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Review

Optimization and simplification of transcatheter aortic valve implantation therapy

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Abstract

Introduction: Transcatheter aortic valve implantation (TAVI) is now a widely adopted therapy for the treatment of elderly patients with severe aortic stenosis. Improved pre-procedural screening, increased operators’ experience and technology advancement have made this technique highly reliable and standardized.

Areas covered: The purpose of this review article is to provide an overview of the strategies that can be adopted to optimize the TAVI procedure (pre-interventional work-up and procedural simplification and early discharge).

Expert commentary: Optimization of TAVI therapy is already a reality and has shown to be safe in most patients, but its penetration has to face with real-world practice. The adoption of a minimalistic and optimized approach requires integration of multidisciplinary competences and an extended, dynamic conception of heart team, which also includes patients’ families, referring cardiologist and general practitioners.

Key words: TAVI, Optimization, Minimalistic Approach, Early Discharge, Cost-effectiveness
1. Introduction

Transcatheter aortic valve implantation (TAVI) has given a great impulse to less-invasive percutaneous interventions for structural heart disease. Since the first cases performed in humans by Alain Cribier in 2002, the transcatheter therapy for severe aortic stenosis (AS) has had a rapid development, becoming a reliable and effective treatment for patients at increased surgical risk when a transfemoral approach is feasible (1,2).

During the first years of its adoption in clinical practice, TAVI has been tackled as a very complex procedure and its periprocedural management was similar to surgical interventions than interventional therapies. Patients were admitted many days before the procedure, undergoing many (and sometimes useless) preliminary exams; the procedure was systematically carried out in hybrid rooms, under general anesthesia and transesophageal guidance and with active involvement of the interventional cardiologist, vascular surgeon, echocardiographist and anesthesiologist; post-procedural hospitalization was very long with consequential delayed patients’ functional recovery. Therefore, it was questioned whether an interventional procedure with such features was sustainable and applicable on a large scale. In recent years, many groups have been working on local programmes, which incorporate specific pre-, peri- and post-procedural pathways aimed at simplification of the TAVI pathway. The objectives of these pathways are to identify a more efficient system for patient assessment screening, to optimize the TAVI procedure without compromising its safety, to accelerate patient’s recovery and mobilisation after the procedure and to minimise unnecessary use of medical resources.

The purpose of this review article is to provide an overview of the strategies that can be adopted to optimize the TAVI procedure.

2. Pre-procedural management

Before the TAVI era, a proper multidisciplinary team approach had been used sporadically and inconsistently to manage patients with cardiovascular diseases. However, the complexity of managing patients with severe symptomatic AS and multiple comorbidities in an elderly population has required the
combined efforts of multiple subspecialties, which has rendered a single specialty–based care model anachronistic.

The TAVI procedure requires a number of preparatory evaluations and exams aimed at confirming the clinical and anatomical indication for TAVI (echocardiogram, computed tomography). Ideally these investigations should be performed without admitting the patient in hospital to reduce the number of hospitalizations and to increase patients’ compliance (Figure 1).

Generally, individuals with symptomatic severe AS come to physician observation as outpatient or directly from emergency department if the valvulopathy has already compromised patient conditions. Depending on patient’s hemodynamic, different management ranging from rescue bridge aortic balloon valvuloplasty to medical therapy optimization prior to TAVI, can be proposed to each patient.

Patients coming to observation with no critical symptoms allow to adopt an integrated program for evaluating the indication to TAVI treatment and optimizing hospitalization time and costs. Dedicate echocardiographic clinics welcome patients with asymptomatic AS or with AS-related symptoms. A first transthoracic echocardiogram is performed to confirm severity and type of AS. After establishment of AS severity, patients with clearly related symptoms are then evaluated for treatment.

