TAVI for Native Aortic Valve Regurgitation

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UBC

HEART CENTRE AT ST. PAUL'S HOSPITAL

Disclosure Statement of Financial Interest

Consultant:

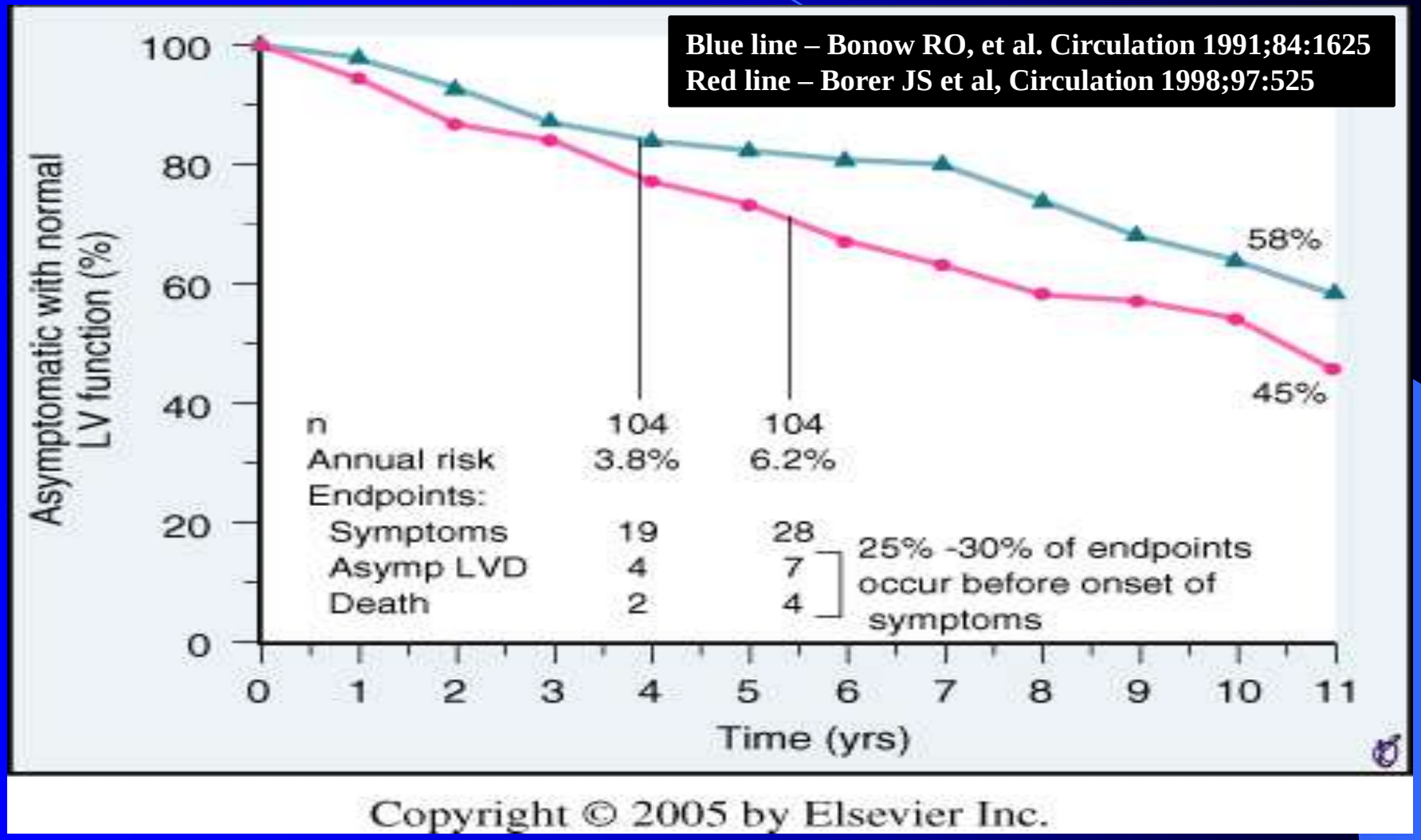
- Edwards Lifesciences

- JC Medical Inc.

Causes of aortic regurgitation

- **Aortic cusp abnormalities**
  - Perforation (eg, infective endocarditis)
  - Cusp shrinkage
    - Rheumatic disease
    - Rheumatoid disease
    - Ankylosing spondylitis
  - Bicuspid aortic valve
- **Loss of commissural support**
  - Ventricular septal defect
  - Dissection (tears) of the aorta
- **Aortic root abnormalities**
  - Dilatation
    - Marfan syndrome
    - Familial conditions
    - Ehlers-Danlos syndrome
    - Pseudoxanthoma elasticum
    - Idiopathic
  - Distortion (aortitis)
    - Syphilis
    - Rheumatoid arthritis
    - Ankylosing spondylitis
    - Nonspecific aortitis
    - Dissecting hematoma

Survival in Patients with Asymptomatic AI



Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine, 7th ed., Õ ûÀ í fengqz 2005

