Key Issues in Transcatheter Aortic Valve Replacement

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As more data accumulate on the use of transcatheter aortic valve replacement (TAVR), a number of issues have emerged. Among them are the use of conscious sedation vs general anesthesia (GA) for patients undergoing TAVR, the need for embolic neuroprotection for TAVR, the differences between self-expanding and balloon expandable TAVR, and the next generation of TAVR devices that are striving to improve upon the current generation to arrive at an ideal technology.

ANESTHESIA FOR PATIENTS UNDERGOING TAVR

Ron Waksman, MD, Medstar Washington Hospital Center, Georgetown University, Washington, DC, USA, examined the different options in anesthesia for patients undergoing TAVR, specifically comparing local anesthesia with monitored anesthesia care (MAC) to GA. Although no randomized data are available that compare these 2 options, data from clinical experience show a number of benefits of MAC compared with GA including shorter procedure duration, shorter time spent in the intensive care unit, and shorter hospital stays (Table 1) [Ben-Dor I et al. *Cardiovasc Revasc Med*. 2012].

Despite these positive outcomes with MAC, Dr Waksman noted that real-world experience shows that about 95% of TAVR in the United States (and 30% in Europe) is performed with GA [Bufton KA et al. *J Cardiothorac Vasc Anesth*. 2013]. However, he said the trend is moving toward a simpler approach to TAVR using MAC instead of GA, and he encouraged conscious sedation for all patients if feasible.

He cautioned, however, against being too aggressive with using MAC and cited data from a study by Rouen et al [*Heart*. 2014] in which high-surgical-risk patients with severe aortic stenosis underwent a simplified transfemoral TAVR with only local anesthesia and fluoroscopic guidance without the presence of an anesthesiologist. He emphasized the need to always have an anesthesiologist in the room in case a conversion from MAC to GA is needed, citing data showing the rate of conversion ranges from 11% to 25% depending on the series and most commonly for arrhythmias and hypotension (Table 2).

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EMBOLIC NEUROPROTECTION

Highlighting that embolic strokes remain a devastating complication after TAVR despite improvements in patient selection, devices, and procedural techniques, Susheel Kodali, MD, Columbia University Medical Center, New York, New York, USA, talked about the potential need for cerebral embolic protection during TAVR. He emphasized that although the risk of stroke after TAVR is reduced with increased operator experience, the need for cerebral protection may extend beyond reduction in stroke risk to protection against silent infarcts that occur frequently after TAVR, which are associated with severe adverse neurologic and cognitive effects and place a person at a 5-times higher risk of stroke than persons without silent infarcts [Sacco RL et al. *Stroke*. 2013]. He described evidence of the benefit of embolic protection during TAVR from 2 recently presented randomized clinical trials—CLEAN-TAVI [NCT01833052; Linke A et al. TCT 2014] and DEFLECT III [NCT02070731; Lansky AJ et al. ACC 2015]—both of which showed that embolic protection significantly reduced diffusion-weighted magnetic resonance imaging lesion number and total volume.

He emphasized, however, that magnetic resonance imaging is not sufficient to determine the true benefit of embolic protection during TAVR and said that demonstration of clinical improvement will be necessary. He said that cerebral protection with TAVR will become the standard of care in the future if additional studies can confirm consistent reductions in neuroimaging stroke

Table 1. Studies Comparing MAC vs GA

	N	Procedure Duration, min	Hospital Stay, d	ICU Stay, d	Requirements of Catecholamines, %	VARC-Defined Complications, %	30-Day Mortality, %
Ben-Dor I et al. *Cardiovasc Revasc Med*. 2012	92 (MAC 70, GA 22)	MAC 91, GA 155 (P = .008)	MAC 5, GA 7.5 (P = .06)	MAC 27 h, GA 72 h (P = .07)	—	NS	MAC 4.2, GA 18.1 (P = .05)
Dehédin B et al. *J Cardiothorac Vasc Anesth*. 2011	125 (MAC 34, GA 91)	MAC 80, GA 120 (P < .001)	MAC 8.5, GA 15.5 (P < .001)	—	MAC 23, GA 90 (P < .001)	NS	MAC 9, GA 7 (P = .9)
Bergmann L et al. *Anaesthesia*. 2011	151 (MAC 100, GA 51)	—	MAC 12.6, GA 15.4 (P = .2)	MAC 3.4, GA 4.6 (P = .08)	MAC 15, GA 29 (P = .03)	NS	MAC 6, GA 10 (P = .3)
Yamamoto M et al. *Am J Cardiol*. 2013	174 (MAC 130, GA 44)	MAC 78, GA 93 (P = .002)	MAC 8.1, GA 12.2 (P = .001)	MAC 3.3, GA 3.9 (P = .04)	—	NS	MAC 7.8, GA 6.7 (P = .5)
Oguri A et al. *Circ Cardiovasc Interv*. 2014	2326 (MAC 949, GA 1377)	—	MAC 7, GA 7 (P = .03)	MAC 3, GA 3 (P = .08)	—	AR, MAC 19.1 vs GA 15 (P = .015)	MAC 8.7 GA 8.3 (P = NS)
Dall'Ara G et al. *Int J Cardiol*. 2014	2807 (MAC 1095, GA 1712)	MAC 87, GA 139 (P < .01)	MAC 7.9, GA 9.8 (P < .01)	—	—	AKI, MAC 2.7, GA 4.4 (P = .04)	MAC 7, GA 5.3 (P = NS)

