Masters of Cardiothoracic Surgery

Minimally invasive rapid deployment Edwards Intuity aortic valve implantation

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Clinical vignette

The corresponding video is a rapid deployment aortic valve replacement (RDAVR) using the first generation of the Intuity RDAVR system (Edwards Lifesciences; Irvine, CA, USA) via a minimally invasive approach (*Video 1*). The patient is a 73-year-old female with symptomatic, severe aortic stenosis. She has NYHA III symptoms with a mean aortic valve gradient of 50 mmHg. The patient has a mildly dilated ascending aorta (4.0 cm) and a previous pacemaker insertion, without any other significant comorbidities. The left ventricular function and coronary arteries are normal. Exposure is achieved through an upper hemi-sternotomy approach using an inverted T-incision extending into the fourth intercostal space. RDAVR was chosen in order to facilitate the minimal invasive approach.

Surgical technique

Preparation

No special preparation is required for upper hemi-sternotomy RDAVR surgery. If RDAVR is planned via a right anterior mini-thoracotomy approach, then a preoperative computed tomography scan should be performed in order to assess the position of the ascending aorta in relation to the sternum. The patient is positioned in the same manner as for standard aortic valve replacement (AVR) surgery. The groins should be exposed in case femoral venous cannulation is required.

Exposition

Our standard approach for minimal invasive AVR involves a upper hemi-sternotomy. The skin incision is started at the sterno-manubrial junction and extended 5-8 cm inferiorly. An oscillating saw is used to perform either a J- or inverted T-incision into the fourth intercostal space. Entering the third intercostal space may result in inadequate exposure of the aortic valve and right atrial appendage for venous cannulation. If the atrial appendage cannot be safely cannulated, open or percutaneous cannulation of the femoral vein can be performed.

The above approach can be used in nearly all isolated AVR patients, including obese patients and those requiring reoperative surgery or concomitant replacement of the ascending aorta.

Operation

The ascending aorta is cannulated in the standard fashion, while the assistant applies downward traction via an Adson clamp placed on the aortic adventitia. The right atrial appendage can be cannulated directly or via a subxiphoid tunnel. As stated above, femoral venous cannulation may be required when the atrial appendage is difficult to visualize. Cardioplegia is delivered antegrade via the aortic root or directly into the coronary arteries. Venting of the left ventricle can be performed through the aortic valve or via the right superior pulmonary vein, the main pulmonary artery, or the roof of the left atrium.

The calcified aortic valve is removed in the standard manner for AVR surgery. However, excessive debridement of annular calcification should be avoided in order to prevent large annular defects. Patients with a bicuspid aortic valve or a non-spherical aortic annulus may not be good candidates for RDAVR. Accurate sizing of the annulus

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is key to success of the procedure. Some force should be necessary in order to advance the cylindrical component of the sizer through the aortic annulus, while the phlange portion should not be able to cross the annulus.

Correct sizing of the annulus is crucial for all rapid deployment valves, since the surgeon is unable to conform the annulus to the sewing ring, as is the case for conventional AVR surgery with sutures. Overestimating the size of the annulus will result in a paravalvular leak. Underestimating the size of the annulus will lead to valve "pop-out", which is immediately apparent to the surgeon. Valve "pop-out" requires immediate re-replacement of the aortic valve either with a second, properly sized Intuity prosthesis or a conventional bioprosthetic valve.

Once the proper size is confirmed, the corresponding valve is washed in saline solution for two minutes and then loaded onto the delivery system. Three braided, non-pledgeted 2-0 sutures are placed at the nadir of each aortic valve sinus using a figure-of-eight or horizontal mattress technique. The sutures are then separately placed at the black markers of the sewing ring of the Intuity valve and snared with a tourniquet.

The valve is lowered into place in the aortic annulus and the tourniquets are snared. Care must be taken to ensure that the valve is properly seated in the aortic annulus. Proper seating may be confirmed by inserting a 5 mm thoracoscope into the valve delivery system. The second generation of the device (i.e., Intuity Elite) has several modifications to ease insertion of the valve into the annulus, and the use of a thoracoscope is probably not required.