All TAVI candidates should perform computed tomography angiography (CTA). ECG-gated CTA is the core element of the pre-procedural planning of TAVI, both to improve the accuracy of TAVI prosthesis sizing, to anticipate and predict potential complications, and to reduce peripheral vascular complications (3, 4). CT systolic reconstruction of the annulus orthogonal to the center-axis of the left ventricle outflow tract allows for an optimal assessment of minimal and maximal diameter, circumference, and area measurements, avoiding the systematic underestimation of TTE major axis of annulus (5). Moreover, CTA allows for a careful measurement of the size of the sinuses of Valsalva, the coronary ostia distance from the annulus, which identifies patients at risk for coronary occlusion during TAVI, the size of the aorta at the sino-tubular junction, and the extent and position of aortic calcifications (6).

Once a first evaluation of aortic valve pathology by clinic, echocardiogram and CTA, the final decision for treatment strategy is best achieved by a multidisciplinary, collaborative Heart Valve Team that includes cardiologists with expertise in valvular heart disease, structural interventional cardiologists, imaging
specialists, cardiovascular surgeons, cardiovascular anaesthesiologists, and cardiovascular nursing professionals (7). Patient management relies on a shared decision-making approach based on a comprehensive understanding of the risk-benefit ratio of different treatment strategies and integration of patient preferences and values. Pillars of this integrated evaluation are the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score, frailty, main organ system dysfunction, life expectancy and procedure-specific impediments. Frailty is central to the decision-making process but difficult to define precisely and can be fairly subjective. (8)

Patients for whom TAVI is considered futile because the expected benefit is less than the expected risk or life expectancy is <1 year, can be reasonably treated with medical therapy alone or with balloon valvuloplasty in order to obtain almost a partial symptoms’ improvement. In this context, geriatric evaluation to estimate frailty status of TAVI candidates is also a key component of the heart team.

According to current guidelines, patients undergoing valve replacement also require a pre-procedural evaluation of coronary artery disease (CAD) (2). CAD screening can be performed in an isolated hospitalization prior to TAVI, but this leads to costs increment. Chieffo et al. described an original approach which foresaw the integration of CAD screening during cardiac CT for aortic root assessment, reserving invasive CA for patients in whom CT is contraindicated, or when a significant proximal coronary artery lesion is detected at CT-coronary angiogram (9). The authors enrolled 491 patients that were divided into 2 groups: one group of patients who were assessed only with cardiac CT/CTCA (n=375), and the other group of patients who were assessed with both cardiac CT/CTCA and invasive CA (n=116). They found that this strategy was safe and effective, allowing with a single test the acquisition of a wide range of information on aortic annulus, peripheral access sites, and coronary artery anatomy. However, it must be pointed out that CA was required anyhow in almost 30% of patients in whom CAD was screened using CT only (9).

An additional approach to CAD screening recently described by our group foresees performing an invasive CA and ad hoc PCI at the time of TAVR procedure (10). When this strategy is adopted, the catheterization laboratory is initially equipped only for CA. This can be performed using either the radial or the femoral artery, according to the operator’s preference. When the femoral artery is used, this one should be contralateral to the common femoral artery eventually selected for large-bore sheath insertion. When no
CAD is found, the catheterization laboratory is then equipped for TAVI and the procedure is carried out in a standard fashion. In case of CAD, the treatment strategy and completeness of revascularization is determined based on coronary anatomy: If the operator decides to perform PCI, TAVI can reasonably follow revascularization if PCI was successful, uncomplicated and did not required large amount of contrast dye. On the contrary, TAVR can be postponed. This approach demonstrated to be feasible and safe even for patients requiring not-complex PCI (10). Severe CAD was found in 22.5% of patients. Among patients with severe CAD, 53 patients (8.8%) underwent uncomplicated PCI. After PCI, TAVI was postponed in 2 patients (0.3%). In 83 patients (13.8%), coronary angiography showed severe CAD that was left untreated. After TAVI, all-cause and cardiovascular 30-day mortality rates were 2.4% and 1.4%, respectively. Disabling stroke, myocardial infarction, and life-threatening bleeding occurred in 0.5%, 0.8%, and 4.0% of patients, respectively. Acute kidney injury II or III rate was 3.3%. At 2 years, all-cause mortality rate was 14.1%. Disabling stroke and myocardial infarction occurred in 2.5% and 1.8% of patients, respectively. Patients undergoing TAVI and PCI in the same session had similar rate of the composite of death, disabling stroke, and myocardial infarction when compared with patients without CAD, and patients with severe CAD left untreated (TAVR+PCI: 10.4%; severe CAD left untreated: 15.4%; no-CAD: 14.8%; P=0.765) (10).

