

# Balloon Aortic Valvuloplasty for Highest Risk Patients Before TAVI or AVR



**Dariusz Dudek**

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**Chair, Education & Training Committee**

**The European Association of Percutaneous Cardiovascular Interventions (EAPCI ESC)**

## Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

*Balloon valvuloplasty may be considered :*

- As a bridge to surgery or TAVI in haemodynamically unstable patients who are at high risk for surgery
- In patients with symptomatic severe AS who require urgent major non-cardiac surgery
- As a palliative measure in selected individual cases when surgery is contraindicated because of severe comorbidities and TAVI is not an option

# BAV Registry

- BAV procedures were performed and patients were enrolled from October 2012 and July 2015 in Krakow:



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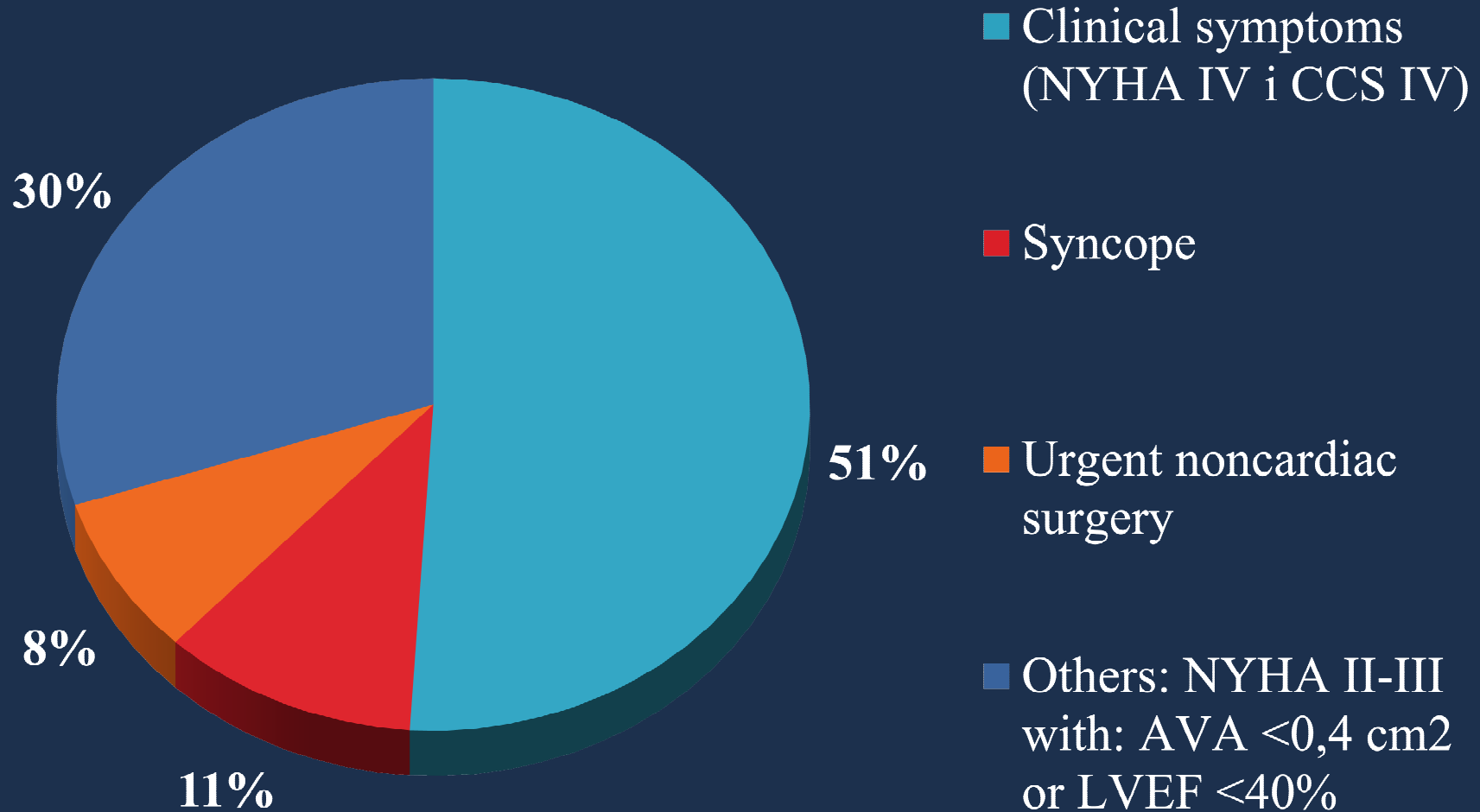


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# Methods

- Data on 112 consecutive patients with severe AS who underwent 114 BAVs were assessed.
- Follow-up data were prospectively collected for one year after BAV.
- All patients were discussed during Heart Team meeting and finally qualified for BAV.
- The treatment strategy including balloon catheters size was based on echocardiographic assessment.

# Indications for BAV



# Demographic data and medical history

Variable	Value (n = 112)
Age [years], median (IQR)	84 (79-87)
Women, n (%)	70 (62.5)
BMI (kg/m <sup>2</sup> ), mean $\pm$ SD	18.5 $\pm$ 3.5
Coronary artery disease, n (%)	94 (83.9)
Previous myocardial infarction, n (%)	51 (45.5)
Previous PCI, n (%)	40 (35.7)
Previous CABG, n (%)	7 (6.25)
Arterial hypertension, n (%)	98 (87.5)
Diabetes mellitus, n (%)	50 (44.6)
Chronic renal insufficiency, n (%)	65 (58.0)

# Demographic data and medical history

Variable	Value (n = 112)
Cerebrovascular events, n (%)	19 (17.0)
Atrial fibrillation, n (%)	51 (45.5)
Peripheral vascular disease, n (%)	22 (19.6)
Peripheral artery intervention, n (%)	5 (4.4)
COPD/asthma, n (%)	17 (15.1)
Neoplasm, n (%)	14 (12.5)
Previous radiotherapy, n (%)	2 (1.8)
Porcelain aorta, n (%)	3 (2.7)
Previous heart failure decompensation, n (%)	41 (36.6)
Cardiogenic shock, n (%)	2 (1.8)

# Acute and long-term outcomes of percutaneous balloon aortic valvuloplasty for the treatment of severe AS



Catheterization and  
Cardiovascular Interventions

## Acute and long-term outcomes of percutaneous balloon aortic valvuloplasty for the treatment of severe aortic stenosis

Marzena Daniec, MD<sup>1</sup>, Bartłomiej Nawrotek, MD<sup>2</sup>, Danuta Sorysz, MD, PhD<sup>1</sup>, Tomasz Rakowski, MD, PhD<sup>1</sup>, Artur Dziewierz, MD, PhD<sup>1</sup>, Łukasz Rzeszutko, MD, PhD<sup>1</sup>, Paweł Kleczyński, MD, PhD<sup>1</sup>, Jarosław Trębacz, MD<sup>2</sup>, Marek Tomala, MD, PhD<sup>2</sup>, Krzysztof Żmudka, MD, PhD<sup>2</sup>, Dariusz Dudek, MD, PhD<sup>1,2,\*</sup>

