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# Mechanisms, treatment and course of paravalvular aortic regurgitation after percutaneous implantation of the CoreValve aortic prosthesis

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Transcatheter aortic valve implantation (TAVI) is an alternative treatment for patients with a severe symptomatic aortic stenosis and a high surgical risk. Initial series suggest the procedure is associated with a high success rate and low in-hospital mortality [1,2]. However, one limitation relates to paravalvular aortic regurgitation (AR). We aimed to identify possible mechanisms related with AR, and study its treatment and progression after percutaneous implantation of a CoreValve prosthesis.

In April 2008, our hospital started a program of TAVI with the CoreValve aortic prosthesis (Medtronic, Irvine, CA) for patients with a high surgical risk. All the patients were assessed by a multidisciplinary team. Until December 2010 we had treated 144 patients with severe symptomatic aortic valve stenosis.

The third-generation CoreValve aortic prosthesis is a biological prosthetic trileaflet valve of porcine pericardium, fitted and sutured onto a self-expanding nitinol structure with an 18 French release system. There are currently 2 valve sizes: small (the 26 mm prosthesis for aortic annulus sizes from 20 to 23 mm) and large (the 29 mm prosthesis for annulus sizes from of 23 to 27 mm). The length of both sizes of prosthesis is 50 mm. The last 20 (14.2%) patients underwent with the new Accutrak delivery Catheter system.

Access was femoral in 90.8% of cases. In 13 patients the subclavian artery was used as the access route as they had peripheral arterial disease of the femoro-iliac artery. The aortic prosthesis was released under fluoroscopy-guided angiographic control. After implantation of the CoreValve prosthesis the degree of AR was quantified according to Sellers grade and echocardiography. A control echocardiogram was performed at 72 h, and at 6 months of follow-up in 111 patients (78.7%).

Normally, it was defined as a correct position of the CoreValve prosthesis when the portion inside the left ventricular outflow tract (LVOT) was approximately 4 to 8 mm below the aortic valve annulus. A "too low" implantation was defined as the distal edge of the valve

**Table 1**
Baseline characteristics of the study population, n = 141.

| | |
|---|---|
| Age, years | 79.5 ± 6.4 |
| Sex (female) | 88 (62%) |
| BMI, kg/m$^2$ | 29.3 ± 5.4 |
| NYHA functional class | |
| Class II | 16 (11.3%) |
| Class III | 77 (54.6%) |
| Class IV | 48 (34%) |
| Angina | 28 (19.9%) |
| Syncope | 7 (5%) |
| Prior valve surgery | 9 (6.4%) |
| Coronary disease | 44 (31.2%) |
| Prior surgical revascularization | 14 (9.9%) |
| PCI prior to the procedure | 21 (14.9%) |
| Frailty | 17 (12.1%) |
| Charlson index | 3.5 ± 1.9 |
| Karnofsky | 58.6 ± 20 |
| Logistic EuroSCORE (%) | 20.2 ± 13 |
| Renal failure (creatinine >2 g/dL) | 32 (22.7%) |
| Porcelain aorta | 9 (6.4%) |
| Cardiovascular risk factors | |
| Diabetes Mellitus | 51 (36.2%) |
| Hypercholesterolemia | 70 (49.6%) |
| Hypertension | 108 (76.6%) |
| Smoking | 29 (20.6%) |
| Echocardiographic parameters | |
| Maximum gradient, mm Hg | 79 ± 22 |
| Mean gradient, mm Hg | 501 ± 16 |
| AVA, cm$^2$ | 0.62 ± 0.2 |
| Aortic annulus, mm | 22.3 ± 1.7 |
| Ejection fraction,% | 63 ± 13 |
| LVEF <40% | 19 (13.5%) |

PCI: Percutaneous coronary intervention; AVA: Aortic valve area; EuroSCORE: European System for Cardiac Operative Risk Evaluation. BMI: Body mass index; NYHA: New York Heart Association.