Finally, the optimization of pre-TAVI screening requires additional key components that should be incorporated: The local TAVI team should also assess whether a patient can be eligible for a minimalistic approach by looking beyond the traditional clinical and anatomical criteria and incorporating additional clinical, non-clinical and psychosocial factors that could affect patient’s post-procedural recovery. These include patient engagement, willingness to participate in cardiac rehab, and possible presence of dementia. During pre-TAVI assessment physicians should assess family dynamics to determine if patients will have the support needed at home for a successful recovery. Also, given the age and complexity of the majority of TAVI patients, geriatricians should be involved in patient selection process from the onset.

Once evaluation is completed, patients’ admission can be performed only a day before the date of the intervention, thus allowing TAVI centre to optimize resources and shorten the waiting list.
3. Peri-procedural management

At the beginning of TAVI experience, general anaesthesia with endotracheal intubation was generally performed due to the various clinical and procedural issues associated with the treatment of high-risk patients. Also, surgical cut-down of the common femoral artery was initially the preferred strategy for transfemoral procedures due to the usage of very large bore sheaths (up to 24 French).

The components of a minimalist TAVI strategy include fully percutaneous transfemoral vascular access using percutaneous endovascular closure devices (Prostar or Proglide) for obtaining haemostasis, monitored anesthesia control (i.e., conscious sedation) without general anesthesia, reduction or elimination of intraprocedural TEE guidance, and reduction or elimination of balloon pre-dilation before valve implantation.

Many operators still perform TAVI in a hybrid room. However, TAVI can be also safely performed in a regular catheterization laboratory by a cardiac surgeon or interventional cardiologist. The presence into the lab of both figures at the same time is not mandatory; however it is key that 1 cardiac surgeon is always promptly available to manage life-threatening complications (i.e. heart perforation).

Recent studies demonstrated that transfemoral TAVI can be performed via the percutaneous route with similar risk of vascular complications and briefer post-procedural length of stay than the surgical isolation of the common femoral artery (11-12).

In observational and retrospective studies, conscious sedation, compared with general anaesthesia, has been associated with fewer requirements for inotropes/vasopressors, shorter length of hospital stay, and shorter procedural/intervention times, with earlier patient mobilization (13-15).

Performing CTA prior to intervention and with increasing operator experience, TAVI can be safely performed under fluoroscopic guidance, leaving the necessity of TEE imaging for challenging cases or in case of suspect post-deployment device malfunction. A number of studies have demonstrated that TAVI performed exclusively under angiographic guidance with back-up TTE is feasible and associated with reasonably good outcomes, similar to those of angiography and TEE-guided procedures (16-18).

Balloon aortic valvuloplasty (BAV) before valve implantation has to be carefully evaluated because of the risk of stroke and severe aortic regurgitation requiring emergency TAVI. Some studies have demonstrated
that avoiding predilatation is safe and feasible and permits to shorten time procedure and lower contrast volume either with balloon- and self-expandable prosthesis even if cerebral embolization seems to be more frequent early after balloon-expandable implantation with no-BAV strategy than with prior BAV according to DW-MRI findings (19, 20). Nevertheless, the majority of TAVI patients had cerebral lesions consistent with infarcts in the absence of obvious functional impairments. A clear association between the total volume of cerebral lesions and the occurrence of neurological symptoms has previously been shown, but the long-term effect of subclinical brain lesions after TAVI is yet unknown (21).

Rapid pacing during TAVI is mandatory when BAV is performed and/or a balloon expandable valve is implanted. The insertion of a right ventricular lead is time-consuming and has been associated with vascular complications and right ventricular perforation. A strategy of systematic pacing through the left ventricular wire in patients undergoing TAVI was adopted with favourable results.

