Percutaneous Aortic Balloon Valvuloplasty (PABV)

Time for a Renaissance?

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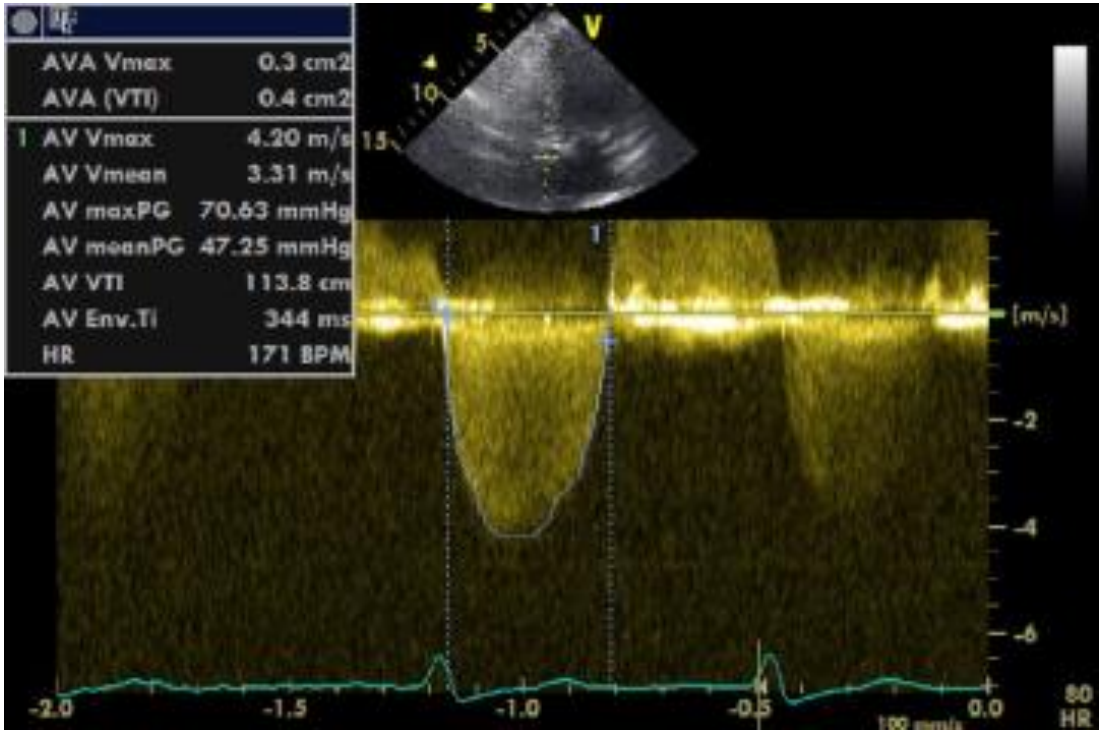
B.J., a 90 year old female with known hypertension was admitted with chest pain and acute pulmonary edema refractory to medical treatment

