patient no. | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| BSA(m2) | 1.5 | 1.75 | 2 | 2.25 | 2.5 |
| cardiac output (l/min) | 4.5 | 5.25 | 6 | 6.75 | 7.5 |
| Valve EOA (cm2) | 1.3 | 1.3 | 1.3 | 1.3 | 1.3 |
| Mean pressure gradient | 13 | 17 | 22 | 28 | 35 |

| <u>Player 1</u> | <u>Player 2</u> |
|---|---|
| H 1.6m | H 2.0m |
| W 50 kg | W 80 kg |
| BSA 1.5 $m^2$ | BSA 2.15 $m^2$ |

- **Expected PPM -**

  Step 2 –

  Compare mEOA to normal table references based on LVOT measurement (projected EOA)

  **<u>Expected PPM</u>** =>

  **Minimal EOA > Projected EOA**

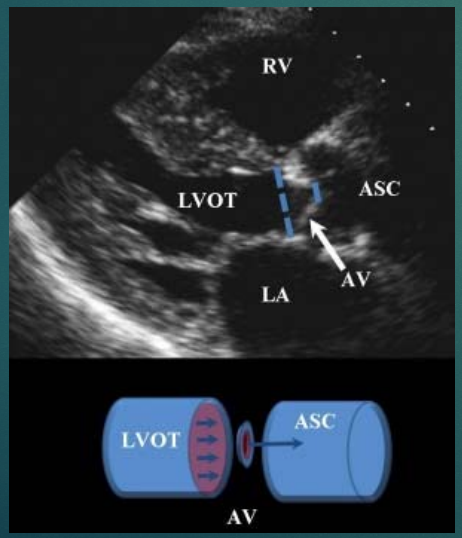
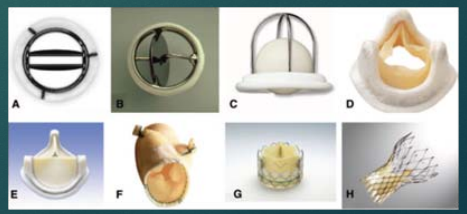



**Table 1. Normal Reference Values of EOAs for the Aortic Prostheses**

| | Prosthetic Valve Size, mm | | | | | | |
|---|---|---|---|---|---|---|---|
| | 19 | 21 | 23 | 25 | 27 | 29 | Reference |
| Aortic stented bioprosthesis | | | | | | | |
| Mosaic | 1.1±0.2 | 1.2±0.3 | 1.4±0.3 | 1.7±0.4 | 1.8±0.4 | 2.0±0.4 | 10 |
| Hancock II | . . . | 1.2±0.1 | 1.3±0.2 | 1.5±0.2 | 1.6±0.2 | 1.6±0.2 | 10 |
| Carpentier-Edwards Perimount | 1.1±0.3 | 1.3±0.4 | 1.50±0.4 | 1.80±0.4 | 2.1±0.4 | 2.2±0.4 | 10 |
| Carpentier-Edwards Magna* | 1.3±0.3 | 1.7±0.3 | 2.1±0.4 | 2.3±0.5 | . . . | . . . | 11, 20 |
| Biocor (Epic)* | . . . | 1.3±0.3 | 1.6±0.3 | 1.8±0.4 | . . . | . . . | 12 |
| Mitroflow* | 1.1±0.1 | 1.3±0.1 | 1.5±0.2 | 1.8±0.2 | . . . | . . . | 13 |
| Aortic stentless bioprosthesis | | | | | | | |
| Medtronic Freestyle | 1.2±0.2 | 1.4±0.2 | 1.5±0.3 | 2.0±0.4 | 2.3±0.5 | . . . | 10 |
| St Jude Medical Toronto SPV | . . . | 1.3±0.3 | 1.5±0.5 | 1.7±0.8 | 2.1±0.7 | 2.7±1.0 | 10 |
| Aortic mechanical prostheses | | | | | | | 10 |
| Medtronic-Hall | 1.2±0.2 | 1.3±0.2 | . . . | . . . | . . . | . . . | 10 |
| Medtronic Advantage* | . . . | 1.7±0.2 | 2.2±0.3 | 2.8±0.6 | 3.3±0.7 | 3.9±0.7 | 14 |
| St Jude Medical Standard | 1.0±0.2 | 1.4±0.2 | 1.5±0.5 | 2.1±0.4 | 2.7±0.6 | 3.2±0.3 | 10 |
| St Jude Medical Regent | 1.6±0.4 | 2.0±0.7 | 2.2±0.9 | 2.5±0.9 | 3.6±1.3 | 4.4±0.6 | 27 |
| MCRI On-X | 1.5±0.2 | 1.7±0.4 | 2.0±0.6 | 2.4±0.8 | 3.2±0.6 | 3.2±0.6 | 27 |
| Carbomedics Standard | 1.0±0.4 | 1.5±0.3 | 1.7±0.3 | 2.0±0.4 | 2.5±0.4 | 2.6±0.4 | 10 |