In order to avoid late bleeding due to vascular complication a careful management of site access is mandatory. Although pre-operative CT imaging of major vascular axes helps to detect any unfavourable vascular characteristics, at the beginning of the TAVI intervention, performing an angiogram from contralateral femoral artery is useful to reduce vascular complication by directly visualizing the relationship between the femoral head, the inferior epigastric artery and the femoral bifurcation. In fact, a femoral puncture above the inferior epigastric artery or below the femoral bifurcation has been associated with an increased risk of vascular complication and retroperitoneal bleeding (22-24) that can become evident during the early post-procedural period and prolong length of stay after TAVI. At the end of the procedure, final crossover angiography of the main vascular access is recommended to verify arteriotomy closure success as well as ilio-femoral vessel integrity. Dissections detected during the final angiography can be treated with balloon angioplasty or uncovered stents if required. Incomplete arteriotomy closure or ilio-femoral leakages can be managed first, depending on the severity of the findings, with prolonged manual compression, balloon valvuloplasty or covered stents in cases of persistent vascular leakage despite prolonged manual compression (25). Femoral pseudo-aneurysm can be treated with manual or echocardiography-guided compression but in cases of deeper or difficult location surgery play an important role.
4. Post-procedural management

Accurate and optimized post-operative management is a crucial step of TAVI therapy (Figure 2).

Postprocedural length of stay is one of the main factors contributing to the increase in peri-procedural costs of TAVI. The most frequent issues that usually prolong hospitalizations after TAVI are: unnecessary prolonged immobilization, bleeding, conduction disturbances, and acute kidney injury, being the need for prolonged monitoring for acute atrioventricular block far the most important one.

Early mobilization promotes rapid return to baseline status, reduces nosocomial complications, and decreases length of stay in the frail elderly. Cardiovascular nurses should play a pivotal role in supporting patients in the early recovery phase after TAVI to mitigate the risks of geriatric deconditioning (26).

After the procedure, invasive monitoring equipment should be reserved in very selected patients with hemodynamic instability and should discontinued expeditiously, once clinically indicated. Early multidisciplinary communication of clinical variables that could affect patients’ capacity to remain treated under the directives of the pathway must be well standardized in each center. These variables included hemodynamic instability, new conduction disturbances, vascular access complications and urinary retention not responsive to protocol-driven interventions, and other clinical findings such as changes in hemoglobin, renal function, altered neurological vital signs and signs of delirium.

Reconditioning to baseline status is facilitated when nurse-led rapid mobilization and activity protocol are adopted. In addition, hydration and nutrition guidelines should be also established.

During the last decade, the reduction in diameter of the delivery systems, in conjunction with better pre-operative vascular screening and increasing operator experience have led to a reduction in vascular complications. However, vascular complications remain among the most frequent adverse events associated with transfemoral TAVI (TF-TAVI) procedures (27).

A careful site access monitoring and serial haemachrome exams in the early 72 hours permit to identify any late issues such as bleeding, hematoma or pseudo-aneurysm formation. In case of suspicious of vascular complication, Doppler ultrasound of inguinal regions should be performed to diagnose an eventually underlying problem. For negative-cases, in the presence of continuous haemoglobin loss CT scans of pelvic
region should be performed to discover any hidden, potentially life-threatening problem (such as retroperitoneal bleeding). Nevertheless, the necessity of a positive fluid balance to sustain patient’s haemodynamic in the early post-operative period may cause anaemia due to hemodilution. Therefore, carefully clinical examinations must guide laboratory tests’ interpretation in order to differentiate real haemoglobin falls from false cases.

Conduction disturbances and implantation of pacemaker (PM) are common events during or after TAVI, and can affect the quality of life and prognosis of patients. The most prevalent conduction disturbance following TAVI is left bundle branch block (LBBB) and complete atrioventricular block (AVB) that lead to PM implantation (28,29), with about 33% and 50% of PMs being implanted within the first 24 and 48 hours post TAVI, respectively (30,31). The figure 3 shows the flow charts summarizing our suggested proceedings in case of conduction disturbances (High degree AVB and LBBB). It must be underlined that the new occurrence of LBBB was associated with an increased risk of developing severe AVB only after several months from valve implantation (32). Therefore, in the absence of baseline RBBB, the new onset of LBBB alone should not represent a reason for prolonging the hospitalization period.

