Complications of Transcatheter aortic valve implantation (TAVI)

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Transfemoral transcatheter aortic valve implantation (TAVI) is nowadays a routine therapy for elderly patients with severe aortic stenosis (AS) and high perioperative risk.
With growing experience, further development of the devices, and the expansion to "intermediate-risk" patients, there is increasing interest in performing this procedure under conscious sedation (TAVI-S) rather than the previously favoured approach of general anesthesia (TAVI-GA).

TAVI types

Ø Under conscious sedation (TAVI-S)
Ø With general anesthesia (TAVI-GA)
Complications occurring during TAVI-S may result in a need for unplanned intubation. The requirement for conversion to GA has been shown to be as high as 17% (1). Vascular complications requiring surgical intervention were given as the most common indication. Emergency or urgent induction of general anesthesia is often accompanied by hypotension. Greenet al. revealed postintubation hemodynamic instability to occur in 11-44% of emergency in-hospital intubations (2).
Chronic pulmonary obstructive disease, increased age and pre-intubation hemodynamic instability were associated with postintubation hemodynamic instability (2,3). As these three factors may frequently coexist in urgent TAVI conversion, the risk of hemodynamic instability in such patients is expected to be high. Consequently, the presence of an experienced cardiac anesthesiologist would seem to be a necessity.
Time saving is frequently proposed as an advantage of a TAVI-S strategy, however, where the relevant information is provided in these studies, marked variability and complexity exists in the choice of hemodynamic monitoring utilized.
As a result, time-consuming complex monitoring may limit the utility of procedure duration, or CathLab time, as a valid endpoint. Furthermore, the learning curve inherent to operators performing TAVI and the utilization of an arterial cut-down technique are likely to bias time end-point measurements in favor of TAVI-S. Procedure time was often not defined.
As TAVI-GA patients were sometimes partially extubated in the ICU, time and place to gain full consciousness were different to TAVI-S patients. Therefore, the ICU time and the time to mobilize the patient inevitably had to be longer. If the patient is extubated on the table, the time to mobilization should normally depend on the process of the operation and sufficient postoperative analgesia (4).
From the authors' point of view, in TAVI patients undergoing femoral arterial access, effective and efficient vessel closure is probably the most important factor determining time to mobilization.
Postprocedural outcomes such as 30-day mortality (5,6), permanent pacemaker implantation (7), fluoroscopy time (8), andacute kidney injury (AKI) (9) have also been used to compare TAVI-GA and TAVI-S. These endpoints reflect an overall procedural outcome. Within the first 48 hours after implantation cardiac causes are the predominant determinant of mortality. After day 15 non-cardiac causes, including sepsis, cancer and stroke appear to determine mortality (10).
With an incidence of 2-51%, permanent pacemaker implantation is common after TAVI. Device design, radial force exerted on the left ventricular outflow tract, and implantation technique may influence the requirement for subsequent permanent pacing. Preexisting

conduction disturbances and periprocedural atrioventricular block have also been identified as risk factors (11).
The incidence of AKI is associated with decreased short- and long-term outcome after TAVI. AKI is reported in up to 28% of cases and is considered to be multifactorial (12). Inadequate kidney perfusion caused by hypotension during rapid ventricular pacing, debris and thromboembolism to the kidneys and contrast agent were argued as procedural causes.
Although still under discussion, impaired preoperative renal function and dehydration has been shown to be associated with post-contrast AKI (13).
Renal function is impaired in higher age. A decrease of renal blood flow, less cortical mass and sclerosis/remodeling of the glomeruli to nonfunctional tissue is additive to inadequate electrolyte and water intake. In conjunction with chronic diuretic therapy and preoperative fasting time, geriatric patients arrive at the operation room in a state of relative hypovolemia.
Elhmidi et al described the incidence of AKI after TAVI between 8 and 57% (14). Blood transfusion, access route (transapical), preoperative creatinine clearance, hypertension, and perioperative bleeding were identified as risk factors (15). Unexpectedly the amount of contrast agent used was not associated with the incidence of AKI in this analysis. Nevertheless, only a small number of the described studies reported the amount of contrast used during the procedure (16).
Hypotension may occur during the induction of general anesthesia. To date there is no evidence that general anesthesia itself is a risk factor for AKI. A recent analysis of 13,026 patients undergoing endovascular abdominal aortic aneurysm repair revealed that general anesthesia was not an independent risk factor for AKI (17).
The 30-day mortality rate, permanent pacemaker requirement, and AKI to be less useful for determining the appropriate anesthesiologic strategy in TAVI patients. Data about anesthesia-related peri- or very early postprocedural mortality and morbidity are not available.
When it comes to limited financial resources, the cost-effectiveness of medical procedures becomes increasingly important. Some authors have proposed TAVI-S as a more cost effective means of performing the procedure by avoiding the routine presence of an anesthetic team and thus reducing labor costs (15). TAVI-guidelines strongly recommend a “Heart Team” approach to patient care, with inclusion of a cardiac anesthesiologist. Performing TAVI procedures without an anesthesiologist in order to save time or money is not standard compliant and this fact should be taken into account when waiving the anesthesiologist for financial reasons.

