

# Edwards Intuity rapid deployment valve results in aortic valve replacement

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**Objective.** The percentage of patients above 65 years-old has increased in the last 20 years. Also, the percentage of candidates who need an aortic valve replacement with concomitant coronary bypass surgery has increased from 5% to 25%. In cardiac surgery, prolonged cardiopulmonary bypass and aortic cross-clamp time are strong independent risk factors for postoperative mortality and morbidity. The purpose of this study is to analyze the short-term outcomes with the use of Edwards Intuity rapid deployment valve in single and double procedure surgeries. **Material.** Twenty-nine patients underwent aortic valve replacement with an Intuity valve between April 2021 and May 2022 at our institution. **Results.** Mean age was 70.86 years old  $\pm$  6.56 years, with a mean EuroSCORE of 2.42%. Concomitant coronary bypass surgery was performed in 12 cases (41%). The average cross-clamp time in isolated aortic valve replacement was 70 minutes, with a cardiopulmonary bypass time of 106 minutes. For 2 concomitant procedures, the cross-clamp time was 115 minutes with a cardiopulmonary bypass of 140 minutes. Mean follow-up was 2.05 months. Mortality at 30 days was 10.3%. As yet, none have required definitive pacemaker placement. **Conclusions.** The use of the Intuity valve in elderly patients, as well as in concomitant procedures, seems to be a reasonable alternative with good results in the short and medium term. However, a greater number of cases and experience using it are required.

**Key words:** Aortic valve replacement; Biological heart valve prosthesis; Rapid deployment valve.

**Objetivo.** El número de pacientes mayores de 65 años ha incrementado en los últimos 20 años. A su vez, el porcentaje de candidatos que ameritan un implante valvular aórtico con una revascularización miocárdica concomitante ha incrementado de 5 a 25%. En la cirugía cardíaca, la prolongación de los tiempos de circulación extracorpórea y pinzado aórtico son fuertes factores de riesgo independientes para mortalidad y morbilidad postoperatoria. El objetivo de este estudio es analizar los resultados a corto plazo con el uso de la válvula Edwards Intuity en cirugías de procedimiento simple y doble. **Material.** Veintinueve pacientes fueron sometidos a un implante valvular aórtico con válvula Intuity entre abril 2021 y mayo 2022 en nuestra institución. **Resultados.** La edad promedio fue de 70.86 años  $\pm$  6.56 años, con EuroSCORE de 2.42%. Un segundo procedimiento concomitante fue realizado en 12 casos (41%). El tiempo de pinzado aórtico en reemplazo valvular fue 70 minutos, con un tiempo de circulación extracorpórea de 106 minutos. Para cirugía de 2 procedimientos, el tiempo de pinzado fueron 115 minutos con una circulación extracorpórea de 140 minutos. La media de seguimiento fue a 2.05 meses. Mortalidad a los 30 días fue de 10.3%. Hasta el momento, ninguno ha ocupado colocación de marcapasos definitivo. **Conclusiones.** El uso de la válvula Intuity en pacientes de edad avanzada, así como en procedimientos concomitantes, parece ser una alternativa razonable con buenos resultados a corto y mediano plazo. Sin embargo, se requiere un mayor número y experiencia en su uso.

**Palabras clave:** Reemplazo valvular aórtico; Prótesis valvular aórtica biológica; Válvula de liberación rápida.

*Cir Card Mex* 2023; 8(2): 29-31.

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Aortic valve stenosis is by far the most common valve pathology treated surgically or by transcatheter aortic valve implantation due to the poor results obtained with conservative management in symptomatic aor-

tic stenosis [1]. Its main etiology is age-related degeneration and progressive calcification commonly detected in patients 65 years and older [2]. In a study of 82 million Medicare beneficiaries aged 65 years or older, the adjusted rate of aortic valve replacement (AVR) increased 1.6% per year from 1999 to 2011, culminating in an estimated prevalence of 2% to 7% in people aged more than 65 years. In those older than 75 years, the combined prevalence of all aortic stenosis was

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12.4% and the prevalence of severe aortic stenosis was 3.4% [3]. The Society of Thoracic Surgeons database in the United States shows that the number of patients older than 80 years has increased from 12% to 24% during the last 20 years. At the same time, the percentage of candidates requiring AVR and concomitant coronary bypass grafting (CABG) has increased from 5% to 25% [2].

