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CLINICAL RESEARCH

Transapical aortic valve implantation in Rouen: Four years' experience with the Edwards transcatheter prosthesis

Implantation transapicale de valves aortiques à Rouen : quatre années d'expérience avec la bioprothèse transcathéter Edwards

Pierre-Yves Litzler^{a,*}, Bogdan Borz^b, Hassiba Smail^a, Jean-Marc Baste^a, Catherine Nafeh-Bizet^a, Arnaud Gay^a, Christophe Tron^b, Matthieu Godin^b, Jerome Caudron^c, Camille Hauville^b, Jean-Nicolas Dacher^c, Alain Cribier^b, Hélène Eltchaninoff^b, Jean-Paul Bessou^a

^a Department of Thoracic and Cardiovascular Surgery, Charles Nicolle University Hospital, 1, rue de Germont, 76000 Rouen, France

^b Department of Cardiology, University Hospital-Charles Nicolle, 6000 Rouen, France

^c Department of Radiology, University Hospital-Charles Nicolle, 6000 Rouen, France

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KEYWORDS

Aortic stenosis;
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Summary

Background. – The first French transapical transcatheter aortic valve implantation (TAVI) was performed in July 2007 in our department.

Aims. – To report 4-year outcomes of transapical implantation with the Edwards transcatheter bioprosthesis.

Methods. – We prospectively evaluated consecutive patients who underwent transapical implantation with an Edwards transcatheter bioprosthesis between July 2007 and October 2011. Patients were not suitable for conventional surgery (due to severe comorbidities) or transfemoral implantation (due to poor femoral access).

Abbreviations: BAV, balloon aortic valvuloplasty; CABG, coronary artery bypass graft; ICU, intensive care unit; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; PASP, pulmonary artery systolic pressure; PET, polyethylene terephthalate; PCI, percutaneous coronary intervention; SD, standard deviation; TTE, transthoracic echocardiography.

* Corresponding author. Fax: +33 2 32 88 84 59.

E-mail address: pierre-yves.litzler@chu-rouen.fr (P.-Y. Litzler).

MOTS CLÉS

Sténose aortique ;
TAVR ;
Transapical

Results. – Among 61 patients (59.0% men), mean logistic EuroSCORE was $27.5 \pm 14.9\%$ and mean age was 81.0 ± 6.8 years. Successful valve implantation was achieved in 59/61 patients (96.7%) of patients. The other two patients required conversion to conventional surgery due to prosthesis embolization and died. Six additional patients died in the postoperative period. Causes of perioperative death were two septic shocks (one of peritonitis), two multi-organ failure, one ventricular fibrillation and one respiratory insufficiency. Intraprocedural stroke was not observed in any patient. The actuarial survival rates at 1, 2 and 4 years were 73.8%, 67.2% and 41.0%. During this 4-year period, four patients died of cardiovascular events, but no impairment of transprosthesis gradient was observed.

Conclusion. – Our series of 61 patients who underwent transapical implantation of the Edwards transcatheter bioprosthesis shows satisfactory results, similar to other reports, considering the high level of severity of patients referred for this method. Transapical access is a reliable alternative method for patients that cannot benefit from a transfemoral approach.

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Résumé

Contexte. – La première implantation française d'une valve aortique transcathéter (TAVI) a été réalisée dans notre service en juillet 2007.

Objectif. – Nous rapportons le suivi pendant quatre années de nos implantations transapicales avec la bioprothèse Edwards transcathéter.

Méthodes. – De juillet 2007 à octobre 2011, nous avons évalué prospectivement 61 patients consécutifs (EuroSCORE logistique : $27,5 \pm 14,9\%$). Leur âge moyen était de $81,0 \pm 6,8$ ans et 59,0% étaient des hommes. Tous ces patients ont bénéficié d'une implantation transapicale de la bioprothèse Edwards transcathéter. Tous ces patients avaient été récusés pour la chirurgie conventionnelle en raison de comorbidités sévères et n'étaient pas éligibles pour une implantation transfémorale à cause de mauvais axes iliofémoraux.

