Percutaneous Aortic Valvuloplasty: Long-Term Survival

Angioplasty Summit – Seoul April 27, 2007

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Background

- Although Aortic Valve Replacement (AVR) is a surgical procedure with low surgical mortality and excellent long-term results, there exists a large cohort of patients who represent high-risk for AVR or are frankly inoperable.
- Most of these patients are managed medically with a concomitant inexorable downhill course and very high mortality.
- Percutaneous Aortic Valve Replacement (PAVR) shows great promise for this cohort of patients.
- However, PAVR is some years from being available to the general public.
- In the meantime, we need a treatment for the high-risk and inoperable patients that will serve as a bridge to PAVR when it is finally available.

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Do patients with valvular heart disease receive treatment according to established guidelines?

31.8% did not undergo intervention, despite NYHA class III/IV symptoms

- 92 hospitals from 25 countries
- 5,001 patients from April-July, 2001

Courtesy Martin Leon

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EUROPEAN SOCIETY OF CARDIOLOGY

A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease

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Aims To identify the characteristics, treatment, and outcomes of contemporary patients with valvular heart disease (VHD) in Europe, and to examine adherence to guidelines.
Methods and results The Euro Heart Survey on VHD was conducted from April to July 2001 in 92 centres from 25 countries; it included prospectively 5001 adults with moderate to severe native VHD, infective endocarditis, or previous valve intervention. VHD was native in 71.9% of patients and 28.1% had had a previous intervention. Mean age was 64±14 years. Degenerative aetiologies were the most frequent in aortic VHD and mitral regurgitation while most cases of mitral stenosis were of rheumatic origin.
Coronary angiography was used in 85.2% of patients before intervention. Of the 1269 patients who underwent intervention, prosthetic replacement was performed in 99.0% of aortic VHD, percutaneous dilatation in 33.9% of mitral stenosis, and valve repair in 46.5% of mitral regurgitation; 31.7% of patients had ≥1 associated procedure. Of patients with severe, symptomatic, single VHD, 31.8% did not undergo intervention, most frequently because of comorbidities. In asymptomatic patients, accordance with guidelines ranged between 66.0 and 78.5%. Operative mortality was <5% for single VHD.
Conclusions This survey provides unique contemporary data on characteristics and nent of patients with VHD. Adherence to guidelines is globally satisfying as nvestigations and interventions.