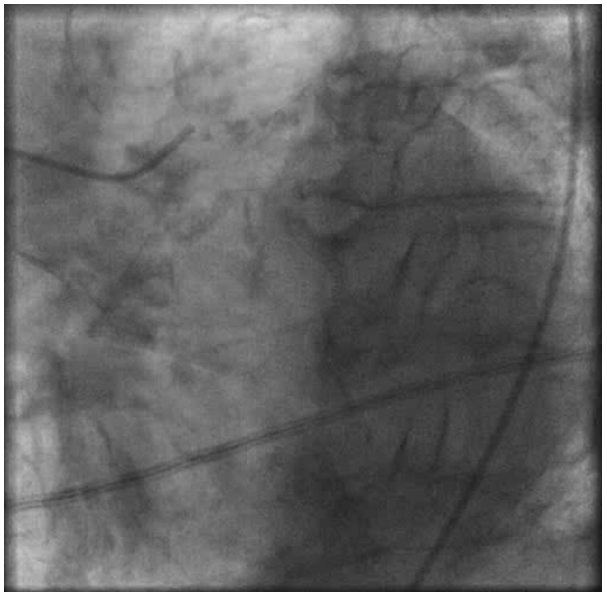
HR-100 BP-90/40 mmHg Sat on O2-84%

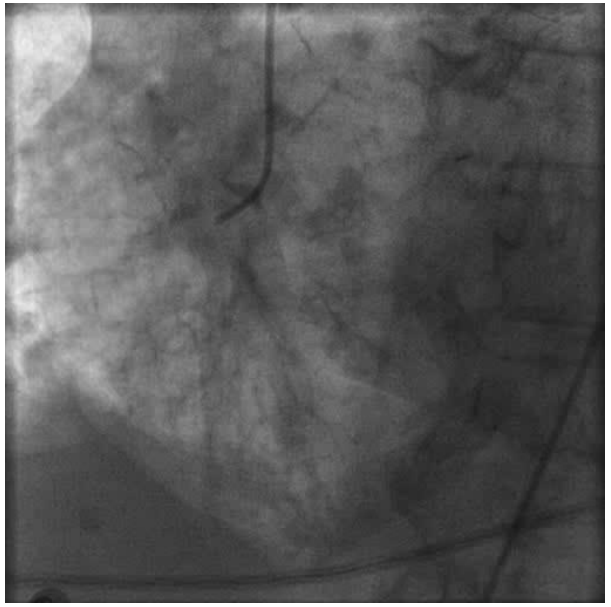
Lab: Hg 11.3 Cr 1.6 Troponin 17

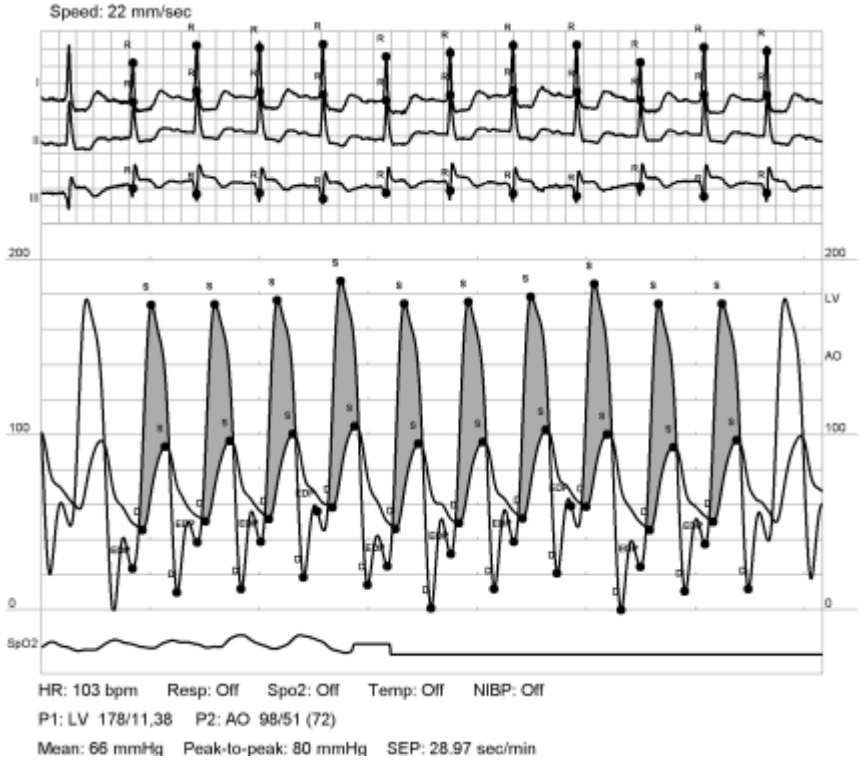
Echo: Moderate global LV dysfunction LVEF-37% and severe aortic stenosis