Conventional AVR requires the extensive use of sutures and is therefore time consuming in terms of cardiopulmonary bypass (CPB) and aortic cross-clamp (XCT) times. A new generation of bioprostheses, based on expandable stents and designed to be placed without too many sutures, allows a rapid aortic valve replacement, leading to shorter XCT and CPB times. This results in less myocardial ischemia, lower complication rates, shorter stays, and similar survival rates compared to conventional AVR [4]. Among the advantages of a rapid deployment aortic valve, the possibility of performing necessary concomitant procedures such as CABG is thus maintained. Regarding the reduction in time, aortic XCT is an independent predictor of serious cardiovascular morbidity, with an increased risk of 1.4% for each added minute [2].

Edwards Intuity valve (Edwards Lifesciences LLC, Irvine, CA, USA) a rapid deployment valve, is composed of three bovine pericardium leaflets built on a frame covered by a balloon-expandable stainless-steel skirt. The valve component itself is identical to the conventional Magna Ease valve (Edwards Lifesciences AG, Horw, Switzerland). For implantation, three sutures are placed through the annulus at the nadir of each sinus and then passed through the corresponding marks on the nadir portion of the valve suture ring. The valve is positioned at the aortic annulus using these guiding sutures and three tourniquets, with the stent and polyester cloth seated directly below the aortic annulus. Once the valve is properly seated, the expandable frame is deployed with one balloon inflation. Finally, the guiding sutures are tied [1].

The purpose of this study is to analyze the short-term results with the use of the Edwards Intuity rapid deployment valve in single AVR surgeries and concomitant procedures, such as AVR plus CABG.

## MATERIAL

This is an observational and retrospective study in which all patients who had an Edwards Intuity valve implanted between April 2021 and May 2022 at our institution were registered. All patients underwent an intraoperative transthoracic echocardiogram to assess the functionality of the prosthesis.

Variables of age and gender of each patient were recorded, preoperative risk was calculated with the EuroSCORE scale. Operative variables collected were the type of implanted prosthesis, if there was concomitant surgery (CABG) and the number of vascular grafts, aortic XCT, CPB time, postsurgical

aortic valve gradient, paravalvular leaks, and need for surgical reintervention. Eventualities upon discharge or death were registered. Follow-up consultation timeframe was according to each surgeon criteria. Mean and standard deviation were calculated for quantitative variables.

## RESULTS

The Edwards Intuity prosthetic valve was implanted in 29 patients between April 2021 and May 2022 at our institution. The mean age was 70.86 years old  $\pm$  6.56 years. The male to female ratio was 1.9:1. Mean EuroSCORE of 2.42%  $\pm$  2.2%.

Regarding the surgical procedure (**Table 1**), the mean aortic XCT in single AVR was 70  $\pm$  23 minutes, with a CPB time of 106  $\pm$  43 minutes. Concomitant CABG was performed in 12 cases (41%). For AVR plus CABG, aortic XCT was 115  $\pm$  26 minutes with a CPB time of 140  $\pm$  25 minutes. Two patients received 19mm prostheses (6%), ten received 21mm prostheses (34%), twelve received 23mm prostheses (41%) and five received 25mm prostheses (17%). The mean valve gradient of the aortic prosthesis was 8.5 mmHg  $\pm$  4.1 mmHg. There were 5 paravalvular leak prostheses. In 2 patients it was necessary to relocate the valve due to moderate paravalvular leak reported in the intraoperative echocardiogram.

Seven patients (24%) underwent re-exploration due to excessive bleeding. The mean follow-up time was 2.05 months. 30-day mortality was 10.3%. None have required permanent pacemaker implantation.