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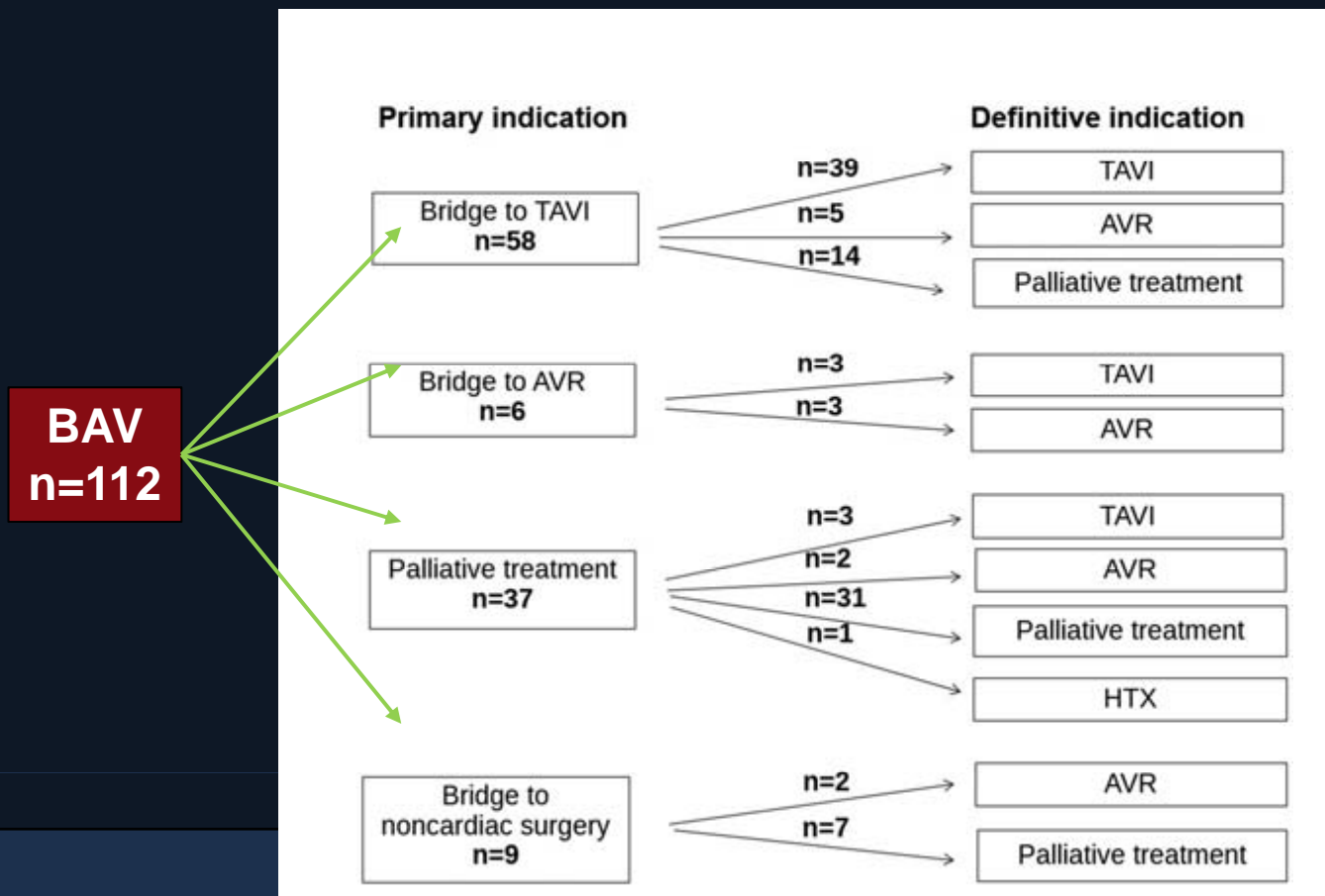
<sup>2</sup> Department of Interventional Cardiology, Institute of Cardiology, Jagiellonian University Medical College, the John Paul II Hospital, Krakow, Poland;



