



Venus-A Valve Clinical updates

*1-year outcomes from
the First Multicenter Trial in China*

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On behalf of the Venus-A
Valve Trial Investigators

Background

- **Trascatheter Aortic valve Replacement (TAVR) has been showed to be effective in treatment of extreme or high risk patients with severe aortic stenosis.**
- **Up to date, there were several different devices have been effectively and safely used in clinical practice.**
- **VENUS-A is a new TAVR device developed in China. Its performance during the procedure and long-term outcomes need to be confirmed.**

The Venus A-Valve

- **The Venus A-Valve**

- Self-expanding nitinol stent frame carrying a trileaflet bioprosthetic valve made of porcine pericardial leaflets
- 19Fr (No need big sheath)

- **Specific features**

- Mildly tapered rather than flared inflow
- Radiopaque markers at 4 mm distal to the inflow to guide deployment
- 3 outflow tabs rather than hooks



Investigators & Study Centers

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Applicant



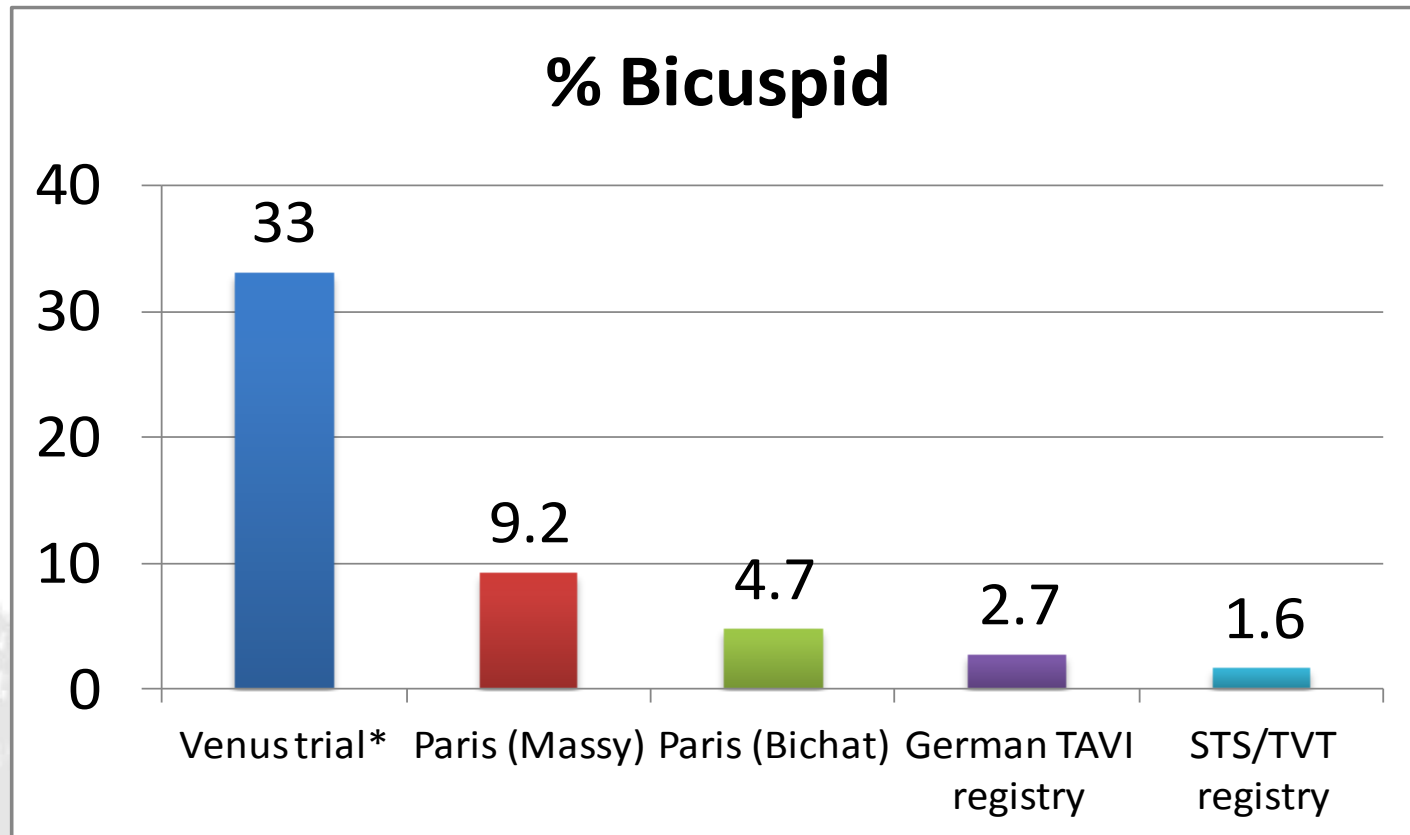
Venus MedTech Co.,Ltd

C R O



Medical(Beijing)
MedTech Co.,Ltd

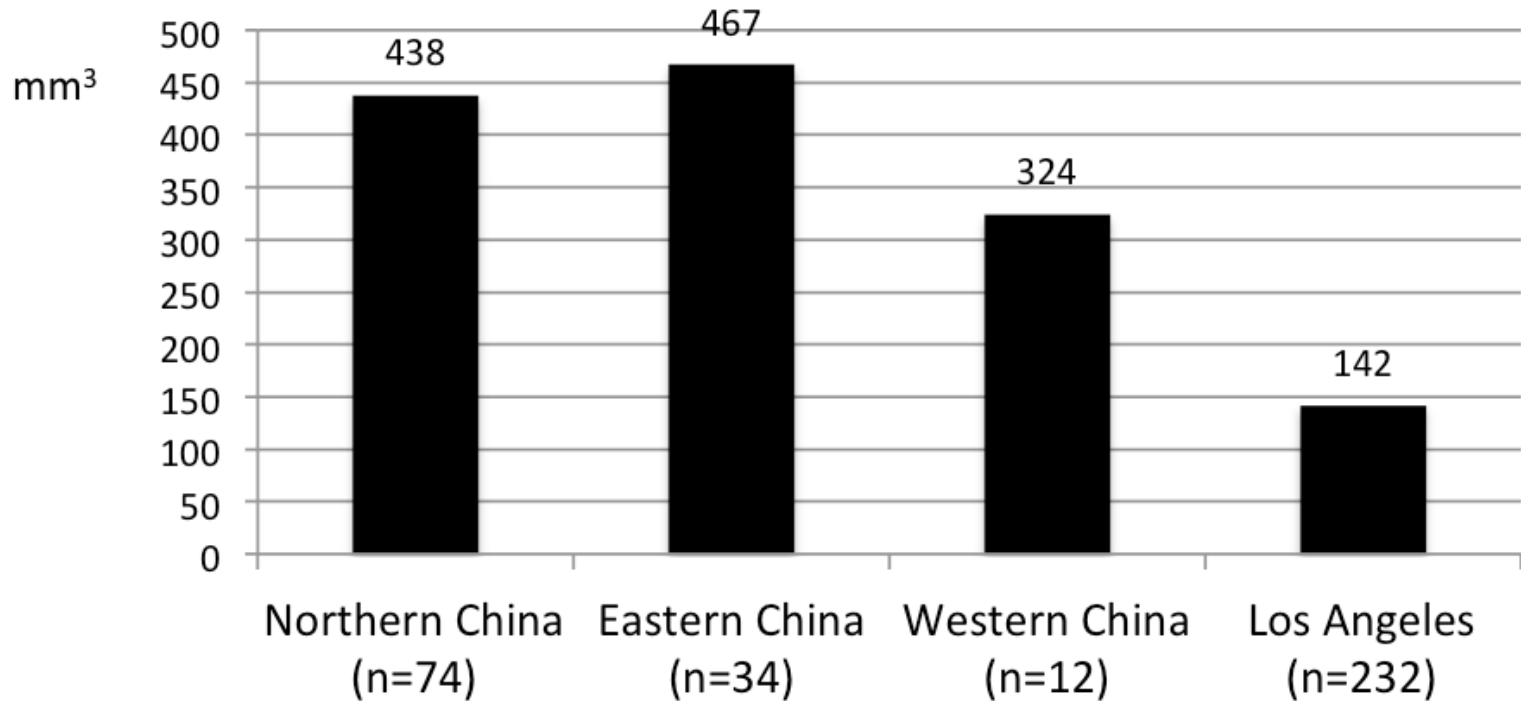
Characteristics of Chinese patients with AS



- **More Bicuspid Valves Than In EU And US**
- **Bicuspid in screened patients close to 50%**

