Rapid deployment aortic valve replacement devices: Too many unanswered questions

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Surgical inspection of deployed rapid deployment aortic valve replacement device.

Central Message

Rapid deployment aortic valve replacement devices require much more study before definitive recommendations regarding their use can be made.

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In this issue of the *Journal*, Sohn and colleagues¹ have completed an extensive meta-analysis of outcome studies for rapid deployment aortic valve replacement (RDAVR) devices versus conventional aortic valve replacement. Two vendors' RDAVR products were studied, Edwards Intuity (Edwards Lifesciences, Irvine, Calif) and St Jude Sorin Perceval (St Jude Medical, St Paul, Minn). Sohn and colleagues¹ found that implantation of these devices shortened the duration of cardiopulmonary bypass and cardioplegic arrest. In addition, both were associated with a significant increase in permanent pacemaker insertion.

The question, not answered in this study, arises as to the difference between pacemaker insertion rate versus long-term pacemaker dependence. Insertion rates would be expected to be increased in medical systems that optimize care for the shortest hospital length of stay (United States), as opposes to systems where longer stays do not have a major impact on medical decision making (Europe). What we do not know from the analysis of Sohn and colleagues¹ are the pacemaker dependence rates.

Another data point not included in this analysis is the difference between these RDAVR devices. Because all industry-sponsored trials support the study of a single device, with or without controls and random assignment to open surgery, meta-analysis is the only way for surgeons to assess performance and outcome between competing devices such as Intuity and Perceval. Because there were not enough patients for one of the devices in this study to provide adequate power to distinguish, no comparative analysis was done for pacemaker insertion rates or for hemodynamic performance, which is especially important in the smaller valve sizes.

The durability of these devices was also not addressed. Head-to-head comparison (by meta analysis) will be

required to determine whether there is any durability advantage to either RDAVR device.

Few hospitals will be stocking two devices for the same application, so surgeons will be consulted by hospital administrators to choose which device they prefer. In RDAVR, surgeons are left without hard evidence to support such a recommendation, and they will continue to be dependent on information and opinion from industry colleagues. Future investigators, including industry-sponsored clinical researchers, regulatory bodies, large payers, medical provider systems, and independent meta-analysts, are encouraged to pick up where Sohn and colleagues¹ have left off to provide consultant surgeons with comparative analyses on heart block, durability, morbid outcomes, and hemodynamic performance in the smaller valve sizes.

Regulatory bodies and large medical care systems are encouraged to make data available to researchers so that unbiased analysis can provide the facts that we all need to make proper decisions for our patients.

Reference

1. Sohn SH, Jang MJ, Hwang HY, Kim KH. Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: a meta-analysis. *J Thorac Cardiovasc Surg*. 2018;155:2402-12.e5.