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Christiaan F. J. Antonides, Michael J. Mack & A. Pieter Kappetein

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THE HEART TEAM REVIEW

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Approaches to the Role of The Heart Team in Therapeutic Decision Making for Heart Valve Disease

Christiaan F. J. Antonides, MD[a], Michael J. Mack, MD[b,c], and A. Pieter Kappetein, MD, PhD[a]

[a]Department of Cardio-Thoracic Surgery, Erasmus University Medical Center Rotterdam, Thoraxcentrum, Rotterdam, The Netherlands; [b]Baylor Scott and White Healthcare System, Baylor University Medical Center, Baylor Heart and Vascular Hospital, Dallas, Texas, USA; [c]The Heart Hospital Baylor Plano, Plano, Texas, USA

ABSTRACT

Multidisciplinary decision making is becoming increasingly important in health care with ever growing therapeutic options available in complex cases. This is also true for cardiovascular medicine, where the introduction of percutaneous coronary intervention caused a revolution in the treatment of coronary artery disease. Currently, with the development of transcatheter procedures to repair or replace heart valves, the treatment of valvular heart disease is subject to a similar transition. Especially the treatment of severe aortic stenosis in high- and intermediate-surgical-risk patients has changed significantly, with the emergence of the transcatheter aortic valve replacement (TAVR) as an accepted treatment. In order to oversee the extensive set of diagnostic and therapeutic options it is suggested that decision making is performed in a multidisciplinary team, i.e. a Heart Team. This review gives a summary of the changes that have taken place and continue to take place in the treatment of aortic, tricuspid and mitral valve disease. Furthermore, an overview is provided of the advantages and limitations of shared decision making. Three possible models of decision making in the treatment of patients with severe aortic stenosis are discussed in detail. Subsequently, surgical risk scores, the assessment of frailty in possible TAVR candidates and the necessity of Heart Team reimbursement are discussed.

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KEYWORDS Aortic stenosis; frailty; heart valve disease; multidisciplinary decision making; Heart Team; transcatheter aortic valve replacement

Introduction

With an increasing number of therapeutic options, multidisciplinary decision making (MDM) has become increasingly important for the evaluation of options in medicine, especially in patients with complex diseases. MDM has proven value in disciplines such as cancer treatment, where comprehensive decision making in so-called tumor boards resulted in a change of diagnostic or therapeutic strategies and improved outcomes.[1,2]

Heart Teams, as multidisciplinary teams in cardiovascular disease are usually named, have played a crucial role in decision making. The European Society of Cardiology recommends the consultation of a heart team in the management of valvular heart disease,[3] heart failure,[4] and myocardial revascularization.[5] A heart team usually consists of cardiologists, cardiac surgeons, interventionists, imaging specialists, anesthetists and midlevel providers. In some cases, the expert opinion of a general practitioner, geriatrician or intensive care specialist can be of additional value.

The evolution of the heart team concept started with a focus on coronary artery disease (CAD). Initially, the options for treatment of CAD were optimal medical therapy and coronary artery bypass grafting (CABG). The introduction of percutaneous coronary intervention (PCI) revolutionized the treatment of CAD and became an alternative treatment option to CABG. Some studies showed, however, that patients who would benefit most of CABG actually received PCI treatment due to the less invasive nature of PCI.[6] This resulted in a call for standardized pre-operative assessment of patients.[7]

The invasive treatment of heart valve diseases is undergoing a similar revolution with the introduction of transcatheter heart valve repair and replacement. Of special significance is the rise of the transcatheter aortic valve replacement (TAVR), which is now a first-choice option in patients with severe aortic stenosis (AS) who are considered extreme, high risk or intermediate risk for surgical aortic valve replacement.[3] Furthermore, transcatheter options for mitral and tricuspid valve disease have been developed or are in development and might become increasingly viable as an alternative treatment option. This raises the question whether there is a similar risk of inappropriate use of treatments in heart valve disease now and in the future.

The purpose of this paper is to describe the innovations in therapeutic options for heart valve disease and discuss the rationale for involvement of a Heart Team in decision making. Furthermore, patient categories to be discussed with MDM, the use of pre-operative surgical risk scores, professionals to be involved in decision making and the limitations and other advantages of shared decision making in valvular heart disease will be discussed.