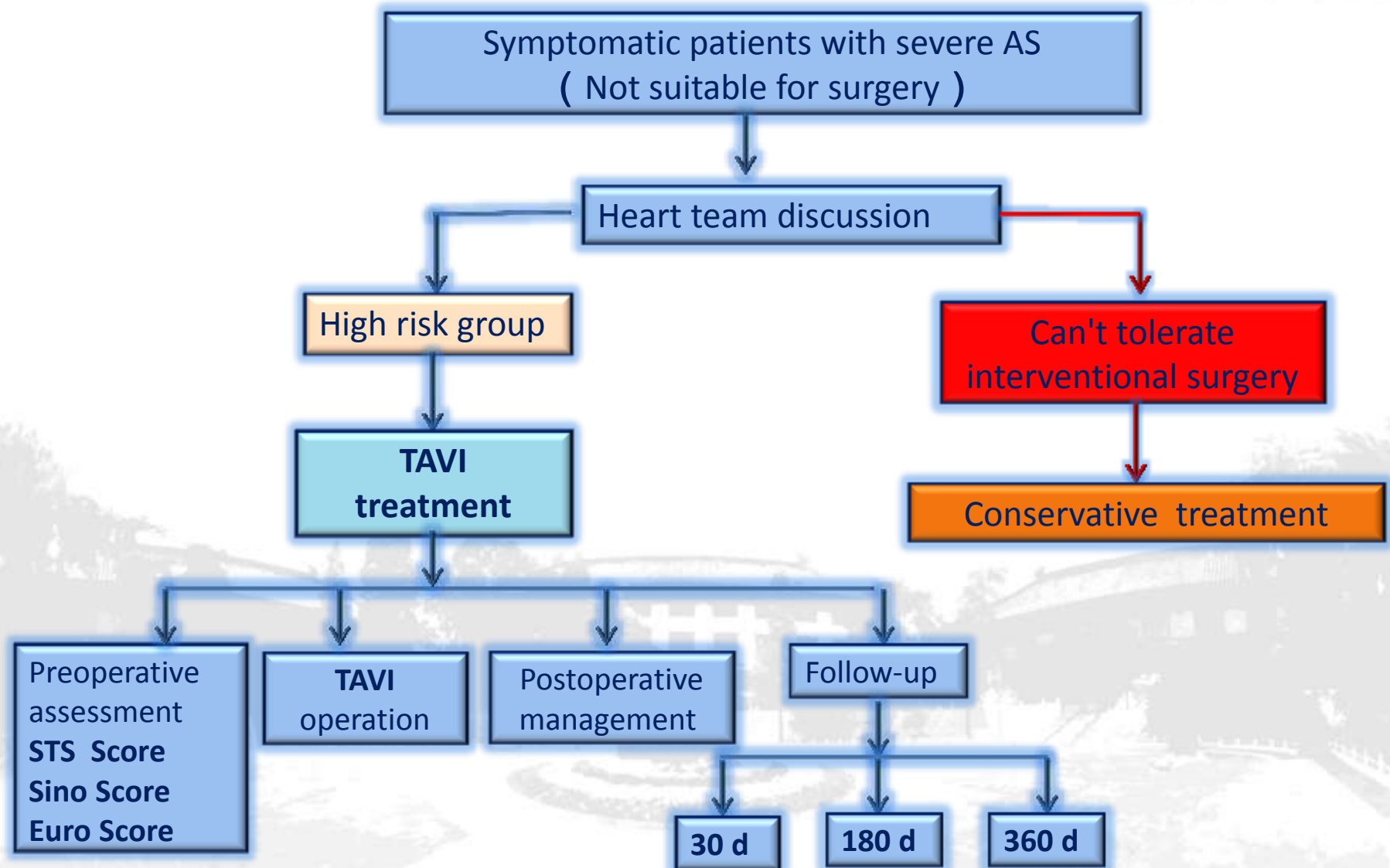
Hayashida et al, Circ Intv 2013
Himbert et al, AJC 2012
Bauer et al, AJC 2014
Mack et al, JAMA 2013

Characteristics of Chinese patients with AS



- **More calcified valves**
- **Regional variations in aortic valve calcium volume**