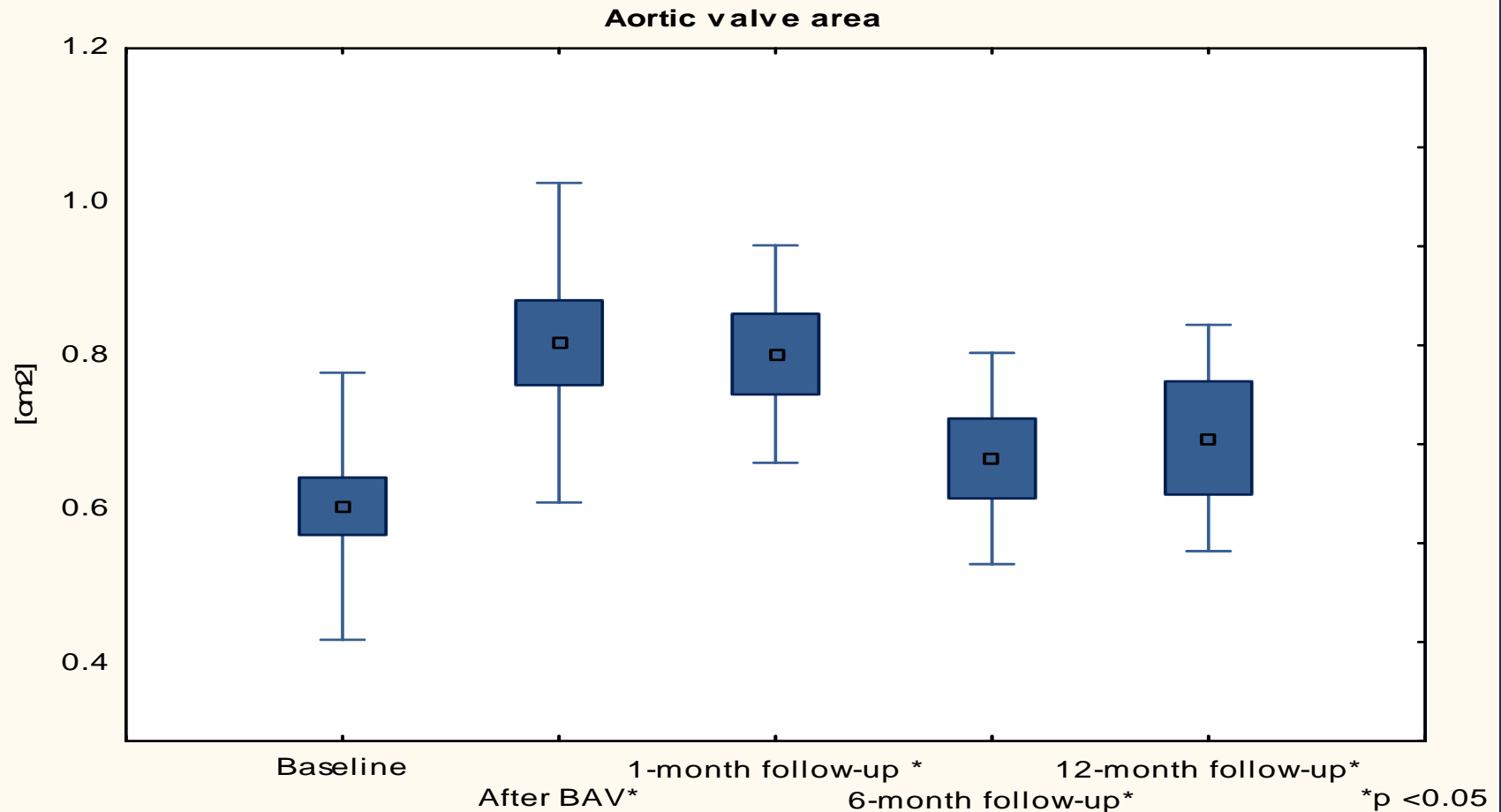
## Original Studies

# Acute and long-Term Outcomes of Percutaneous Balloon Aortic Valvuloplasty for the Treatment of Severe Aortic Stenosis

Marzena Daniec,<sup>1</sup> MD, Bartłomiej Nawrotek,<sup>2</sup> MD, Danuta Sorysz,<sup>1</sup> MD, PhD,  
Tomasz Rakowski,<sup>1</sup> MD, PhD, Artur Dziewierz,<sup>1</sup> MD, PhD, Łukasz Rzeszutko,<sup>1</sup> MD, PhD,  
Paweł Kleczyński,<sup>1</sup> MD, PhD, Jarosław Trębacz,<sup>2</sup> MD, Marek Tomala,<sup>2</sup> MD, PhD,  
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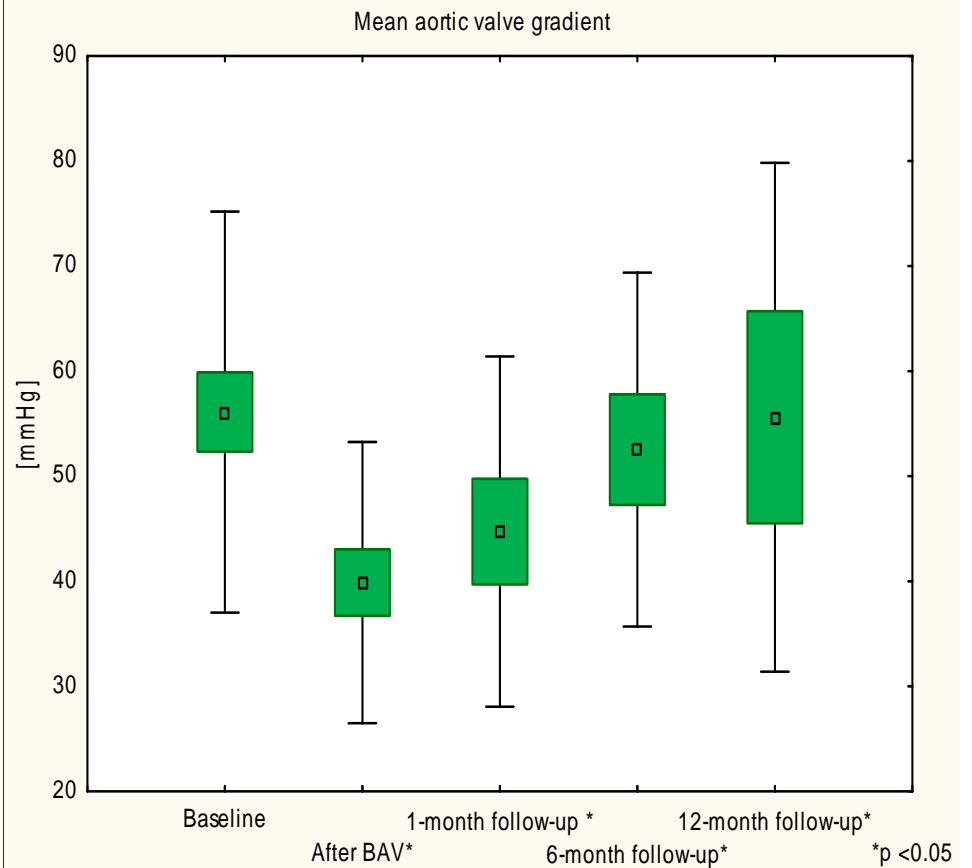
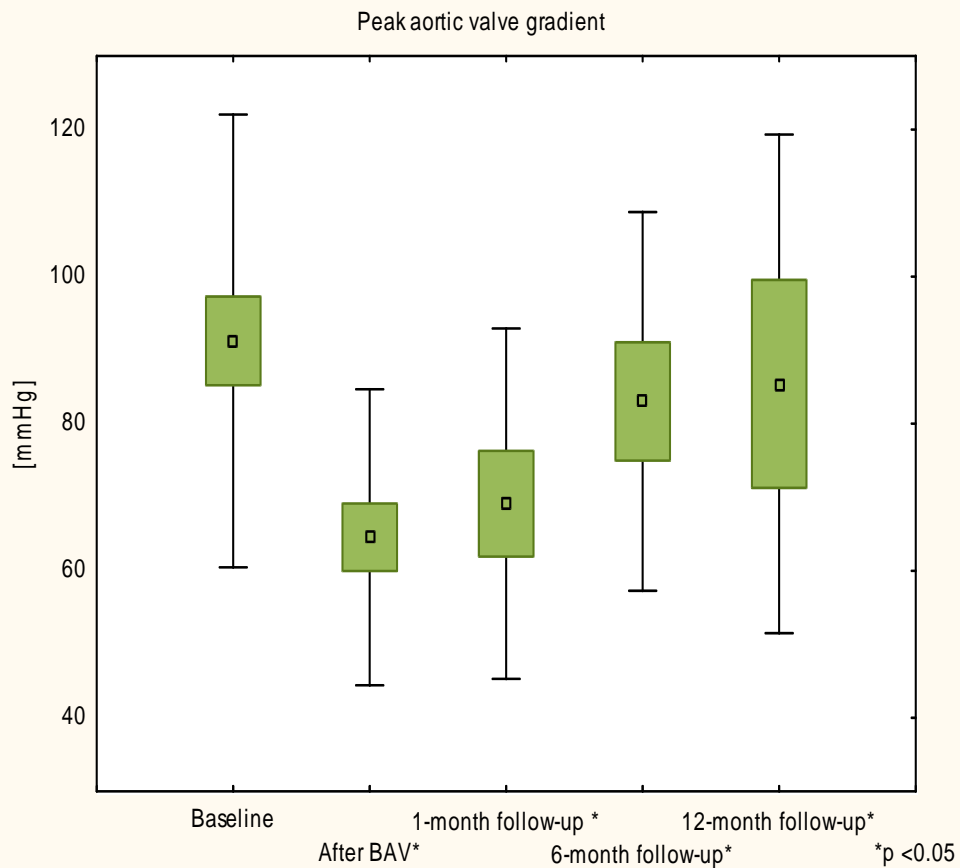


