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Guidelines on valvular heart disease in clinical practice

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Valvular heart disease (VHD) remains an important public health problem[1]. Decision making for intervention is often complex because valvular heart disease is now most often seen in the elderly population with a high frequency of comorbidities contributing to an increased risk for intervention.

The new VHD guidelines[2] were felt to be necessary for two main reasons: firstly, the importance of a collaborative approach between cardiologists and cardiac surgeons in the management of patients with valve disease has led to the production of a joint document by the ESC and EACTS in order to provide a more global view. Secondly, new evidence has been accumulated and therapeutic options have changed, in particular due to the introduction of percutaneous intervention techniques such as transcatheter aortic valve implantation (TAVI) and percutaneous edge-to-edge mitral valve repair.

We are going to concentrate the discussion here on the application of these percutaneous interventional techniques in the management of patients with aortic stenosis (AS), mitral regurgitation (MR), or, more briefly, after bioprosthetic dysfunction.

General comments

Decision making in patients with VHD should ideally be undertaken by a "Heart Team" with particular expertise in VHD including cardiologists, cardiac surgeons, imaging specialists, anaesthetists and, if needed, other specialists such as geriatricians, intensive care specialists and pneumologists. This "Heart Team" approach is particularly advisable in the management of high-risk patients.

The decision-making process for any intervention should answer the following questions:

– Is valvular heart disease severe? Echocardiography is a key technique but an integrative approach should always be used to check consistency between the different echocardiographic measurements as well as the anatomy and mechanisms of VHD[3,4]. Consistency between the results of a diagnostic investigation and clinical findings should also be checked.
– Does the patient have symptoms? This is a prerequisite since today percutaneous techniques should only be used in patients with overt symptoms and/or heart failure.
– Are symptoms related to valvular heart disease? This relationship could be difficult to establish especially in the elderly population with multiple comorbidities. This will require comprehensive evaluation involving other specialists such as pneumologists.
– What is the patient's life expectancy and expected quality of life? Patients eligible for intervention should have a life expectancy of more than one year and should also be likely to gain improvement in their quality of life taking into account their comorbidities. Here again consultation with other specialists may be needed in order to exclude patients who are likely to die or lack any functional benefit due to their comorbidities.
– Will the benefit of intervention outweigh the risks? Registries worldwide have consistently shown that in current practice therapeutic interventions for VHD are underused in high-risk patients with symptoms for reasons that are often unjustified[5,6]. The decision to intervene in a patient with VHD should rely on the individual risk-benefit analysis suggesting that an improvement in prognosis as compared to the natural history outweighs the risk of intervention and its potential late consequences. The natural history of VHD could be derived from contemporary series. Validated scoring systems enable patient life expectancy to be estimated according to extra-cardiac factors[7]. Estimation of operative mortality is more difficult. There are various multivariate scoring systems such as the EuroSCORE or STS score but these

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scores lack accuracy in estimating operative mortality in patients with valve disease, especially those at high risk[8,9]. In parallel, there is no specific scoring system to predict outcome after transcatheter interventions. This underlines the importance of not relying on single numbers to assess patient risk but reaching a conclusion through the process of shared decision making by a multidisciplinary team[10].

– What are the patient's wishes? Intervention should of course not be performed in patients who are unwilling to undergo it. On the other hand, the fact that a patient wishes to undergo TAVI in place of surgery is not a sufficient argument, in isolation, if this is not the option chosen by the "Heart Team".
– What are the local resources? This should be taken into account particularly as regards outcomes after surgery or percutaneous intervention in the specified centre. Patient transfer to a more specialised centre could be considered.

Percutaneous interventions in aortic stenosis

As a general principle some sort of intervention is theoretically indicated in all patients with severe AS who are symptomatic. The decision by the "Heart Team" will define the strategy which will be either surgical aortic valve replacement or TAVI, balloon valvuloplasty (BAV) or finally medical therapy if life expectancy and possibility of functional improvement are too limited due to comorbidities.

INDICATIONS FOR BALLOON AORTIC VALVULOPLASTY

Today the main indication of BAV is as a bridge to surgery, or TAVI, where BAV may be considered in patients who are haemodynamically unstable, those with severely reduced left ventricular function who are at high risk for surgery or in patients with symptomatic severe AS who require urgent non-cardiac surgery[11]. Balloon valvuloplasty in isolation may also be considered as a palliative measure in a few selected individual cases where surgery is contraindicated because of severe comorbidity and TAVI is not an option.

INDICATIONS FOR TRANSCATHETER AORTIC VALVE IMPLANTATION

As a general principle the task force of the ESC/EACTS guidelines emphasises that TAVI should only be performed by a "Heart Team" who assess individual patient risk as well as the technical suitability of TAVI and access issues.

The performance of the procedure should be restricted to hospitals with cardiac surgery on site and experience in the management of high-risk patients with valve disease in order to optimise patient selection, safety of the procedure with the availability of immediate rescue surgery, and postoperative care.

From current data mostly based on randomised studies and large registries[12-17], the indications for TAVI[2,18] are as follows:

TAVI is recommended in patients with severe symptomatic AS who are, according to the "Heart Team", considered unsuitable for conventional surgery because of severe comorbidities but are likely to gain improvement in their quality of life and to have a life expectancy of over one year.

Among high-risk patients who are still candidates for surgery the decision should be individualised. TAVI should be considered as an alternative to surgery in those patients for whom the "Heart Team" favours it, taking into consideration the respective advantages and disadvantages of the two techniques. Some risk score thresholds have been proposed for the performance of TAVI such as logistic EuroSCORE >20% or STS score >8-10%. On the other hand, frailty and conditions such as porcelain aorta, history of chest radiation or patent coronary bypass graft may make patients less suitable or even contraindicated for surgery despite score values below the admitted thresholds[19]. This re-emphasises the fact that risk assessment should mostly rely on the clinical judgement of the "Heart Team" in addition to the combination of scores.