Natural History of AI

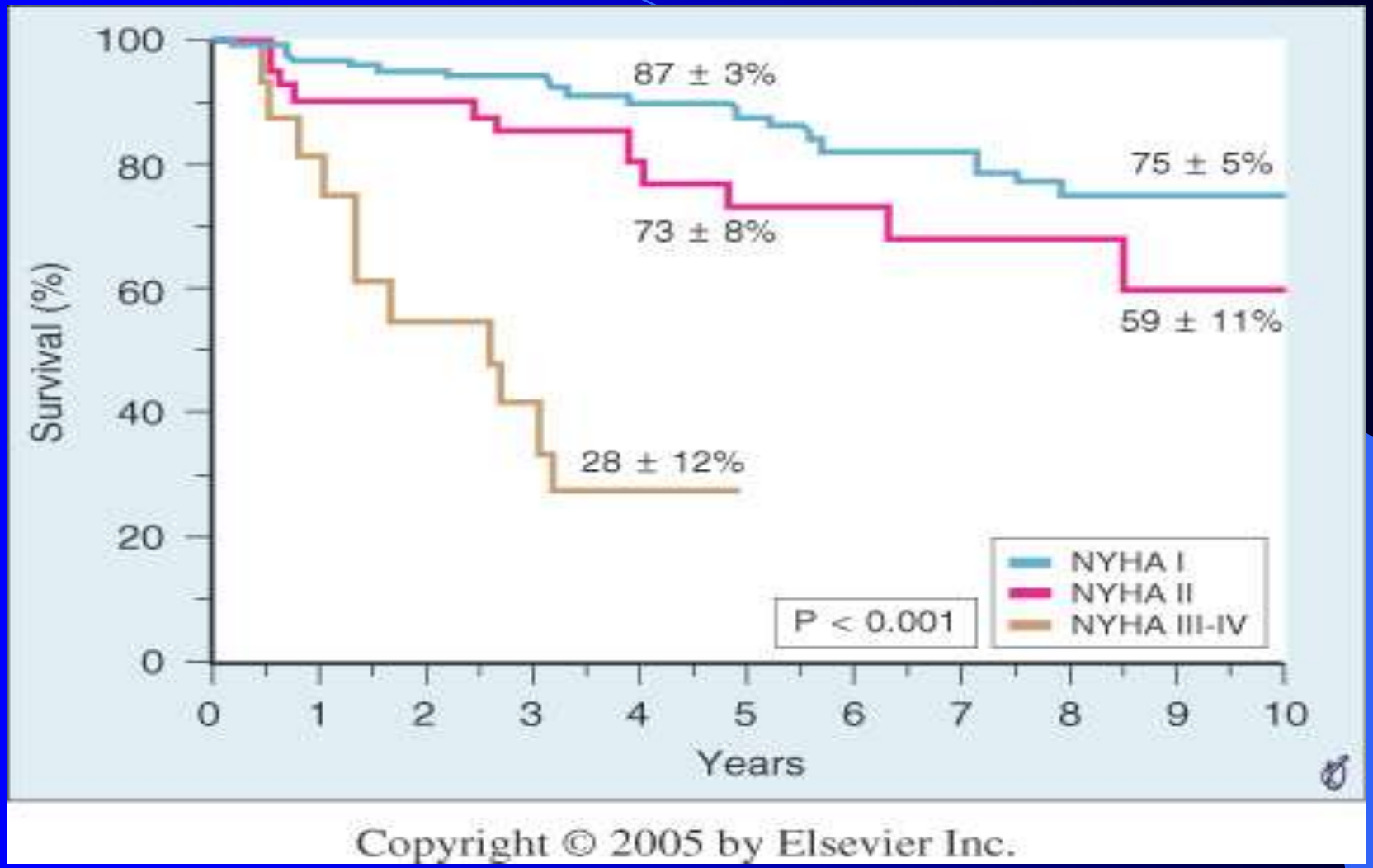
TABLE 57-11 -- Natural History of Aortic Regurgitation

Asymptomatic Patients with Normal LV Systolic Function	
Progression to symptoms and or LV dysfunction	<6%/yr
Progression to asymptomatic LV dysfunction	<3.5%/yr
Sudden death	<0.2%/yr
Asymptomatic Patients with LV Systolic Dysfunction	
Progression to cardiac symptoms	>25%/yr
Symptomatic Patients	
Mortality rate	>10%/yr

LV = left ventricular.

From Bonow RO, Carabello B, de Leon AC Jr, et al: ACC/AHA guidelines for the management of patients with valvular heart disease. J Am Coll Cardiol 32:1486, 1988.

