

*Full Length Research Paper*

# **Short-term follow-up of patients implanted with aortic valve bioprosthesis sutureless type Intuity Elite at the Robert Debré University Hospital in Reims (France)**

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Received 15 April, 2021 ; Accepted 1 June, 2021

**To report the operative data, the immediate surgical results and the short-term follow-up of patients who were implanted with an Edwards's elite Intuity bioprosthesis at the Thoracic and Cardiovascular Surgery Department of Reims (France). This was a retrospective and prospective study that was carried out from May 2015 to October 2017 in the Thoracic and Cardiovascular Surgery Department of the Robert Debré Hospital. 20 patients were operated on for aortic valve stenosis using vertical midline sternotomy and "L" ministernotomy approaches with implantation of a rapidly deploying aortic valve bioprosthesis of the Intuity Elite bioprosthesis type from Edwards Lifesciences. The results of the study showed that minimal leaks occurred and a permanent dual chamber pacemaker was implanted in a patient for third degree atrioventricular block. Post-surgery symptoms observed in patients included dyspnea, palpitation and infectious *Enterococcus faecium* endocarditis. In conclusion, "Sutureless" valves allow easier surgical implantation and shorter aortic clamping times than sutured prostheses. Meanwhile, Intuity Elite maintains a better transvalvular gradient.**

**Key words:** Elite Intuity, follow-up, bioprosthesis, aortic valve.

## **INTRODUCTION**

Surgical aortic valve replacement is the gold standard for the treatment of symptomatic aortic stenosis with excellent clinical and hemodynamic results in the short and long term (Valfre et al., 2010). From 2002, Transcatheter Aortic Valve Implantation (TAVIs) have been a therapeutic alternative with good results for

inoperable patients or at high operative risk (Thomas et al., 2011), (Rodés-Cabau et al., 2010). The so-called "sutureless" rapid deployment valves represent the most recent surgical treatment option that can be offered both for the most fragile patients and in the case of associated procedures, as for standard patients. These sutureless

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valves, including Edwards' Elite Intuity Bioprosthesis, would allow less tightening times and facilitate minimally invasive surgery. We therefore initiated a study to evaluate this bioprosthesis. The aim of our work is to report operative data, the immediate post-operative consequences and the short-term follow-up of patients who have benefited from the implantation of an Edwards elite intuity bioprosthesis.

## MATERIALS AND METHODS

We conducted a retrospective and prospective study from May 2015 to October 2017 in the thoracic and cardiovascular surgery Department of the Robert Debré hospital of the Reims Hospital and University Center. This study involved 20 patients operated on for isolated or associated aortic valve stenosis, with implantation of a rapidly deploying aortic valve bioprosthesis such as Intuity elite bioprosthesis from Edwards Lifesciences. For follow-up, our patients were clinically evaluated; an electrocardiogram and an echocardiography were performed. We did a descriptive analysis: for qualitative variable, we used percentages. For quantitative variable, we used means and standard deviations.

## RESULTS

### Operative data and immediate postoperative consequences

We identified 04 female and 16 male patients. The mean age of the patients was 75.20 years [59 years-88 years]. Ten patients were diabetic of which 09 was type 2 and one was type 1. The mean Euroscore II was 2.52 [1.02-6.16]. The mean ejection fraction was 53.68 [45-67]. The initial approach was a vertical midline sternotomy for 19 patients and an "L" ministernotomy for one patient. The mean duration of extracorporeal circulation (ECC) was 106.35 mm [range: 64 -224 mm]. The mean aortic clamping time was 73.29 mm [range: 44 -131 mm]. Patients who had associated bypass surgery had a mean duration of ECC of 134.5 min [110-224]. The mean clamping time was 93.25 min [72-131]. For isolated aortic valve replacements, the mean ECC time was 84.3 min [64-112], and the mean clamping time was estimated at 57.3 min [44-75] (Figures 1 and 2).

The mean size of the intuity was 23.42 mm in diameter (Table 1). All valves were successfully implanted (100%) (Figures 3 and 4). Three minimal prosthetic leaks were noted. The mean immediate postoperative gradient was 10.49 [range: 3-16]. The mean immediate postoperative ejection fraction was 52.27 [range: 32-65]. Three patients had a complete arrhythmia by atrial fibrillation (CA/AF) postoperatively. We did not note any major postoperative bleeding. The average length of stay in intensive care was 05 days [range: 3 days-9 days]. A definitive double chamber pace maker was implanted in a patient for third degree atrioventricular block.

## Follow-up

Symptoms were: 03 patients had stage 2-3 dyspnea. One patient (5%) complained of palpitations (Figure 5).

