# Early outcomes after isolated aortic valve replacement with rapid deployment aortic valve

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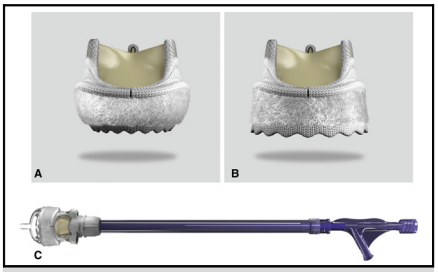
## ABSTRACT

**Objective:** Minimal access aortic valve replacement is associated with favorable clinical outcomes; however, several meta-analyses have reported significantly longer crossclamp times compared with a full sternotomy. We examined the procedural and early safety outcomes after isolated rapid deployment aortic valve replacement by surgical approach in patients enrolled in the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve trial.

**Methods:** The Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve trial was a prospective, multicenter, single-arm study, with successful implants in 287 patients with aortic valve stenosis who underwent rapid deployment aortic valve replacement using the EDWARDS INTUITY Valve System (Edwards Lifesciences, Irvine, Calif). Patients were evaluated perioperatively for procedural times and technical success rates; at discharge, for hospital length of stay; and, at 30 days, for early adverse events.

**Results:** A total of 158 patients underwent isolated aortic valve replacement through a full sternotomy (n = 71), upper hemisternotomy (n = 77), or right anterior thoracotomy (n = 10). Mean age at baseline was 75.7 ± 7.2 years. Mean aortic crossclamp and cardiopulmonary bypass times (minutes) were similar for full sternotomy and upper hemisternotomy, 43.5 ± 32.5/71.6 ± 41.8 and 43.1 ± 13.1/69.6 ± 19.1, respectively, and significantly longer for right anterior thoracotomy, 88.3 ± 18.6/122.2 ± 22.1 ($P < .000$). Early adverse event rates were similar, and in-hospital mortality rates were low regardless of surgical approach.

**Conclusions:** These data suggest that isolated rapid deployment aortic valve replacement through an upper hemisternotomy can lead to shorter crossclamp times than has been reported historically in the literature. This may facilitate minimal access aortic valve replacement by eliminating the issue of prolonged crossclamp times. Further, low in-hospital mortality and new permanent pacemaker implant rates were observed regardless of surgical approach. (J Thorac Cardiovasc Surg 2016;■:1-9)




EDWARDS INTUITY valve (Edwards Lifesciences, Irvine, Calif).

**Central Message**

RDAVR may facilitate the use of minimal access surgical techniques.

**Perspective**

RDAVR may facilitate the use of minimal access surgical techniques by reducing the longer aortic crossclamp times often incurred. We present the results of patients in the TRITON trial undergoing isolated AVR using RDAVR through a full sternotomy or minimal access surgery.

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Aortic valve replacement (AVR) through the use of a minimal access incision can be performed safely without increased risk of death or major complications and may provide both cosmetic and clinical benefits for selected patients with aortic valve disease.[1] It is hypothesized that reduced surgical trauma through maintenance of chest

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**Abbreviations and Acronyms**

AVR = aortic valve replacementp
FS = full sternotomy
ICU = intensive care unit
MIS = minimally invasive surgery
MUS = mini upper sternotomy
PVL = paravalvular leak
RAT = right anterior thoracotomy
RDAVR = rapid deployment aortic valve replacement
TRITON = Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve
UHS = upper hemisternotomy

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wall integrity leads to decreased postoperative pain and disability, reduced blood loss, shorter ventilation times, and reduced intensive care unit (ICU) and hospital length of stays.[2] Furthermore, specific patient subsets, such as those with pulmonary dysfunction, may derive further benefit from using a minimal access incision for AVR.[3]