Once annular seating is confirmed, the balloon is inserted through the holder and the stent is deployed using balloon inflation with saline to the appropriate pressure (3-4 atm) for a period of ten seconds. The balloon is deflated thereafter and the delivery system is removed. The guiding sutures are tied and final inspection of the valve is performed in order to confirm proper seating.

Completion

Closure of the aorta, sternum and subcutaneous tissues are performed in the usual manner. Transesophageal echocardiography is performed to confirm good function of the Intuity valve prosthesis and to rule out a paravalvular leak. Hemodynamic performance is usually excellent, with transvalvular gradients that are superior to that which the Intuity was based on, i.e., Edwards Perimount Magna Ease. The reasons for this improved performance are speculative, but are probably related to the flared subvalvular stent in the left ventricular outflow tract which appears to optimize laminar flow across the valve prosthesis.

Comments

The development of rapid deployment aortic valves represents a significant advancement for AVR surgery. Two clinical scenarios justify the use of these devices: (I) facilitation of minimal invasive surgery (MIS) in patients requiring isolated AVR; and (II) minimization of myocardial ischemic time in high-risk patients. The first scenario applies to a large group of patients, since MIS techniques are currently applied in a small proportion of patients requiring isolated AVR. The second scenario applies to patients with left ventricular dysfunction or those requiring complex combined procedures. Another patient population that can greatly benefit from these devices are patients with a calcified homograft or stentless valve. The surgeon can simply remove the leaflets of these valves and then insert a rapid deployment device without the need to perform a challenging redo-root replacement procedure.

One of the main reasons for the low proportion of patients undergoing MIS AVR is surgeon resistance to adopting these techniques because of their perceived increased complexity and technical demand. Finding a way to facilitate MIS AVR surgery for the surgeon will therefore be an important step in increasing acceptance of these techniques. Although myocardial ischemic times are a frequent focus of studies on rapid deployment valves, this endpoint is simply a marker for ease of implantation. The majority of patients undergoing isolated AVR surgery will not receive a large clinical benefit from a 20-30 minutes reduction in myocardial ischemic time. However, one can assume that this reduction in time made the procedure significantly easier for the surgeon to perform. Patients requiring complex multivalve or combined procedures, as well as those with a low preoperative ejection fraction, would also benefit from rapid deployment valves. For these patients, a 20-30 minutes reduction in ischemic time would be clinically relevant and would lower the risk of serious perioperative cardiac morbidity or mortality.

Several studies have revealed benefits for MIS AVR surgery when compared to conventional, full sternotomy surgery, including randomized controlled trials (1-3). Murtuza *et al*. published a meta-analysis of MIS *vs*. conventional AVR studies (4). They included over 20 studies consisting

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of more than 4,000 patients. MIS AVR was associated with a significant reduction in mortality, shorter ICU and hospital lengths of stay, and decreased ventilation times and transfusion rates. However, MIS AVR was also associated with longer myocardial ischemic, cardiopulmonary bypass, and operative times. Increasing the proportion of MIS AVR surgery will require the development of methods that shorten the ischemic time and improve the ease of implantation.

We performed a multicenter, prospective, randomized, controlled trial comparing MIS AVR with the Edwards Intuity valve to standard full-sternotomy AVR with a conventional stented bioprosthesis (5). A total of 100 patients were randomized into the two groups. Patients randomized to MIS AVR with the Intuity valve had a significantly shorter aortic cross clamp time, despite the fact that these procedures were performed with MIS techniques. In addition, Intuity patients had significantly lower transvalvular gradients and a lower proportion of patient-prosthesis mismatch when compared to those who received a conventional bioprosthesis.

Rapid deployment valves significantly facilitate the performance of MIS AVR surgery, which can be objectively confirmed by the observed reductions in ischemic and operative times. In addition to facilitating MIS AVR surgery, rapid deployment valves may also be beneficial for patients who would benefit from significant reductions in myocardial ischemic times. Perioperative and early follow up results are very favorable, but further data and follow up is required.

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