EOA is expressed as mean values available in the literature.
*These results are based on a limited number of patients and thus should be interpreted with caution.



# Avoidance of PPM

- Alternate complex procedures
  - Aortic root enlargement
  - Prosthetic model with superior hemodynamic performance
    - Stentless vs. stented AVR
  - TAVI

# Introduction – aim of study

- Examine and compare
  - Hemodynamics
  - Early and mid term outcomes
- In patients with expected PPM that were treated by stentless AVR or TAVI

# Methods

- Inclusion:
  - At least expected moderate PPM
- Exclusion:
  - Bicuspid valve

# Methods

- Retrospective
- Tel – Aviv medical center

- January 2009 – December 2011
  - 200 TAVI - 86 with at least expected moderate PPM
  - 49 stentless freestyle medtronics patient similar in charchteristics to the TAVI cohort

- Echocardiography – baseline, pre-discharge and 3 months post-implantaion.
- Operative risk assessment – EuroScore and Charlson Score.

| Variables | TAVI(total 86) | AVR(total 49) | P value |
|---|---|---|---|
| BSA | 1.81±0.18 | 1.86±0.20 | 0.2 |
| Age | 82.4±5.05 | 73.0±7.77 | <0.001 |
| Gender (male) | 28(32%) | 16(32%) | 0.9 |
| **Echocardiographic parameters** | | | |
| EF% | 56.8±6.5 | 55.0±7.9 | 0.2 |
| LVOT | 1.95±0.11 | 1.94±0.13 | 0.7 |
| Peak pressure trans-aortic gradient | 78.8±21.3 | 75.5±31.6 | 0.5 |
| Mean pressure trans-aortic gradient | 47.9±13.7 | 43.1±19.2 | 0.2 |
| AVA ($cm^2$) | 0.64±0.15 | 0.71±0.17 | 0.2 |
| **Aortic Regurgutation** | | | |
| · 0 | 34(39%) | 22(45%) | |
| · Mild | 49(57%) | 22(45%) | 0.05 |
| · Moderate | 3(4%) | 3(6%) | |
| · Severe | 0 (0%) | 2(4%) | |
| NYHA class | III (75%); IV (25%) | II (8%)<br>III (65%): IV (27%) | 0.01 |
| Atrial fibrillation | 15(17%) | 8(16%) | 0.9 |
| Prior CABG | 14(16%) | 3(6%) | 0.09 |
| **Logistic EuroScore II** | 6.831 | 4.54 | 0.004 |
| **Charlson's score** | 6.4±1.4 | 5.5±1.4 | 0.001 |

# TAVI vs. SAVR

- TAVI cohort compared to SAVR
  - Older patients
  - more symptomatic
  - smaller end diastolic, end systolic diameters and LV mass
  - higher logistic Euro-score II and Charlson co-morbidity scores