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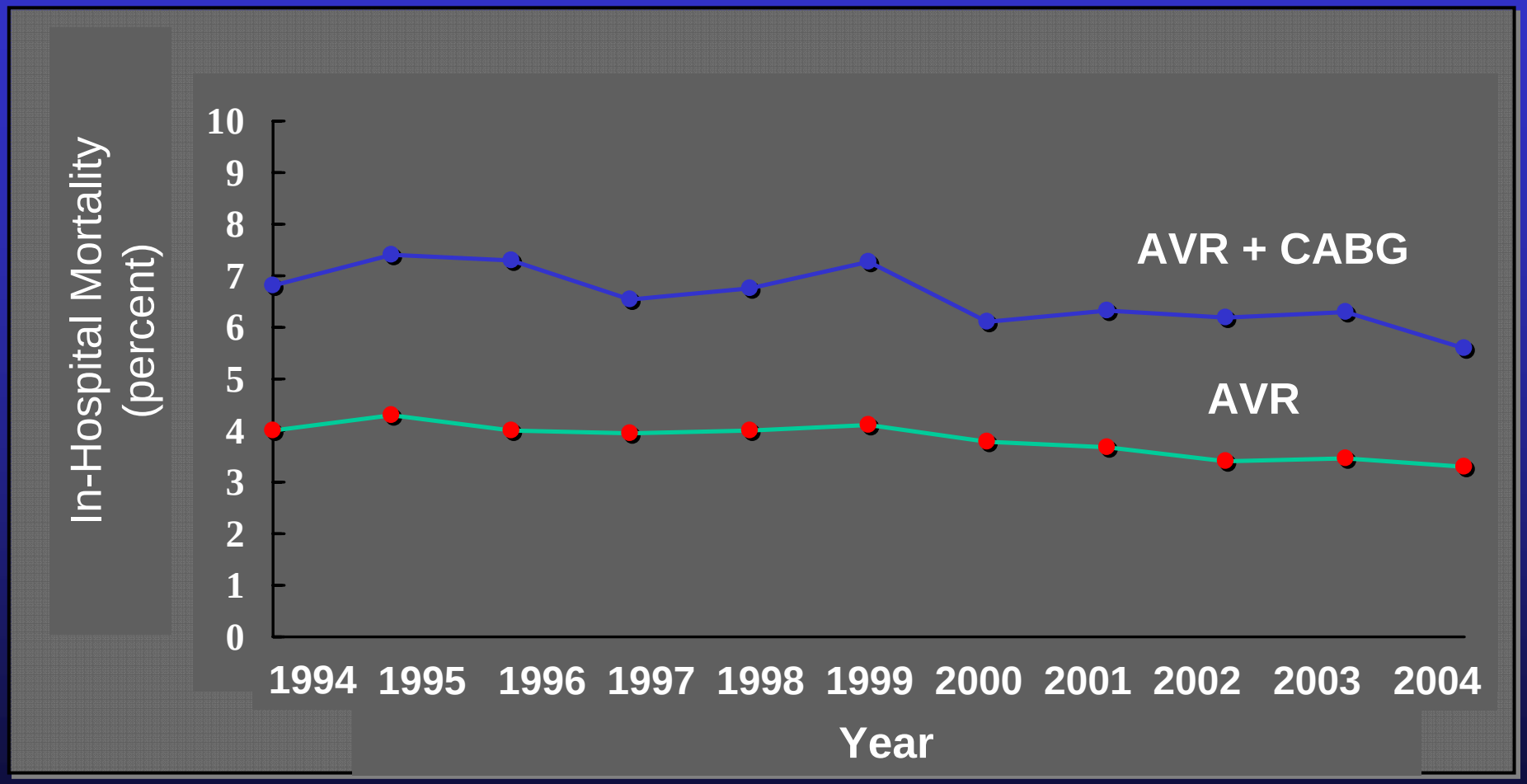
Aortic Valve Replacement Hospital Mortality



Society of Thoracic Surgeons Database, 2005 [www.sts.org]

Operative Mortality / Comorbidity

Euro Heart Survey on Valvular Heart Disease

1231 Patients operated in 92 centers from April to July 2001

Introduction

- For more than twenty years, Percutaneous Balloon Aortic Valvuloplasty (PBAV) has been an effective treatment for short-term palliation of signs and symptoms of critical aortic stenosis in patients who are not candidates for aortic valve replacement.
- Because of a prohibitively high restenosis rate, this procedure fell into disfavor soon after its introduction in 1985.
- Although the procedure was generally abandoned after 1990, some centers including our own have continued to perform it on a regular basis for true “no option” patients.
- We have observed that hemodynamic restenosis does not always correlate with clinical recurrence in these elderly patients who are otherwise limited by age and co-morbid disease.

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Methods

- In order to assess the magnitude and duration of palliation in this population, we have retrospectively examined the clinical course of patients who underwent PBAV in our center during the past six years.
- No formal prospective criteria were followed in the determination of suitability for AVR.
- All patients were referred by cardiologists and/or cardiac surgeons from outside our institution.
- All were functional classes 3 and 4.

Methods, cont.

- All patients were deemed by their referring physicians to be unsuitable candidates for aortic valve replacement.
- In general, patients were felt to be too old or too frail for AVR, or were rejected on the basis of significant co-morbidities such as advanced pulmonary disease or cancer.
- In support of the accuracy of this assessment, two patients in the cohort had AVR subsequent to early clinical recurrence following apparently successful and uncomplicated PBAV.
  - One patient died immediately post-operatively, and the second patient died within one month.

Technique

- All efforts were made to keep procedures as short and simple as possible.
- Patients were fully evaluated prior to the procedures.
  - All with echocardiography.
  - Many with prior diagnostic cardiac cath.
- If coronary angioplasty was necessary, this was done as a separate procedure.
- Right heart catheterization and cardiac output measurements were not routinely performed.
- Overriding principle was that in these elderly very sick patients complications could be minimized by minimizing procedure time and avoiding all but essential procedural components.
- Most procedure times were kept under 30 minutes.