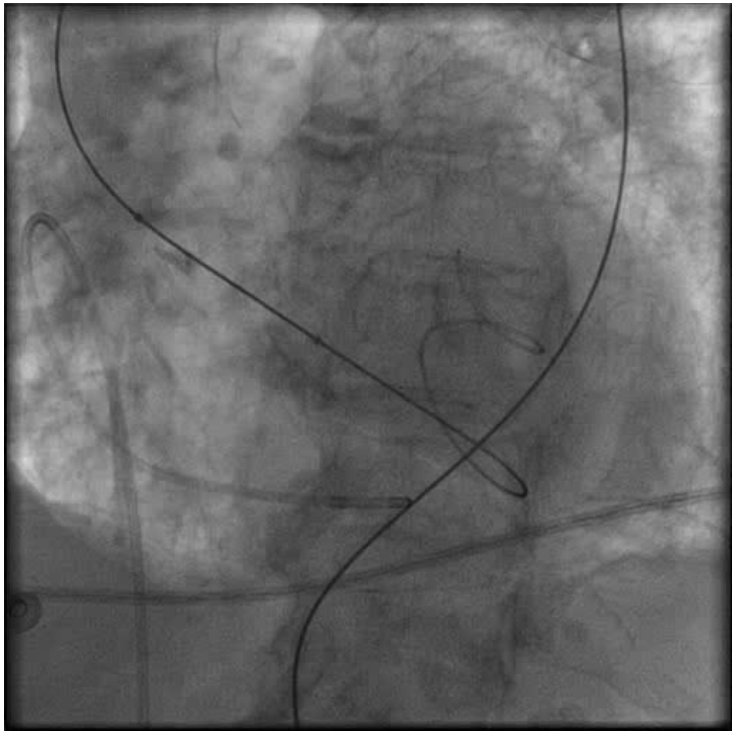


Cath. Pre Procedure

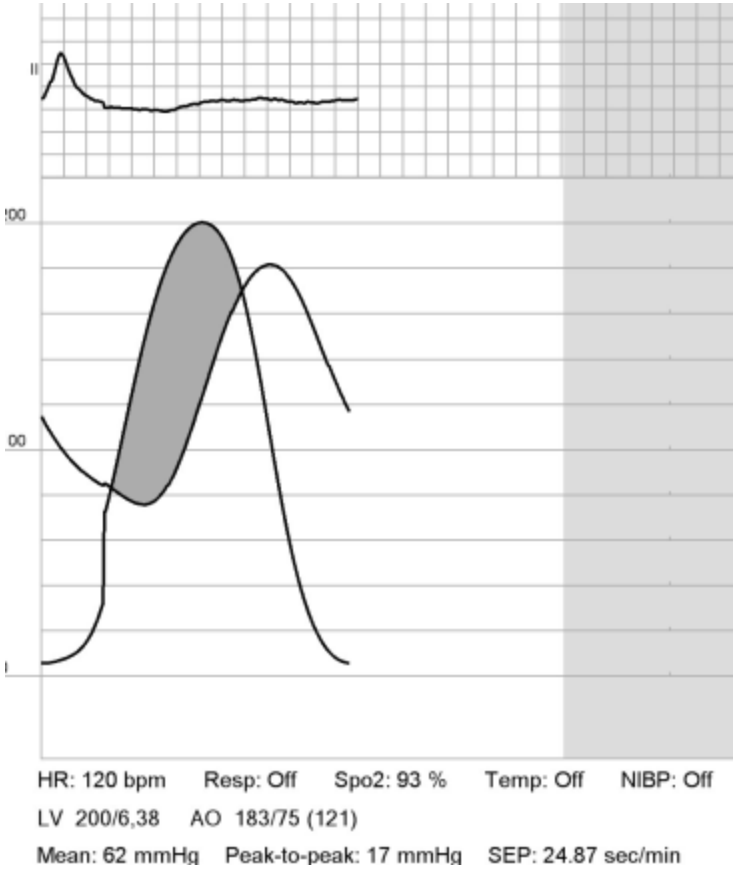


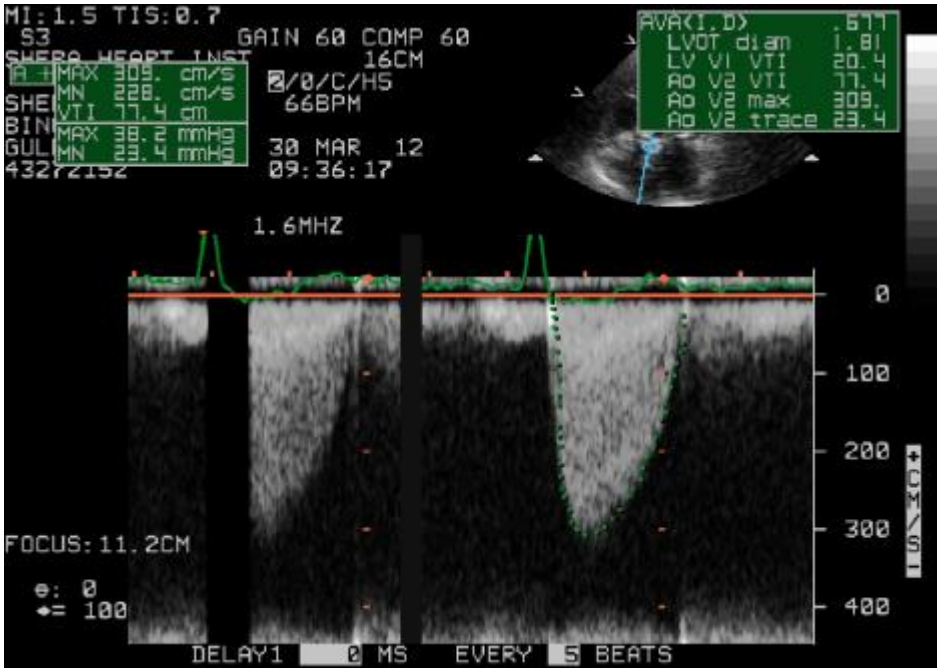






Post Procedure





Patient improved clinically and was discharged home on day 5.

3 month follow-up: Stable

Echo: LVEF 55%, severe AS

Plan: AVR? TAVI? Med. treatment?

- Moderate-to-severe AS occurs in 5% of individuals 75 to 86 years of age, and critical AS is seen in 5% of those 85 years of age
- Percutaneous aortic valvuloplasty was developed as a nonsurgical option in the 1980s.
- It was found to have a role in managing unstable and critically ill patients such as those in cardiogenic shock or refractory heart failure.

Percutaneous balloon aortic valvuloplasty. Acute and 30-day follow-up results in 674 patients from the NHLBI Balloon Valvuloplasty Registry.