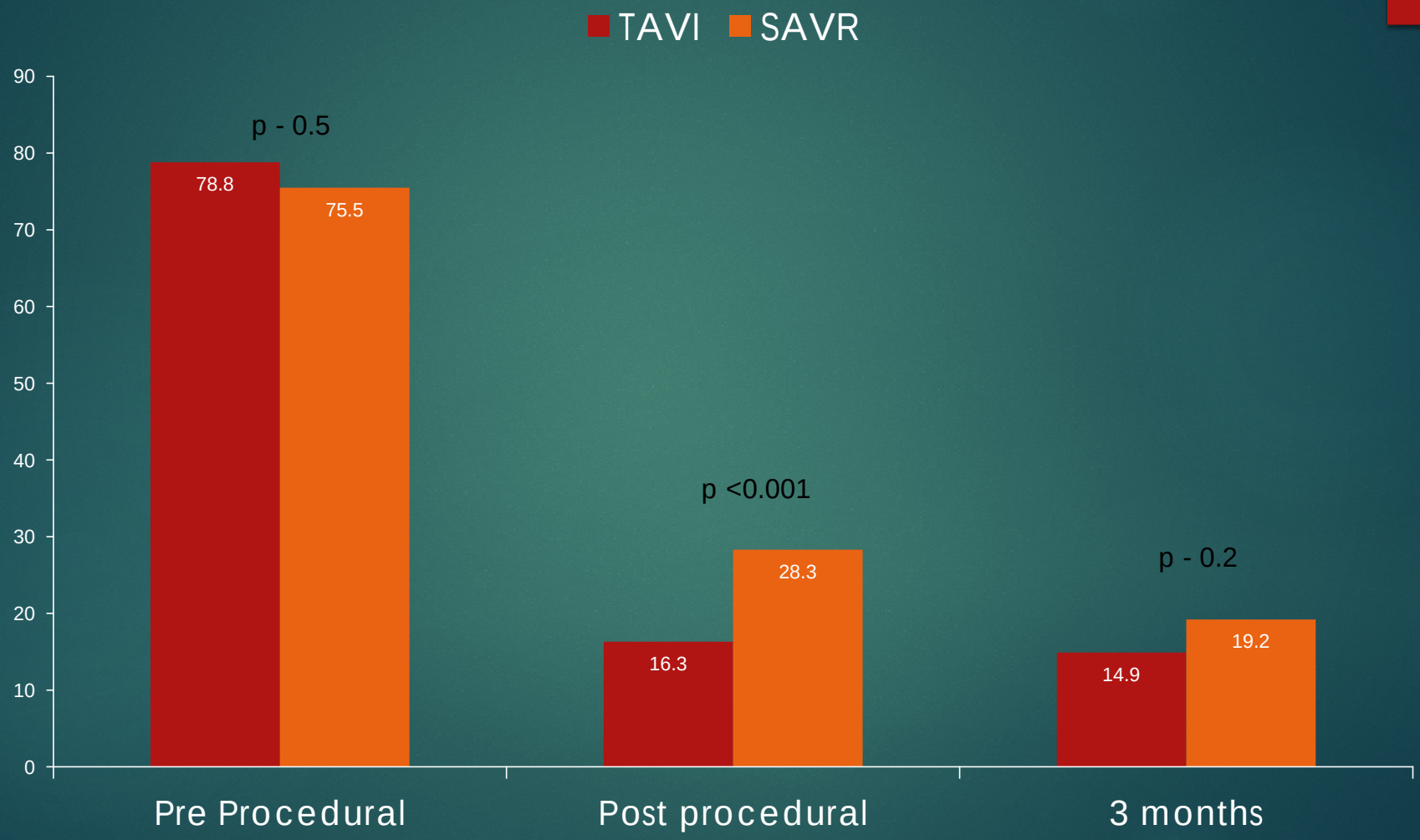
- As expected TAVI patients were older and sicker.