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Technique

- All procedures were performed from a retrograde approach using a single balloon.
- Balloon sizes varied from 18 mm to 23 mm.
- A single 20 mm balloon was used for the majority of procedures.
- Some procedures were started with an 18 mm balloon followed by a 20 mm balloon.
- Occasional procedures were started with the 20 mm balloon with subsequent step-up to a 23 mm balloon.
- In most cases an effort was made to rupture the balloon, but this technique was not uniformly applied.

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Cohort

- 38 symptomatic patients with Critical Aortic Stenosis.
- Ages 65-95 (mean age 80).
- Follow-up 3-78 months (mean 42 months) after PBAV.
- 19 men and 19 women.
- All patients were functional classes 3 and 4.
- All were prohibitively high-risk for Aortic Valve Replacement (AVR).
- Initial decision that a patient was not a surgical candidate was never made by the physician performing the valvuloplasty procedure.
- Vast majority of patients were referred for specific purpose of aortic valvuloplasty.

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Assessment of Risk

- Logistic Euroscore
  - Range 14.0% - 84.1%
  - Mean 57.5%
  - Median 62%
- STS Predicted Risk
  - Range 14.2% - 79.2%
  - Mean 39.7%
  - Median 35%

Comparative Risk vs. PAVR

Cohort	Logistic Euroscore (%)	STS Score (%)
Vancouver (CE)*	28.0	
Revival (CE)*	33.3	13.0
Leipzig (CE)*	27.1	
CoreValve	25.5	
PBAV	57.5	39.7

*Cribier-Edwards Valve

**Transapical

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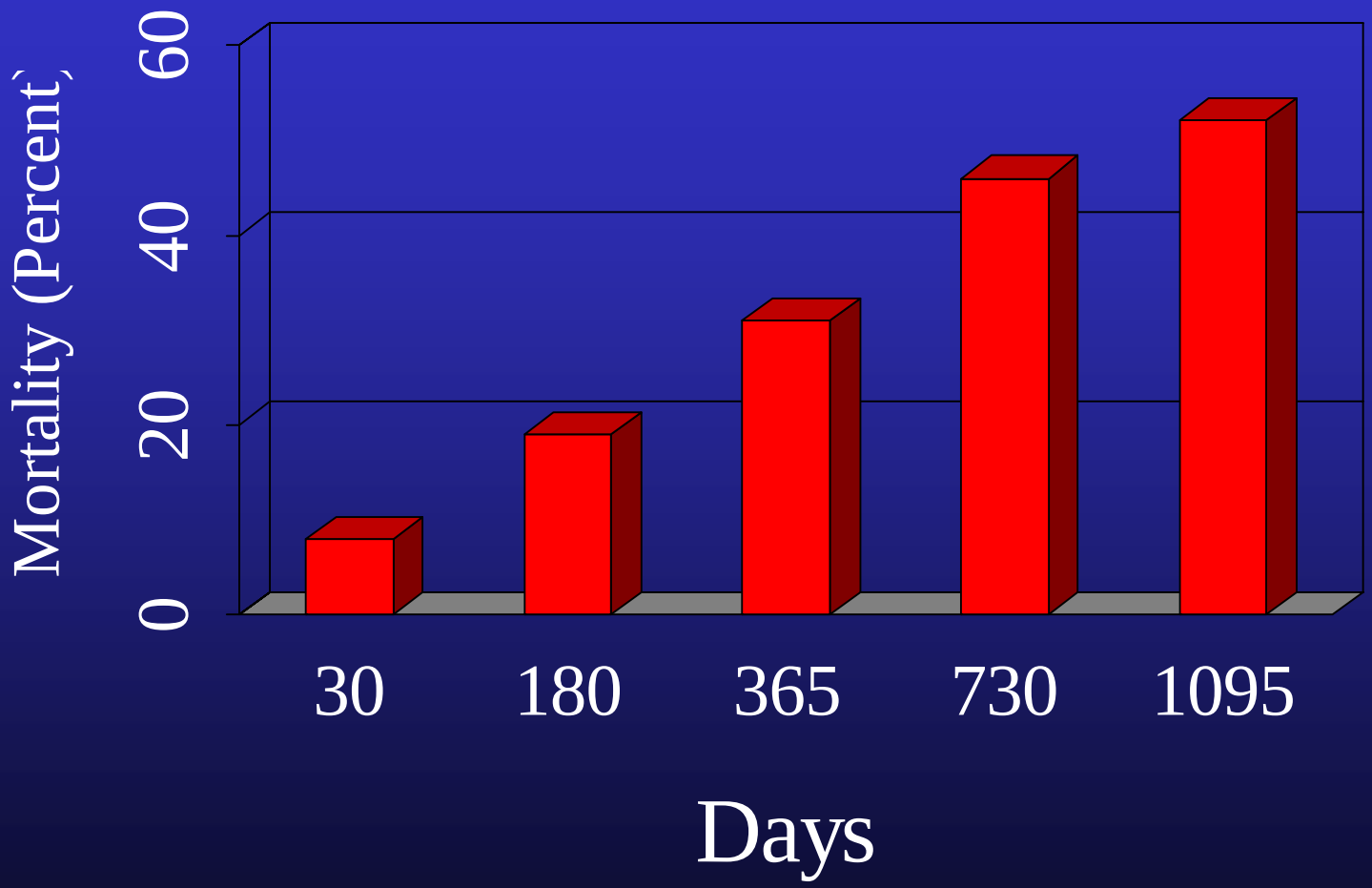
Results