CONTACT Christiaan F. J. Antonides c.antonides@erasmusmc.nl Department of Cardio-Thoracic Surgery, Erasmus University Medical Center Rotterdam, Thoraxcentrum, Rotterdam, The Netherlands.

Discussion

Developments in heart valve surgery

Aortic valve stenosis

The burden of aortic valve disease, especially in elderly people, is an important public-health issue. Studies have shown a prevalence of AS of 0.4% in the general population, but up to 2.8% in people of 75 years or older,[8] while a meta-analysis showed a prevalence of severe AS ranging from 1.2% to 6.1% in elderly populations.[9] Patients with severe AS, if left untreated, have a limited life expectancy.[10] The most utilized therapeutic options in severe AS are surgical aortic valve replacement (SAVR) and, more recently, transcatheter aortic valve replacement (TAVR). The potential risk of an unfavorable outcome after surgery in high-risk patients meant that many patients were not referred to SAVR.[11] However, TAVR is now an effective option in inoperable patients, with proven superiority over medical therapy[12] and non-inferior to SAVR in high-risk patients.[13,14] Recently, TAVR as a treatment option for patients with intermediate surgical risk was demonstrated to be non-inferior to SAVR and was approved as well.[15,16] TAVR as therapy for low-surgical risk patients is currently under investigation in randomized trials and shows promising first results in nonrandomized studies.[17]

Recent trends illustrate a sharp increase in the number of TAVRs procedures, while the number of SAVR procedures remains relatively unchanged, resulting in a more than 2-fold increase in the total number of aortic valve replacements in Germany (Figure 1).[18,19–21] This is not the same in every country though, which is attributable to different reimbursement strategies.[22] Although TAVR is less invasive compared to SAVR, the procedure is of course not without risks. TAVR associated risks include: post-procedural aortic regurgitation (mostly paravalvular),[23] necessity for new permanent pacemaker implantation,[23] complications associated with vascular access,[14,16] and neurological complications.[12,24]

Mitral valve

Similar to aortic stenosis, mitral valve regurgitation (MR) is common in the elderly population, with a reported prevalence of 1.7% in the general population, increasing to 9.3% in the population of 75 years or older.[8] MR is subdivided into primary (degenerative) and secondary (functional, as a consequence of e.g. heart failure or left ventricular dysfunction) MR and is associated with high morbidity and mortality.

Degenerative MR is most often repaired by traditional sternotomy or minimal access heart surgery and shows superior survival compared to optimized medical therapy.[25,26] A new minimal-invasive therapeutic option for MR is transcatheter mitral valve repair (TMVR), a procedure where the midpoints of the posterior and anterior leaflets are approximated with transcatheter placement of a clip, resulting in a double-orifice mitral valve and subsequent reduction of MR. High-surgical-risk patients undergoing TMVR show comparable survival rates to mitral valve surgery patients.[27,28] A recent meta-analysis confirmed these results, however the rate of recurrent MR is significantly higher after TMVR compared to surgical repair.[29] Since its approval, first in Europe and in 2013 in the US (for degenerative MR in high-surgical risk patients only), a steady increase in the number of TMVR procedures is seen each year.[30,31] Multiple devices are currently in development for mitral valve repair or replacement.[32]

Tricuspid valve

A substantial number of the general population has at least a trace of tricuspid regurgitation (TR) and the percentage of persons with at least mild TR in the elderly population (≥70 years) is significant (29.5%).[33] Others confirm a higher prevalence of moderate to severe TR in the elderly population and report an increased risk of mortality for both isolated TR and TR in the presence of left-sided heart disease.[34,35] The impact of mild to moderated TR, however, is not well known.

Although studies on isolated tricuspid valve repair report a high per- and post-operative mortality rate,[36–38] the number of tricuspid valve replacements and repairs increases gradually both as an isolated procedure and as a concomitant procedure.[39] Due to an increasing appreciation of tricuspid valve pathology and high mortality rates of isolated tricuspid surgery, a variety of innovative, less-invasive techniques, have been developed. These devices include: transcatheter tricuspid valve implantation within surgically placed dysfunctional bioprosthetic valves (valve in valve), vena cava valves (either in both the superior and inferior vena cava or isolated in the inferior vena cava), tricuspid annuloplasty, and coaptation devices (e.g. MitraClip and PASCAL). None of these techniques, however, are currently implemented as a clinical standard.[40]

Advantages of a multidisciplinary approach in cardiac disease

On the face of it, decision making in a multidisciplinary team like a Heart Team has important advantages over solitary decision making. Figure 2 represents the conceptual strengths and weaknesses of the Heart Team model. First, medicine is becoming increasingly complex with various therapeutic options to be considered in older patients with more comorbidities. The combined expertise of a Heart Team provides the basis for a more balanced appraisal of a specific case. This is specifically important if the availability of clear supportive evidence (e.g. risk scores) is limited.