Both patient clinical characteristics and procedural features have been reported as predictors of new-onset LBBB and PM requirement.

Clinical factors such as male gender, absence of prior valve surgery, the presence of porcelain aorta, and pre-existing conduction abnormalities (mainly preexisting RBBB, but also pre-existing left anterior hemiblock and first-degree AV block) are independent predictors of the need for PM post TAVI.

Intra-procedural AV block and modifiable factors such as implantation depth, use of the CoreValve/Evolut R and Lotus systems, and balloon pre-dilatation are each independently associated with an increased likelihood of conduction disturbances development and PM necessity (28,33,34). Moreover, low LVOT/annulus ratio and prosthesis oversizing in small annulus are other important risk factors to consider during device selection phase (35-38).

Current European recommendations suggest a period of clinical observation and ECG monitoring for up to seven days prior to implanting a PM in patients with high degree or complete AV block because a significant proportion of conduction abnormalities resolves early within the post-TAVI period and there is increased
risk of late mortality or repeat hospitalizations for heart failure associated with cardiac pacing, particularly in patients with low LVEF and higher rates of PM dependency (28,39). Moreover, PM implantation demonstrated to have a negative impact on the evolution of left ventricular ejection fraction post TAVI (30,40). This observation period may be shortened only in cases of complete AV block with slow escape rhythm, in whom an early PM implantation on the same day as TAVI is safe and may be beneficial, enabling more rapid patient mobilization. (41)

To limit costs and complications, we are moving toward an even earlier hospital discharge following TAVI that make challenging the application of these protocols but interestingly, the adoption of early discharge strategies (within 24–72 hours) post TAVI in selected cases has not been associated with an increased risk of re-hospitalization or sudden cardiac death (42,43), suggesting that 24 hours of ECG monitoring (instead of 72 hours as recommended in ESC guidelines) may be sufficient in patients with no conduction abnormalities immediately following the procedure. (32)

Acute kidney injury (AKI) is another TAVI complication to prevent and manage. Careful hydric balances and creatinine levels monitoring are part of the post-operative management. The RenalGuard System protocol demonstrated to reduce AKI rates after TAVI and should be recommended at least for patients with severe renal disease (eGFR < 30 ml/min/m²) at baseline in order to prevent worsening of already compromise renal function (44).

Today in the majority of patients undergoing TAVI are elderly and frail, and the duration of hospitalization is a crucial issue for themselves and their families. Bedridden time after procedure seems as a constriction for them and problems related with prolonged immobilization (such as thromboembolic events) have to be considered in TAVI population. Therefore, early mobilization and discharge after TAVI seem logical options in patients not experiencing procedure-related complications.

5. Costs analysis

A few studies have shown that TAVI in patients with AS at extreme and high surgical risk provides good economic, as well as, clinical value (45-47). Preliminary data from PARTNER 2A suggest that even for intermediate risk patients TAVI has a favourable cost-effectiveness (48).
TAVI is a fast-moving field, with rapid improvements not only in technology, but also in patient selection, intra-procedural care, and avoidance of complications. Considering the aging of population and the expanding indication to percutaneous treatment of AS to larger populations, optimization of TAVI management is a primary objective of institution for limiting its costs, especially dealing with public health systems.

In many centers, a simplified or minimalist approach to TAVI – fully percutaneous under local anesthesia, avoiding TEE guidance and cardio-surgeon assistance in a regular catheterization laboratory - is already routine and has been shown to permit a safe early discharge (within 24-72 hours) of patients and to decrease the cost of TAVI (41,49) (Table 1).

