

A Comparative Study of the Follow-Up and Hemodynamics *in vivo* of 21 mm Carpentier-Edwards Supra-Annular and Perimount Bioprostheses

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Introduction and objectives. Analysis and comparison of the clinical performance and hemodynamics *in vivo* of 21 mm Carpentier-Edwards supra-annular (CESA) and Perimount (CEPM) aortic bioprostheses.

Methods. A follow-up study was made of 40 patients implanted a 21 mm CESA (n = 21) or CEPM (n = 19) prosthesis between October 1992 and September 1997. All eligible survivors (14 CESA, 12 CEPM) were assessed echocardiographically.

Results. There were no significant differences between models in the effective orifice area (1.6 cm² for CESA, 1.44 cm² for CEPM), peak flow rate (rest: 2.5 m/s for CESA, 2.3 m/s for CEPM; post-dobutamine: 3.4 m/s for CESA, 3.3 m/s for CEPM), mean flow rate (rest: 1.7 m/s for CESA, 1.6 m/s for CEPM; post-dobutamine: 2.5 m/s for CESA, 2.2 m/s for CEPM), peak gradient (rest: 28.3 mmHg for CESA, 21.6 mmHg for CEPM; post-dobutamine: 48.4 mmHg for CESA, 41.6 mmHg for CEPM), and mean gradient (rest: 15.8 mmHg for CESA, 12.0 mmHg for CEPM; post-dobutamine: 28.5 mmHg for CESA, 22.5 mmHg for CEPM).

Conclusion. In our experience, these two prosthetic models have similar hemodynamic characteristics in small aortic annuli.

Key words: Echocardiography. Surgery. Aortic stenosis. Valvular prosthesis.

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Estudio comparativo del comportamiento clínico y hemodinámico de las bioprótesis aórticas de Carpentier-Edwards Supra-Annular y Perimount de 21 mm

Introducción y objetivos. Se pretende analizar y comparar el comportamiento clínico y las características hemodinámicas *in vivo* de las bioprótesis aórticas de Carpentier-Edwards Supra-annular (CESA) y Perimount (CEPM) de 21 mm.

Métodos. Se realizó un estudio de seguimiento clínico a todos los pacientes (n = 40) que habían recibido una prótesis aórtica CESA (n = 21) o CEPM (n = 19) de 21 mm entre octubre de 1992 y septiembre de 1997. Asimismo, se realizó un estudio ecocardiográfico, en reposo y con dobutamina, a todos los supervivientes que autorizaron la prueba y cuya prótesis resultó ser normofuncionante (CESA, n = 14; CEPM, n = 12).

Resultados. No encontramos diferencias significativas entre ambos modelos en lo que se refiere a área efectiva del orificio protésico (1,6 cm² para CESA y 1,44 cm² para CEPM), velocidad pico (reposo: 2,5 m/s para CESA, 2,3 m/s para CEPM; posdobutamina: 3,4 m/s para CESA, 3,3 m/s para CEPM), velocidad media (reposo: 1,7 m/s para CESA, 1,6 m/s para CEPM; posdobutamina: 2,5 m/s para CESA, 2,2 m/s para CEPM), gradiente pico (reposo: 28,3 mmHg para CESA, 21,6 mmHg para CEPM; posdobutamina: 48,4 mmHg para CESA, 41,6 mmHg para CEPM) y gradiente medio (reposo: 15,8 mmHg para CESA, 12,0 mmHg para CEPM; posdobutamina: 28,5 mmHg para CESA, 22,5 mmHg para CEPM).

Conclusión. En nuestra experiencia, estos dos modelos bioprotésicos muestran un comportamiento hemodinámico similar en anillos aórticos pequeños.

Palabras clave: Ecocardiografía. Cirugía. Estenosis

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INTRODUCTION

The choice of a suitable cardiac replacement valve is a problem that the surgeon often confronts. The durability of the prosthesis (particularly bioprostheses) and its hemodynamic characteristics must be weighed (especially in patients with a small native aortic annulus).