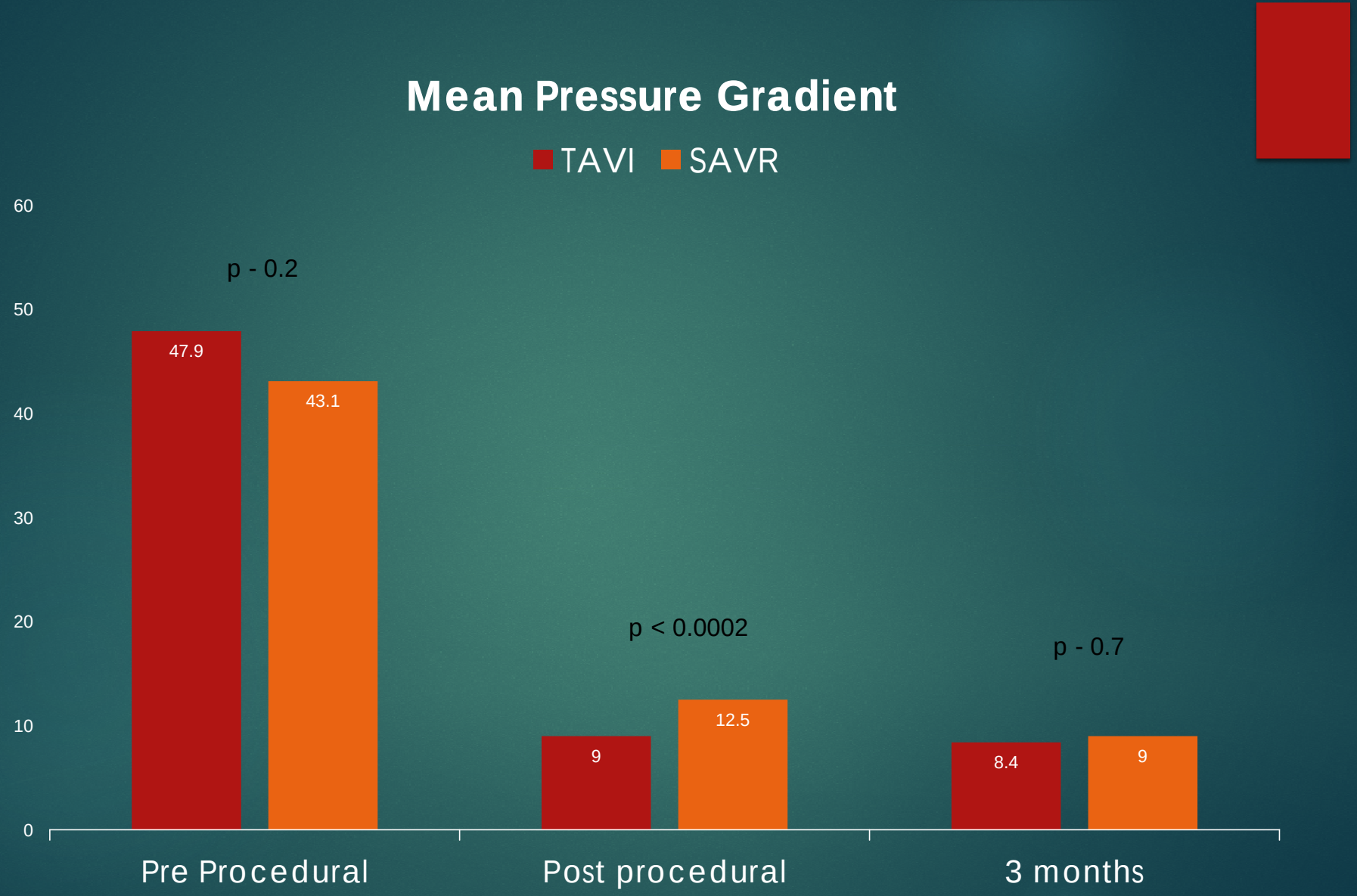
# Operative Outcomes and Operative Mortality

- TAVI
  - CoreValve
  - 47 patients (55%) had concomitant PCI
- SAVR
  - 3 patients (6%) - intervention on thoracic Aorta
  - 23 patients (47%) had concomitant CABG