Our group compared outcomes for high-risk or inoperable patients (average age about 80 years; approximately 55% women) who underwent transfemoral TAVI at our institution between June 2007 and July 2014 and were discharged home either within 72 hours (n = 107) or after 3 days (n = 358) (41). Devices used were predominantly Edwards balloon-expandable Sapien and Sapien XT (n = 127) and Medtronic self-expanding CoreValve (n = 331). The mean length of stay was 2.2 days in the early-discharge group and 6.5 days in the late-discharge group (p<0.001). Among the early discharges, 28.9% left the hospital within 24 hours, 30.5% within 48 hours, and 43.8% within 72 hours. A propensity-matched based analysis showed that compared with those discharged later, patients discharged early had lower rates of in-hospital bleeding (7.9% vs 19.4%; p=0.014), major vascular complications (2.3% vs 9.1%; p=0.038) and new pacemaker implantation (7.9% vs 18.5%; p=0.021). However, there was no difference in 30-day rates of the composite safety endpoint of death, permanent pacemaker implantation, bleeding, and re-hospitalization for any cause or any of its components. In multivariable regression analysis, NYHA class IV heart failure and any bleeding were associated with a lower likelihood of early discharge, while the presence of a permanent pacemaker before TAVI and a more recent year of procedure predicted early discharge (41).

The incremental cost-effectiveness ratio of minimalistic TAVI strategies is still unclear. In a small U.S. series of 142 patients (n=70 undergoing minimalistic transfemoral TAVI and n=72 undergoing standard transfemoral TAVI) Babaliaros et al. demonstrated that that the minimalistic strategy decreases the cost of TAVI ($2,869 estimate) and can be used frequently to prevent the overhead associated with hybrid
operating rooms and general anesthesia (49). In this field, the multicenter Multidisciplinary, Multimodality, but Minimalist (3M) TAVR trial (NCT02287662) and FAST-TAVI study (NCT02404467) (50) will provide invaluable insights from the real effectiveness and reproducibility of this minimalistic approach (Table 2). Preliminary results of the 3M TAVR trial have been recently presented (51). The Vancouver 3M clinical pathway primarily focuses on next day discharge after transfemoral TAVI. Patients were enrolled from 13 centers from United States and Canada. The primary outcomes were a composite of all-cause death or stroke by 30 days and the proportion of patients successfully discharged home the day following TAVI. A total of 411 patients were enrolled and received both SAPIEN XT and SAPIEN 3 transcatheter heart valve (Edwards Lifesciences, Irvine, CA). Inclusion criteria for the study were in 55% of screened patients. The median age was 84 years with a median STS score of 4.9%. Next day discharge home was achieved in 80.1% of patients, and within 48 hours in 89.5%. The composite of 30-day all-cause death or stroke occurred in 2.9%, with neither component of the primary outcome affected by hospital TAVI volume. Rates of major vascular complication (2.4%), in-hospital readmission (9.2%), cardiac readmission (5.7%), and new PM implantation (5.7%), were low and in line with previous TAVI series using newest generation TAVI devices (52).

6. Conclusions
Simplifying and optimizing the TAVI procedure is not speculative but many of the areas discussed in this review are already standard practice in many institutions. In experienced centers, this minimalist approach to TAVI is as safe and effective as the more standard traditionalist approach.

7. Expert commentary
During the first years of its adoption in clinical practice, TAVI has been tackled as a very complex procedure and its periprocedural management was more similar to surgical interventions than interventional therapies. In recent years many groups have been working on local programmes, which incorporate specific pre-, peri- and post-procedural pathways aimed at simplification of the TAVI pathway. The objectives of these pathways are to identify a more efficient system for patient assessment screening, to optimize the
TAVI procedure without compromising its safety, to accelerate patient’s recovery and mobilisation after the procedure and to minimise unnecessary use of medical resources. The local TAVI team should assess whether a patient can be eligible for a minimalistic approach by looking beyond the traditional clinical and anatomical criteria and incorporating additional clinical, non-clinical and psychosocial factors that could affect patient’s post-procedural recovery. Early mobilization and discharge after TAVI seems a logical option in patients not experiencing procedure-related complications, especially dealing with elderly, frail patients with increased risk of hospitalization-related complications. In experienced centers, a minimalist approach to TAVI is as safe and effective as the more standard traditionalist approach.

