



TRANS CATHETER AORTIC VALVE REPLACEMENT (TAVR) IN LOW RISK PATIENTS

Abu Bakar Saad

In inoperable severe symptomatic aortic stenosis, transcatheter aortic valve replacement (TAVR) has been demonstrated to be a reasonable option in high to intermediate risk patients. TAVR has also been shown to be non-inferior to surgical valve replacement. TAVR is now widely accepted as standard of care as evidenced by previous 6 randomized control trials¹. (Table -1)

NOTION trial conducted recently has also revealed results of TAVR in low risk patients with severe aortic stenosis. Similarly, STS / ACC TVT registries have favorable outcomes.

Waksman et al. conducted nonrandomized study of 200 low risk surgical patients with severe symptomatic aortic stenosis who underwent TAVR with balloon expandable Sapien 3 valve without general anaesthesia through transfemoral approach. The 30 day results showed no mortality and 0.5% risk of stroke. At 30 days CT scan showed leaflet hypoattenuation representing leaflet thickening².

This cohort was then compared with low risk patients undergoing surgical aortic valve replacement. Comparable short term outcomes were shown. In STS/ ACC TVT registry demonstrated a 30 day mortality of 3%, stroke of 1.8% and 1 year mortality of 15.2% for TAVR in low risk patients.

So the learning points from this 200 patients cohort with no mortality at 30 days and lower risk of stroke, paravalvular leak, need for permanent pacemaker or new onset atrial fibrillation etc are that TAVR is a reasonable option in low risk severe aortic stenosis patients. But there were certain limitations including missing long term follow up, using only one type of device in all procedures and leaflet thickening at 30 days detected by CT scan³.

In conclusion, these smaller trials show favorable short term outcomes in low risk patients with severe aortic stenosis. Results of these trials after 10 years will give a better glimpse for future decisions.

Values are %.

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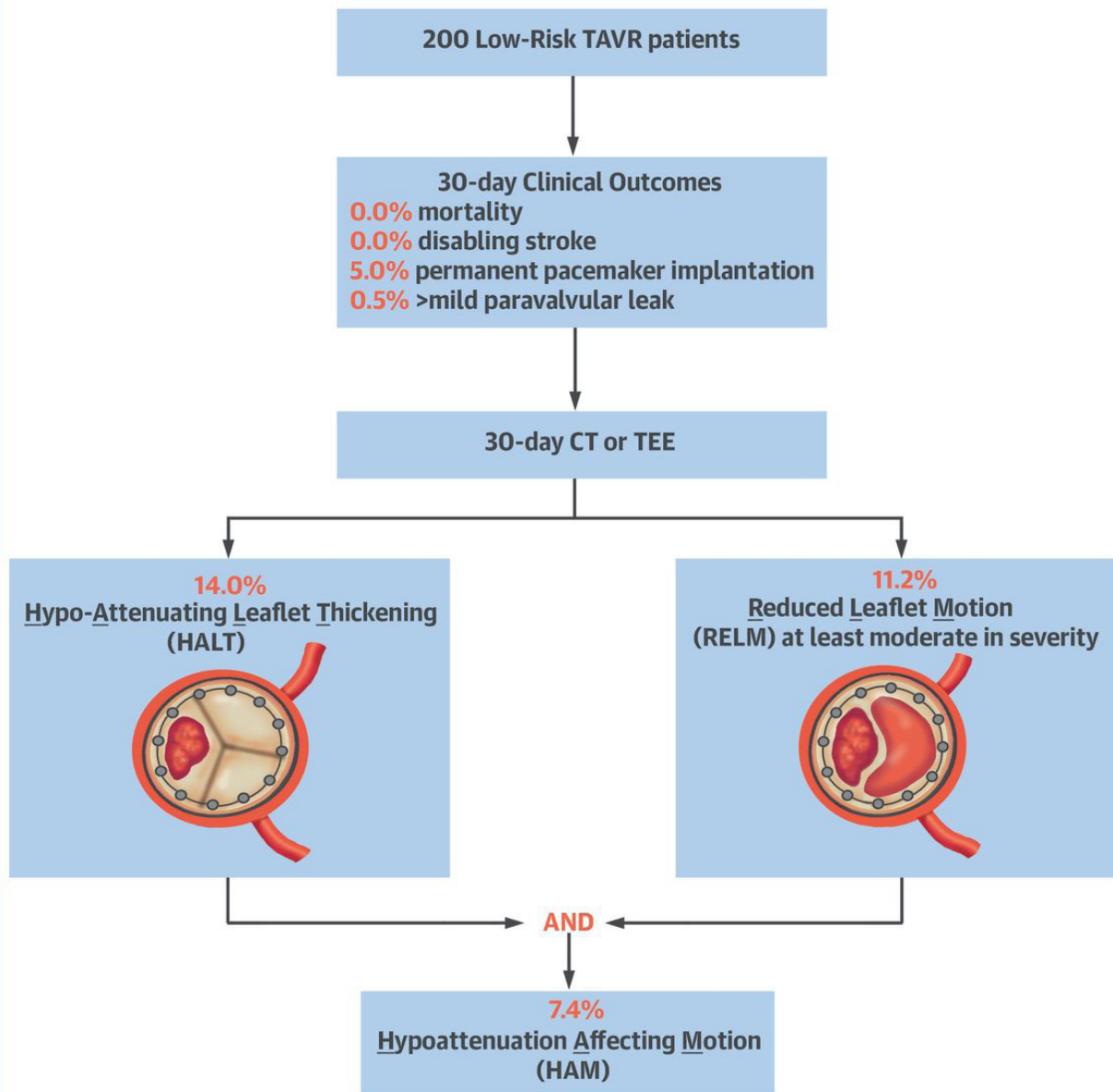
Table -1: Summary of the 7 Completed RCTs and STS/TVT Registry in TAVR