Secondly, use of expensive therapeutic options is likely to be restricted in patients where the benefits of treatment are questionable. Additionally, if an invasive treatment is deemed not to be beneficial for patients, extensive and detailed non-invasive care can be organized immediately. At the same time, underutilization of therapeutic options can be avoided. Furthermore, an open-minded, multidisciplinary approach minimizes disagreements between individual clinicians.

Another advantage of the Heart Team is that the pre-operative diagnostic work-up will become more standardized, since a protocolized and complete pre-operative assessment is a requirement to have a successful multidisciplinary meeting. Finally, an open discussion about therapeutic options in complex patients creates an environment for clinicians to discuss and expand their knowledge (“Every day is a school day”).

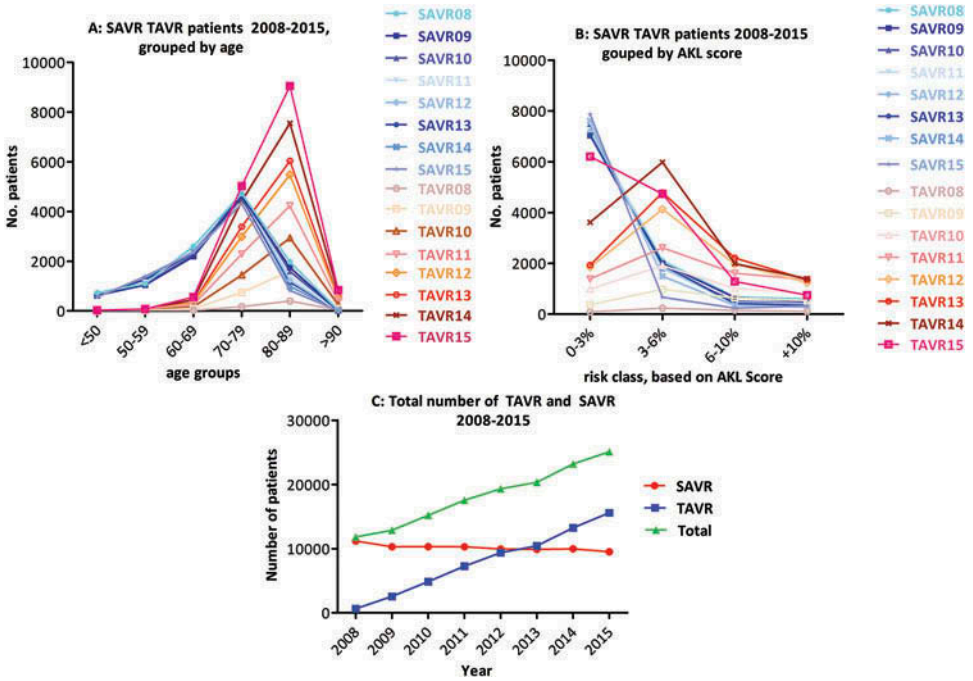

Figure 1. Number of TAVR and SAVR procedures from 2008 to 2015 in Germany. (A) Total number of SAVR and TAVR procedures performed in Germany from 2008 to 2015 grouped by age category per year. (B) Total number of SAVR and TAVR procedures from 2008 to 2015 grouped according to risk scores (AKL: aortenklappen score) per year. (C) Total number of SAVR, TAVR and combined number of AVRs from 2008 to 2015. Adapted from Sektorenübergreifende Qualität in Gesundheitswesen (2008–2014) and Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (2015).[18–21.]