Circulation. 1991;84:2383-2397

TABLE 3. Indications for Aortic Valvuloplasty

Major reason	
Old age	421 (63%)
Mental condition	29 (4%)
Noncardiac disability	300 (45%)
CNS	32 (5%)
Pulmonary	111 (17%)
Renal insufficiency	47 (7%)
Neoplasm	47 (7%)
Peripheral vascular disease	21 (3%)
Hematologic disease	18 (3%)
Hepatic disease	15 (2%)
Generalized disability	79 (12%)
Other disease	54 (8%)
Cardiac disability	186 (28%)
No reason given	25 (4%)
Preferences	
Physician preference	566 (84%)
Patient preference	576 (86%)
"Bridge" procedure	43 (7%)
Surgical consultation	
Obtained	259 (40%)
Surgery recommended	51/259 (20%)

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TABLE 5. Hemodynamics at Baseline and After Aortic Valvuloplasty

	Baseline	Post	Change
Mean aortic valve gradient (mm Hg)			
n=635			
Mean±SD	55±21	29±13*	−26±17
Range	12–136	0–82	−117 to −12
Peak-to-peak aortic gradient (mm Hg)			
n=631			
Mean±SD	65±28	31±18*	−34±23
Aortic valve area (cm^2)			
n=636			
Mean±SD	0.5±0.2	0.8±0.3*	0.3±0.2
Range	0.1–1.4	0.1–3.4	−0.2 to 2.8
Cardiac output (l/min)			
n=639			
Mean±SD	4.0±1.2	4.1±1.3*	0.1±0.7
Mean aortic pressure (mm Hg)			
n=606			
Mean±SD	87±16	90±17*	3±16
LV end-diastolic pressure (mm Hg)			
n=643			
Mean±SD	22±9	19±9*	−3±8
PA systolic pressure (mm Hg)			
n=513			
Mean±SD	31±13	30±12*	−2±9
Heart rate (beats/min)			
n=644			
Mean±SD	83±17	86±19*	2±13

*$p<0.0001$ vs. baseline.

Data represent only those patients in whom paired data (both before and after valvuloplasty) were available. The available number (*n*) is noted for each value. In general, aortic valve gradient decreased by half and the valve area improved by 65%. LV, left ventricular; PA, pulmonary arterial.

Percutaneous balloon aortic valvuloplasty. Acute and 30-day follow-up results in 674 patients from the NHLBI Balloon Valvuloplasty Registry.

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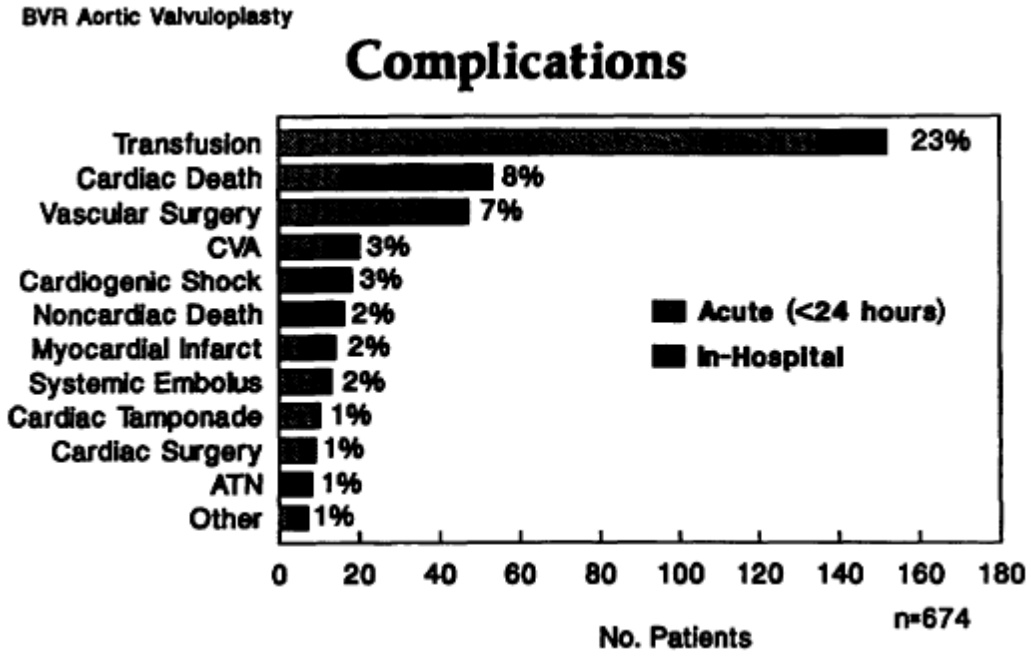

	Total mortality	Cardiovascular causes
Acute (<24 hours)	17 (3%)	16 (2%)
At hospital discharge	69 (10%)	53 (8%)
At 30-day follow-up	92 (14%)	71 (11%)

Conclusions

- This study reinforces the use of PBAV, even if restenosis is inevitable, for improving the quality of life for elderly patients in whom a surgical alternative is a poor or unacceptable option.

- This improvement is most likely to occur in those symptomatic patients who have yet to develop an associated cardiomyopathy and generalized debilitation.

- The most important predictor of event-free survival after BAV was left ventricular function at baseline (ejection fraction >25%).

- BAV may be a forgotten therapy, but analysis suggests that it offers benefits to the very elderly high risk patient who is looking for significant symptomatic improvement that is not available from medical therapy alone.

Several technical and procedural improvements are now available for PABV that did not exist 30 years ago when Cribier first described the procedure:

- Rapid ventricular pacing (200 to 220 bpm)
- Improved low profile balloons with faster inflation– deflation times
- Bridge to TAVI if AVR is no option

However, did these improvements actually change the outcome post PABV?

