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APPENDIX. CONFERENCE DISCUSSION

Dr A. Bochenek (*Katowice, Poland*): I think it is a very important paper because it shows us that TAVI in a failing aortic valve prosthesis is possible, and is possible during the femoral and during the apical approach.

You have pointed out the limitation of this study, but this study, together with the previous study by Pasic from the Hetzer centre and the groups of Walther and Mohr, gives us more valid information about the early problems and longer term results.

In this study the technical success was 94%, but procedural success, defined as adequate valve placement and function on discharge from the hospital, was only 50%. The primary safety end point, including MACCE, was only 44%, early mortality 11%, one-year mortality, 28%.

First question. How many patients in your group were disqualified completely from surgery, and in how many patients did the surgeon have a role in the decision to disqualify the patient from surgery? I know that this is a very difficult group, and we are very happy that somebody is helping us to sort out this problem in our department, but the results are not good. In a good centre, the results, even with a difficult operation, can be better. How many patients were completely disqualified from surgery?

The other question is the approach. We know from the other study that the apical approach maybe is easier because the transapical approach is independent of the degree of patient pericardial disease and advancing the wire antegrade is easy, repeatable, and simple. How many patients were disqualified because of a very calcified aortic and iliac vessel in this group?

One more question about the valvuloplasty. What was the indication for valvuloplasty before the deployment of this valve?

Dr Mueller: I fully agree that the results are not perfect. There is need for improvement. The main thing I think is that the positioning of the CoreValve in a small bioprosthetic valve is cumbersome, because there is a very strong tendency to move inwards, and in many of these what we did find were negative results due to this fact. Perhaps the development of a smaller CoreValve could overcome this problem. The smaller CoreValve will come. In our centre, we decided if we do have very small surgical valves implanted, we prefer an Edwards prosthesis implanted, and we do have better results then.

We presented and discussed all of our patients with our cardiovascular team. All but one were not accepted for surgery by them. But this was a study and we could treat them.

Regarding your other question, in the first two patients with pure aortic, or stenosis of the bioprosthetic valve, we did a valvuloplasty because we were used to it, and in the next, we avoided it.

Dr F. Mohr (*Leipzig, Germany*): I think you already made a very good point, that a balloon-expandable valve of the same size, like the bioprosthesis most likely, works much better than a self-expanding type design in our hands also, and there should be a clear message here.

And I also want to point to a paper, which I do think is important, concerning the structure and leaf pathology of some valve types which have a very high profile, like, for example, the Mitroflow and/or the Trifectam, implanted in a small root, are contraindications for a kind of TAVI, because it is very likely that by dilating the frame a little bit you may occlude the coronary ostia. So these are things we should consider in defining which is the optimal type of TAVI route. I think transapical is a very good one since you can approach the mitral as well, but also I think you made the point that the self-expanding type is not the optimal design. Aortic regurgitation with a balloon-expandable type valve does not occur in the frame, and I think this is advantageous. But, still, we need to look at the valves we have implanted at the very beginning, because from that experience you can decide whether you can or cannot do it.

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EDITORIAL COMMENT

Re-operation: a thing of the past? Transcatheter aortic valve-in-valve implantation for failed surgical bioprosthesis

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Transcatheter aortic valve implantation (TAVI) has become a reliable treatment modality for aortic valve stenosis. More than 10 years after the first implantation, it is still debatable which patients may benefit from TAVI compared with surgical aortic valve replacement (SAVR) although the Partner A study [1] described a well-defined patient population as optimal candidates for TAVI. Evidence for further indications is still needed.

Aortic valve re-operation may carry a higher perioperative risk compared with first-time SAVR because patients are older but technically speaking, redo-SAVR is not extremely demanding [2]. Transcatheter aortic valve-in-valve implantation (ViV TAVI) might

be of particular interest for some patients scheduled for SAVR as a redo-procedure, for instance, in those with patent coronary artery grafts.

