

Transcatheter aortic valve implantation: how to decrease post-operative complications

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Transcatheter aortic valve implantation (TAVI) is a therapeutic option widely used for the treatment of severe aortic stenosis in the elderly. Careful pre-procedural screening, operator experience, and technological innovations, accounted for a safe, reliable, and standardized procedure. To further decrease post-operative complications, few steps are important: careful planning of the procedure by the Heart Team, clinical and diagnostic evaluation including electrocardiogram, echography, and computed tomography of the heart and great vessels. This approach will allow a selection of ideal candidates for the procedure, the best vascular approach, the selection of patients candidates for early discharge, and last but not least, simplification of the TAVI procedure. Although the procedure is reaching the ‘simplicity’ of coronary interventions, it should always be kept in mind the possibility, albeit remote, that life-threatening complication could ensue, requiring the prompt intervention of the cardiovascular surgeon.

Introduction

The percutaneous aortic valve prosthetic implant [transcatheter aortic valve implantation (TAVI)] represents a real revolution in the field of interventional cardiology for the treatment of symptomatic aortic stenosis in elderly or high-risk surgical patients. Today TAVI plays a fundamental role in the treatment also of patients with severe aortic stenosis at high and intermediate risk^{1,2} and probably, in the future, at low risk. Over the years, TAVI has also undergone an evolution, from a complex and relatively risky procedure, to an effective, standardized and safe procedure, thanks to a set of factors such as the experience of the operators, the development of new generation devices and finally, to the screening and pre-procedural planning.

In order to minimize post-intervention complications, it is necessary to start with patient selection and procedural planning, so that the fundamental steps to be followed can be summarized as follows:

- (1) pre-procedural planning strategies
- (2) intra-procedural strategies

- (3) post-procedural strategies

Pre-procedural planning strategies

The pre-procedural phase is the first important step towards a procedure with the best results. The appropriate selection of patients makes use of the assessment by the Heart Team (clinical and interventional cardiologist, cardiac surgeon, anaesthesiologist, etc.) who will choose who benefits most from surgical or percutaneous aortic valve replacement, who does not benefit from any intervention (or of aortic valvuloplasty only) based on life expectancy (<1 year post-procedure) and improvement of symptoms (clinical improvement <1 New York Heart Association class).

The evaluation of surgical risk scores [Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score and Euro score II] is important, as well as the non-strictly surgical risk (e.g. fragility, life expectancy, organ dysfunction, presence of senile dementia, previous thoracic irradiation, thoracic cage and/or spine deformity, etc.).

The evaluation of the ideal candidate for TAVI is supported by some pre-procedural diagnostic tests, which can

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be performed before admission, thus reducing hospitalization times and the costs deriving from it. These tests include colour Doppler echocardiography, the first means of diagnosis of severe aortic stenosis, and angio-computed tomography (CT) with contrast medium with simultaneous electrocardiographic recording of the heart and large vessels in order to analyse different aspects important for the procedure, the first of all is to highlight possible anatomical contraindications to the procedure. Imaging testing also allow the accurate choice of vascular access (femoral, trans-subclavian, direct aortic, trans-apical), the prosthesis and its size and finally, and to highlight potential predictors of complications (e.g. annulus rupture, occlusion of coronary ostia, vascular complications, etc.).^{3,4} The systolic reconstruction of the angio-CT images of the aortic annulus with the central axis of the left ventricular outflow tract, allows a precise evaluation of the minimum and maximum diameters, of the circumference and of the measurement of the area of the annulus,⁵ unlike what happens with the colour Doppler echocardiogram, whose measurements are very often underestimated. The angio-CT also allows the study of the measurement of the sinuses of Valsalva, of the aorta and the sino-tubular junction, of the distance of the coronary ostia from the valvular plane (so as to highlight the potential risk of coronary occlusion during TAVI) and of the quantification of aortic calcifications, in addition to their distribution,⁶ all important details in the planning of the intervention.

According to current guidelines, patients requiring valve replacement require a pre-procedural assessment of the coronary artery.² Screening for ischaemic heart disease can be performed in an admission prior to TAVI, also to reduce the exposure of the patient to the contrast agent, especially in case of need for coronary angioplasty, but this would however lead to an increase in the costs of hospitalization. An alternative approach, described by Chieffo *et al.*,⁷ involves the integration of coronary artery disease screening during CT angiography for the evaluation of the heart and aortic anatomy, reserving the coronary angiography in cases where a coronary artery has a significant proximal stenosis (about 20% of patients) or in patients in whom CT angiography (severe chronic renal failure) is contraindicated. Another possible strategy is to perform coronary angiography, and possible angioplasty [percutaneous coronary intervention (PCI)] *ad hoc*, during the TAVI procedure. In the case of critical coronary artery disease, the treatment strategy and completeness of revascularization are determined by coronary anatomy.