# Aortic valve area (AVA)



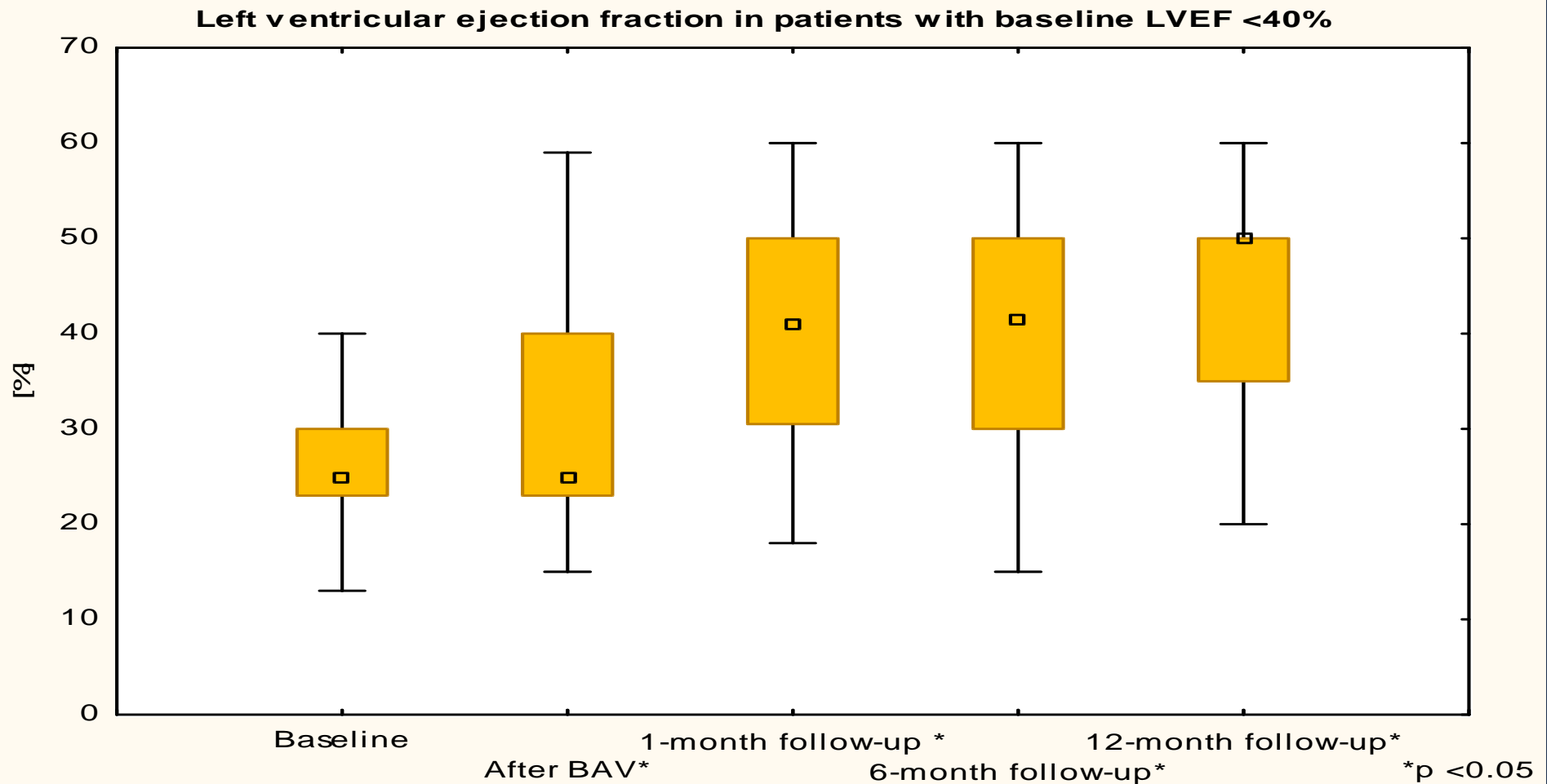
Baseline	After BAV	1-month follow-up	6-month follow-up	12-month follow-up
$0.59 \pm 0.18 \text{ cm}^2$	$0.82 \pm 0.24 \text{ cm}^2$	$0.74 \pm 0.21 \text{ cm}^2$	$0.63 \pm 0.17 \text{ cm}^2$	$0.63 \pm 0.17 \text{ cm}^2$

# Peak and mean aortic gradient



Baseline	After BAV	1-month follow-up	6-month follow-up	12-month follow-up
max. $94.0 \pm 27.6$ mmHg	$65.4 \pm 20.0$ mmHg	$69.6 \pm 23.7$ mmHg	$85.3 \pm 25.2$ mmHg	$89.2 \pm 32.9$ mmHg
mean. $58.0 \pm 17.8$ mmHg	$40.5 \pm 14.6$ mmHg	$43.4 \pm 17.4$ mmHg	$53.6 \pm 18.1$ mmHg	$51.0 \pm 7.7$ mmHg

# Left ventricular ejection fraction in patients with baseline LVEF <40 %



Before BAV  
25 (23-30)