1991 ➡ 2011

Percutaneous aortic balloon valvuloplasty (PABV) - a preliminary treatment strategy in the transcatheter aortic valve implantation (TAVI) era

Claire-Marie Tissot et al. EuroIntervention 2011;7:49-56

Reappraisal of percutaneous aortic balloon valvuloplasty as a preliminary treatment strategy in the transcatheter aortic valve implantation era

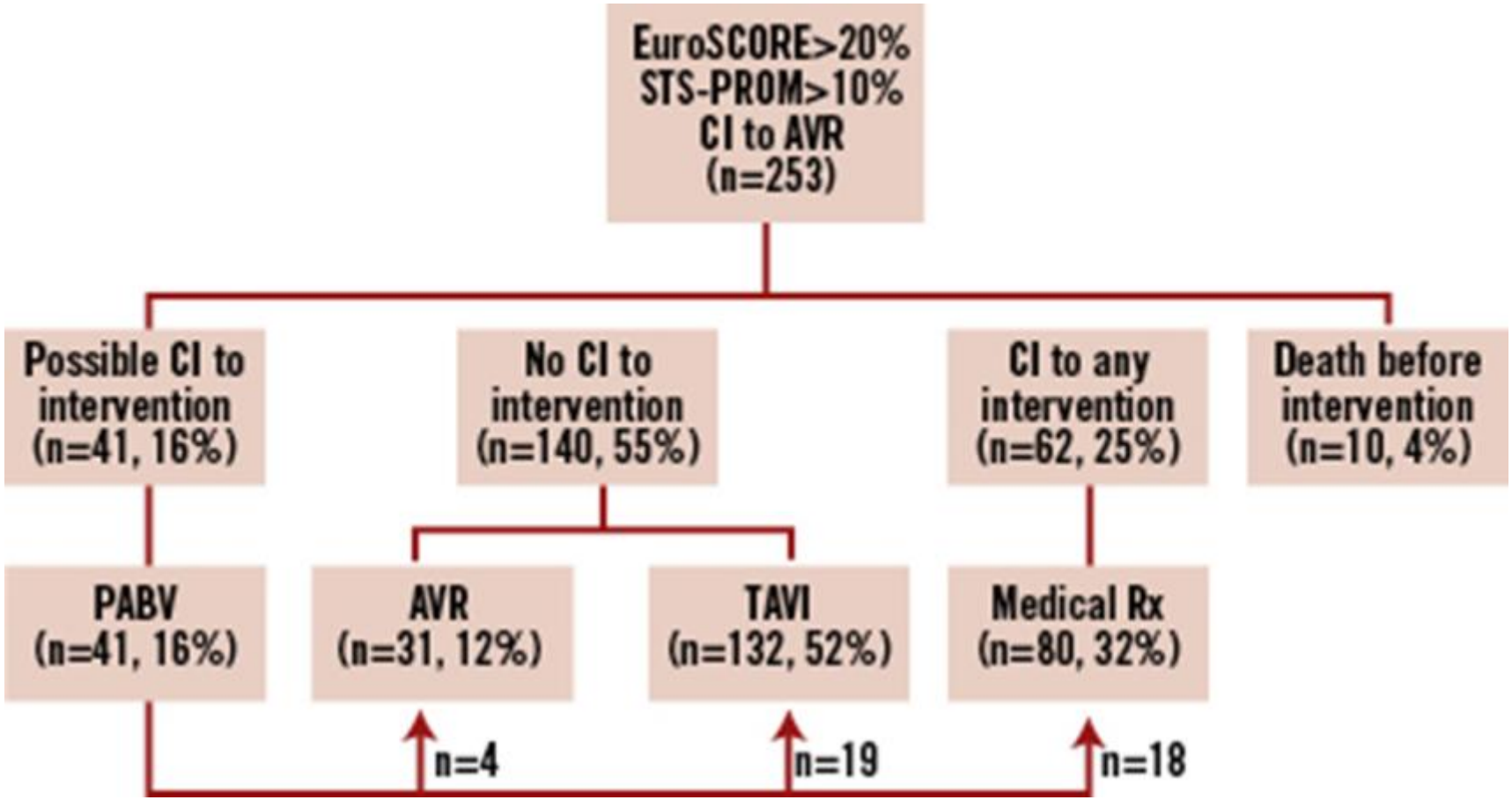

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Table 1. Baseline characteristics of the whole study population.