VENUS-A Trial Flow Chart

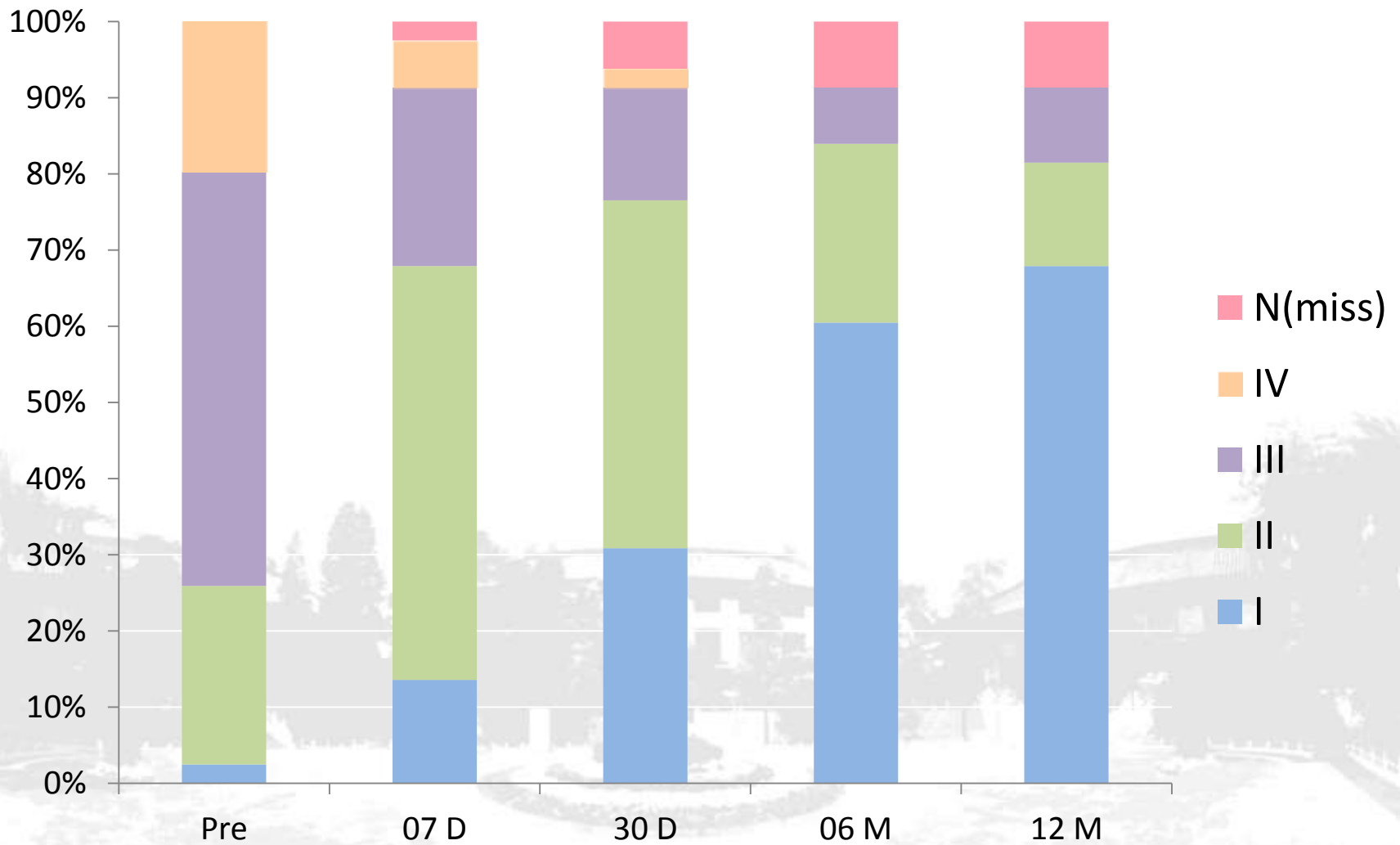


Procedure Success

- **Procedure Success : 95% (N=101)**
- **Cause of Death:**

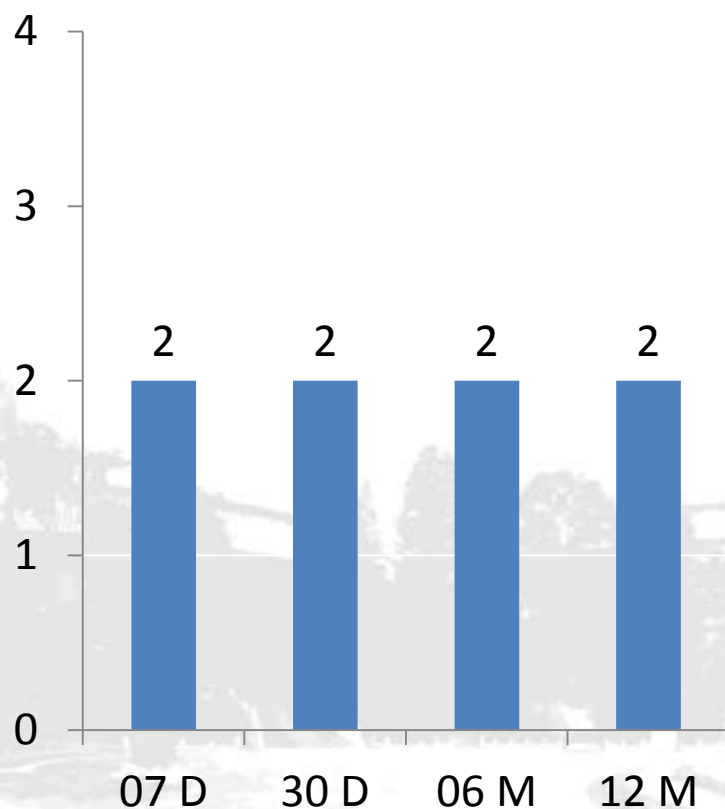
Case NO.	age	sex	special clinical consideration	time of death	cause of death
1	75	F	Procedure failure due to no calcification: → emergent SAVR	Day 7	Pulmonary infection
2	72	M	COPD	Day 30	Circulatory failure
3	92	F	Transfemoral procedure failure → next day transaortic SAVR successful	Day 10	Multiple organ failure
4	78	M	Not clear	Day 4	Sudden death
5	77	M	Not clear	Day 18	Sudden death