If the operator decides to perform the PCI, the TAVI can reasonably be performed during the same procedure in those cases in which the PCI is effective, not complicated and has not required excessive quantities of contrast medium. Otherwise, the TAVI can be post-dated to a later date.⁸ In support of the PCI + TAVI strategy in the same session, there are reassuring data showing that these patients had the same rate of composite death, disabling stroke, and myocardial infarction, of patients without significant coronary artery disease and of patients with untreated severe coronary artery disease (TAVI + PCI: 10.4%, severe untreated coronary heart disease: 15.4%, absence of coronary heart disease: 14.8%, $P = 0.765$).⁸

Finally, returning to the angio-CT evaluation with contrast medium, in cases of chronic renal failure TAVI can be performed in absence of CT angiography, with pre-procedural angiographic evaluation of the iliac-femoral axes and with the use of prostheses that, with reasonable safety can also be implanted only with echocardiographic and angiographic evaluation (self-expanding prostheses such as Evolute™ R and Evolute™ Pro, Medtronic and Portico™, Abbott, Abbott Park, IL, USA), so as to minimize the dose of iodinated contrast with less risk of post-procedural renal failure. In the context of prevention of renal failure from contrast media, the possibility of performing CT angiography supported by RenalGuard System® nephroprotection device (PLC Medical Systems Milford, MA, USA), generally used in patients with glomerular filtrate estimated $\leq 30 \text{ mL/min/1.73 m}^2$, according to the Cockcroft-Gault formula.⁹ This device was developed to reduce the toxic effects that the contrast agent may have on the kidneys, and which could lead to the reduction of contrast nephropathy [contrast-induced nephropathy (CIN)] in patients at risk. This therapy is based on the principle, supported by literature,¹⁰ that by creating and maintaining a high production of urine, the contrast medium can be more quickly eliminated, reducing its toxic effects. The RenalGuard System® can also be used a few hours before, during and after the TAVI procedure, with excellent results in terms of CIN prevention.¹¹ The choice of a non-ionic and iso-osmolar contrast medium such as iodixanol (Visipaque, GE Healthcare, Little Chalfont, Buckinghamshire, UK), or the use of devices that coupled with the injection system can also be useful in reducing up to 40% the amount of contrast agent injected to the patient without worsening the quality of the images (e.g. DyeVert™ PLUS, Osprey Medical Inc.).¹²

Intra-procedural planning strategies

In order to minimize the potential post-procedural complications of TAVI, the planning of the procedure is also a key aspect which consists of some technical measures listed below, which in addition to several purely procedural aspects also include pain management.

Transcatheter aortic valve implantation is usually performed in normal cath lab, except for some cases in which hybrid operating room is needed (e.g. trans-apical, direct aortic, trans-succlavian, surgical isolation of the common femoral artery). The presence of cardiac surgeon in the room is no longer mandatory, provided that he is ready and available to intervene in the event of severe complications at risk of life.

For pain management patients are subjected to local groin anaesthesia associated with or without conscious sedation with morphine-like substances. This strategy, compared to general anaesthesia with oro-tracheal intubation, is associated with less need for inotropic/vasopressor drugs, shorter duration of hospitalization, lower procedural times, and early patient mobilization,¹³⁻¹⁵ with consequent simplification of the post-operative path.

Among the fundamental aspects of the minimalistic and simplified approach of TAVI is the completely percutaneous

access to the femoral artery and the closure of access at the end of the procedure. In this regard, it is particularly important to puncture the vascular access for TAVI under fluoroscopic guidance from the contralateral artery, thus avoiding that the puncture falls on the femoral bifurcation and to ensure that it is performed centrally on the front of the artery in order to maximize effectiveness of the vascular closure systems with Prostar[®] XL and Perclose ProGlide[®] (Abbott, Abbott Park, IL, USA). The angiographic control of the efficacy of the haemostasis obtained with the vascular closure systems (with injection of a few centilitres of contrast medium using the contralateral femoral access) is useful, which allows to exclude blood spills that in the immediate future may not be clinically evident and which, in the post-procedure, could lead to anaemization, the need for transfusions, tests such as angio-CT and repair by the vascular surgeon with prolongation of hospitalization.

At the end of the procedure, the contralateral femoral arterial introducer is also removed, and even in this case, it is possible to use vascular closure systems (e.g. FemoSeal[™] and Angio-Seal[™], Terumo, EU).

In several centres, the placement of a protective guidewire (e.g. V-18[™] ControlWire[™] Guidewire, Boston Scientific, Marlborough, MA, USA) is common at the ipsilateral superficial femoral artery with the vascular access for TAVI, so as to be able to proceed quickly to repair the artery with a balloon and/or stent implant in case of malfunction of the vascular closure device, in some cases avoiding the intervention of the vascular surgeon.