- Pre-PBAV all patients were functional classes 3 and 4.
- All procedures were initially successful and uncomplicated.
- Two patients (5%) died during hospitalization.
  - One from ischemic bowel.
  - One from renal failure.
- One patient died at 11 days outside of hospital from unknown cause (30 day mortality 8%).
- Two patients had AVR within 3 months after PBAV.
  - Both died shortly after surgery.

Results, cont.

- After 36-months there were 19 deaths (5 non-cardiac).
- Mortality was 19% at 6 months, 31% at 12 months, 46% at 24 months, and 52% at 36 months.
- Four patients have survived more than 4 years and 2 have survived more than 5 years – all without re-intervention.
- Eight patients (21%) required re-interventions, 7 between 6 and 12 months after initial PBAV.
- Three patients had 2 re-interventions; one had 3 re-interventions.
- Need for re-intervention did not appear to affect survival.

Mortality



Pre-operative Risk vs. Mortality

- There was a loose correlation between Logistic Euroscore and mortality.
  - Most patients with Euroscores > 70 died in the first year.
- However:
  - Two patients with Euroscores of 80 and 69 were alive at 3 and 4 years respectively.
  - Several patients with Euroscores in 50 – 69 range survived more than two years.

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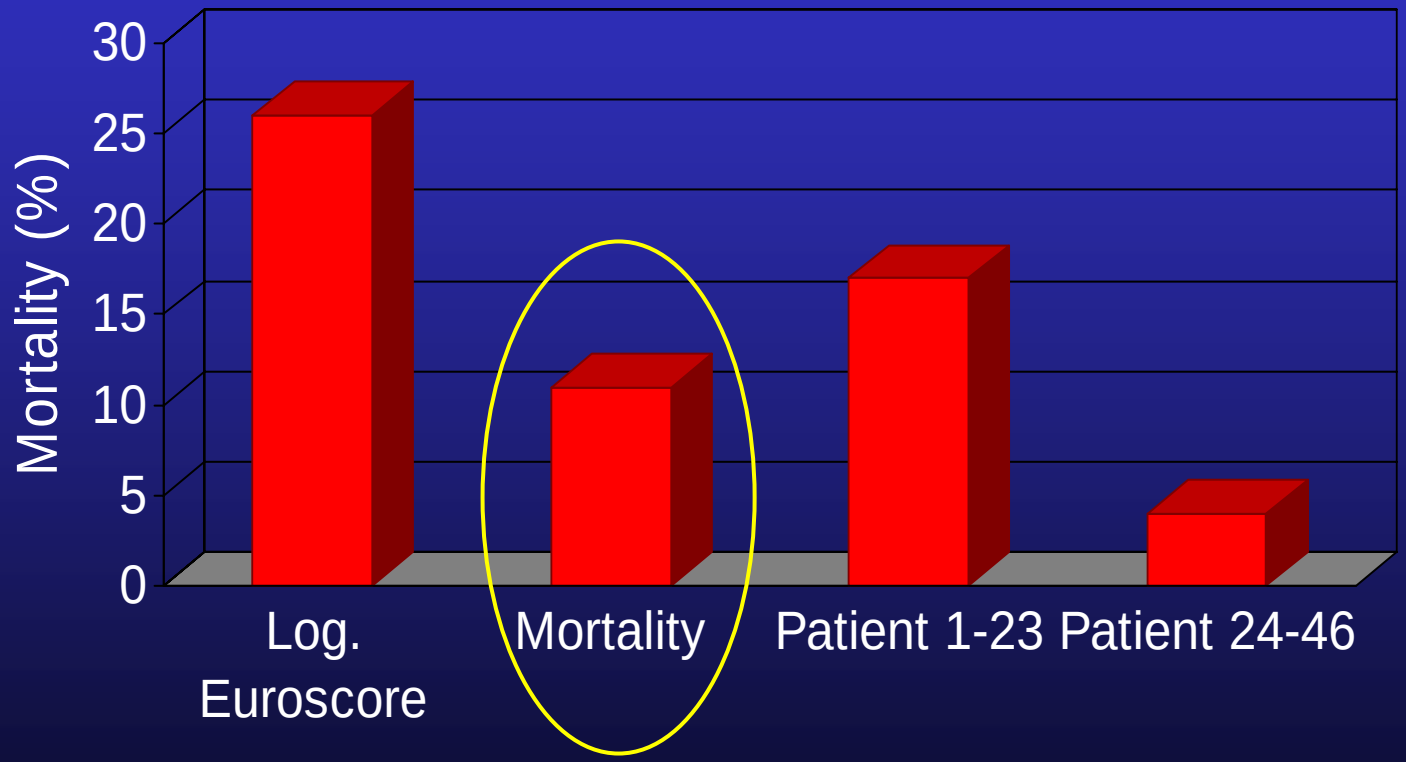
Comparison to PAVR

Retrograde Approach: Vancouver (n=45)