ABBREVIATIONS

CESA: Carpentier-Edwards Supra-Annular.
 CEPM: Carpentier-Edwards Perimount.
 AATS: American Association of Thoracic Surgeons.
 STS: Southern Thoracic Society

The Carpentier-Edwards Supra-Annular, model 2650 (CESA), a porcine bioprosthesis, and the Carpentier-Edwards Perimount, model 2900 (CEPM), a prosthesis of bovine pericardium, are two cardiac valve models manufactured by the same company (Baxter Edwards AG, Horw, Switzerland). Clinical follow-up studies of these two bioprostheses have shown satisfactory and comparable results with respect to durability.¹⁻⁶ However, information obtained from comparisons of their hemodynamic characteristics *in vivo* is inconclusive and either appears in the context of general studies or has been obtained by invasive intraoperative methods (not echocardiographic).^{7,8}

In this retrospective study we will briefly describe our intermediate-term clinical experience with these bioprostheses implanted in small aortic annuli. Likewise, we will attempt to determine if the small sizes (21 mm) of these two bioprosthesis models, implanted in aortic position, show significant and clinically relevant differences with respect to their hemodynamic behavior.

METHODS

This retrospective study included a total of 40 patients who had undergone implantation of a 21 mm Carpentier-Edwards aortic bioprosthesis (CESA: n=21; CEPM: n=19) in the 5-year period from October 1992 to September 1997. The prosthesis was selected at random and implanted in accordance with the surgeon's preferences.

The surgical technique was similar in all the patients. In every case the prosthesis was implanted with protected polyester U sutures and the patch on the ventricular side of the native aortic annulus.

The patients' clinical information was obtained from medical records and follow-up data by telephone interviews with the patients or their relatives. The clinical follow-up was completed in 40 patients. The closure period was 2 months (November and December 1997). The definitions of events adhered strictly to the recommendations of the joint committee of the AATS and STS for reporting of morbidity and mortality after cardiac valve surgery.⁹

All survivors were offered echocardiographic assessment of the prosthesis. Patients were not inclu-

ded in the study or were excluded if: *a*) they did not consent to participate in the study; *b*) presented echocardiographic evidence of bioprosthesis dysfunction due to the appearance of primary degenerative phenomena (except minor central prosthetic incompetence), and *c*) the echocardiographic study could not be entirely completed, whatever the reason. The echocardiographic studies were all made by the same echocardiographic specialist in accordance with the applicable recommendations.^{10,11} M-mode bidimensional transthoracic echocardiography was carried out with a Hewlett Packard Sonos 2000 instrument with a 2.5/2.0 MHz transthoracic probe (Hewlett Packard Inc. Andover, U.S.). The heart was visualized with standard parasternal long-axis and short-axis, longitudinal apical, four-chamber, and subcostal views. Peak and mean transprosthetic flows were measured. The peak and mean transprosthetic gradients were estimated with a modified Bernoulli formula and the effective valve orifice was estimated by the continuity equation. All these calculations were made with the echocardiographic software. The measurements were made at rest and after administering an intravenous infusion of dobutamine at a dose of 10 µg/kg/min during 3 min. Likewise, the left ventricular shortening fraction was determined at rest and post-dobutamine to assess left ventricular function.

The statistical analysis was made with the SPSS statistical program, version 7.5 for Windows. Values are expressed as mean±standard deviation. The mean values were compared with non-parametric tests (Mann-Whitney). The categorical variables were compared with contingency tables and the χ^2 test (corrected with the Yates' formula when necessary) or the Fisher exact test. Values of $P < .05$ were considered statistically significant.

RESULTS

No significant differences were appreciated between the CESA and CEPM groups with respect to sex (16 women and 5 men in the CESA group, 17 women and 2 men in the CEPM group; $P > .2$), mean age (71.6±6.2 years for the CESA group, 71.1±4.2 years for the CEPM group; $P > .6$) and mean follow-up (26.6±20.8 months, range 0-60 months for the CESA group; 28.2±16.7 months, range 0-56 months for the CEPM group; $P > .8$). The mean body surface was 1.62±0.1 for the CESA group and 1.61±0.1 for the CEPM group ($P > .8$).