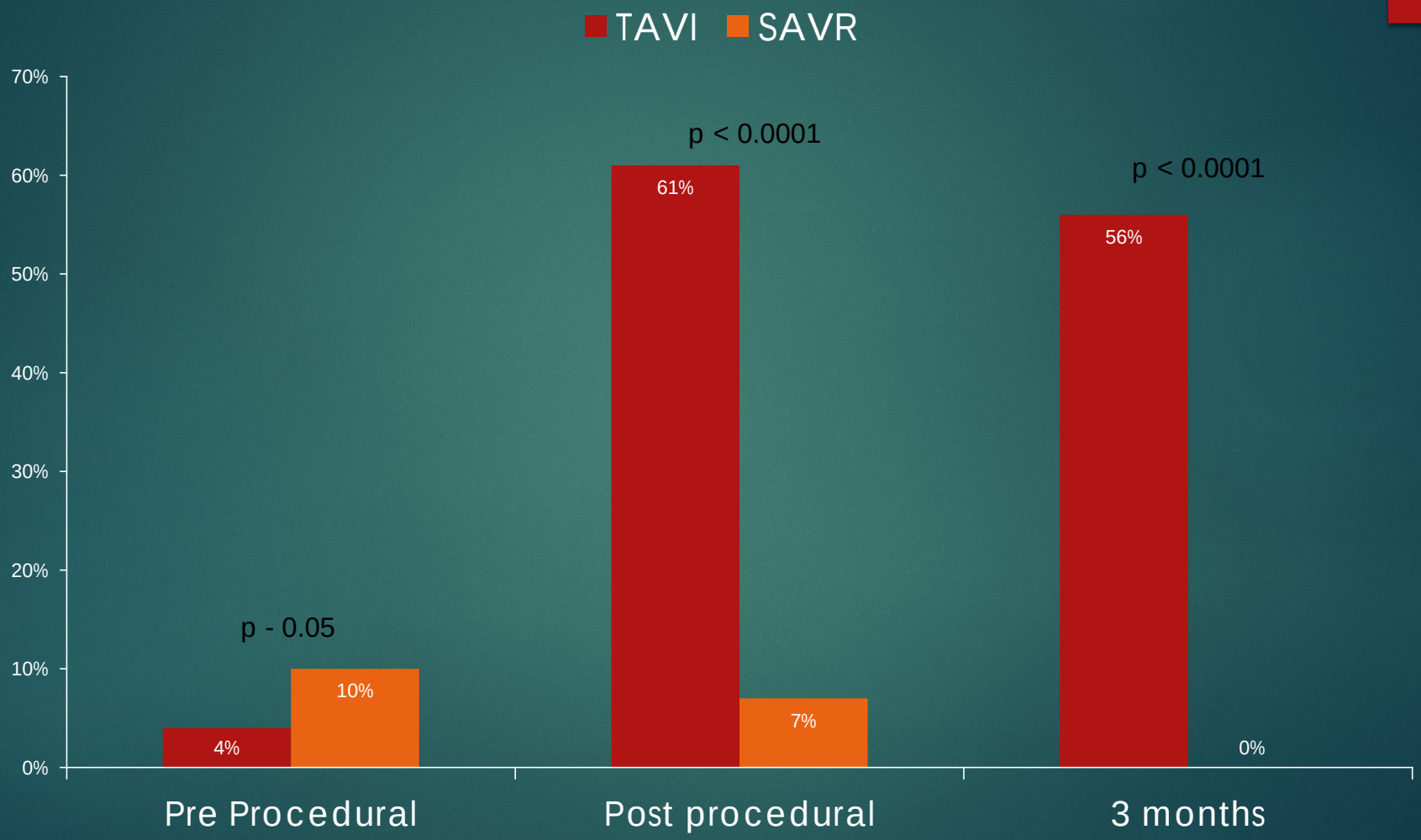
- Both groups had the same length of stay in hospital – average of 7 days