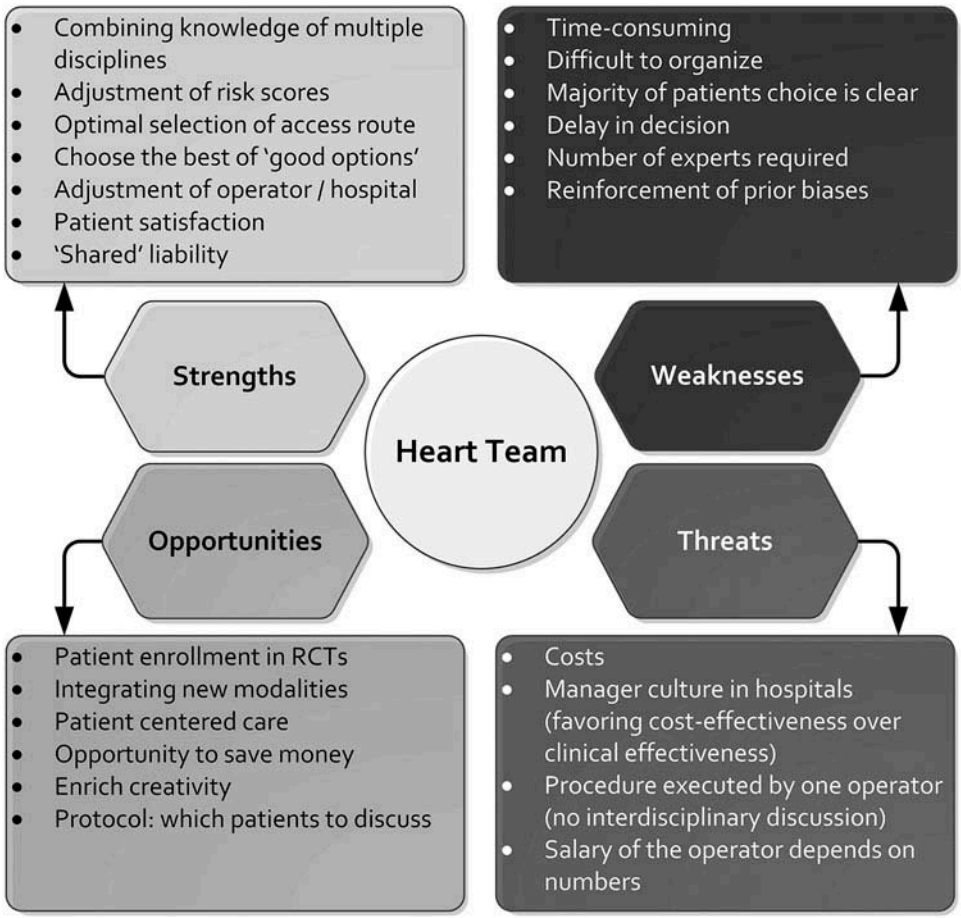

Figure 2. The Heart Team illustrated according to the Strengths, Weaknesses, Opportunities, and Threats model (SWOT).

Moreover, complex cases sometimes require creative solutions which are not always supported by protocols and guidelines. The Heart Team offers a platform for "creative solutions," and an opportunity to share responsibility for these treatments. Finally, these discussions can deliver an important contribution to the education of medical students and clinical residents in one of the most difficult and rapidly evolving subjects of medicine.

Although evidence of the benefit of Heart Teams is limited, one report has shown that in-hospital mortality and 1-year mortality in patients admitted to the hospital for heart failure was significantly lower if they were discussed in a Heart Team, compared to patients not discussed in a Heart Team.[41]

The Heart Team in valvular heart disease

Although decision making in a Heart Team is a key element in the treatment of patients with heart valve diseases, the referral pathways, organization and the exact constitution of the Heart Valve Teams are not standardized. Figure 3 shows three possible models of decision making in patients with severe aortic stenosis. Each model comes with specific advantages and disadvantages that will be summarized below.