Résultats. – L'implantation de la valve a été réalisée avec succès chez 96,7% des patients. Deux patients ont nécessité une conversion en chirurgie conventionnelle à cause de la migration de la valve et sont morts. Six autres patients sont morts dans la période postopératoire. Les causes de décès périopératoires ont été : deux chocs septiques dont un avec péritonite, deux défaillances multiviscérales, une fibrillation ventriculaire et une insuffisance respiratoire. Aucun accident vasculaire cérébral per procédure n'a été observé chez aucun patient. Le taux de survie actuarielle à un, deux et quatre ans a été respectivement de 73,8%, 67,2% et 41,0%. Durant cette période de quatre ans, quatre patients sont décédés de causes cardiovasculaires. Aucune dégradation du gradient transprothétique n'a été observée durant cette même période.

Conclusions. – Notre série de 61 implantations de la bioprothèse transcathéter Edwards montre des résultats satisfaisants et comparables à la littérature, considérant le niveau élevé de gravité des patients proposés pour cette technique. La voie transapicale est une méthode alternative fiable pour les patients ne pouvant bénéficier de la voie transfémorale.

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Background

In April 2002, the first human percutaneous aortic valve implantation was performed in Rouen [1]. Different approaches quickly became feasible and, despite the historical use of the antegrade transeptal approach, the retrograde approach became popular during 2005, with the development of the RetroFlex catheter [2]. Due to the large diameter of the first models of the RetroFlex catheter (22/24 F) and the presence, in numerous patients, of small-calibre vessels or vascular disease, the idea of a transapical approach emerged. In 2005, after an animal feasibility study [3], the first patients were implanted via a small anterolateral mini thoracotomy [4,5]. In July 2007, the first transapical implantation in France was performed in our department. Since this time, 61 patients have been

implanted using this approach. We report the 4-year outcomes of these patients.

Methods

Between July 2007 and October 2011, 61 patients have been implanted using a transapical approach. A transfemoral approach was not appropriate in these patients due to small-calibre vessels, vascular disease or porcelain aorta. These consecutive patients were included in a prospective, single-centre registry. All patients selected by our multidisciplinary team had severe, degenerative aortic stenosis, and were included according to the inclusion criteria of successive European trials and registries (Partner, Source, France2). All patients gave written informed consent.

The screening process included transthoracic echocardiography (TTE) in all patients. An annulus diameter of 18–21 mm was considered appropriate for the 23 mm prosthesis and more than 21–24.5 mm for the 26 mm prosthesis. Selective coronary angiography, aortoiliac angiography and computed tomographic iliofemoral angiography were systematically performed. Patients with an iliofemoral diameter less than 7 or less than 8 mm (for the 23 or 26 mm SAPIEN valves, respectively) or 6 or 6.5 mm (for the 23 or 26 mm SAPIEN XT valves, respectively) led to the transapical approach.

Patients and procedure

From July 2007 to September 2010, the procedures were performed using a SAPIEN valve and an Ascendra 1 delivery system. This valve was made of three bovine pericardial leaflets sewn onto a stainless steel stent frame partially covered with a synthetic polyethylene terephthalate (PET) fabric sealing cuff. Thereafter, the procedures were performed using an Ascendra 2 delivery system with a 22 F internal diameter sheath and a SAPIEN XT valve. This valve uses a cobalt chromium frame.

All procedures were performed under general anaesthesia in a conventional cardiac surgery operating theatre using a mobile imaging system GE OEC 9900 C-arm.