# Peak Pressure Gradient

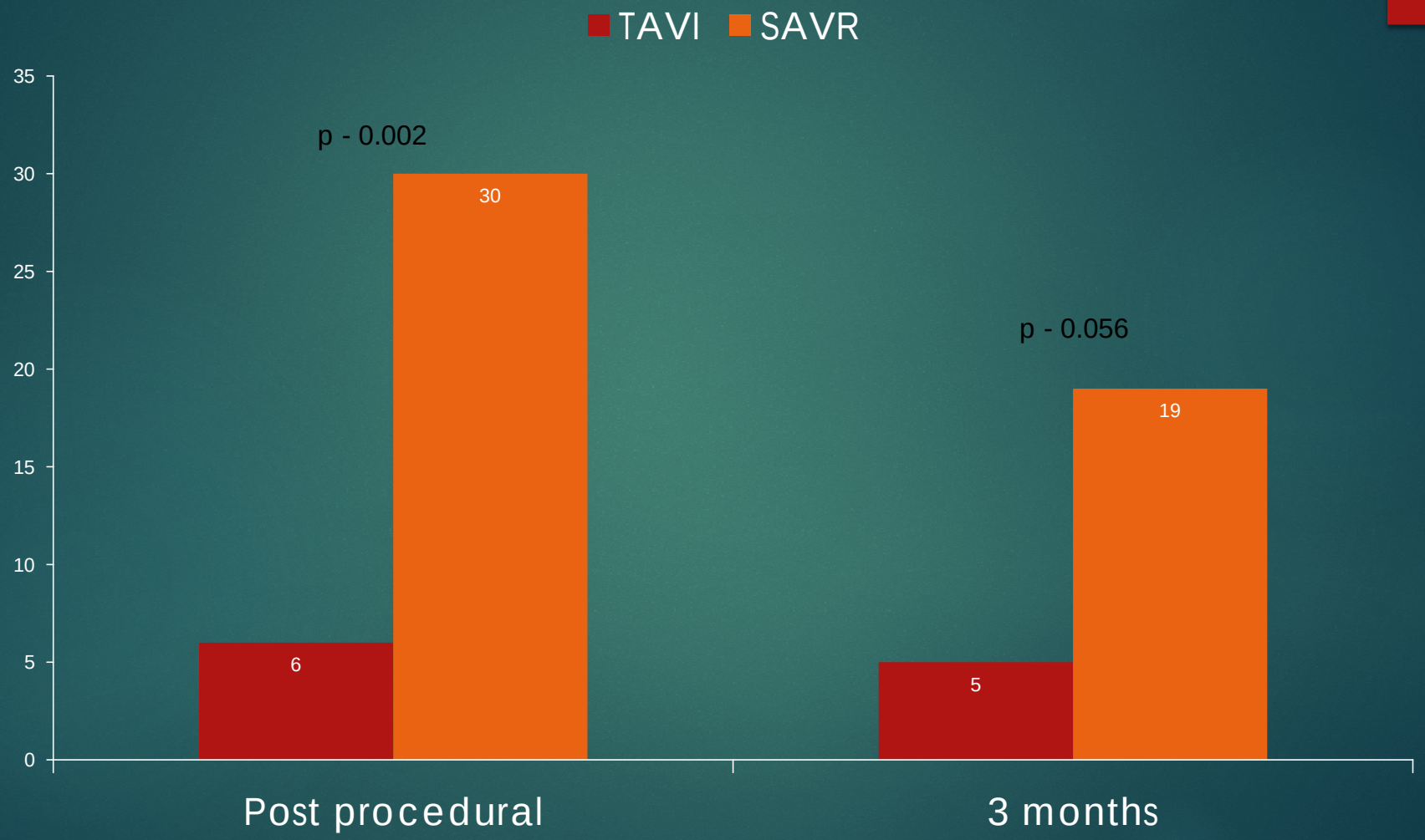



Mean Pressure Gradient
TAVI
SAVR
60
50
40
30
20
10
0
p - 0.2
47.9
43.1
p < 0.0002
9
12.5
p - 0.7
8.4
9
Pre Procedural
Post procedural
3 months