Survival in Patients with AI



Survival without surgery in 242 patients with chronic aortic regurgitation

Dujardin KS, et al. Circulation 99:1851, 1999

TAVI for AI

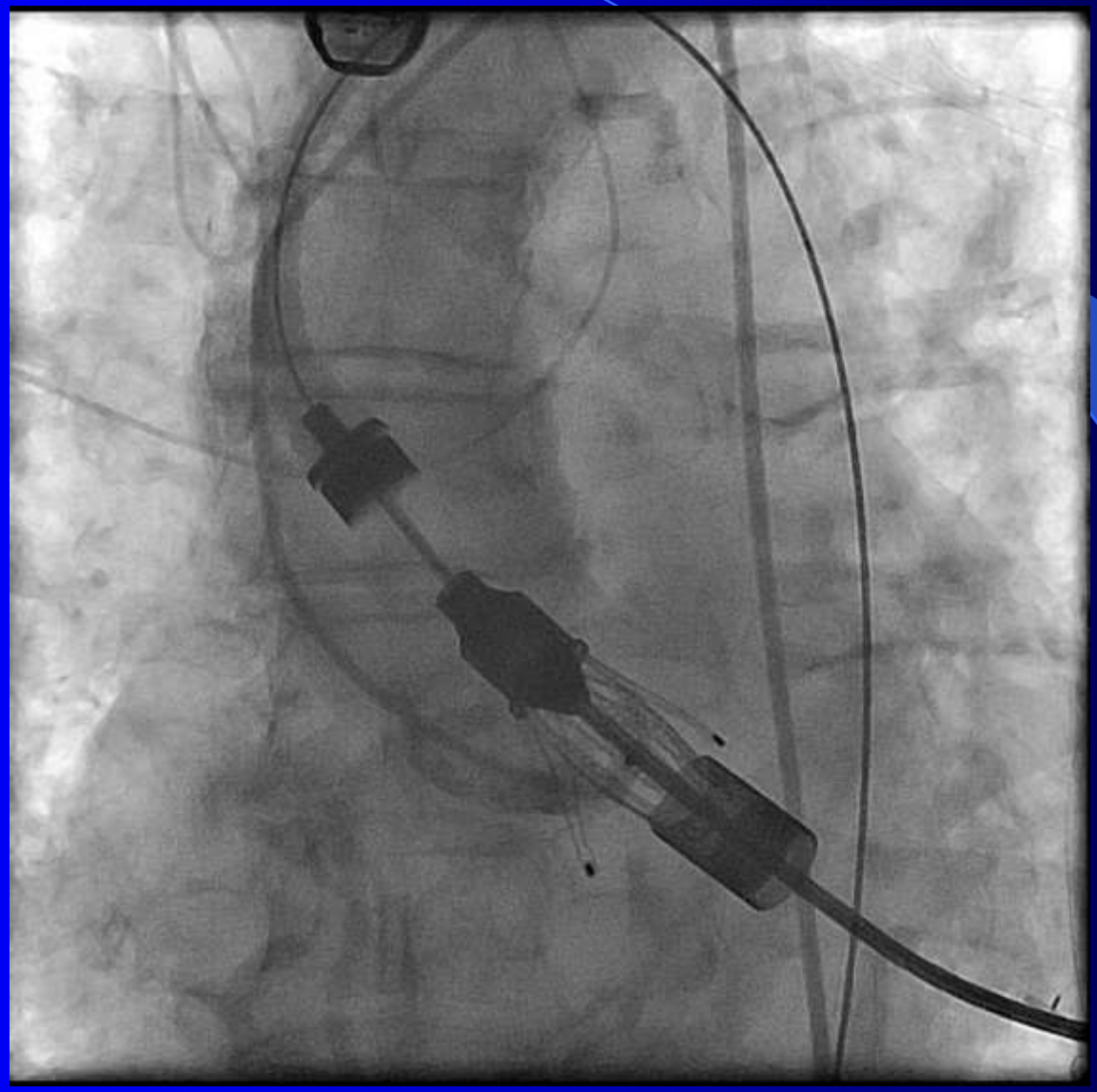
JenaValve

- **JenaValve's unique "3-feeler element"** allows the clinician to accurately position the prosthesis in the anatomically correct position during implantation thus ensuring a precise sub-coronary alignment within the patient's native valve.