Risk Category/Device	Trial/Registry (Ref. #)	30-Day Mortality		30-Day Stroke		1-Year Mortality	
		TAVR	SAVR	TAVR	SAVR	TAVR	SAVR
Inoperable							
Balloon-expandable	PARTNER 1B (1)	5.0	N/A	6.7	N/A	30.7	N/A
Self-expanding	CoreValve Extreme Risk (2)	8.4	N/A	4.0	N/A	24.3	N/A
High							
Balloon-expandable	PARTNER 1A (3)	3.4	6.5	3.8	2.1	24.2	26.8
Self-expanding	CoreValve High Risk (4)	3.3	4.5	4.9	6.2	14.2	19.1
Intermediate							
Balloon-expandable	PARTNER 2A (5)	3.9	4.1	5.5	6.1	12.3	12.9
Balloon-expandable (propensity matched)	PARTNER S3i (9)	1.1	4.0	2.7	6.1	7.4	13.0
Self-expanding	CoreValve Intermediate Risk (6)	2.2	1.7	3.4	5.6	6.7	6.8
Low risk							
Self-expanding	NOTION trial (7)	2.1	3.7	1.4	3.0	4.9	7.5
All comers	STS/ACC TVT Registry*	3.0		1.8		15.3	

ACC = American College of Cardiology; NOTION = The Nordic Aortic Valve Intervention Trial; PARTNER = Placement of AoRTicTraNscatheter Valve Trial; RCT = randomized controlled trial; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVR = transcatheter aortic valve replacement; TVT = Transcatheter Valve Therapy.

•Personal communication, STS/ACC TVT Registry Stakeholder Advisory Group presentation, March 1, 2018.

CENTRAL ILLUSTRATION: Transcatheter Aortic Valve Replacement (TAVR) in Low-Risk Patients: Clinical Outcomes



Waksman, R. et al. *J Am Coll Cardiol.* 2018;72(18):2095-105.

REFERENCES

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2. Waksman R, Rogers T, Torguson R, Gordon P, Ehsan A, Wilson SR, et al. Transcatheter Aortic Valve Replacement in Low-Risk Patients With Symptomatic Severe Aortic Stenosis. *J Am Coll Cardiol.* 2018 Oct 30;72(18):2095-2105.
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