If the angio-CT should show strong predictors of malfunctioning of the vascular closure system (e.g. unfavourable vascular anatomy such as severe tortuosity and/or calcifications of the artery, marked obesity, etc.), the surgical exposure of the femoral artery is performed, so as to avoid the consequences of any malfunction of the vascular closure device.

Another important procedural aspect is to evaluate the possibility of not performing pre-TAVI valvuloplasty, this would lead to the reduction of severe aortic insufficiency, to a lower volume of contrast medium and to the potential reduction of the risk of stroke, although it would seem to increase in cases of implantation of balloon-expandable prostheses.

In cases where valvuloplasty is not performed and post-dilation of the implanted prosthesis is not necessary, it is possible not to use the temporary pacemaker (PM) which is still a cause of complication, although not frequent: perforation of the right ventricle. In the case in which instead it is decided to use the temporary PM, it is good to evaluate at the end of the procedure its possible removal in the cath-lab room, after careful evaluation of the electrocardiogram, so as to avoid the potential perforation of the right ventricle in the phases following the procedure. If there is a clear need to leave the temporary PM in situ (complete atrioventricular block) or in the presence of predictors of complete atrioventricular block (e.g. right bundle branch block, left anterior hemi-block, first-degree atrioventricular block, bi-fascicular block, low implant of the valve, CoreValve/Evolut R/Pro implant, pre-dilatation, oversizing in small annulus, etc.)¹⁶⁻²² can be left in situ until clinically indicated, following the patient with serial

electrocardiograms. In some cases, the left ventricular guidewire can be used instead of the temporary PM as a lead for rapid pacing during the TAVI procedure.

Post-procedural planning strategies

After TAVI patients can be followed in semi-intensive unit, and in some cases even in non-intensive care wards, for post-operative monitoring.

The first 24-h post-TAVI are the most delicate and patients should be carefully and globally monitored with particular attention to water balance, electrocardiogram, haemoglobin and renal function.

It is good to regularly hydrate the patient with saline solution so as to favour the elimination of the contrast medium (or if it is used, prolong the use of the RenalGuard for the first 6- to 12-h post-TAVI) and in order to maintain the water balance which tends to be positive, relying on the echocardiographic guide which provides important information on the patient's filling status (e.g. lower vena cava, systolic pulmonary arterial pressure) as well as on the proper functioning of the prosthesis etc.

Contrast-induced nephropathy usually occurs with an increase in serum creatinine of 0.5 mg/dL or 25% or more of the baseline value in the first 72 h following administration of the contrast medium²³ and is sometimes independent of the presence or absence of pre-procedural chronic renal insufficiency. For this reason, kidney function should be checked daily and periodically upon discharge. Among the blood-chemistry tests are included the full blood count (the reduction of 1-2 g/dL of haemoglobin are considered normal for the TAVI procedure) and the electrolytes.

The removal of the urinary catheter and early mobilization, also possible thanks to the closure of vascular accesses already in the cath lab, is the first step towards the reduction of hospitalization, which favours the appearance of various complications, mostly of an infectious nature. Therefore patients should be encouraged to early mobilization, unless there is haemodynamic instability, vascular complications, little or no urinary output not responsive to diuretic therapy, or substantial changes in haemoglobin, renal function, and neurological status.

The conduction disorders that most frequently lead to the definitive PM implantation are the left bundle branch block and the complete atrioventricular block^{16,24}; in 33% of cases, the PM is implanted in the first 24-h post-TAVI and in 50% of the cases, in the 48-h post-procedure,^{25,26} and in any case, the onset of left bundle branch block, unless there is already a pre-existing right bundle branch block, alone is not a valid reason to prolong hospitalization. The European guidelines recommend a 72-h post-TAVI monitoring before implanting the PM in patients with complete atrioventricular block, both because a significant proportion is resolved in the immediate post-procedure, and for the various negative effects of conduction by artificial PM on the cardiac pump function.

With the aim of reducing the complications and costs deriving from prolonged hospitalization, in selected patients, it is possible to follow the strategy of early discharge (within 24-72 h) of post-TAVI patients, considering that

there are data to support them that show how this protocol has not been associated with a high risk of rehospitalization or sudden cardiac death,^{27,28} suggesting that in patients without post-TAVI conduction disorders, monitoring for 24 h may generally be sufficient.²⁹

Conclusions

The reduction of post-TAVI complications is the result of pre-, intra-, and post-procedural planning strategies. The availability of new devices, the experience of operators, and clinical cardiologists in patient management at all levels, pre- and post-procedural, make it possible to reduce and promptly manage complications during surgery and in the post-TAVI period. This procedure appears to be closer and closer to the 'simplicity' of coronary angioplasty, although it must be borne in mind that it is always possible for events to occur that may put the patient's life at risk and that may require the intervention of the cardiac and/or vascular surgeon.

Conflict of interest: none declared.

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