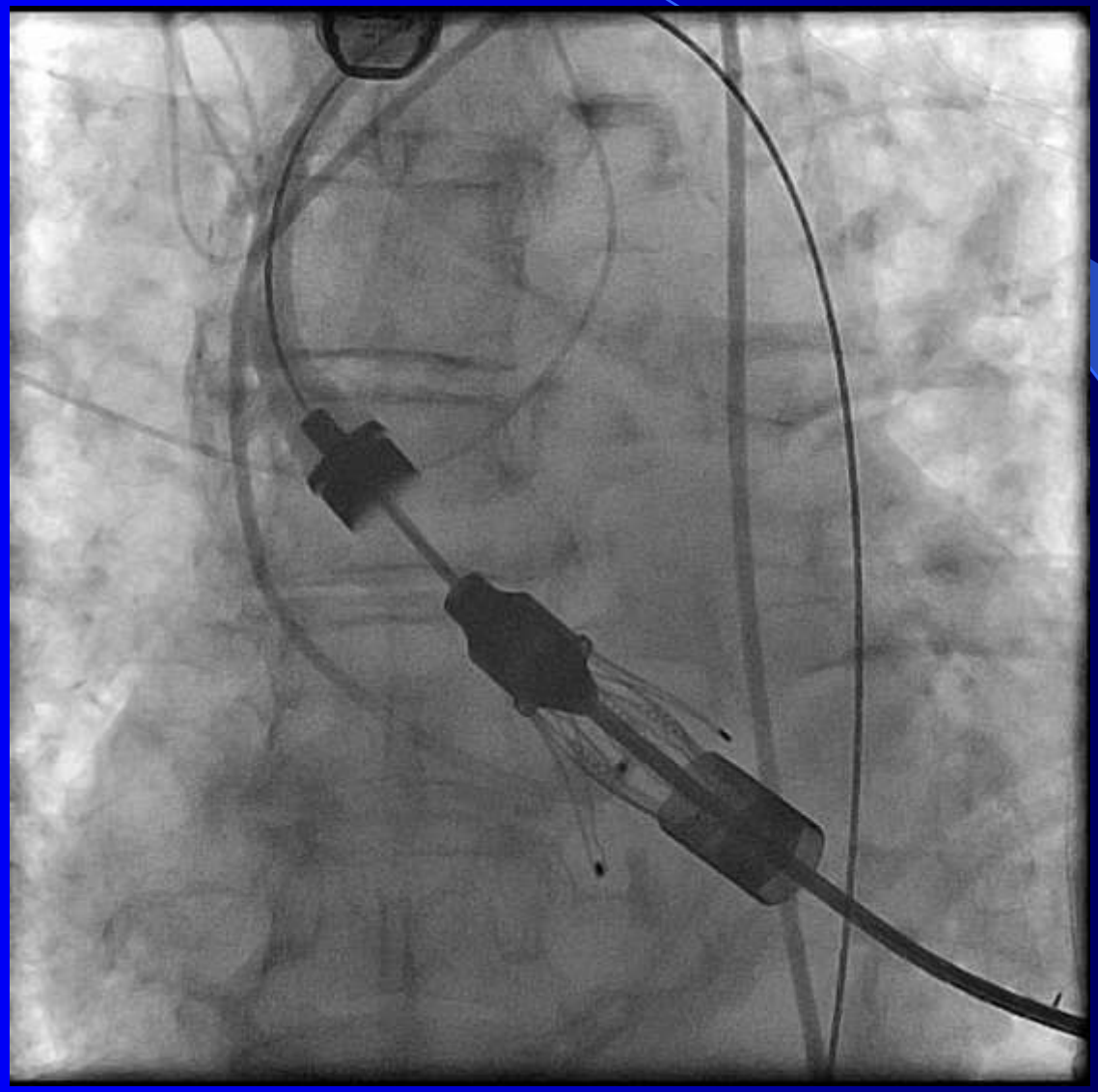
- **JenaClip™ anchoring and clipping mechanism** allows the patient's native valve leaflets to be clipped onto the valve enabling the JenaValve to be firmly anchored in the correct anatomical position and provide active fixation and resistance to migration.