At the present stage TAVI should not be performed in patients at intermediate risk for surgery, and trials are required in this population. The results of the ongoing randomised trials such as PARTNER 2 and SURTAVI are awaited.

When the indication for TAVI is considered, contraindications, both clinical and anatomical, should be investigated.

TAVI should not be performed in patients with severe primary associated diseases of other valves which make a major contribution to the patient's symptoms and which can be treated only by surgery. This pertains mainly to primary MR when associated with severe AS. Non-severe secondary MR usually improves after the aortic valve has been treated and is not a contraindication. The presence of dynamic hypertrophic cardiomyopathy also requires an appropriate treatment, which could be either surgical or interventional, before TAVI can be considered.

There are also anatomical contraindications which can be related to inadequate annulus size. This emphasises the critical role of annulus sizing using an integrative approach and multimodality imaging before TAVI[20].

Patients at risk of coronary ostial obstruction could also be excluded by taking into account several factors such as a short distance between the aortic annulus and coronary ostia, small aortic sinuses, and asymmetric severe valve calcification.

Finally, inadequate vascular access contraindicates a transfemoral or subclavian approach. This should be judged by an integrative evaluation of vessel size, degree of calcification and tortuosity. For patients who are not candidates for a transarterial approach, the choice between a transapical or a transaortic approach will be made by the "Heart Team" based on the individual patient's characteristics.

There are also relative contraindications where patients may undergo TAVI according to the decision of the "Heart Team" if there is a strong clinical need.

These conditions are as follows: patients with bicuspid valve can be treated by TAVI if the aortic annulus is not too large and calcification not too severe and/or asymmetric in order to avoid severe paravalvular leaks after TAVI. In case of untreated severe coronary artery disease combined percutaneous coronary intervention and TAVI have been shown to be feasible but more data are required before a firm recommendation can be made. The question as to

whether to proceed as well as the chronology of interventions should be the subject of individualised discussion based on the patient's clinical condition, coronary anatomy and extent of myocardium at risk. Finally, in the case of haemodynamic instability or left ventricular ejection fraction <20%, it seems more appropriate to perform BAV as a bridge to TAVI rather than primary TAVI where experience is limited.

Percutaneous intervention in mitral regurgitation

Primary MR covers all aetiologies in which intrinsic lesions affect one or several components of the mitral apparatus. In secondary mitral regurgitation valve leaflets and chordae are structurally normal and MR is secondary to left ventricular enlargement and remodelling due to idiopathic cardiomyopathy or ischaemic disease.

In patients with primary MR the "Heart Team" will choose between surgery, preferably conservative, which carries excellent long-term results when it is durable, valve replacement, percutaneous repair, or medical therapy.

In the case of secondary MR the alternative strategies are similar but surgery carries a higher risk and is less durable. Optimal medical management must be the first step except in patients where coronary bypass is also needed. In patients who are not operable, extended heart failure treatment including cardiac resynchronisation, ventricular assist device, and heart transplantation should be discussed. This entails the involvement of heart failure specialists and arrhythmia specialists in the "Heart Team".

Indications for percutaneous intervention

The edge-to-edge technique is the only one which is currently used. The amount of evidence concerning the percutaneous edge-to-edge procedure is much more limited than that on TAVI[21-23]. The ESC/EACTS task force on VHD, as well as the ESC task force on Heart Failure, stated that percutaneous edge-to-edge procedures may be considered in patients with symptomatic severe primary or, most importantly, secondary MR, despite optimal medical therapy, who fulfil the echocardiographic criteria for eligibility, are judged inoperable or at high surgical risk by the "Heart Team" and who have a life expectancy greater than one year. The aim here is mainly to improve symptoms[2,24].

More evidence is needed and trials are ongoing comparing edge-to-edge mitral valve repair with medical therapy in patients with secondary MR refractory to optimal medical management.

Percutaneous treatment of bioprosthetic failure

If late valve deterioration occurs in a patient with a bioprosthesis, reoperation is recommended in patients with significant haemodynamic dysfunction.

The evidence available on the percutaneous treatment of bioprosthetic failure by transcatheter valve-in-valve implantation is limited and mostly relates to the aortic position[25,26].

Percutaneous balloon intervention should be avoided in the treatment of stenotic left-sided bioprostheses. TAVI can only be considered in symptomatic inoperable or high-risk patients as assessed by the "Heart Team".

Conclusion

The main messages from the new ESC/EACTS guidelines on VHD concerning percutaneous interventions in AS and MR are as follows:

- A dedicated "Heart Team" approach is necessary for the optimal management of patients, in particular when they are at high risk. The decision-making process requires a comprehensive cardiac and extra-cardiac evaluation. Risk stratification before intervention should mainly be based on the decision of the "Heart Team", complementary to the use of risk scores which requires further refinement.
- TAVI is an established treatment in inoperable patients and selected high-risk patients. Percutaneous mitral valve repair is at an earlier stage but may be a useful treatment in selected high-risk patients with severe MR, mainly secondary. Further evaluation is needed.
- The respective roles of surgical and percutaneous intervention are likely to change in the future when better evidence is available with longer follow-up, and technology as well as safety is improved. These changes should not be supported by "feel good" behaviour but by better evidence which is expected in the future.

Conflict of interest statement

A. Vahanian has received speaker's fees/honoraria from Edwards Lifesciences and is on the advisory boards of Medtronic and St. Jude Medical. O. Alfieri is a consultant for Valtech and has received speaker's fees/honoraria from Abbott.

Online data supplement

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