The first flowchart (Figure 3A) represents a model where every patient, after the diagnosis of severe AS by a cardiologist, is referred to the Heart Team. The Heart Team will assess the case and carefully consider the practical options: optimal medical therapy (OMT), TAVR, and SAVR. Advantages of this model are: complete and careful consideration of every case, minimal risk of a possible conflict of interest, learning opportunity for decision making in all patients with AS. Disadvantages, however, are: time-consuming and expensive, lack of professional frailty and/or mental health assessment (by e.g. a geriatrician). Two studies reviewed this model and report OMT in 6–7% of the patients, while the remaining patients either received TAVR (12–43%) or SAVR (51–82%).[42,43]

In Model 3B (Figure 3B), patients with possible AS are seen by a cardiologist of a Heart Valve Clinic who can then refer them directly to a cardiac surgeon, interventional cardiologist or to the Heart Team. The cardiac surgeon or interventional cardiologist can decide on SAVR/TAVR or can decide to discuss the patient in the Heart Team. Advantages of this model are: "fast-track" for patients who are clear SAVR and TAVR candidates (e.g., young patients with low surgical risk as a SAVR candidate), preselection of patients to be discussed in the Heart Team. Disadvantages include: only a select group of patients are discussed by the Heart Team, potentially leading to a higher probability of disagreement. As a future perspective, a similar fast-track could possibly be proposed for patients who are clear TAVR or SAVR candidates. A local protocol defines which patients are directly referred for treatment and which ones will be discussed in the Heart team.

Model 3C (Figure 3C) is a model of a Heart Valve Center as has been proposed before where the goal is to center all specific knowledge on aortic stenosis.[44,45] A referred patient by a Heart Valve Clinic is seen by both a cardiologist and a cardiac surgeon of the Heart Valve Center. They can then decide that a patient needs further discussion in a Heart Team and, possibly, that extra diagnostic research has to be done. The patient can also directly be referred to SAVR, TAVR, or OMT. The advantages are: both cardiologist and cardiothoracic surgeon see the patient, minimizing a potential conflict of interest, possible fast-track, and the creation of a specialized center in aortic stenosis. The disadvantages are: time-consuming (with limited human resources) and expensive.

A recent evaluation of 250 different TAVR centers reported that a Heart Team is consulted in 97% of the centers and that both a cardiac surgeon and a cardiologist are often present (95.6% and 96.8% respectively); however, the involvement of other specialists is not common. Furthermore, at least one surgical risk score for clinical evaluation of the patient is used in nearly all centers. Interestingly, frailty is only tested in 44% of the cases, with over 20 different standards being used.[46]

Traditional surgical risk scores are often used to distinguish between possible SAVR and TAVR candidates. The European Society of Cardiology/European Association of Cardio-Thoracic Surgery guideline on the management of valvular heart disease recommends surgical risk stratification performed primarily by a Heart Team with the aid of the logistic EuroSCORE and STS score.[3] A trial comparing the EuroSCORE with a score based on age, creatinine and ejection fraction in cardiac surgery patients showed similar accuracy, highlighting the need for more accurate pre-operative risk scores.[47] Furthermore, these scores do not take aspects such as frailty and mental health status into consideration. Other scores, such as the OBSERVANT-score,[48] FRANCE-2 score,[49] the SURTAVI risk stratification model,[50] and the German Aortic Valve Score[51] have been developed to specifically assess mortality risk in patients undergoing TAVR (and SAVR), but have shown limited additional accuracy in predicting 30-day mortality in comparison with EuroSCORE and STS score in different datasets.[52,53]

The impact of pre-procedural frailty on post-operative outcome after TAVR has been the subject of interest in TAVR research. Frailty is a state of decreased physiologic reserve, resulting in vulnerability when a stressor is applied. Since the number of high-risk patients increases with age, the number of frail patients gradually increases as well. As mentioned earlier, many different scores to assess frailty are used. Criteria that have been used to assess frailty include but are not limited to: gait speed, grip strength, activities of daily living (using the Katz index), and serum albumin. These criteria have shown to be a predictor of decreased long-term survival after TAVR, similarly quality of life (QoL) did not significantly increase after TAVR in the frail patient subgroup.[54,55] A recent review confirms the association between frailty and decreased survival after TAVR but recognizes the lack of a uniform definition of frailty and a standard protocol to assess frailty in possible TAVR candidates.[56] Efforts are made, though, to find prognostic scores to assess frailty, specifically for patients with severe AS. A recent multicenter comparison of multiple frailty indices has clearly shown that an EFT score (chair standing, mini-mental assessment score, albumin and hemoglobin outperformed all other indices).[57] However, with the lack of these clear boundaries, it would be recommended to consult an expert on this subject, for example a geriatrician. Another option would be to consult a general