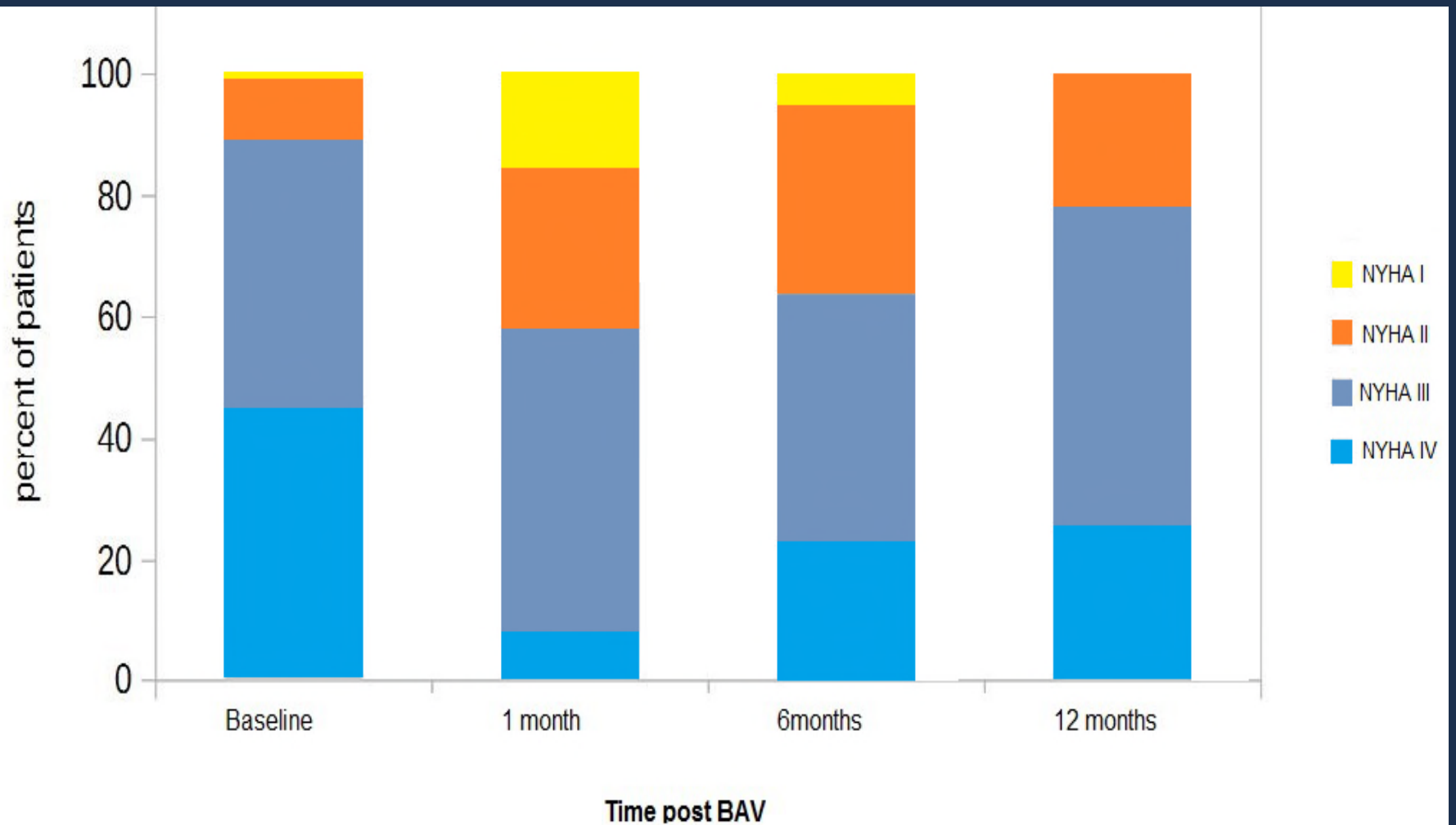
After BAV  
25 (23-40)

1-month follow-up  
41 (30.5-50)

6-month follow-up  
41.5 (30-50)

12-month follow-up  
45 (35-50)