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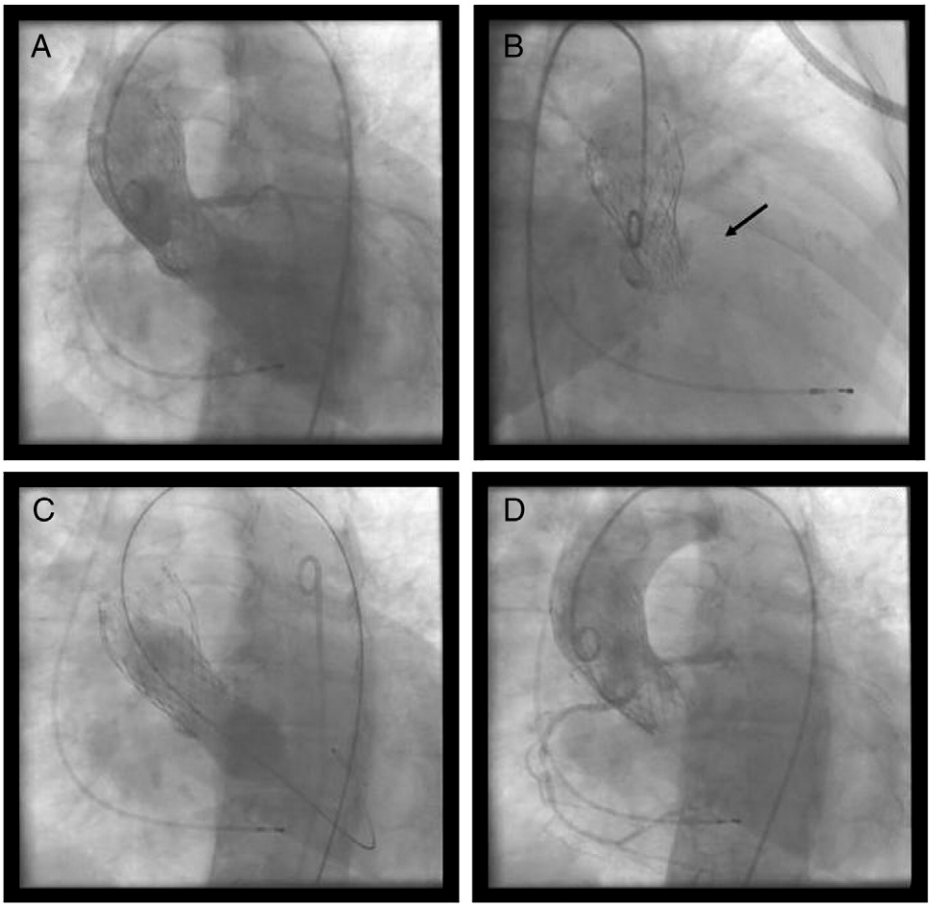


**Fig. 1.** Underexpansion of the CoreValve aortic prosthesis. (A) Severe paravalvular AR after prosthesis implantation. (B) Underexpansion of the aortic prosthesis. (C) Post-implant aortic valvuloplasty. (D) Disappearance of the paravalvular AR.

frame (commonly referred to as the "inflow" aspect) positioned more than 12 mm below the annulus, in the LVOT. A "too high" implantation was defined as the inflow aspect positioned above the annulus level.

The prosthesis was considered to have inadequate expansion/apposition when there was a severe AR with the prosthesis in the correct position but with deformation of the nitinol structure due to annulus calcification and/or paravalvular leakage on the echocardiogram.

The relation between the different diagnostic methods to quantify the degree of AR was studied with the Pearson correlation coefficient (for variables with a normal distribution) and the degree of concordance using the Kappa index.

TAVI was successful in 141 (97.9%) cases (Table 1). The immediate post-procedure aortography showed that 38 patients (26.9%) had paravalvular AR grade >2+ Sellers. The following mechanisms were identified: in 32 patients AR was secondary to inadequate expansion/apposition due to native annulus calcification, requiring balloon postdilatation to optimize the result and achieve reduction in the degree of AR (Fig. 1). No association was found between prosthesis size and the need for postdilatation: 21.5% with the small prosthesis versus 30.6% with the large prosthesis ($P = 0.22$). The cause of AR in the other 6 patients was incorrect positioning of the prosthesis: 5 patients with a low implantation, treated with implantation of a second prosthesis in 4, and in the fifth patient it was possible to reposition the prosthesis after snaring it with a loop (Fig. 2). One patient in whom the implant was high required a second prosthesis (Fig. 3).

In the final angiography, 46 patients (32.6%) had AR 2+, 54 patients (38.3%) 1+ and 41 patients (29.1%) absent. At the 72 h echocardiogram: 33 patients (23.4%) had moderate AR, 56 (39.7%) mild and 52 (36.9%) absent.

Control echocardiography at 6 months was performed in 111 patients (78.7%): 21 (18.9%) had moderate AR, 52 (46.8%) mild and 38 (34.2%) absent. The correlation between the final angiography and the 72-hour echocardiogram was $r = 0.658$, and the Kappa index between the 72-hour and the 6-month echocardiograms was 0.722.

These results suggest that although a severe AR is frequent immediately after implantation of the CoreValve prosthesis, identification of the causative mechanism followed by its treatment led to excellent results, with severe AR being exceptional. However, mild–moderate residual AR, possibly due to incomplete apposition of the prosthesis to the calcified native valve annulus, occurred in 70.9% of cases by angiography and 63.1% by echocardiography, similar data to those of other studies [1,2].

In those cases with severe post-procedure AR, its mechanism was identified by angiography and echocardiography and solved during the same procedure. In the event of inadequate expansion/apposition of the prosthetic valve, this was postdilated in 23% of the cases. The consequences of this postdilatation and its long-term effect on the valve structure required a longer follow-up, though Gurvitch et al. [3] with a clinical follow-up of 3 years, found no prosthetic dysfunction. Koos et al. [4] showed that the patients with greater valve calcification, assessed by computed tomography, had an increased risk of AR, with later dilatation being more frequent.

The other mechanism of AR is the incorrect positioning of the prosthesis in relation to the native valve annulus. In our series, this was responsible for the AR in 6 (4.2%) patients. In these cases, implantation of a second prosthesis is feasible and efficient, as also seen in other series [2,5].