## Why not "simplify" TAVI?

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Aortic stenosis among the elderly is associated with a substantial increase in morbidity and mortality once symptoms such as angina, syncope, or heart failure develop. Since 2002, transcatheter aortic valve implantation (TAVI) has been established as an emerging therapeutic approach for patients with unacceptable surgical risk and a less invasive alternate treatment option for patients at high risk for open-heart surgery. Meanwhile, more than 60,000 patients underwent TAVI procedures worldwide and the dramatic growth in TAVI will possibly continue over the next years. New technology advances promise to simplify TAVI and to improve outcome by reducing the rate of TAVI-specific issues such as stroke, paravalvular aortic regurgitation, acute kidney injury, vascular complications, and conduction disturbances.

Mendiz and co-workers report about their initial experience of 21 patients suffering from severe aortic valve stenosis undergoing direct TAVI without balloon valvuloplasty for pre-dilatation with use of the self-expanding Medtronic CoreValve prosthesis (1). In six patients (28.6%), post-dilatation had to be performed due to frame underexpansion – in two patients (9.5%) as reason for moderate-to-severe paravalvular aortic regurgitation. Six patients (28.6%) required permanent pacemaker implantation following TAVI due to conduction abnormalities. Direct TAVI in Mendiz' single center study resulted in a very good procedural result with a 30-day survival rate of i95%! Interestingly, no patient suffered from cerebrovascular events.

Before the deployment of a transcatheter heart valve (THV), current medical practice requires right-ventricular, rapid burst pacing (>180 bpm) with induction of a functional cardiac arrest for up to 30 seconds for balloon aortic valvuloplasty (BAV). This step is thought to be necessary to pre-dilate the native aortic valve and to facilitate an accurate positioning of the THV. With use of the self-expanding CoreValve prosthesis, valve positioning and deployment is then performed without the need for further rapid pacing.

BAV has been shown to have numerous detrimental effects: i) the functional cardiac arrest induced by rapid pacing for BAV leads to transient coronary, cerebral, and renal ischemia. ii) In patients with impaired left ventricular ejection fraction, prolonged cardiac depression after rapid pacing is observed and may result in hemodynamic failure and/or systemic inflammatory response syndrome (SIRS) (2), which both are associated with a high peri-procedural mortality. iii) BAV has been identified as a major source of embolization of thrombotic and valvular material and increases the risk for coronary obstruction with subsequent myocardial infarction and stroke. (3, 4) iv) the local trauma in the left-ventricular outflow tract caused by BAV contributes to conduction disturbances with the need for permanent pacemaker implantation after TAVI (5).

Although clear evidence supporting rapid pacing and BAV for TAVI is lacking, this step is currently believed to be necessary for valve preparation prior to device placement. Recently, a pilot study of Grube et al. has shown that TAVI without BAV is feasible and safe, since the self-expanding CoreValve is able to "dilate" the stenosed aortic valve through the radial forces of the self-expanding nitinol frame itself, in which the prosthesis is mounted (6). According to the mentioned study, ommitting BAV allows the delivery of the THV in a controlled fashion without hemodynamic compromise of the patient and without an increased post-dilatation rate to overcome paravalvular aortic regurgitation due to frame underexpansion (7).

Therefore, the avoidance of rapid pacing and balloon valvuloplasty for pre-dilatation of the native aortic valve in TAVI patients might be an option to reduce (i) coronary ischemia with periprocedural cardiac depression of left ventricular function, (ii) events of thrombembolization causing stroke or myocardial infarction, and (iii) renal ischemia/reperfusion injury with the induction of acute kidney injury and SIRS.

This study by Mendiz and co-workers emphasizes

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that direct CoreValve implantation without balloon pre-dilatation is feasible and safe, resulting in similar acute safety and efficacy as the current TAVI standard approach, and that the abandonment of balloon pre-dilatation is one approach to simplify the TAVI procedure.

## Disclosure:

Dr. Eberhard Grube is a proctor for CoreValve/Medtronic. Dr. Jan-Malte Sinning reports no conflicts.

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