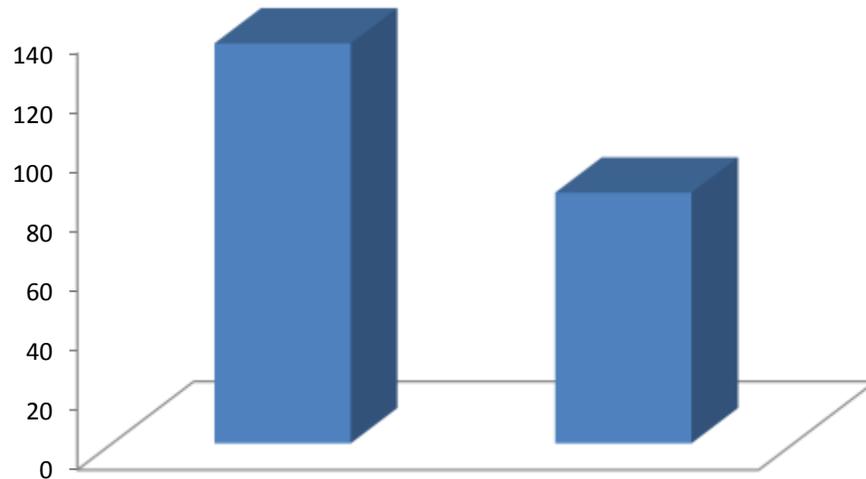
Electrocardiogram: One patient had complete arrhythmia due to postoperative atrial fibrillation. Three patients were in first degree AV block.

Echocardiography: The mean gradient at 01 year for the nine patients was 8.01 mmHg. The average diameter of the implanted bioprostheses was 23.22 mm. Two minimal prosthetic leaks were noted. *Enterococcus faecium* infectious endocarditis was discovered in February 2017 in one patient (approximately 16 months after implantation).

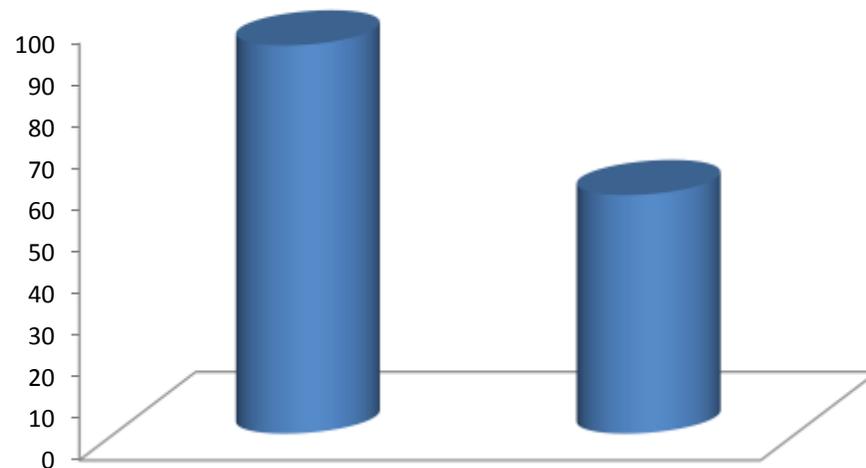
## DISCUSSION

Edwards Intuity Bioprostheses are a new generation of rapid deployment valve. It is a bioprosthesis mounted on a self-expanding stent. This study on Edwards Intuity Elite bioprostheses, initiated by our center, noted an average age of 75.2 years [59 -88 years]. This age is similar to those found in several studies (Barnhart et al., 2017 ; Kocher et al., 2013; Borger et al., 2013). The sex ratio is one woman for four men. 50% of our patients were diabetic, while the TRANSFORM (Multicenter Experience with Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) study (Barnhart et al., 2017) found 33.1% of diabetics. The size of our sample could explain this difference. The average euro score II of our patients was 2.52%, while TRANSFORM [6] found a euro score II at 3.3%. Our patients therefore have the same surgical prognosis as those of TRANSFORM (Barnhart et al., 2017).

The route of entry was a high ministernotomy in 5% and a complete sternotomy in 95% of cases. TRANSFORM (Barnhart et al., 2017) performed 40% complete sternotomy and 32.8% high ministernotomy. It is also noted that 48.8% of the patients in the series by Kocher et al. (2013) and 72.1% of the patients in the series by Borger et al. (2013) operated for an isolated valve replacement benefited from a minimally invasive approach. The complete sternotomy allows for better exposure; however the intuity bioprosthesis facilitates access to minimally invasive surgery (Borger et al., 2013). This latest generation Edwards suture less allows easier access to minimally invasive surgery. They can be useful in certain circumstances (certain redux, highly calcified rings, associated procedures), and as such should be part of the therapeutic arsenal in modern aortic surgery. This bioprosthesis with mini-approach, minimally invasive ECC and sutureless valve could represent a true third therapeutic route between conventional surgery and TAVI (Transcatheter Aortic Valve Implantation). Edwards Intuity Bioprosthesis represents one of the latest generations of direct implantation valves. Between



**Figure 1.** comparison of ECC durations of aortic valve replacements + Coronary artery bypass grafting (left), and isolated Aortic valve replacement (right).