**Table 1. Intraoperative and postoperative data**

Variable	Value
<b>Single AVR</b>	17 (59)
Aortic XCT (minutes)	70 $\pm$ 23
CPB time (minutes)	106 $\pm$ 43
<b>AVR with concomitant CABG</b>	12 (41)
Aortic XCT (minutes)	115 $\pm$ 26
CPB time (minutes)	140 $\pm$ 25
Number of vascular grafts	2.6 $\pm$ 1
<b>Prosthesis size</b>	
19 mm	2 (6)
21 mm	10 (34)
23 mm	12 (41)
25 mm	5 (17)
<b>Mean valve gradient of aortic prosthesis ( mmHg)</b>	8.5 $\pm$ 4.1
<b>Reexploration for excessive bleeding</b>	7 (24)
<b>Permanent pacemaker</b>	0
<b>30-day mortality</b>	3 (10.3)

The values are n (%) or mean  $\pm$  SD. AVR = aortic valve replacement; XCT = cross-clamp time; CPB = cardiopulmonary bypass; CABG = coronary artery bypass grafting

## DISCUSSION

The indications and contraindications for rapid deployment aortic valves follow the general recommendations for the choice of biological valve prostheses in AVR for patients at an age of 65 years or older [1]. The use of these valves is recommended for patients with comorbidities, old age, delicate aortic wall conditions, as well as for concomitant procedures to reduce aortic XCT [5].

Our study shows the outcomes obtained with the use of Edwards Intuity valve since its introduction in 2021 at our hospital. The technical success of the prosthesis implantation at the first attempt was 93%, a rate close to the one reported in current evidence which is from 94 to 97% [6]. When comparing the results obtained in aortic XCT and CPB times to medical centers with greater experience using this valve, our times are below average. A study published by the Medical University of Vienna analyzing the data of 700 consecutive patients with a Intuity valve implanted show that the aortic XCT and CPB time for single AVR was 58 minutes and 93 minutes respectively; whereas for concomitant procedures,

the time recorded was 97 minutes for aortic XCT and 143 minutes for CPB time [7].

Regarding the limitations of our study, it has a reduced number of patients, it is a retrospective study, and it does not have a control group. However, it allows us to demonstrate that there are other tools besides conventional AVR that can be offered to the patient with the intention of improving their immediate postoperative results.

The use of the Edwards Intuity valve in elderly patients, as well as in concomitant procedures, seems to be a reasonable alternative with good short and medium outcomes. However, a greater number of cases and experience using it are required.

**FUNDING:** None

**DISCLOSURE:** The authors have no conflicts of interest to disclose.

## REFERENCES

- Gersak B, Fischlein T, Folliguet TA et al. Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel. *Eur J Cardiothorac Surg.* 2016;49(3):709-18. doi: 10.1093/ejcts/ezv369.
- Barnhart GR, Shrestha ML. Current Clinical Evidence on Rapid Deployment Aortic Valve Replacement: Sutureless Aortic Bioprostheses. *Innovations (Phila).* 2016;11(1):7-14. doi: 10.1097/IMI.0000000000000232.
- Young C, Laufer G, Kocher A, et al. One-year outcomes after rapid-deployment aortic valve replacement. *J Thorac Cardiovasc Surg.* 2018;155(2):575-585. doi: 10.1016/j.jtcvs.2017.09.133.
- Rahmanian PB, Kaya S, Eghbalzadeh K, Menghesha H, Madershahian N, Wahlers T. Rapid Deployment Aortic Valve Replacement: Excellent Results and Increased Effective Orifice Areas. *Ann Thorac Surg.* 2018;105(1):24-30. doi: 10.1016/j.athoracsur.2017.07.047.
- Berretta P, Di Eusanio M. Aortic valve replacement with sutureless and rapid deployment aortic valve prostheses. *J Geriatr Cardiol.* 2016;13(6):504-10. doi: 10.11909/j.issn.1671-5411.2016.06.006.
- Arribas JM, Rivera JM, Moreno JA et al. Experiencia de 7 años con la protesis aortica de rápido despliegue Edwards Intuity. *Cir Cardio.* 2021; 28(2):77-83. doi: 0.1016/j.circv.2020.08.002.
- Coti I, Haberl T, Scherzer S, Werner P, Shabanian S, Kocher A, Laufer G, Andreas M. Outcome of rapid deployment aortic valves: long-term experience after 700 implants. *Ann Cardiothorac Surg.* 2020;9(4):314-321. doi: 10.21037/acs.2020.04.01.