CE Mark approval for high risk AI patients

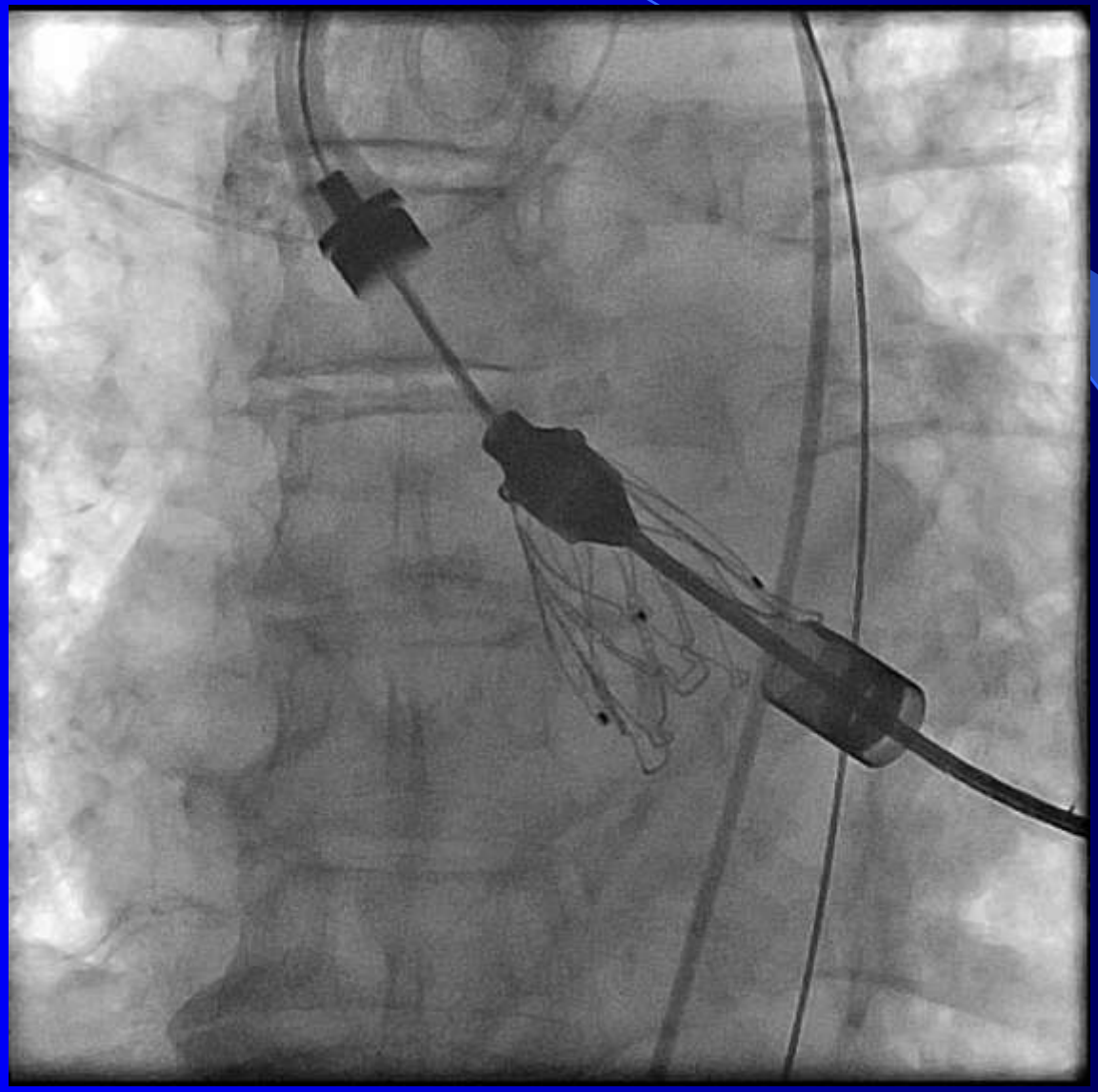
Positioning of 3 Feelers



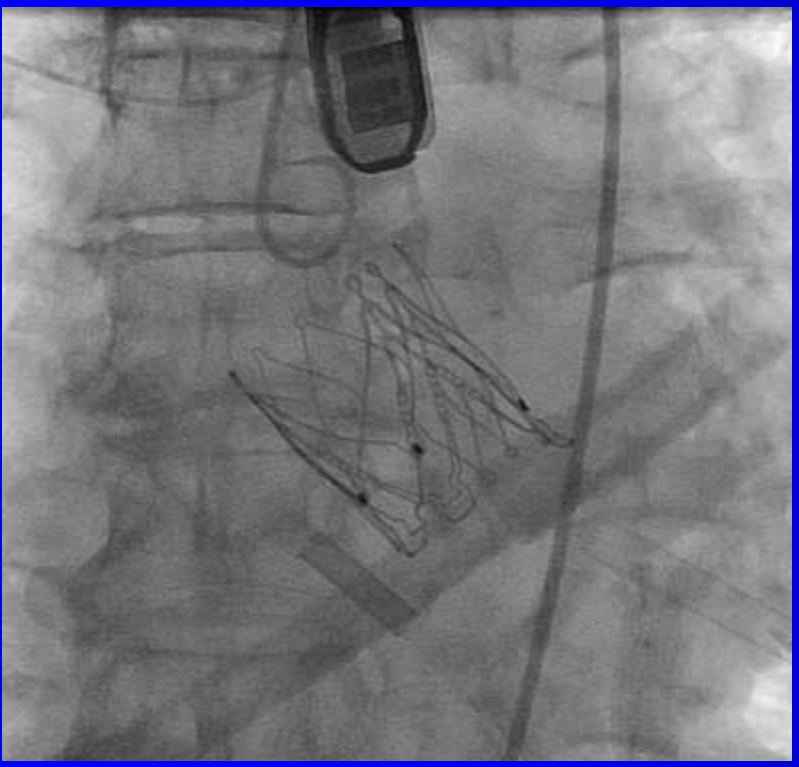
Deployment of LV Side of Valve

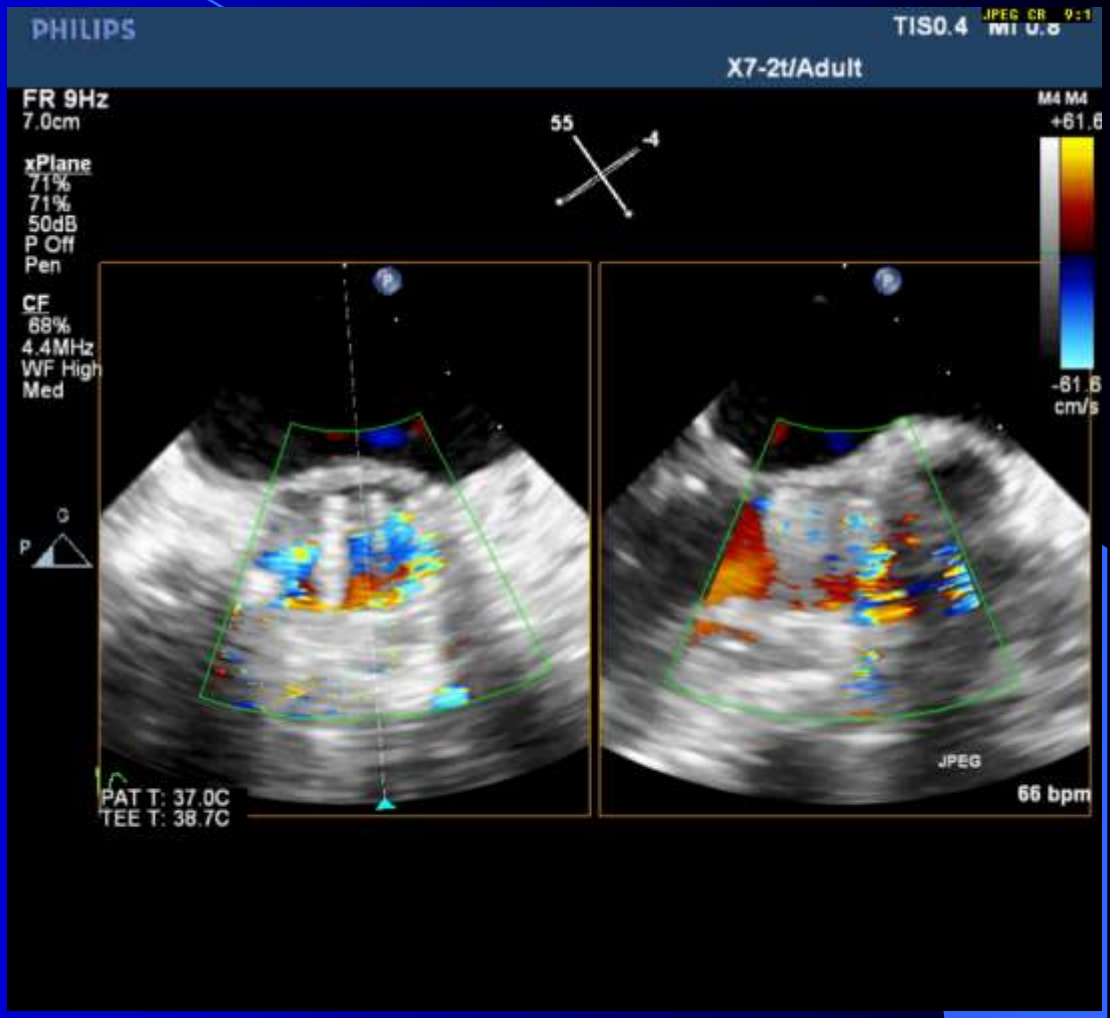


Deployment of Aortic Side of Valve



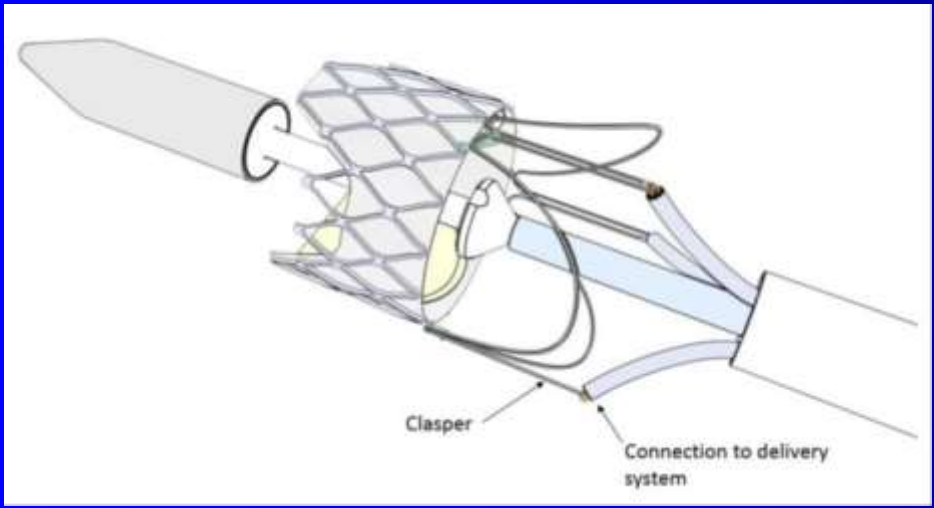
Aortogram and Echo