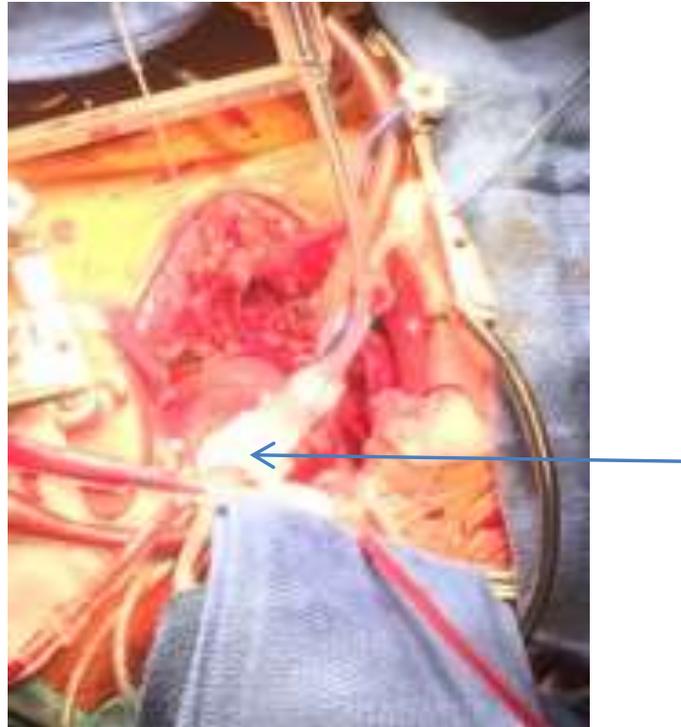
**Figure 2.** Comparison of clamping times for Aortic Valve Replacements + Coronary Artery Bypass (left), and isolated Aortic Valve Replacement (right).

**Table 1.** Average postoperative gradients as a function of diameters, during follow-up.

| Intuity diameter | Medium gradient | n  |
|------------------|-----------------|----|
| 21               | 9,03            | 03 |
| 23               | 11,05           | 11 |
| 25               | 8,5             | 05 |
| 27               | -               | 01 |

standard valves requiring complete decalcification of the ring and several sutures, and TAVI with their complications, notably peri-prosthetic leaks (D'Onofrio et al., 2012; Santarpino et al., 2014), and vascular

complications, sutureless valves represent a pure surgical alternative and response to aortic valve surgery. Edwards's sutureless valve also appears to be a very important alternative in redux surgery as well as in



**Figure 3.** Descent of the intuity bioprosthesis to the level of the native aortic ring (intraoperative view).



**Figure 4.** Bioprosthesis release device.

homograft aortic degeneration where they prevent Bentall redux surgery, the morbidity of which is known (Folliguet and Laborde, 2013). This is an innovative approach in the

case of a much calcified ring (Consistre et al., 2012) or in the case of combined surgery (Borger et al., 2013) where the minutes can be precious in some cases. We