	Overall (n=253)	Primary TAVI or AVR (n=140)	PABV (n=41)	No intervention* (n=72)	p
Age (years, mean±SD)	82±8	82±8	81±8	83±9	0.27
Female gender	122 (48)	64 (46)	19 (46)	39 (54)	0.49
NYHA class			¶‡		0.03
II	10 (4)	5 (4)	0	5 (7)	
III	147 (58)	91 (65)	15 (37)	41 (57)	
IV	96 (38)	44 (31)	26 (63)	26 (36)	
Coronary artery disease					
Previous MI	134 (61)	83 (60)	24 (67)	27 (60)	0.74
Previous PCI	55 (22)	29 (21)	11 (27)	15 (21)	0.69
Previous CABG	52 (21)	30 (21)	10 (24)	12 (17)	0.58
Peripheral artery disease	89 (35)	55 (39)	12 (29)	22 (31)	0.31
Renal failure	102 (40)	43 (31)	24 (59)¶	35 (49)	0.001
Severe COPD	80 (32)	48 (34)	13 (32)	19 (26)	0.50
Cancer	64 (25)	35 (25)	13 (32)	16 (22)	0.53
Porcelain aorta	25 (10)	17 (12)	4 (10)	4 (6)	0.42
≥2 comorbidities	152 (60)	76 (54)	30 (73)	46 (64)	0.07
Aortic valve area					
cm^2	0.69±0.18	0.69±0.18	0.66±0.2	0.69±0.17	0.56
cm^2/m^2	0.40±0.10	0.40±0.1	0.39±0.09	0.40±0.11	0.76
Mean gradient (mmHg)	48±16	50±16	46±14	45±16	0.07
LVEF (%)	48±16	51±15	44±17	45±16	0.01
<30%	33 (13)	11 (8)	6 (15)	16 (22)	0.01
SPAP (mmHg)	50±14	48±13	56±17¶	52±14	0.009
Logistic EuroSCORE (%)					
Mean±SD	28±16	25±12	37±22¶	31±17	<0.0001
Range	3-90	3-74	10-90	3-72	
STS-PROM (%)					
Mean±SD	16±10	15±8	22±12¶	15±9	0.0015
Range	3-62	3-41	7-62	3-46	

*Including the 10 patients who died before intervention; ¶: p<0.05 between PABV and primary TAVI or AVR; ‡ p<0.05 between PABV and medical treatment; Values are expressed as n (%) unless otherwise stated. CABG: coronary artery bypass grafting; CI: contraindication; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard deviation; SPAP: systolic pulmonary artery pressure; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI: transcatheter aortic valve implantation

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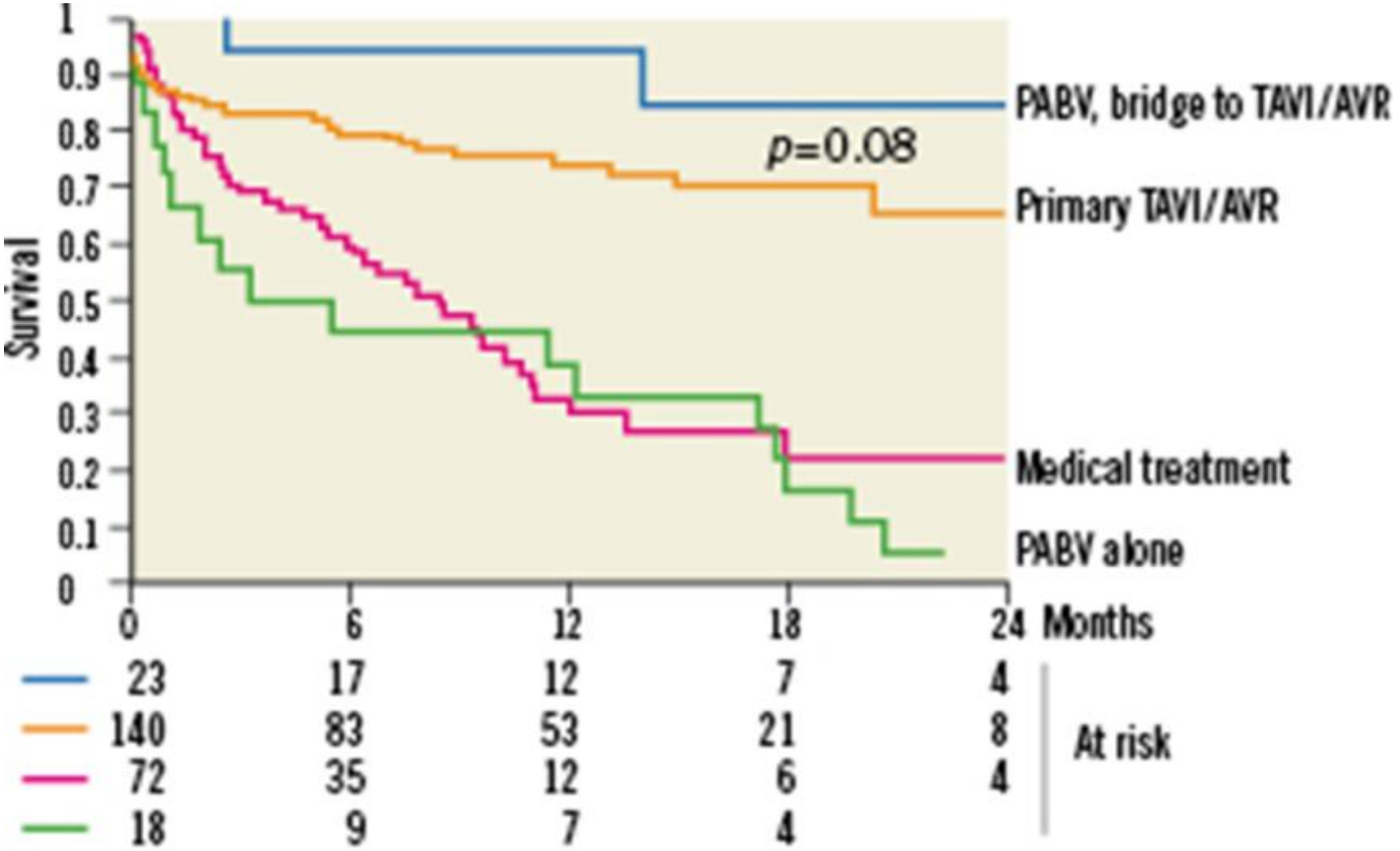