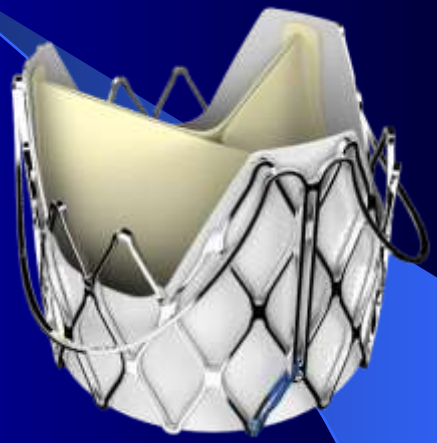


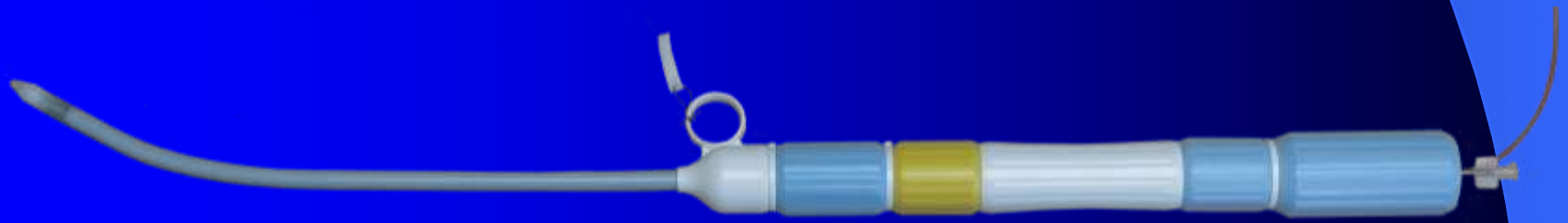


J-Valve™ Ausper System

Jie-Cheng Medical Technology







J•Valve for AI

J•Valve for AI

Clinical Trial (China)

Characteristic	N=107
Age (years)	74.4±5.2
Male (%)	54.2%
EuroSCORE (%)	27.5±8.3
NYHA Class III or IV (%)	97.2