# NYHA after BAV

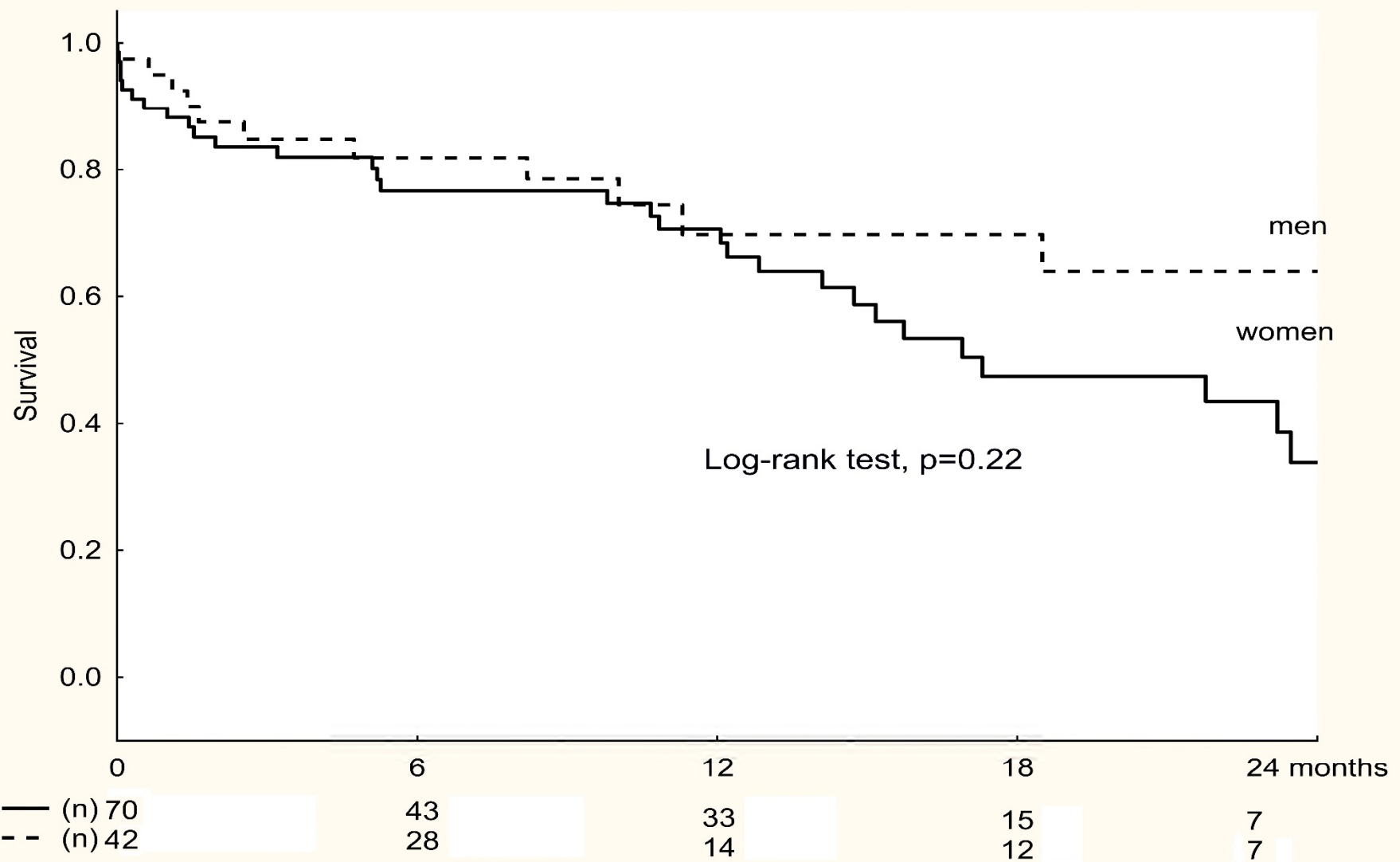


# Procedural complications

Variable	Women (n = 70)	Men (n=42)
Intraprocedural death	2 (2.8%)	1 (2.4%)
In-hospital mortality	8 (11.4%)	2 (4.9%)
Severe aortic regurgitation	1 (1.4%)	0 (0.0%)
Tamponade	3 (4.3%)	1 (2.4%)
Permanent pacemaker implantation	1 (1.4%)	0 (0.0%)
Need for red blood cells transfusion	10 (14.3%)	4 (9.5%)
1 unit	3 (4.2%)	0 (0.0%)
≥2 units	8 (11.3%)	2 (4.8%)
<b>Vascular access site complications</b>	<b>11 (15.7%)</b>	<b>0 (0.0%)</b>
pseudoaneurysm	6 (8.6%)	0 (0.0%)
hematoma	5 (7.1%)	0 (0.0%)

p<0.05 men vs. women

# K-M survival curves for women & men after standalone BAV procedure and after BAV until undergoing TAVI/AVR



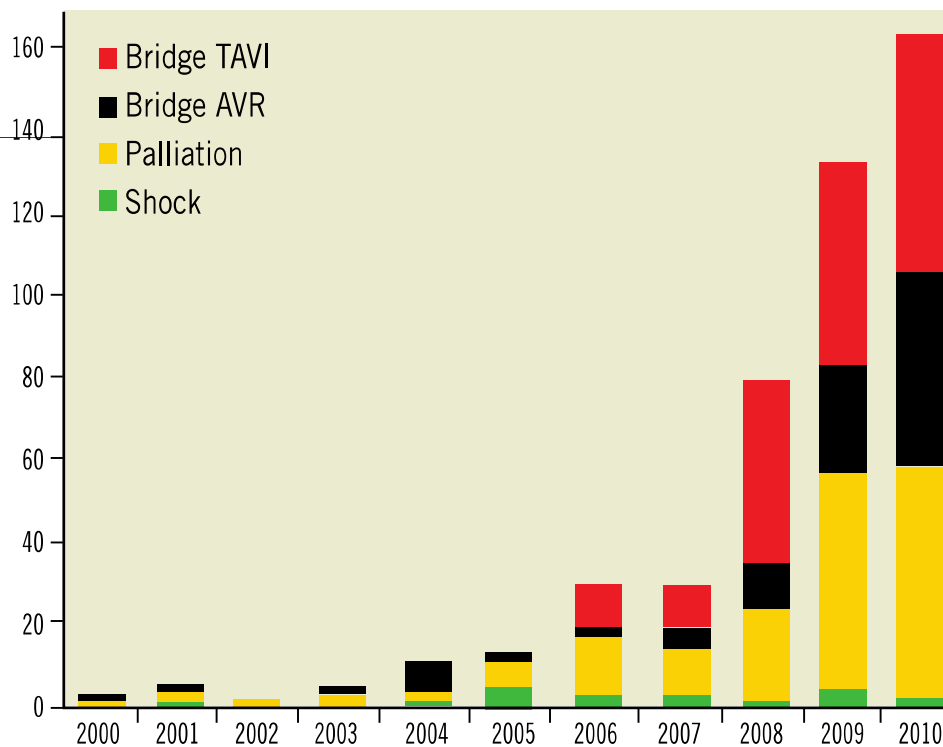
## Women vs men

- **Women were older, with higher profile risk (STS Score) and had more vascular complications after BAV than men.**
- **Despite a higher-risk profile in women hemodynamic outcomes of BAV as assessed by echocardiography were generally comparable between both genders.**
- **Peri-procedural, in-hospital and two-year mortality before definitive treatment were comparable between women and men.**
- **STS above 9.8% was an independent predictor of all-cause mortality only in women.**



# Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era

Francesco Saia<sup>1\*</sup>, MD, PhD; Cinzia Marrozzini<sup>1</sup>, MD; Cristina Ciuca<sup>1</sup>, MD; Paolo Guastaroba<sup>2</sup>, MSc; Nevio Taglieri<sup>1</sup>, MD; Tullio Palmerini<sup>1</sup>, MD; Barbara Bordoni<sup>1</sup>, MD; Carolina Moretti<sup>1</sup>, MD; Gianni Dall'Ara<sup>1</sup>, MD; Angelo Branzi<sup>1</sup>, MD; Antonio Marzocchi<sup>1</sup>, MD



BAV  
n=415

Bridge to TAVI  
n=162 (39%)

Bridge to AVR  
n=97 (23%)

Cardiogenic shock  
n=23 (6%)