Before the surgical procedure, a TTE apical four-chamber view was performed by the surgeon to check the best access to the apex of the left ventricle. Depending on the result, a small (6–8 cm) anterolateral thoracotomy was performed in the fourth or fifth intercostal space. Two concentric purse strings using 2/0 Prolene were achieved, close to the apex, on the lateral wall of the left ventricle. After ventricular puncture, a 0.035 inch Amplatz Extra-Stiff J-tip guide wire (COOK, Bjæverskov, Denmark) was placed through the native aortic valve into the descending aorta. In the first part of the procedure, a valvuloplasty using a 20 mm balloon (Edwards, Irvine, CA, USA) was performed under rapid ventricular pacing (180–220 bpm) using a temporary endocardial right ventricle pacing lead introduced through the femoral vein. The Ascendra delivery system sheath was introduced carefully under fluoroscopic control and the depth of the device was measured using radiopaque markers. Valve positioning was based on fluoroscopy using annular calcification as a landmark. The prosthesis was delivered using rapid ventricular pacing. Removal of the sheath was achieved cautiously by gently tightening the two concentric purse strings using no rapid pacing. The pacing lead was removed at the end of the procedure.

Data collection

Clinical and TTE parameters were obtained at baseline, discharge and 1, 2, 3 and 4 years, and the data were entered into our institutional database.

Statistical analysis

Qualitative variables are expressed as counts and percentages; and quantitative variables as mean \pm standard deviation (SD). All data were analysed using SPSS software (v17).

Table 1 Preprocedural baseline data.

	All patients (n = 61)
Age (years)	81.0 \pm 6.8
Men	36 (59.0)
Hypertension	48 (78.7)
Diabetes	15 (24.6)
Previous MI	22 (36.1)
Previous PCI	23 (37.7)
Previous CABG	21 (34.4)
Atrial fibrillation	19 (31.1)
Neoplasia	14 (23.0)
Chest X-ray	4 (6.6)
Pacemaker	11 (18.0)
Previous BAV	26 (42.6)
Syncope	3 (4.9)
Porcelain aorta	12 (19.7)
Previous stroke	6 (9.8)
Creatinine (μ mol/L)	125.2 \pm 68.5
Body surface area (m ²)	1.78 \pm 0.20
\geq NYHA III	44 (72.1)
Logistic EuroSCORE (%)	27.5 \pm 14.9
Aortic annulus diameter (mm)	21.7 \pm 1.4
Mean aortic gradient (mmHg)	41.0 \pm 13.9
Aortic valve area (cm ²)	0.68 \pm 0.16
PASP (mmHg)	46.1 \pm 15.0
LVEF (%)	56.3 \pm 13.2

Data are mean \pm standard deviation or number (%). BAV: balloon aortic valvuloplasty; CABG: coronary artery bypass graft; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PASP: pulmonary artery systolic pressure; PCI: percutaneous coronary intervention.

Results

Preprocedural characteristics

Patients characteristics are shown in Table 1. Patients were elderly, had a high mean Logistic EuroSCORE (27.5 \pm 14.9%), any many had previous coronary artery bypass graft (CABG) (34.4%) or porcelain aorta (19.7%), contraindicating conventional surgery. An important number of patients had undergone balloon aortic valvuloplasty (BAV) (42.6%), which was performed while the patients waited for implantation, due to the severity of clinical symptoms during the preimplantation period.

Baseline TTE data confirmed the severity of aortic stenosis with a mean valvular area of 0.68 \pm 0.16 cm² (Table 1). Mean aortic annulus diameter, measured by TTE, was 21.7 \pm 1.4 mm. In the 23 and 26 mm valve groups, the mean values were 20.4 \pm 0.9 and 22.9 \pm 0.8 mm, respectively. Left ventricular ejection fraction (LVEF) was moderately altered, with a mean value of 56.3 \pm 13.2% (Table 1). Mitral regurgitation was assessed as more than grade 1 in 34 patients (55.7%).

Procedural outcome

The prosthesis was placed in the appropriate position in 59 of 61 patients (96.7%). There was one migration into

the left ventricle cavity (due to misplacement) and one of migration into the ascending aorta (due to the presence of a bulging septum). These two procedures were converted to surgery using cardiopulmonary bypass with conventional replacement of the valve. These two patients died in the early postoperative period (1 and 6 days). Six more patients died during the postoperative period, at 4, 5, 6, 18, 28 and 40 days, leading to a perioperative mortality of 13.1%. Causes of death were septic shock (one of peritonitis) ($n=2$), multi-organ failure ($n=2$), ventricular fibrillation ($n=1$) and respiratory insufficiency ($n=1$). Intraoperative stroke was not observed in any patient. Postoperative complications were: 23 infectious (37.7%), 13 pulmonary (21.3%), six renal failure (9.8%) (necessitating dialysis in five patients) and three neurological (4.9%). Mean duration in the intensive care unit (ICU) was 3.9 ± 4.6 days and mean hospital stay was 12.9 ± 8.8 days.