The most frequent surgical indication was degenerative calcified aortic stenosis (n=17 and n=18 in the CESA and CEPM groups, respectively), followed by rheumatic disease (n=2 and n=1 for the CESA and CEPM groups, respectively) and dysfunction of a previous prosthesis (n=2 in the CESA group).

TABLE 1. Functional status

	Preoperative (n)		Postoperative (n)	
	CESA	CEPM	CESA	CEPM
Class I	0	0	12	7
Class II	3	2	6	8
Class III	17	12	1	0
Class IV	1	5	0	0
Deaths			2	4

With the exception of 3 patients in the CESA group and another 3 in the CEPM group (who were in atrial fibrillation and receiving anticoagulant treatment), all the rest of the patients were in sinus rhythm in the preoperative period.

Associated procedures were performed in 11 patients in the CESA group (myocardial revascularization in 9 cases, mitral commissurotomy in one case and subaortic membrane resection in one case) and in 8 patients in the CEPM group (coronary bypass in every case).

Four patients died in the hospital (1 in the CESA group and 3 in the CEPM group), so the overall hospital mortality was estimated at 10% (4.8% and 15.8% for the CESA and CEPM groups, respectively; $P>.2$). The causes of hospital mortality were low cardiac output ($n=1$ in CESA, $n=1$ in CEPM), arrhythmias ($n=1$ in CEPM), and respiratory failure ($n=1$ in CEPM).

Clinical follow-up

Two patients died after hospital release, neither of them from causes related with the valve. One of them (in the CESA group) died at 15 months due to congestive heart failure and the other (in the CEPM group) at 39 months due to carcinoma of the prostate.

One patient in the CESA group, previously in atrial fibrillation, suffered a cerebral transitory ischemic episode at 45 months of follow-up, but had a complete functional recovery. Echocardiographically, a significant periprosthetic dehiscence was observed in 2 patients in the CESA group at 34 and 53 months of follow-up, respectively. There was no case of valvular

thrombosis, structural failure, or endocarditis in any of the groups, and no patient required reoperation.

The preoperative and postoperative functional of the patients is shown in Table 1.

Echocardiographic study

Five patients in the CESA group and 3 in the CEPM group were excluded from the study. The causes of exclusion were non-consent in 2 patients in the CESA group and in 3 of the CEPM group, significant periprosthetic dehiscence in 2 patients in the CESA group, and atrial fibrillation with a rapid ventricular response, which contraindicated the administration of intravenous dobutamine, in one patient in the CESA group. Therefore, the complete echocardiographic study (at rest and post-dobutamine) was made in 14 patients in the CESA group and in 12 patients in the CEPM group. The mean follow-up period for the echocardiographic study was 27.5 ± 17.4 months (range, 3-60 months).

None of the patients studied presented left ventricular dilatation and the mean thickness of the middle interventricular septum was 14.7 ± 2.2 mm (range, 11.7-19 mm) for the CESA group and 14.8 ± 2.7 mm (range, 9.4-19 mm) for the CEPM group, $P>.05$.

The pre-dobutamine left ventricular shortening fraction was $37.5\pm 7.6\%$ (range, 25%-49.3%) for the CESA group and $35.1\pm 7.3\%$ (range, 19.4%-48.9%) for the CEPM group. After the administration of dobutamine, the mean value of the shortening fraction increased to $48.4\pm 5.7\%$ (range, 39.2%-56%) for the CESA group and to $42.9\pm 6.5\%$ (range, 31.8%-54.8%) for the CEPM group.

Only one patient in the CESA group had a subaortic gradient of 33 mm Hg. In no case was evidence of primary structural failure appreciated. The mean effective valvular area was estimated as 1.60 ± 0.49 cm² (range, 1.06-3.03 cm²) for the CESA model and 1.44 ± 0.24 cm² (range, 1.05-1.92 cm²) for the CEPM model. There was no significant difference between them ($P>.5$).

Two CESA valves and 6 CEPM valves showed minor central prosthetic incompetence.