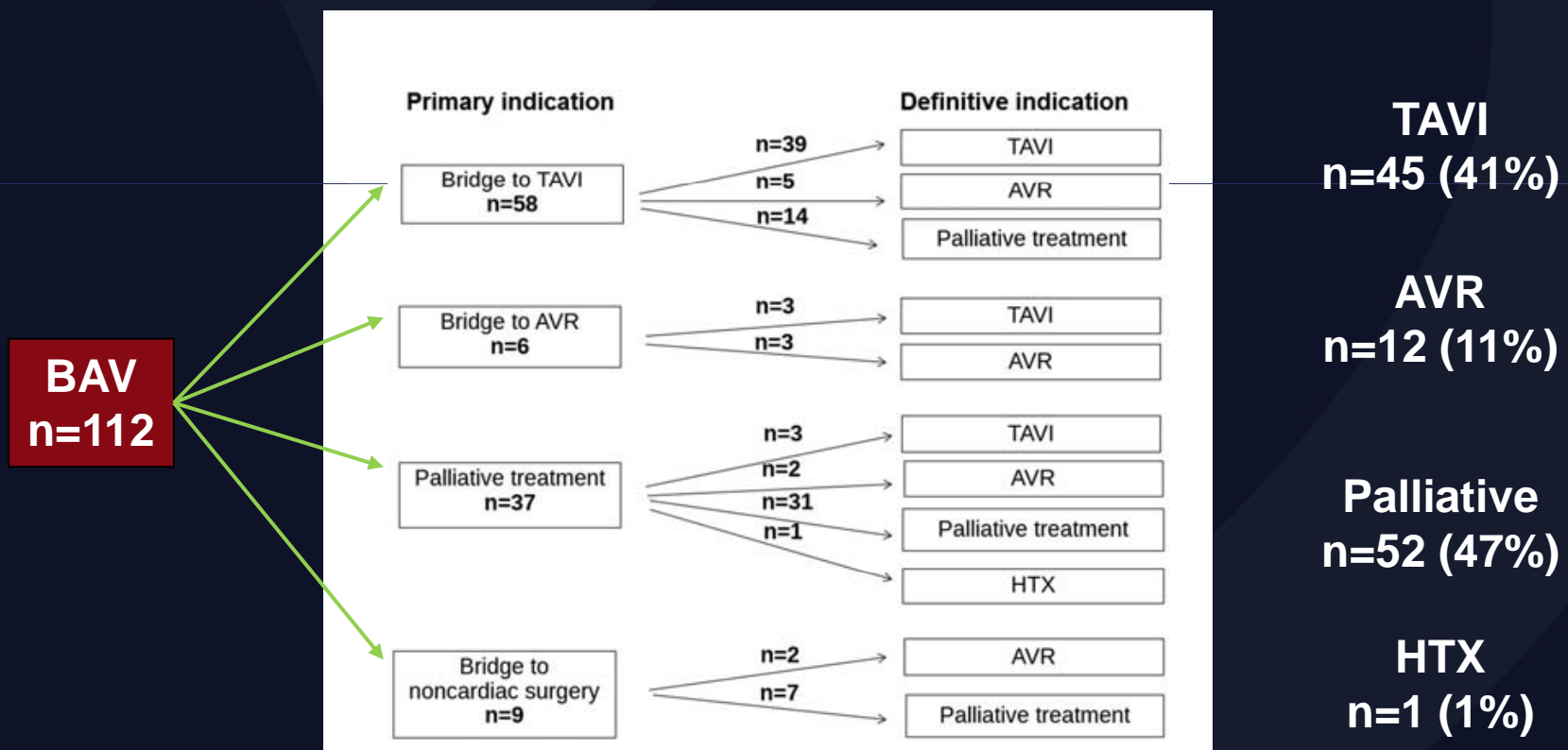
Palliation  
n=133 (32%)



## Original Studies

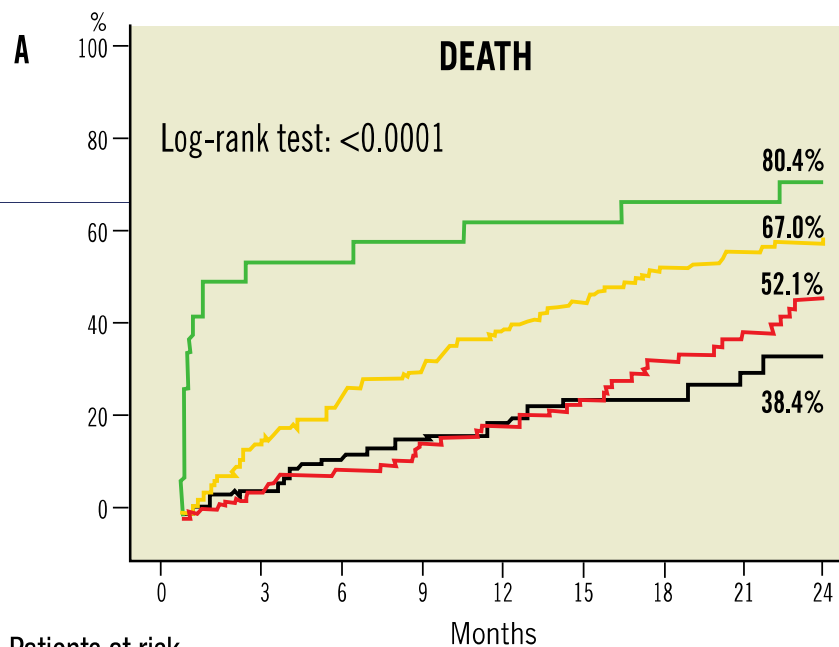
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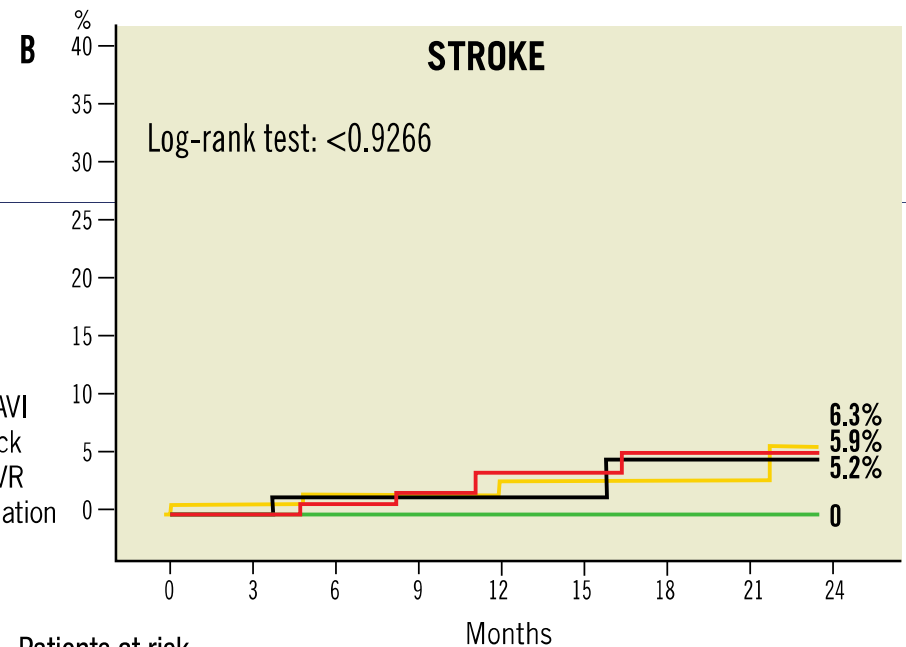


# Emerging indications, in-hospital and long-term outcome of balloon aortic valvuloplasty in the transcatheter aortic valve implantation era

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Patients at risk	Months									
	0	3	6	9	12	15	18	21	24	
Palliation	133	109	94	85	73	58	42	33	31	
B-AVR	97	74	57	51	43	29	23	19	16	
Shock	23	9	8	7	6	6	5	5	4	
B-TAVI	162	123	91	71	63	51	38	29	22	