8. Five-year view

Although TAVI is a complex procedure, important steps towards simplification and optimization of the procedure have already been made. In some centres, a simplified or minimalist approach to TAVI is already routine and has been shown to be as safe and effective as the more traditional approach in selected patients. What is key, is that such process of optimization of the pre-, peri- and post-procedural protocols must be accomplished without compromising the safety of the treatment. This concept assumes much more importance in younger patients at lower risk. Of course, there is no a unique method accomplish TAVI optimization; centers should tailor protocols and strategies according to their internal logistics and requirements. The final aim must be to reduce at minimum pre-procedural in-hospital stay, accelerate patient’s recovery and mobilisation after the procedure and to minimise unnecessary use of medical resources.

Key issues

- The TAVI procedure requires a number of preparatory evaluations and exams aimed at confirming the clinical and anatomical indication for TAVI.
- ECG-gated CTA is the core element of the pre-procedural planning of TAVI, both to improve the accuracy of TAVI prosthesis sizing, and to reduce peripheral vascular complications.
- The optimization of pre-TAVI screening requires additional key components that should be
incorporated: The local TAVI team should also assess whether a patient can be eligible for a minimalistic approach by looking beyond the traditional clinical and anatomical criteria and incorporating additional clinical, non-clinical and psychosocial factors that could affect patient’s post-procedural recovery

- Conscious sedation and local anaesthesia, compared with general anaesthesia, has been associated with fewer requirements for inotropes/vasopressors, shorter length of hospital stay, and shorter procedural/intervention times, with earlier patient mobilization.
- Performing coronary angiogram in the same setting of TAVI, before valve implantation, has demonstrated to be feasible and safe even for patients requiring not-complex PCI.
- Accurate and optimized post-operative management is a crucial step of TAVI therapy.
- 24 hours of ECG monitoring (instead of 72 hours, as recommended in ESC guidelines) may be sufficient in patients with no conduction abnormalities immediately following the procedure.
- In order to avoid late bleeding due to vascular complication a careful management of site access is mandatory.
- Considering the aging of population and the expanding indication to percutaneous treatment of aortic stenosis to larger populations, optimization of TAVI management is a primary objective of institution for limiting its costs.
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Declaration of interest

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optimization

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### Tables

#### Table 1. Observational studies for early discharge after TAVI

<table>
<thead>
<tr>
<th>N. of patients</th>
<th>Study design</th>
<th>Age (mean or median)</th>
<th>STS score (mean or median)</th>
<th>Endpoints</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkhalil et al, 2017</td>
<td>268</td>
<td>Minimalist TF-TAVI, sLOS (n=163) vs. pLOS (n=105)</td>
<td>82.7 vs. 82.2 years</td>
<td>8.2% vs. 8.5%</td>
<td>30-days mortality</td>
</tr>
<tr>
<td>Durand et al, 2015</td>
<td>337</td>
<td>Minimalist TF-TAVI, sLOS (n=121) vs. pLOS (n=216)</td>
<td>83.7 vs. 84.2 years</td>
<td>15.6% vs. 17.6%</td>
<td>30-days composite of death and rehospitalization</td>
</tr>
<tr>
<td>Jensen et al, 2015</td>
<td>147</td>
<td>Minimalist TF-TAVI, ED (n=65) vs. SD (n=82)</td>
<td>84 vs. 84 years</td>
<td>8.3% vs. 10.3%</td>
<td>Overall 30-days mortality</td>
</tr>
<tr>
<td>Barbanti et al, 2015</td>
<td>465</td>
<td>sLOS (n=89) vs. pLOS (n=178)</td>
<td>81.1 vs. 80.7 years</td>
<td>6% vs. 6.5%</td>
<td>30-days mortality, Re-hospitalization, Composite safety endpoint</td>
</tr>
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Abbreviations: sLOS, short long of stay (within 72 hours); pLOS, prolonged long of stay (after 72 hours); ED, early discharge (within 48 hours); SD, standard discharge (after 48 hours)