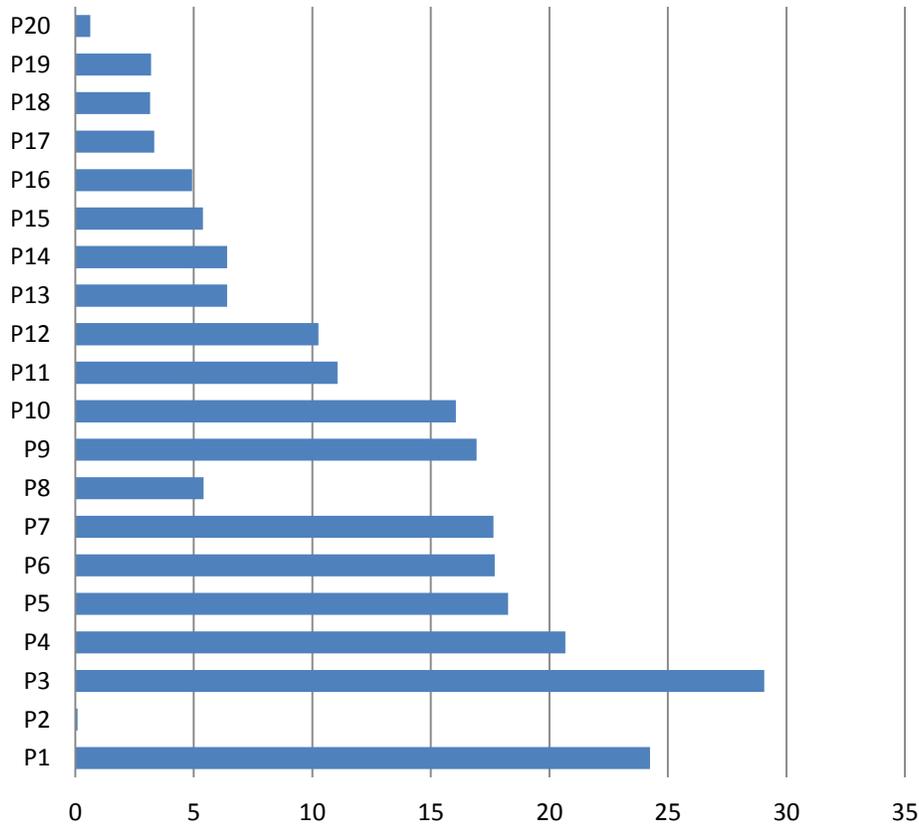


Figure 5. Follow- up.

performed combined surgery in 40% of cases (n = 8). The mean clamping time was 93.25 min [72-131], with an extracorporeal circulation time (ECC) of 134.5 min [110-224]. For isolated aortic valve replacements, the mean clamping time was 57.3 min and the mean cardiopulmonary bypass time was 84.3 min. Kocher et al. (2013) had a clamping time of 41.1+ or -10.6 min, and a ECC time of 60+ or -19 min. As for Borger et al. (2013), the clamping time was 42.2 + or - 15.7, and the ECC time was 59.9 + or - 18.9. Our ECC and cross-clamp times for the isolated procedures are comparable to those of

Kocher et al. (2013) and Borger et al. (2013). Edwards Intuity is an already deployed valve and therefore visibility is sometimes less good during installation. Difficulties may be encountered with the Intuity when lowering the valve in the event of a small sino-tubular junction to the ring. Precautions should be taken in cases of bicuspid, especially type 0, by trying to have three equidistant commissures. Closure of the aortotomy is performed as usual by the surgeon.

The mean postoperative gradients are less important while the gradients at one year seem better with Intuity (Ouazzani et al., 2014). TRANSFORM (Barnhart et al., 2017) has an aortic area of 1.7 cm<sup>2</sup> and an average gradient of 10.3 mmHg. While our series reports an

average gradient of 10.32 mmHg. These elements (aortic surface and gradient) are almost similar to those of TRANSFORM (Barnhart et al., 2017).

Gradients are smaller for "sutureless" valves than for standard aortic valve replacement (D'Onofrio et al., 2013), and slightly greater than gradients for TAVI transapical (D'Onofrio et al., 2012, 2013). The gradient at 01 year in our series was 08.01 mmHg. This value is almost similar to those reported by Kocher et al. (2013) and Borger et al. (2013) for an average gradient of 8.8 mmHg.

The valve has a significantly higher peri-prosthetic leakage rate than sutured valves and less than with apical TAVI. We report a minimal leak rate to 03 patients (15%) at one month. Kocher et al. (2013) mentions a major leak of 0.9% and a minimal leak of 1.4%. Borger et al. (2013) leaks in 1.5% of cases. The small size of our sample and insufficient hindsight could explain our high rates.

Pacemaker levels are significantly higher with "sutureless" valves than with sutured valves (D'Onofrio et al., 2013), and differ according to studies with TAVI (D'Onofrio et al., 2012; Santarpino et al., 2014; D'Onofrio et al., 2013). One (n = 1) patient (5%) was implanted with a pace maker for third degree atrioventricular block.

Kocher et al. (2013) implements a pace maker in 8.9% of cases, and Borger et al. (2013) in 4.3% of cases. Less manipulation of Intuity may explain the exceptional rate of endocarditis. A patient developed an infectious endocarditis due to enterococcus faecium 15 months after the valve was inserted.

Our hospital mortality is zero. Kocher et al. (2013) had in-hospital mortality of 2.1% and late mortality of 7.5%. TRANSFORM (Barnhart et al., 2017) had a mortality of 0.8% (7/839). These Intuity valves have a cost of 5538.75 euros, while standard biological valves have a cost of 2748.35 euros. These sutureless valves therefore incur an additional cost.

## Conclusion

Sutureless valves allow easier surgical implantation and shorter aortic clamping times than sutured prostheses. Borger et al. (2016) reports a 24% reduction in clamping time with Intuity elite bioprostheses compared to sutured bioprostheses. The elite Intuity bioprosthesis therefore provides a theoretical benefit for the most fragile patients and in the event of associated procedures. Intuity Elite maintains a good long-term gradient, but remains responsible for the implantation of a definitive pace maker in 3 to 11.8% of patients (Matthews et al., 2011). This latest generation Edwards sutureless allows easier access to minimally invasive surgery. They can be useful in certain circumstances (certain redox, highly calcified rings, associated procedures), and as such should be part of the therapeutic arsenal in modern aortic surgery (Ouazzani et al., 2014).

## CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

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