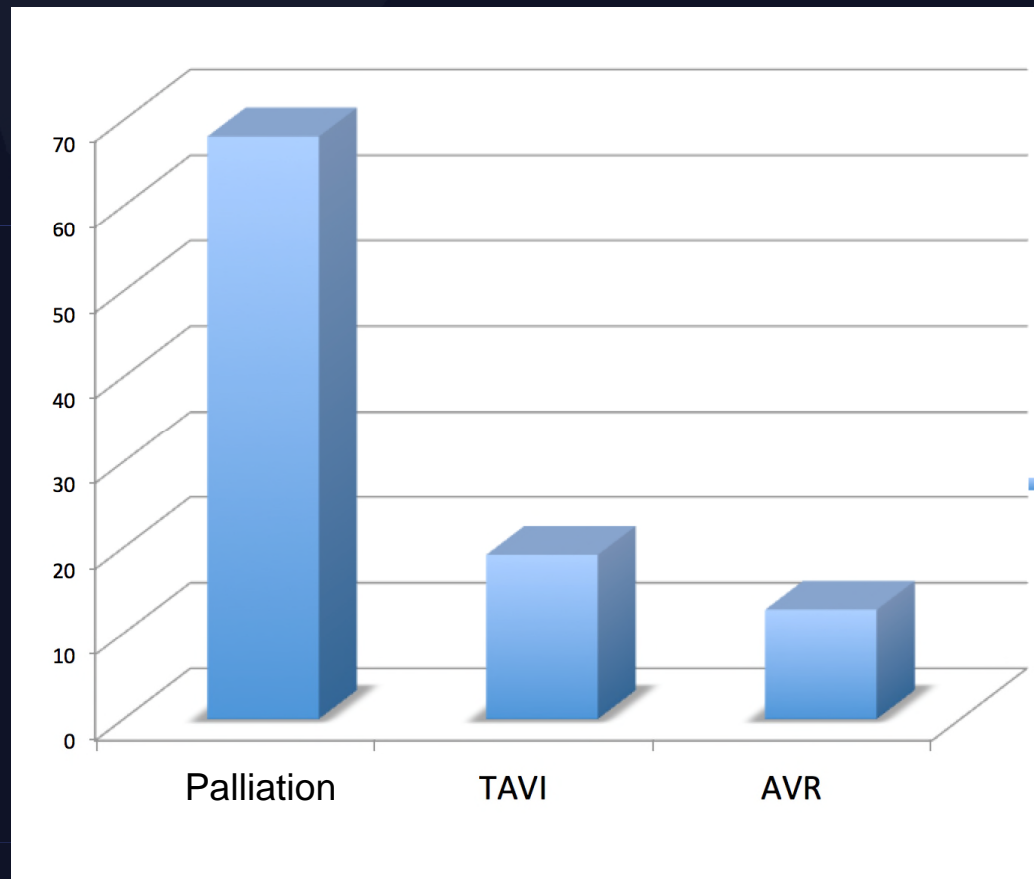


Patients at risk	Months									
	0	3	6	9	12	15	18	21	24	
Palliation	133	108	93	84	72	57	41	32	30	
B-AVR	97	74	56	50	42	28	22	18	15	
Shock	23	9	8	7	6	6	5	5	4	
B-TAVI	162	123	91	71	62	51	38	29	22	



# Zabrze BAV Registry

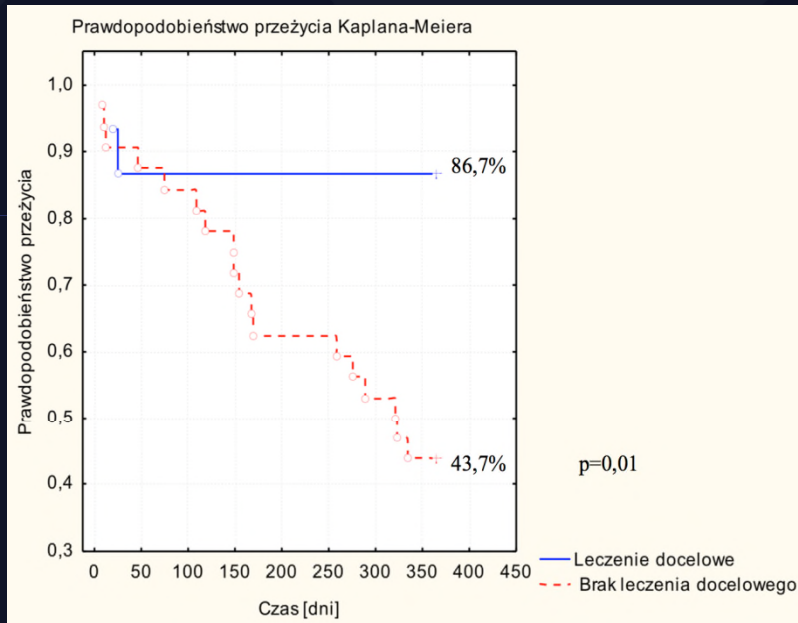
## Destination therapy (n=70)



# Prognosis

## Zabrze BAV Registry

## Kraków Registry



### Cumulative follow-up mortality rate

Variable	Value <sup>c</sup>
Procedural mortality rate <sup>a</sup>	3 (2.7%)
In-hospital mortality rate <sup>b</sup>	10 (8.9%)
30-day mortality rate	10 (8.9%)
6-month mortality rate	19 (16.9%)
12-month mortality rate	25 (22.3%)

<sup>a</sup>Due to procedural complications.

<sup>b</sup>All-cause in-hospital death, including procedural.



# Conclusions (1)

- **BAV is useful procedure in high-risk AS patients, nevertheless limited by long-term outcomes. Limitations concern intermittent improvement of symptoms, AVA, pAVG, and mAVG, however achieved effects can be sufficient in bridging patients for TAVI/AVR.**
- **BAV in some patients results in recovery of initially depressed LVEF (<40%). LVEF improvement with following subsequent evaluation of patients risk may result in final qualification for TAVI/AVR and shows further potential benefit on LVEF after TAVI/AVR.**
- **BAV in patients not suitable for TAVI/AVR or with life expectancy < 1 year, is considered as a last option of treatment with benefits of symptomatic relief.**

## Conclusions (2)

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- **BAV is still a reasonable treatment option in selected patients with AS but planned destination therapy is the key issue in terms of long-term prognosis.**





# Limitations

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- **The main limitation of this prospective, two-center registry is a limited sample size. However, the number of subjects was sufficient to detect differences between time-points.**
- **Collected data were limited by shortened time of follow-up as patients were treated with definitive therapy or could not come for an out-patients visit. What is important, survival rate could be influenced not only by valvular disease but presumably also by severe comorbidities.**