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Table 2. Baseline characteristics of the patients treated by percutaneous aortic balloon valvuloplasty.

	Bridge to TAVI or AVR (n=23)	PABV alone (n=18)	*P*
Age (years, mean±SD)	79±8	83±8	0.12
Female sex	11 (48)	8 (44)	0.83
NYHA class			0.36
II	0	0	
III	7 (30)	8 (44)	
IV	16 (70)	10 (56)	
Cardiogenic shock	6 (26)	6 (33)	0.61
Coronary artery disease	13 (57)	11 (85)	0.14
Previous MI	4 (17)	7 (39)	0.16
Previous PCI	6 (26)	4 (22)	1
Previous CABG	6 (26)	5 (28)	1
Peripheral artery disease	6 (26)	6 (33)	0.61
Renal failure	10 (43)	14 (78)	0.05
Severe COPD	8 (35)	5 (28)	0.74
Cancer	8 (35)	5 (28)	0.74
Porcelain aorta	4 (17)	0	0.12
≥2 comorbidities	16 (70)	14 (78)	0.73
Aortic valve area			
cm^2	0.71±0.19	0.59±0.19	0.05
cm^2/m^2	0.41±0.1	0.36±0.08	0.11
Mean gradient (mmHg)	48±13	43±15	0.21
LVEF (%)	49±17	40±15	0.08
< 30%	3 (13)	3 (17)	1
Logistic EuroSCORE (%)			
Mean±SD	35±21	39±24	0.56
Range	10-90	10-86	
STS-PROM (%)			
Mean (SD	19±10	24±14	0.24
Range	8-47	7-62	

Values are expressed as n (%) unless otherwise stated. AVR: aortic valve replacement; CABG: coronary artery bypass grafting; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SD: standard deviation; STS-PROM: Society of Thoracic Surgeons Predicted Risk of Mortality; TAVI: transcatheter aortic valve implantation

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Table 4. Echographic findings before and after percutaneous aortic balloon valvuloplasty.

	Before PABV	After PABV	*P*
AVA			
cm^2	0.66±0.2	0.87±0.18	<0.001
cm^2/m^2	0.39±0.09	0.48±0.09	<0.001
Mean aortic gradient (mm Hg)	46±14	30±13	<0.001
LVEF (%)	44±17	46±17	0.01
SPAP (mm Hg)	56±17	48±13	0.0001
AR grade			
0	14 (34)	11 (27)	0.57
1	20 (49)	20 (49)	
2	7 (17)	9 (22)	
3	0	1 (2)	

Values are expressed as n (%) unless otherwise stated; AR: aortic regurgitation; AVA: aortic valve area; LVEF: left ventricular ejection fraction; PABV: percutaneous balloon aortic valvuloplasty; SPAP: systolic pulmonary artery pressure