# Aortic Regurgitation



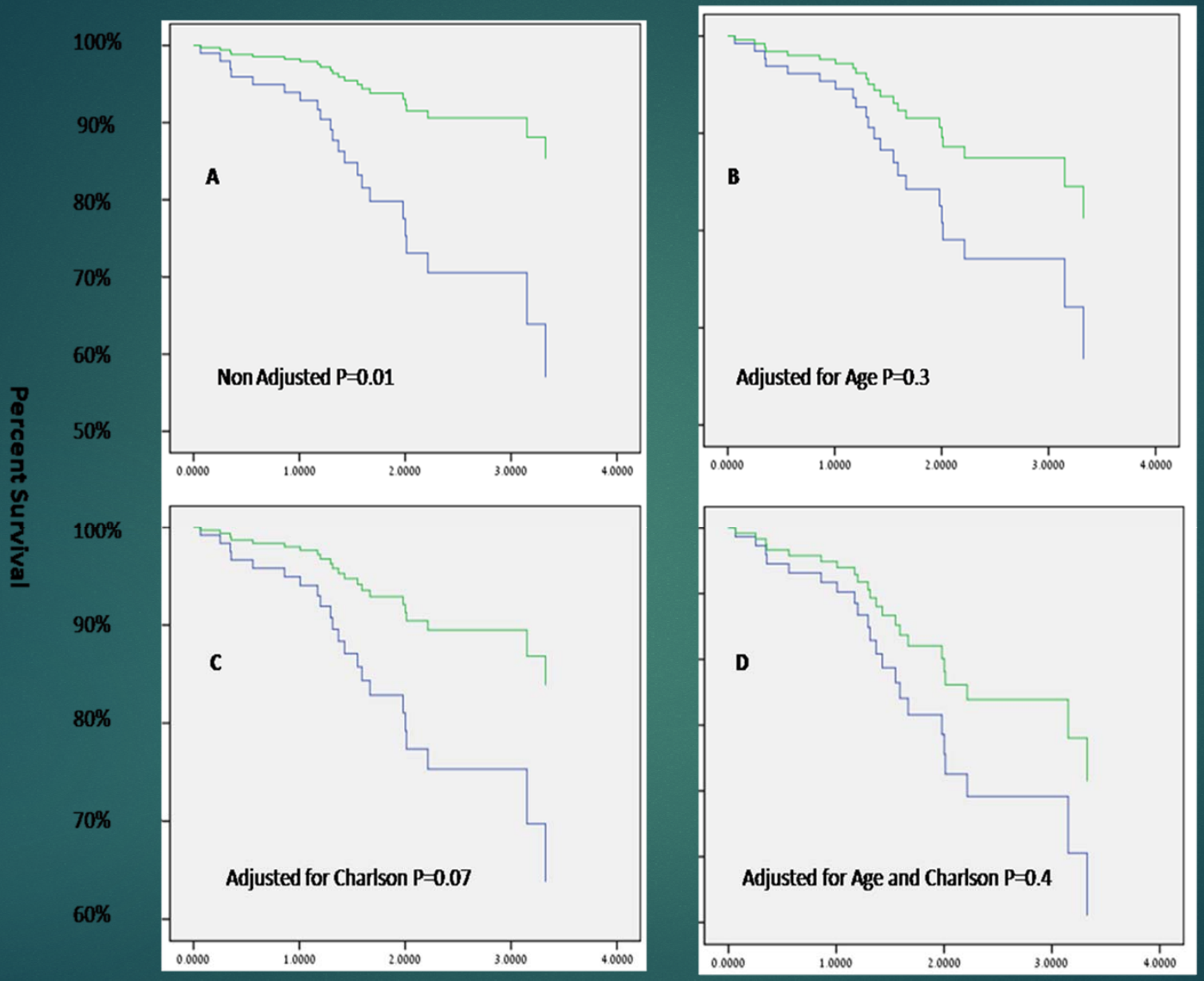
# Post – Procedural Patient Prosthesis Mismatch



# Mortality

- Unadjusted 3-year survival rate was superior in the SAVR vs. TAVI group - 91.6±4.0% Vs. 67.0±7.7%  p=0.01

- Adjustments for age and co-morbidity resulted in loss of the difference in mortality between the groups


Percent Survival
100%
90%
80%
70%
60%
50%
A
Non Adjusted P=0.01
B
Adjusted for Age P=0.3
C
Adjusted for Charlson P=0.07
D
Adjusted for Age and Charlson P=0.4
0.0000
1.0000
2.0000
3.0000
4.0000
Years

# Mortality

- Higher mortality rates associated with:
  - Older age
  - NYHA>III
  - Small stroke volume and atrial fibrillation
  - High comorbidity index

# Discussion

- Immediate hemodynamic performance of TAVI is superior to the stentless valve probably due to use of an oversized valve, leading to some distension of the aortic annulus
- Performing SAVR or TAVI are reasonable choices for patients with anticipated PPM
- The increased un-adjusted mortality observed in TAVI is due to the differences in age and co-morbidities
- After adjustment for the differences in age and co-morbidities between the groups the survival was similar

# Take home message

- Although TAVI should not be used as the procedure of choice in all patients with anticipated PPM, it may be considered as a possible and comparable solution in older and sicker patients with small outflow tract for body surface area.

- The higher prevalence of aortic regurgitation in TAVI may offset the beneficial effect on survival of less PPM in favor of SAVR.

# Thank you