AKI, acute kidney injury; AR, aortic regurgitation; GA, general anesthesia; ICU, intensive care unit; MAC, monitored anesthesia care; VARC, Valve Academic Research Consortium consensus document.

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Table 2. Reasons for Conversion From MAC to GA

	N	Conversion, n (%)	Procedural Complication	Respiratory, n (%)	Cooperation, n (%)	Alternative Access, n (%)
Durand E et al. *JACC Cardiovasc Interv*. 2012	151	5 (3.3)	1 aortic dissection, 1 aortic annulus rupture, 2 vascular ruptures, 1 aortic regurgitation	—	—	—
Bergmann L et al. *Anaesthesia*. 2011	100	17 (17)	15 (88.2%; 12 vascular, 1 tamponade, 2 VF)	—	2 (11.7)	—
Yamamoto M et al. *Am J Cardiol*. 2013	130	6 (4.6)	6 (2 tamponade, 1 severe AR, 1 cardiac arrest, 1 coronary occlusion, 1 stroke)	—	—	—
Ben-Dor I et al. *Cardiovasc Revasc Med*. 2012	70	8 (11.4)	2 (25%; 1 vascular, 1 shock)	3 (37.5)	—	3 (37.5)
Covello RD et al. *Minerva Anestesiol*. 2010	42	3 (7.1)	1 (33%; VF)	—	2 (66)	—
Greif M et al. *Heart*. 2014	461	4 (0.8); 24 (5.2)	4 (CPR); 20 (19 vascular, 1 valve embolization)	—	—	—
Wiegerinck EMA et al. *Int J Cardiol*. 2014	178	4 (2.2)	3 (75%; 2 vascular, 1 embolization)	—	1 (25)	—

AR, aortic regurgitation; CPR, cardiopulmonary resuscitation; GA, general anesthesia; MAC, monitored anesthesia care; VF, ventricular fibrillation.

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lesions that are correlated with improvement in clinical neurologic end points.

SELF-EXPANDING VS BALLOON EXPANDABLE TAVR

Presenting the clinical results on self-expanding vs balloon expandable TAVR, James Hermiller, MD, St Vincent Medical Group, Indianapolis, Indiana, USA, emphasized that there are no data on hard end points such as mortality showing any real differences between the 2 platforms. Both platforms have good effective orifice area and durability, neither is associated with late or intermediate failures, and both have a very good delivery profile. Balloon-expandable TAVR may be better in several niche settings, he said, including in patients who need a permanent pacemaker and those with a horizontal aorta. In addition, early paravalvular leak is better initially with balloon technology but over time may become similar to self-expanding TAVR. A better role for self-expanding TAVR is for valve-in-valve placement and for patients with annular rupture.

Because of the lack of hard evidence on the differences between the 2 platforms, Dr Hermiller said that the choice to use one platform or the other in many circumstances comes down to what the operator is comfortable with. Overall, he emphasized that, despite the debate over one platform vs the other, he thinks both platforms are valuable.

WHAT THE FUTURE HOLDS

David Zhao, MD, Wake Forest School of Medicine, Winston-Salem, North Carolina, USA, briefly described the next generation of TAVR devices and the rapidly evolving technology that is addressing needed improvements to develop the ideal TAVR device with these characteristics:

- Controllable and predictable deployment
- Coronary accessibility and anatomic directional positioning
- Durability
- Lower cost, delivery profile, and permanent pacemaker implantation rate
- Low stroke/thrombotic risk
- Minimal flow obstruction during deployment
- Minimal or no rapid pacing
- Minimal pre- and post-balloon dilatation
- Minimal paravalvular leak
- Minimal valve preparation and loading
- Retrievable and repositionable
- Suitable for aortic stenosis and aortic regurgitation
- Superb hemodynamics

Many of the next-generation devices address some of the issues needed to develop an ideal valve, such as Edwards CENTERA, Medtronic CoreValve Evolut R, Direct Flow, and Boston Scientific Lotus, but, to date, not one addresses all issues in a single device.

Such a device, he thinks, will be developed in the future. Dr Zhao emphasized that the one issue that has not been addressed at all is the issue of cost and said that lowering the cost of TAVR will remain unaddressed until there are 3 or 4 different valves in competition with each other.