30-Day Mortality



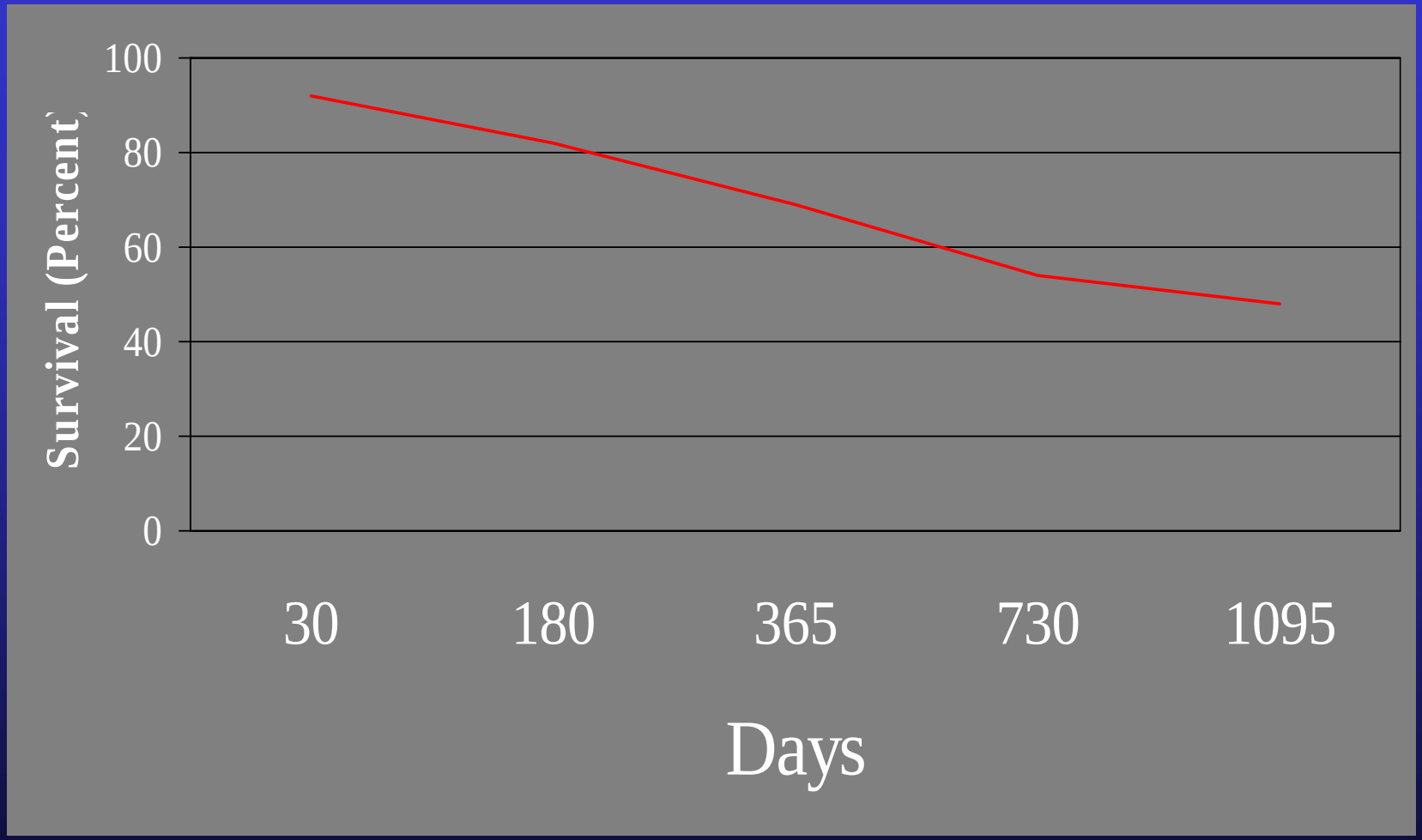
John Webb et al. ACC 2006

Mortality

Cohort	30 Day (%)	6 Month (%)
Vancouver (CE)*	12.1	ca. 20
Revival (CE)*	7.3	14.8
Leipzig** (CE)*	6.6	14.1
CoreValve Gen II	12.7	19.0
PBAV	8.1	18.9