Table 2 summarizes the echocardiographic findings.

TABLE 2. Echocardiographic findings

	At rest			Post-dobutamine		
	CESA	CEPM	P	CESA	CEPM	P
LV shortening fraction	37±8	35±7	>.4	48±6	43±6	>.4
Peak velocity, m/s	2.5±0.5	2.3±0.3	>.2	3.4±0.7	3.3±0.5	>.3
Peak gradient, mm Hg	28±10	22±6	>.09	48±20	42±12	>.4
Mean velocity, m/s	1.7±0.4	1.6±0.3	>.4	2.5±0.5	2.2±0.3	>.1
Mean gradient, mm Hg	16±6	12±3	>.1	28±11	22±6	>.1

DISCUSSION

The appearance of thromboembolic phenomena and hemorrhagic complications secondary to the use of anticoagulants are two important causes of morbidity and mortality in patients with mechanical cardiac valve prostheses. In this sense, prostheses of biological origin are an attractive alternative since they have low intrinsic thrombogenicity and do not require anticoagulant treatment, so they do not present this type of complications. These benefits are especially noteworthy in patients with aortic valve disease, who are generally older patients in sinus rhythm.

Nonetheless, with time bioprostheses suffer degenerative phenomena that undermine their durability. This limitation was a particular concern in the first-generation prosthesis models of bovine pericardium fixed in glutaraldehyde,^{5,12,13} although most of them are no longer on the market. Porcine prostheses, in contrast, are much used since they are more durable than pericardial prostheses.^{5,12,13} Therefore, porcine aortic valve fixed in glutaraldehyde is, to some extent, the gold standard for the manufacture of valvular xenografts.¹⁴

The CEPM prosthesis is an exception to this rule. Since it was introduced on the market in 1981, this bovine pericardial prosthesis has shown long-term durability rates in different clinical studies that are similar to those of porcine bioprostheses.^{1-3,5}

The hemodynamic behavior of bioprostheses is another relevant concern. It is known that replacement valves implanted on the aortic annulus have a stenosing effect that increases in larger prostheses.¹⁴⁻¹⁶ In other words, small prostheses implanted on the aortic annulus require maximum hemodynamic efficiency in order to minimize the transprosthetic gradient.

It is known that the effect of obstruction to flow is less significant, at rest and after exercise, if late-generation, unsupported bioprostheses are implanted.¹⁷ Likewise, there is evidence that the better hemodynamic characteristics of these valvular models favor the regression of ventricular hypertrophy to a greater extent than aortic bioprostheses supported conventionally.¹⁸

The CESA and CEPM valves are two models of bioprosthesis (porcine and bovine pericardial, respectively) manufactured by the same company. In our experience^{6,19} and that of other authors,¹⁻⁵ these bioprostheses have a similar durability. Nonetheless, the information on the hemodynamic characteristics *in vivo* of these two valve models found in the literature is inconclusive. In this sense, Cosgrove et al,⁷ who studied the intraoperative hemodynamics of these prostheses, reported that CEPM valves behaved better. In contrast, McDonald et al⁸ found no significant differences. We undertook the present study with the intention of clarifying this question as far as possible with evidence. Since degenerative phenomena rarely appear

in bioprostheses before the fifth or sixth year of follow-up,¹² we intentionally limited the study to a 5-year period in order to minimize the incidence of dysfunctional prostheses due to primary tissue failure. Therefore, it should be emphasized that all the bioprostheses included in this study were normofunctional.

Our results again show that the CESA and CEPM aortic prostheses have an obstructive behavior and that this obstruction to blood flow is accentuated with dobutamine-induced stress. Nonetheless, we did not appreciate significant differences between the two models in transvalvular gradients and velocities and in effective valvular orifices. However, although we did not obtain significant differences in any case, the pericardial prosthesis always showed lower transprosthetic velocities and gradients, both at rest and after dobutamine administration (Table 2).

CONCLUSIONS

In our experience we found no differences between the CESA and CEPM models with respect to their hemodynamic characteristics.

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