Historically, minimal access incisions for AVR have been associated with longer aortic crossclamp and cardiopulmonary bypass times compared with the standard full sternotomy (FS) approach. Longer periods of myocardial ischemia and exposure to cardiopulmonary bypass may lead to higher morbidity and mortality, particularly in patients requiring concomitant procedures or in higher surgical risk populations.[4] A new class of bioprosthetic valves that enables rapid deployment aortic valve replacement (RDAVR) may facilitate the use of minimal access incisions by neutralizing the difference in myocardial ischemic time often ascribed to using this approach.[5] Previously published data have demonstrated the safety, efficacy, and expedited procedural times enabled by RDAVR.[6-8] Furthermore, the recently published 3-year results of the Surgical Treatment of Aortic Stenosis With a Next Generation Surgical Aortic Valve (TRITON) study have demonstrated low complication rates and excellent hemodynamic performance of the EDWARDS INTUITY valve (Edwards Lifesciences, Irvine, Calif), which was specifically designed to facilitate RDAVR.

The TRITON trial is a prospective, multicenter, single-arm study, with successful implants in 287 patients with aortic valve disease who required elective AVR and underwent RDAVR using the EDWARDS INTUITY Valve System, a balloon-expandable stented trileaflet bovine pericardial bioprosthesis. The surgical incision used was left to the discretion of the operating surgeon. Outcomes from the TRITON study recently have been published demonstrating excellent hemodynamic and safety outcomes with up to 3 years follow-up.[7] The objective of this study was to compare procedural times, discharge outcomes, technical success rates, and early safety outcomes by surgical approach among patients enrolled in the TRITON trial who underwent isolated RDAVR through an FS, upper hemi-sternotomy (UHS), and right anterior thoracotomy (RAT).

## MATERIALS AND METHODS

### Study Population

The TRITON Trial (NCT01445171) is a prospective, nonrandomized, single-arm, multicenter trial conducted in 6 European hospitals. The study design and methods have been described by Kocher and associates.[9] A total of 295 consecutive patients with moderate to severe aortic valve disease requiring elective AVR with or without concomitant coronary artery bypass grafting were enrolled; 287 of these were treated with the EDWARDS INTUITY Valve System (Model 8300A), a stented trileaflet bovine pericardial bioprosthesis with a balloon-expandable, cloth-covered skirt frame at the inflow aspect. A total of 158 of 287 patients underwent isolated RDAVR (Figure 1). The study protocol was reviewed and approved by the Ethics Committee of each participating center, and all patients provided written informed consent.

### Rapid Deployment Aortic Valve Replacement

RDAVR with the EDWARDS INTUITY Valve System (Figure 2) was performed through a minimal access incision (upper hemisternotomy [UHS] or RAT) or FS, as previously described by Kocher and associates,[9] according to surgeon preference.[10] After a standard aortotomy, the diseased aortic valve leaflets were excised and annular calcium was debrided using conventional surgical techniques. Three equidistant guiding sutures were placed through the nadir of each aortic cusp and then through the corresponding position of the valve sewing ring. By using the specialized delivery system, the valve was lowered onto the annulus using the 3 guiding sutures. After the valve was seated, the balloon catheter was expanded to rapidly deploy the valve. After deployment, the delivery system was removed, guiding sutures were tied, and the aortotomy was closed in routine fashion.

### End Points

Clinical follow-up data were collected per protocol at baseline, discharge, and 3 and 12 months postoperatively. For the purposes of this study, patients were evaluated perioperatively for procedural times and procedural and technical success rates; at discharge for hospital length of stay, ICU length of stay, intermediate care length of stay, and in-hospital mortality; and at 30 days for early adverse event rates. The adverse events were adjudicated as per The Society of Thoracic Surgeons Guidelines for reporting mortality and morbidity after cardiac valve interventions,[10] and included all-cause and valve-related mortality, thromboembolic events (stroke, transient ischemic attack, and noncerebral embolic event), study valve thrombosis, major bleeding events, paravalvular leak (PVL), prosthetic valve endocarditis, reoperation for bleeding, and study valve