Cerebravascular disease (%)	6.5
PVD (%)	52.3
CAD (%)	18.7
Prior CABG (%)	1.9
Atrial fibrillation (%)	19.6
DM (%)	15.0

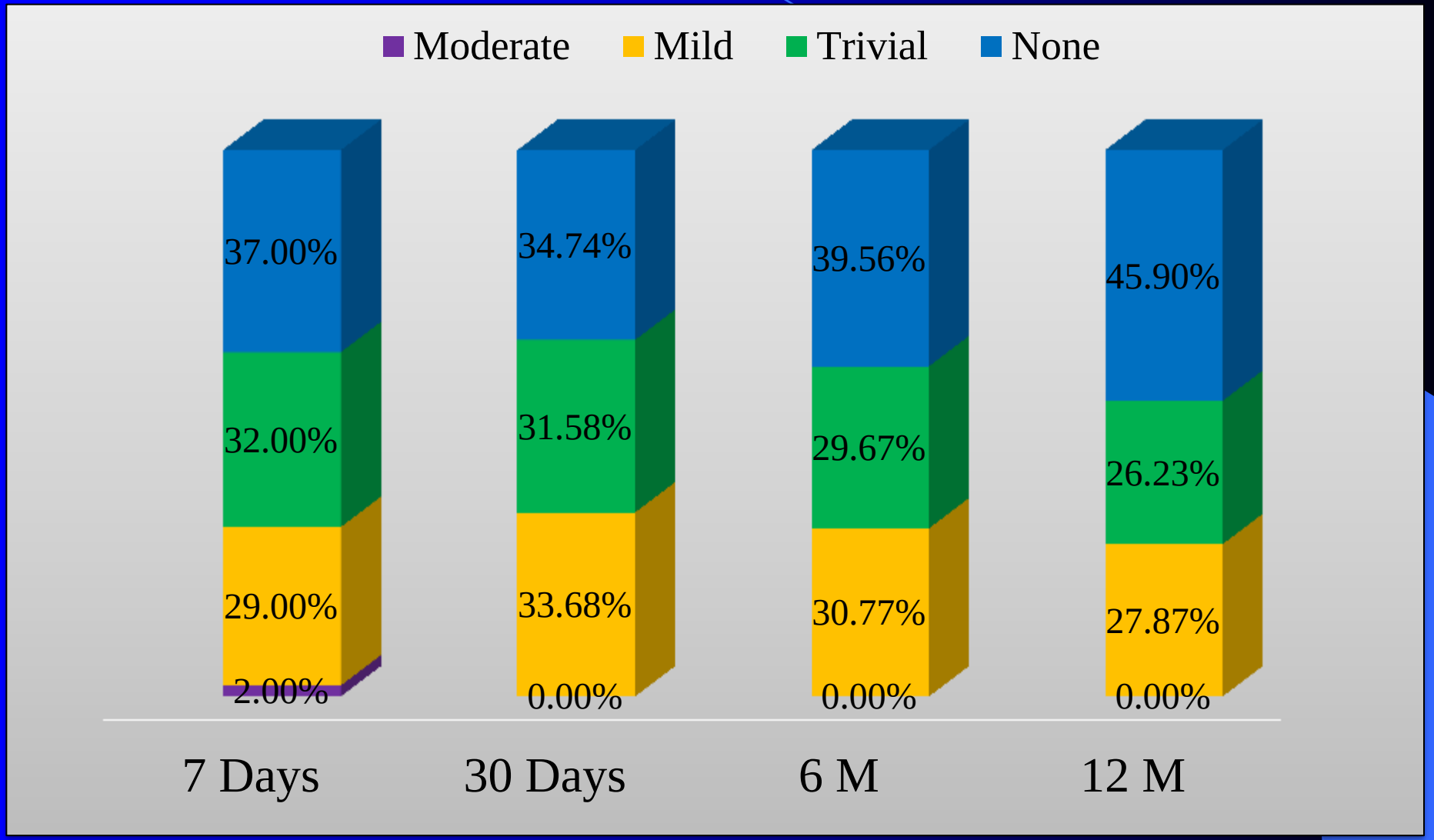
Mortality

All Cause Mortality	All patients N=107 (64 AS and 43 AI)
Intraoperative death (%)	0
30-day mortality (%)	4.67
6-month mortality (%)	5.65
12-month Mortality (%)	5.65