#### Table 2. Key features of the 3MTAVR trial and the FAST-TAVI study

<table>
<thead>
<tr>
<th>3MTAVR trial (NCT02287662)</th>
<th>FAST-TAVI study (NCT02404467)</th>
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<tbody>
<tr>
<td>Study type</td>
<td>Prospective, single arm, multicenter</td>
</tr>
<tr>
<td>Transcatheter heart valve type</td>
<td>Edwards SAPIEN XT and SAPIEN 3</td>
</tr>
<tr>
<td>Follow-up</td>
<td>30-day and 1-year</td>
</tr>
<tr>
<td>Estimated enrollement</td>
<td>411 patients</td>
</tr>
<tr>
<td>Estimated study completion date</td>
<td>May 2018</td>
</tr>
<tr>
<td>Endpoints</td>
<td>• The composite of all-cause mortality or stroke (30-days) • The proportion of patients discharged the next day</td>
</tr>
</tbody>
</table>

23
bleeding (from day 4 to 30 after TAVI)

- All-cause mortality (30-days)
- Stroke (30-days)
- Major vascular complications (30-days)
- Major/life-threatening bleed (30-days)
- Any readmission to hospital (30-days)
- > mild PVR (post-procedural)
- New permanent PM (30-days)
- Conversion to general anesthetic or intubation (periprocedural)
- MI (periprocedural)
- Repeat procedure for valve-related dysfunction (30-days)
- Stage 3 AKI (need for dialysis) (30-days)
- Quality of life as measured by KCCQ and SF-12 at baseline, 2 weeks, 30 days, 1 year
- Economic evaluation and cost effectiveness (peri- and post-procedural)
- Death or stroke at 1 year
- Stratified Analysis of the cumulative incidence of a combination of the primary outcome measures according to patient risk factors and discharge date
- Length-of-Stay (LoS) after TAVI in days
- Quality of life as measured by SF-12v2 at baseline, 30 days, 1 year
- Relative costs of TAVI including hospitalization in either stratum compared to the low-risk/early-discharge group
### Inclusion criteria

- Patients with severe symptomatic AS undergoing elective TF-TAVI with a balloon expandable THV
- Considered at increased surgical risk
- Informed written consent

### Exclusion criteria

- Non-cardiovascular co-morbidity reducing life expectancy to < 3 years
- Any factor precluding 1 year FU
- Inadequate CT image acquisition
- Predicted inability to perform uncomplicate d percutaneous vascular access and closure
- Iliofemoral diameter < 6 mm for SAPIEN XT or <5.5 mm for SAPIEN 3
- Inpatient (unless clinically stable, mobilizing at baseline, and for logistical reasons).
- Significant communicatio n barrier(s) that interfere with ability to follow peri-procedural and discharge instructions
- MMSE < 24/30, 5-m gait > 7 sec and ADL < 6/6
- Insufficient social support

### Consecutive patients with severe AS intended for TF-TAVI using a balloon-expandable THV

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients with severe symptomatic AS undergoing elective TF-TAVI with a balloon expandable THV</td>
<td>Non-cardiovascular co-morbidity reducing life expectancy to &lt; 3 years</td>
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</tr>
<tr>
<td></td>
<td>Insufficient social support</td>
</tr>
</tbody>
</table>

No criteria beyond of IFU
to facilitate next day discharge

• Airway unfavourable for emergent intubation
• Inability to lay supine without conscious sedation or general anesthetic
**Figures**

**Figure 1.** Example of an optimized path for pre-TAVI management.

*For details, refers to Barbanti et al. Circ Cardiovasc Interv 2017 (10)

**Recommended 24 hours before and after TAVI for patients with severe renal disease (eGFR < 30 ml/min/mq).

**Figure 2.** Key aspects for obtaining early and safe discharge after TAVI
**Figure 3.** Flow charts summarizing suggested proceedings in case of high degree atrio-ventricular block (A) left bundle branch block (B).

*In case of occurrence of high degree AVB during the hospitalization, the flow chart A must be followed instead. Telemetry should be carried out in general ward.

**Abbreviations:** AVB, atrio-ventricular block; LBBB, left bundle branch block; PM, Pacemaker; RBBB Right bundle branch block.