The present study [3], which was sponsored by Medtronic, reports on 18 patients from three different centres in Germany who received a CoreValve™ ViV TAVI to treat a degenerated aortic bioprosthetic valve.

Including patients older than 75 years with either a logistic EuroSCORE of ≥15% or one additional self-defined risk factor (i.e., atrial fibrillation) might appear rather arbitrary. But with an overall logistic EuroSCORE of 34%, patient selection seems adequate. Unfortunately, more accurate STS scores are lacking. Procedural success was achieved when echocardiography showed adequate valve placement and function at discharge or on POD 10 without any composite Major Adverse Outcomes (MAE) until discharge.

Indications for TAVI in the presence of a degenerated tissue valve were isolated regurgitation in 33% of patients, isolated stenosis in 28% and a combination of both in 39%. The average time interval since primary AVR was 7 years (range 1–16 years).

Valve-in-valve TAVI represents an attractive and less invasive alternative to conventional redo-surgery and some technical details, as, for instance, the radio-opaque frame of the *in situ* tissue valve facilitates accurate valve-in-valve deployment. Moreover, fluoroscopic orientation requires smaller doses of contrast and also allows for ViV implantation in pure regurgitation of the tissue valve. Sizing is easier because the diameter of the prior valve is usually known from the time of surgery. Finally, the landing zone is more circular and decreases the risk of paravalvular leakage, and annular tear from overexpansion is unlikely. The risk of a permanent aortic valve (AV) Block III with consequent pacemaker implantation is low.

Although ViV TAVI in stented bioprosthesis may be technically less demanding, decision making requires additional experience and expertise; for instance, a profound understanding of the type of surgical bioprosthesis and its construction is important.

In contrast to stented tissue valves, stentless valves pose a unique challenge for ViV TAVI. The absence of struts, sewing ring and fluoroscopic landmarks increase the procedural complexity. In this series, 44% of the ViV procedures were performed in stentless xenografts. This might be the reason for the reported 30% AV blocks with consequent pacemaker implantations in more than 10%.

Further understanding of how a bioprosthesis degenerates is essential. The leaflet's changes increase the difficulty of retrograde passing. A degenerated prosthetic leaflet may generate more embolic events since the debris are sometimes very loose and might detach more easily. This is the reason why experts generally do not recommend balloon pre-dilatation.

It is surprising that the authors performed pre-dilatation in up to 75% of the patients in this series with stenotic degeneration and the fact that two neurological events occurred only in patients with stenotic degeneration points towards the increased risk of embolization after pre-dilatation.

The overall incidence of 30-day Major Adverse Cardiac and Cerebrovascular Events (MACCE) (39%) and 30-day composite MAE (44%) is high but a 30-day mortality of 12% in the presence of high-risk patients with a predicted EuroSCORE mortality of 34% is acceptable.

Transvalvular gradient and effective orifice area (EOA) are further important aspects that deserve detailed attention when performing ViV TAVI. With a baseline mean gradient of 37 mmHg and a valve orifice area of 0.9 cm^2, haemodynamic results were encouraging: mean gradient decreased to 19 mmHg at one year and EOA increased to 1.5 cm^2. Similar results were reported in the literature after ViV with either the Edwards Sapiens™ or the Medtronic CoreValve™ device [4]. But these results also indicate that ViV cannot be repeated several times as transvalvular gradients might then not decrease sufficiently.

TAVI indications will most likely expand in the future. With the current TAVI data, the feasibility of a later ViV TAVI procedure alone does not justify the implantation of tissue valves into younger patients (<60-65 years). The goal of each valve procedure should remain one, and only one, procedure for the rest of the patient's life (ESC Guidelines). Decision making for a patient with a degenerated tissue valve prosthesis is substantially enhanced by the multidisciplinary heart team approach. Taking advantage of the joint expertise of the cardiac surgeon and the interventional cardiologist, ultimately enhances patients safety.

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