Table 1. Incidence of complications following transcatheter aortic valve implantation in our experience, compared with reports in the literature.

A) Vascular injury
Ø Dissection/perforation/occlusion
Ø Prostar failure
Ø Aortic annular dissection
Ø Aortic annular rupture

B) Valve positioning and deployment
Ø Prosthesis dislocation/embolization
Ø Retrograde embolization
Ø Acute coronary obstruction
Ø Paravalvular regurgitation (≥grade 2)
Ø Atrioventricular block requiring pacemaker implantation
Ø Pericardial tamponade
Ø Neurological events (TIA/stroke)

C) ***Cardiogenic Shock***

*D) Systemic inflammatory respon*se:often with fever and nonspecific elevations in leucocyte counts and C-reactive protein (CRP) levels

E) Acute kidney injury

F) Thrombocytopenia

G) Endocarditis (Rare)

Comments Transcatheter aortic valve implantation has, without question, brought new and unprecedented excitement to the field of interventional cardiology.
With the expanding evidence base, along with new technical modifications, more and more interventionalists are eager to learn.
The technical challenges of the procedure, notwithstanding the high-risk patient cohort, makes the learning curve a steep one, with the potential for unexpected complications always readily apparent. For this reason, the importance of specific training, such as that provided by the valve companies through workshops and proctorship, cannot be overemphasized. It is essential that all operators, and indeed members of the implant team, exert extreme vigilance to the development of intraprocedural complications, which could have rapid and potentially lethal consequences.
While most commonly relating to vascular access, these can also result from prosthesis trauma or malposition, or from unanticipated trauma from the pacing or super stiff wire. With sudden and unexplained hypotension often the earliest indicator of major complication, this must prompt an immediate and detailed exclusion of five major pathologies: retroperitoneal bleeding from access site rupture, aortic dissection or rupture, pericardial tamponade, coronary ostial obstruction or acute severe aortic regurgitation. In most cases these can be dealt with quickly, and by percutaneous means, although open surgery might occasionally be necessary. Greater experience with an improved understanding of these risks, along with the development of better devices, deliverable through smaller and less traumatic sheath technology, will undoubtedly improve the safety, and potentially the applicability of TAVI in the future. Forthcoming innovations include the newer generation CoreValve system with operator-controlled steerability to facilitate negotiation of unfolded aortic anatomy, in addition to being fully retrievable and resheathable in the event of dislocation or embolization.
Furthermore, an improved Edwards transfemoral delivery system will soon be commercially available. The Novaflex® system (Edwards Lifesciences Inc., CA, USA) incorporates a unique 360° flex tip for easier valve alignment and enhanced stability during valve deployment. Improvements in sheath technologies are also continually emerging, with both the balloon-expandable and re-collapsible SoloPath, as well as the lower profile 16 Fr e-sheath from Edwards having recently become available. Despite unique design differences, the lower profile format of both systems facilitates the safe access of suboptimal anatomies, minimizing the risk of vascular injury.
Forthcoming trials such as the Surgery Versus TAVI (SURTAVI), a European multicenter randomized trial comparing CoreValve with aortic valve replacement surgery, and of course the PARTNER 2 trial, will prospectively evaluate the usage of TAVI in patients with intermediate risk for conventional surgery. It is our opinion that with such trial data eagerly awaited, the applications of TAVI will soon be extended to include patients with less comorbidity, and that eventually the percutaneous approach will surpass the surgical approach to management of aortic valve disease.

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