Significant aortic insufficiency was observed in 14 patients: nine grade 2 (14.8%) and five grade 3 (8.2%). At day 7, mean LVEF was $59.2 \pm 12.1\%$. At 1 month, the mean aortic orifice areas were 1.67 ± 0.48 and 1.68 ± 0.49 cm² for the 23 and 26 mm valves, respectively.

Long-term results

Full 4-year follow-up data are available for all patients. As shown in Fig. 1, the actuarial survival rates at 1, 2 and 4 years were 73.8%, 67.2% and 41.0%, respectively. Cardiovascular death occurred in four patients during the first year, one during the second year and one during the third year. During the first year, seven patients were readmitted for amputation, mitral endocarditis, pulmonary infection, chronic cardiac insufficiency ($n=2$), diarrhoea and hypothyroidism. During the second and third years, one patient was readmitted for femur fracture and another for vomiting.

At 1 year, the mean aortic orifice areas for the 23 and 26 mm valves, respectively, were 1.8 ± 0.4 and 1.8 ± 0.3 cm². At 2 years, they were 1.6 ± 0.9 and 1.6 ± 0.9 cm², respectively. Evolution of the mean aortic transprostheses gradient is shown in Fig. 2. Mortality in patients with

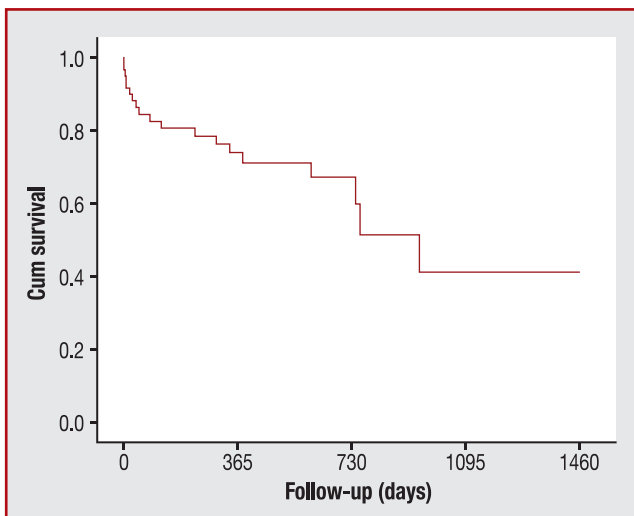


Figure 1. Actuarial survival ($n=61$).

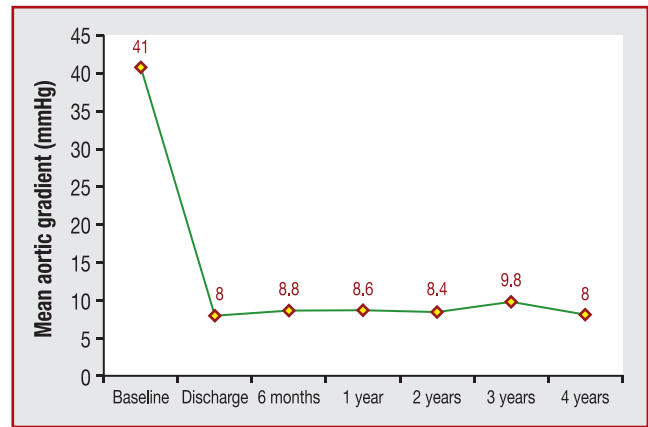


Figure 2. Evolution of mean aortic transprostheses gradient.

preprocedural mitral insufficiency (\leq grade 1 and $>$ grade 1) was 51.8% and 31.4% respectively.