NYHA Class

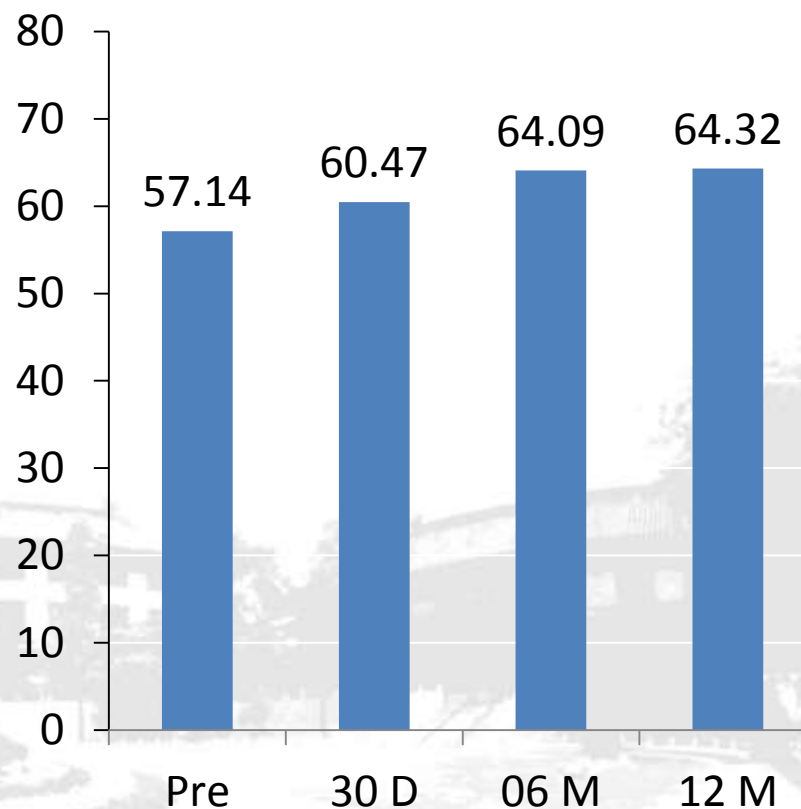


Valve Migration & LVEF Mean

Valve Migration



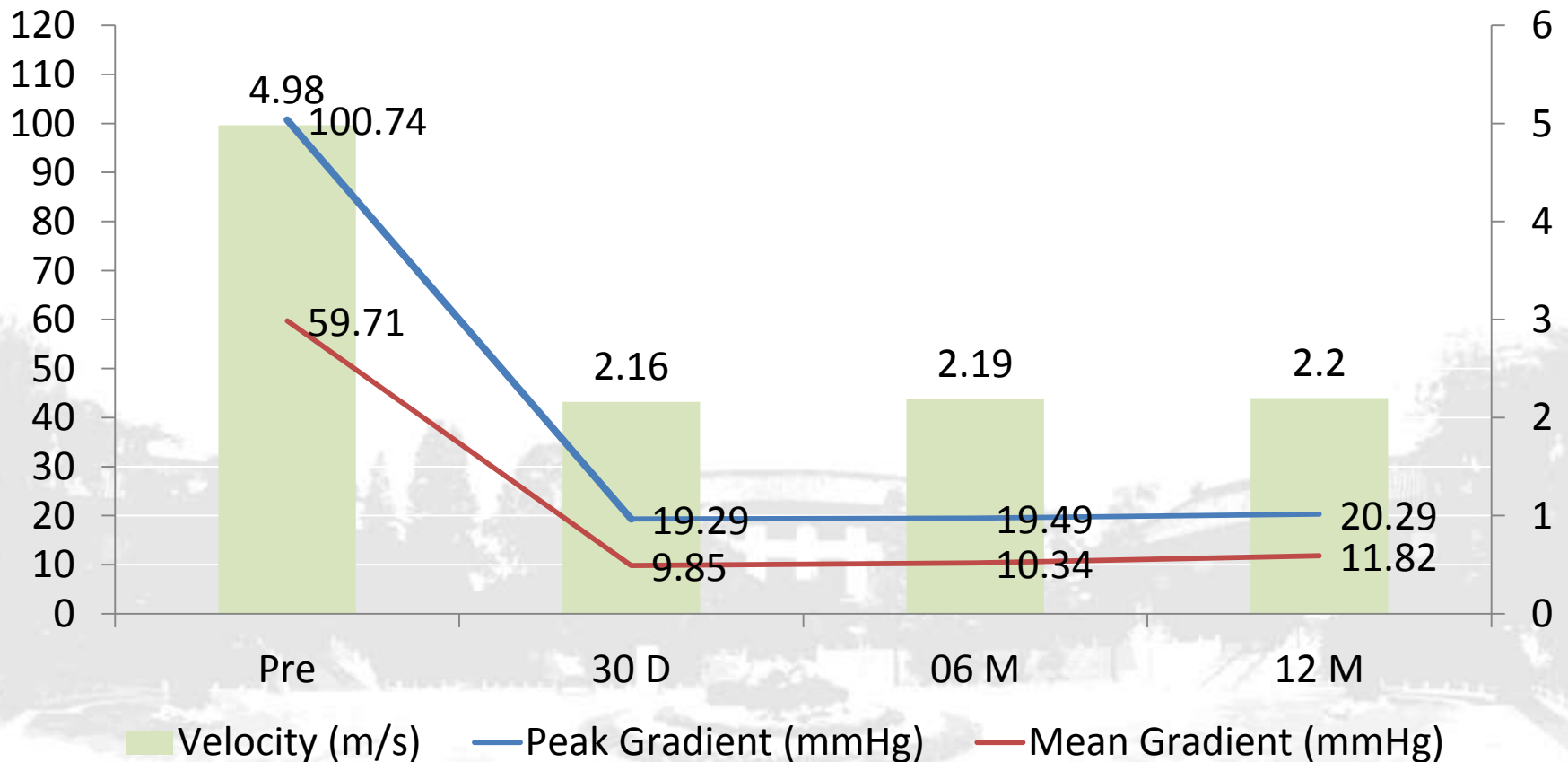
LVEF Mean



Mean & Peak Gradients and Velocity

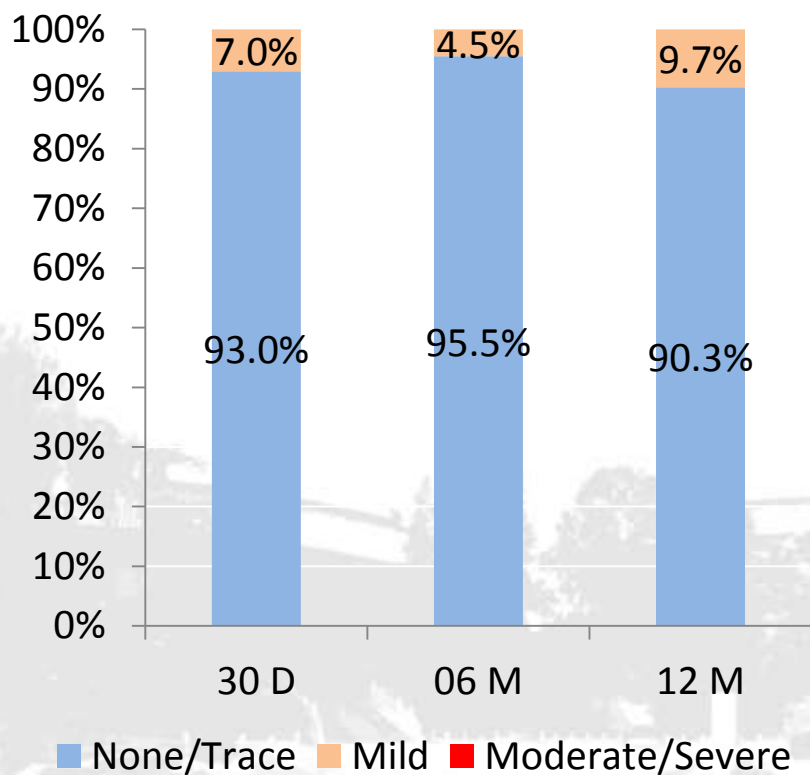
Gradient (mmHg)

Velocity (m/s)

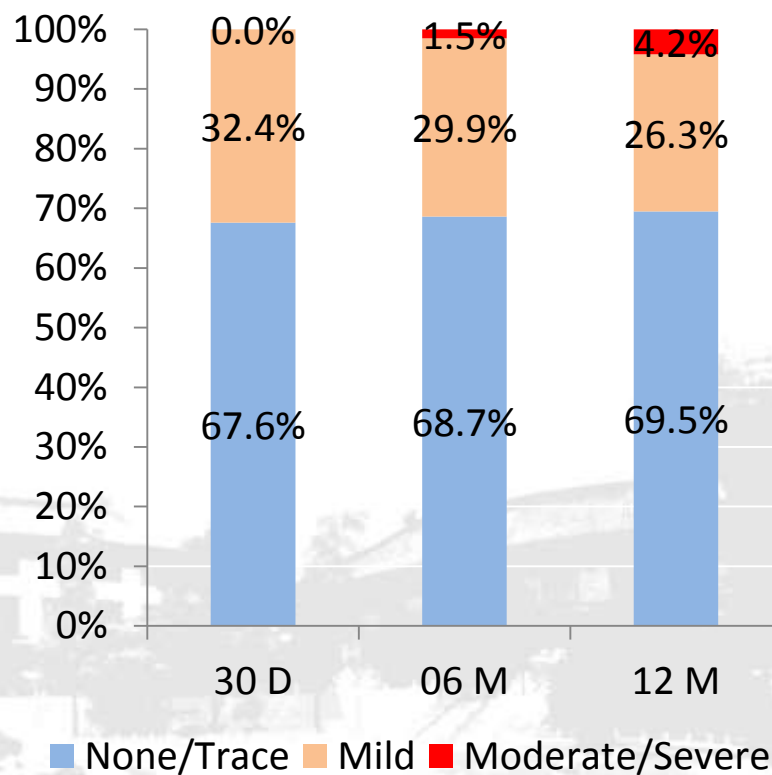


Regurgitation

- **AR**



- **PVL**



Conclusions

- **Venus-A TAVR device is a self-expanding aortic valve with modifications in design, especially in deliver system and radial strength.**
- **During the first clinical TAVR trial in China, the device has been improved according to valvular characteristics in Chinese patients.**
- **Our results show that the Venus-A device is safe and easily positioning, the 1-year mortality is comparable with other contemporary trials, and it is probably more suitable for patients with high volume of calcium and bicuspid.**
- **TAVR technique might be feasible for selected patients with bicuspid.**
- **Long-term follow-up is ongoing.**

Thank you

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China TVI

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