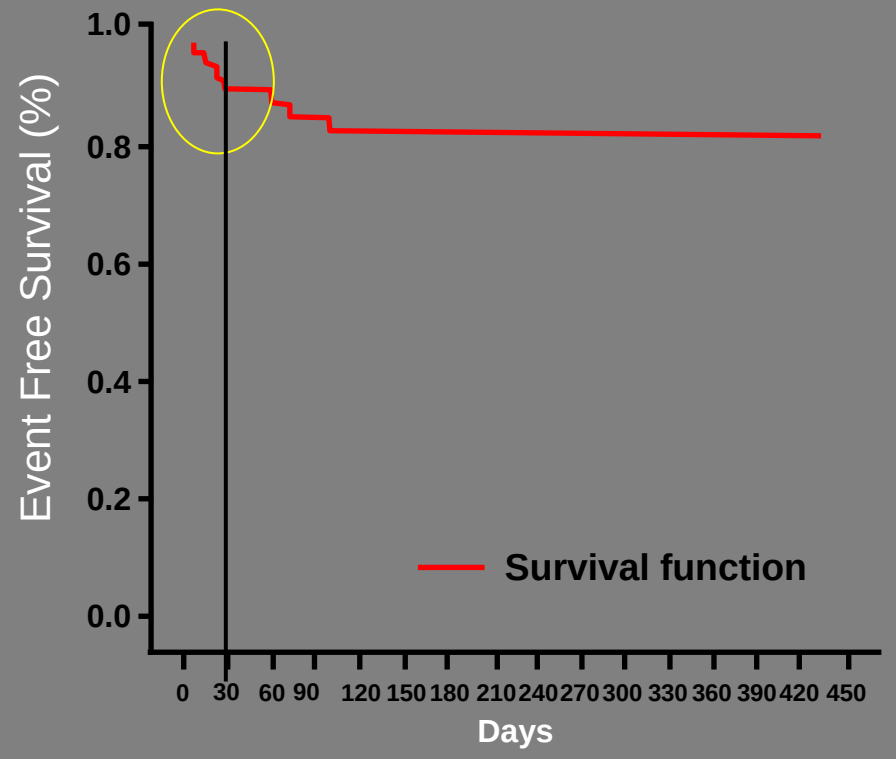
*Cribier-Edwards Valve
**Transapical

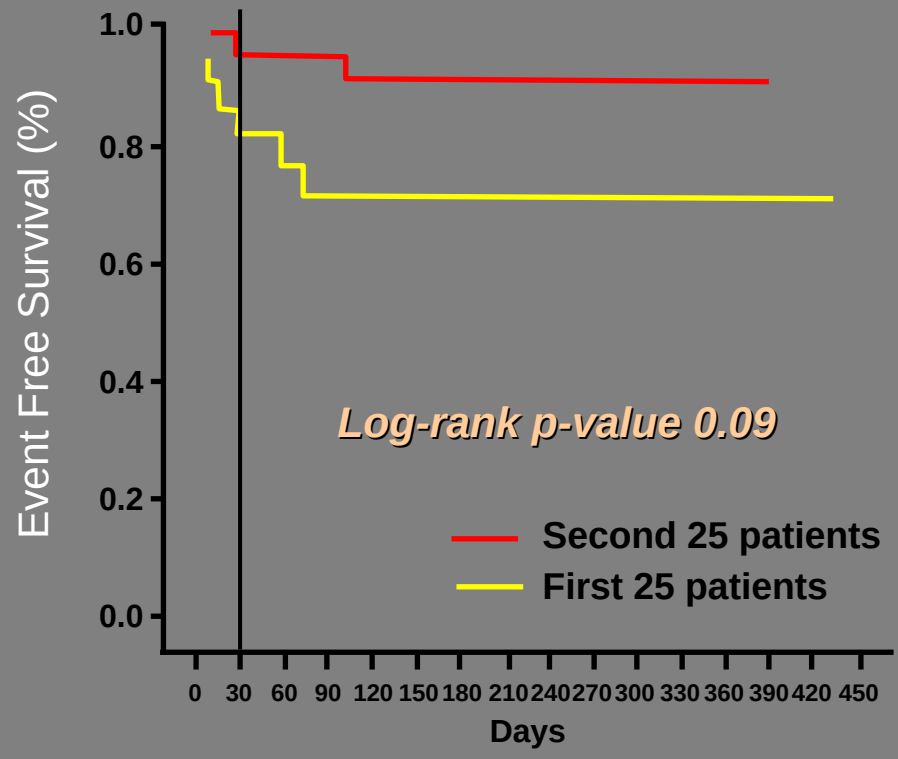
Survival



Transcatheter AVR*: The Vancouver Experience

50 consecutive patients; all patients > 6 months follow-up and 30 patients >1 year follow-up





*Cribier – Edwards Valve

Courtesy of J. Webb via Martin Leon

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Conclusions

- Whether these are good or bad results depends on whether one believes that a glass is half-empty or half-full.
- In this cohort of elderly symptomatic patients with critical aortic stenosis, who were prohibitively high-risk for AVR, 50% survived three or more years, and only a minority required re-intervention.
- The fact that the two patients who crossed over to AVR died peri-operatively lends credence to the high-risk nature of this cohort.
- These data suggest that in the absence of a surgical alternative PBAV is a reasonable palliative procedure for patients with end-stage aortic stenosis.

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Speculation

- It is difficult to compare this cohort to those who have undergone PAVR.
  - The valvuloplasty patients were generally sicker (Logistic Euroscores 58% vs. 30%).
  - PAVR patients have comparable early mortalities with a trend toward more durable results.
- As equipment and technique improve, PAVR will undoubtedly emerge as the superior procedure.
- Until PAVR becomes more generally available, PBAV can bridge the gap between ineffective medical management and definitive AVR in these very sick high-risk patients.

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