Discussion

One of the key points of this single-centre experience with transapical implantation of the Edwards transcatheter aortic valve is the elevated mean Logistic EuroSCORE of $27.5 \pm 14.9\%$. Compared with the transfemoral group in our institution (Logistic EuroSCORE $22.8 \pm 11.8\%$), the severity of the patients referred for the transapical approach has already been highlighted [4,5]. In our group, the patients who are contraindicated for surgery by the heart team are first referred for transfemoral implantation, performed under local anaesthesia. Only patients whose arterial vascular accesses are not convenient are proposed for the transapical approach. Many of them are polyvascular patients with coronary disease. This probably explains the high proportion of previous percutaneous coronary intervention (PCI) (37.7%) and CABG (34.4%) procedures. Despite the fact that these associated pathologies have no direct impact on technical issues during the procedure, they could have a huge influence on postoperative outcome. Transapical implantation of a transcatheter bioprosthesis is a thoracic surgical procedure with chest opening, artificial ventilation and general anaesthesia, and is a more invasive technique than the transfemoral approach.

The follow-up of our patients, despite a significant number of 'minor' postoperative issues such as minor pleural effusion, respiratory insufficiency and pain, shows a non-significantly different long-term survival compared to a transfemoral approach in our institution (78%, 63%, 36% at one, 2 and 4 years; $P=0.670$; data not shown). Similar results have previously been reported by Johansson et al. in a series of 40 patients with a similar survival at 1 year (77%) [6]. Moreover, our survival results are in accordance with those published by Walther et al. in a larger series of 299 patients: 73%, 68% and 58% at 1, 2 and 3 years, respectively [7]. However, unlike the results from Kempfert et al. [8], the presence of preprocedural mitral regurgitation ($>$ grade 1) does not seem, in our series, to have an influence on long-term survival.

In our study, 23.0% of patients had grade 2 or 3 aortic insufficiency. The mechanism of these aortic insufficiencies is mainly paravalvular, as has been previously described [9]. The long-term influence of these paravalvular leaks has not been clearly assessed, but could have a role in the evolution of the clinical status of patients.

During this experience, we have observed a significant improvement in the delivery system, mainly concerning the diameter of the sheath, leading to an easier procedure with reduced myocardial trauma. It is interesting to note that we did not observe any decrease in LVEF between the preprocedural measurement and the 7-day post-procedural measurement ($56.3 \pm 13.2\%$ vs. $59.2 \pm 12.1\%$). Moreover, 16 patients (26.2%) presented with LVEF < 50%, and only one patient (6.3%) in this group died. However, in all cases, the transapical approach is an invasive procedure. The development of other approaches, such as transaortic (through a mini sternotomy or mini right thoracotomy [10,11]) or subclavian [12] approaches could change the criteria for the selection of patients. Patients with low or very low LVEF could be, in the future, proposed for a transaortic or subclavian approach in order to spare ventricular function. However, redo of CABG or porcelain aorta should stay in the field of transapical approach.

As reported previously (Fig. 2), we have not observed an increase in mean transprostheses gradient during the 4 years of follow-up. However, it is important to note that degeneration of bioprostheses usually occurs after 5 years in surgical series. The high rate of mortality (cardiovascular or otherwise) due to the severity of comorbidities, in all the transapical series reported, tends to hide early failures of devices.

Conclusions

Our series of 61 transapical implantations of Edwards transcatheter bioprostheses shows satisfactory results, considering the high level of severity of patients referred for this method. The frailty of the apex of the left ventricle, considered as a main issue by many cardiac surgeons, has not impaired our results. Some new surgical approaches, such as transaortic or subclavian, could lead to a new distribution of the patients between transfemoral and other surgical approaches. Ten years after the first human implantation of a transcatheter bioprosthesis, a large, worldwide experience has been accumulated. The first objective of Alain Cribier has been reached, namely 'to provide an alternative procedure for non-surgical patients'. The future of this promising method has still to be defined and practitioners, within the heart team, will have to determine the best use of this new tool.

Disclosure of interest

Pierre-Yves Litzler reports to be proctor for Edwards-Lifesciences. Alain Cribier reports to be consultant for Edwards-Lifesciences.

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