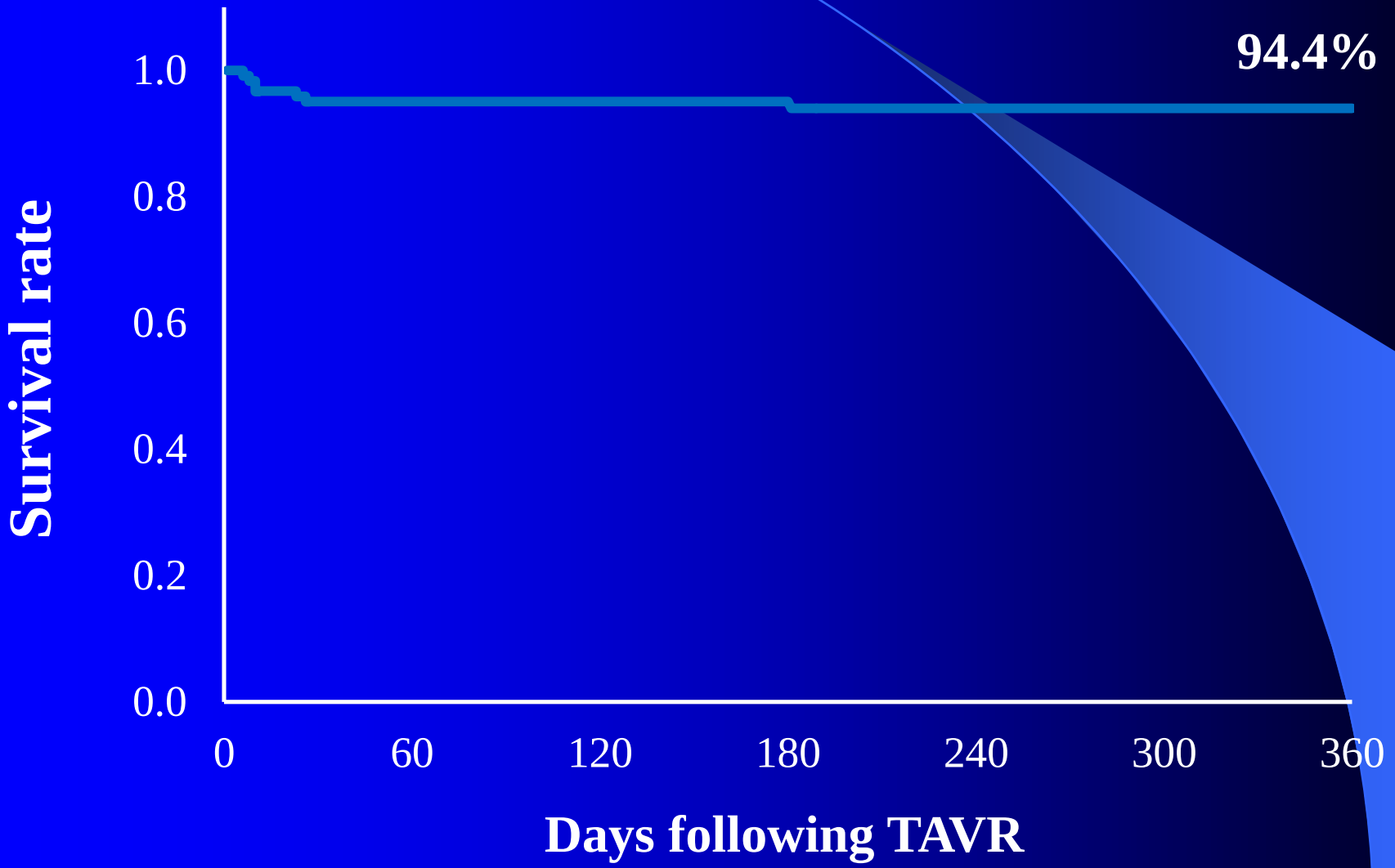
Complications

Complications	30 days	12 months
CVA (%)	0	3.1
MI (%)	0	0
Acute kidney injury (%)	1.0	n/a
Pacemaker(%)	2.8	4.3
Reoperation(%)	0.9	2.4

Paravalvular Leak



Survival


94.4%
1.0
0.8
0.6
0.4
0.2
0.0
Survival rate
0
60
120
180
240
300
360
Days following TAVR


THANKS!