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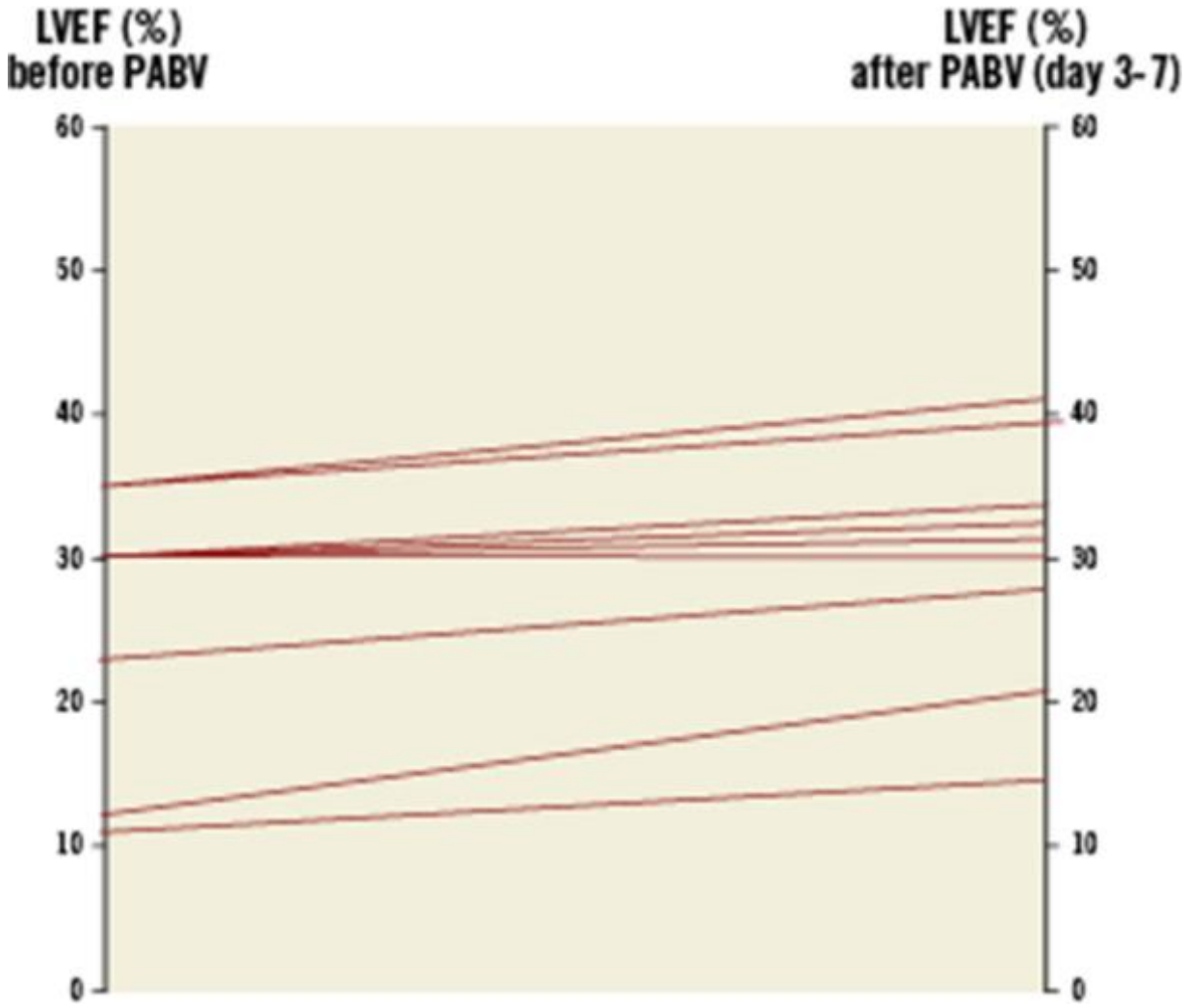

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Table 3. 30-day outcomes in patients treated by percutaneous aortic balloon valvuloplasty.

	Overall (n=41)	Bridge to intervention (n=23)	PABV alone (n=18)	*p*
Major vascular complications	1 (2)	0	1 (6)	0.44
Heart block*	3 (7)	1 (4)	2 (11)	0.57
Mortality	6 (15)	0	6 (33)	0.04
Per-procedure	0	0	0	
30-day cardiac	5 (12)	0	5 (27)	0.01
30-day non-cardiac	1 (3)	0	1 (6)	0.44

Values are expressed as n (%) or mean±SD, unless otherwise stated; PABV: percutaneous aortic balloon valvuloplasty; *Requiring definitive pacemaker

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Table 5. Causes of death in patients treated with percutaneous aortic valvuloplasty.

Time	PABV	Days to death	Cause of death
In-hospital	Alone	1	Multi-organ failure
In-hospital	Alone	3	Multi-organ failure
In-hospital	Alone	11	Multi-organ failure
In-hospital	Alone	18	Pulmonary infection
Post-discharge	Alone	25	Delayed cardiogenic shock
Post-discharge	Alone	28	Delayed cardiogenic shock
Post-discharge	Alone	57	Cardiac failure
Post-discharge	Alone	72	Cardiac failure
Post-discharge	Bridge	79	Cardiac failure
Post-discharge	Alone	96	Cardiac failure
Post-discharge	Alone	164	Cardiac failure
Post-discharge	Alone	364	Cardiac failure
Post-discharge	Bridge	421	Cardiac failure
Post-discharge	Alone	516	Delayed cardiogenic shock
Post-discharge	Alone	529	Renal failure
Post-discharge	Alone	537	Cardiac failure
Post-discharge	Alone	590	Cardiac failure
Post-discharge	Alone	618	Cardiac failure

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Conclusion

- In high-risk patients with aortic stenosis and temporary contraindications to AVR or TAVI, PABV may be used as a bridge to intervention with good mid-term outcomes.
- In others, PABV can be safely used but is associated with a poor outcome.

3.1.8. Aortic Balloon Valvotomy

Class IIb

Aortic balloon valvotomy might be reasonable as a bridge to surgery in hemodynamically unstable adult patients with AS who are at high risk for AVR. *(Level of Evidence: C)*

Aortic balloon valvotomy might be reasonable for palliation in adult patients with AS in whom AVR cannot be performed because of serious comorbid conditions. *(Level of Evidence: C)*

Class III

1. Aortic balloon valvotomy is not recommended as an alternative to AVR in adult patients with AS; certain younger adults without valve calcification may be an exception (see Section 6.1.3). *(Level of Evidence: B)*

Thank You