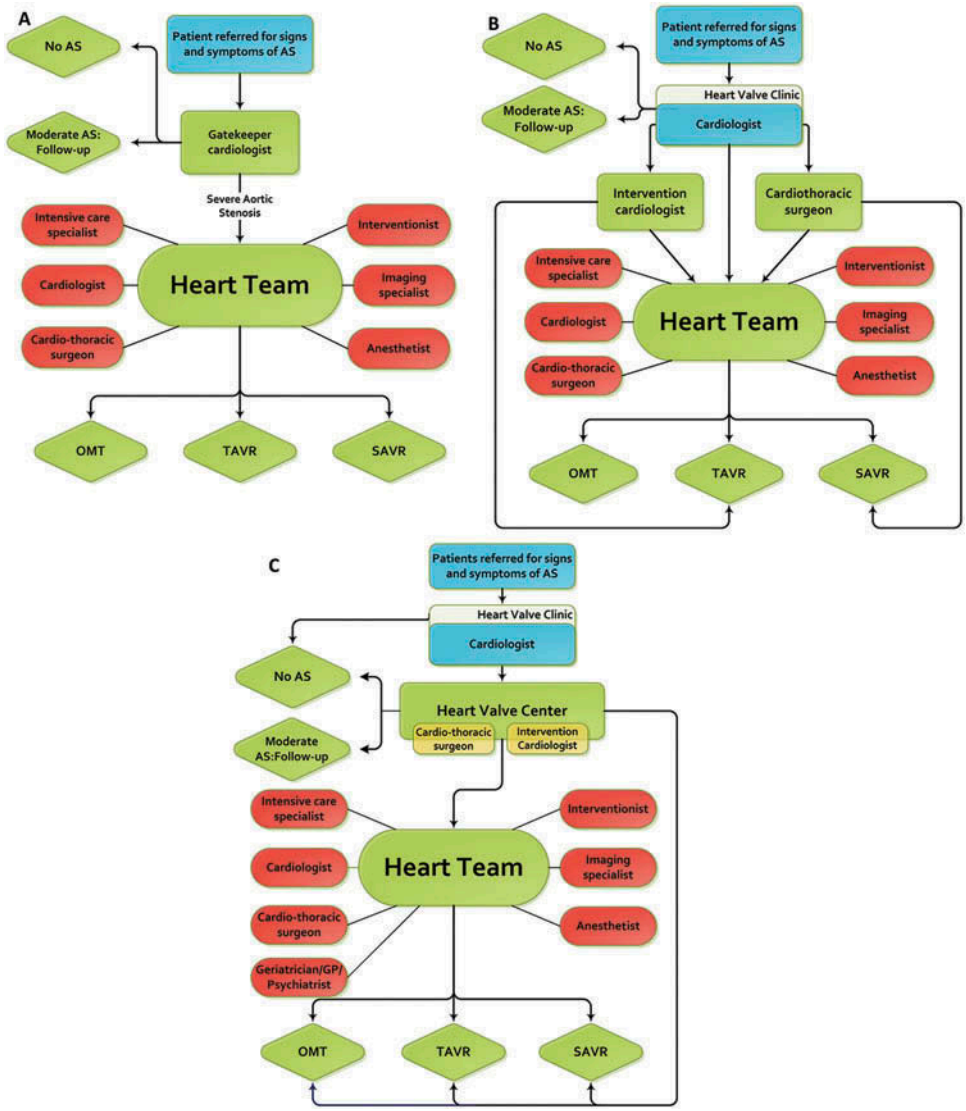

Figure 3. Three different models of implementation of a Heart Team. (A) Model where a cardiologist acts as gatekeeper and every patient with severe AS is discussed in a Heart Team. (B) A cardiologist from a Heart Valve Clinic assesses the possibility of AS, and can refer to the Heart Team or directly to a cardiothoracic surgeon or intervention cardiologist, who can then refer the patient for TAVR/SAVR or also refer the patient to a Heart Team meeting. (C) A cardiologist from the Heart Valve Clinic refers patients with severe AS to a dedicated Heart Valve Center. An interventional cardiologist and cardiac surgeon assess the patient's AS treatment options. If there are/remain doubts about surgical aspects and/or the mental health and frailty of a patient, a patient can be discussed by the Heart Team with the aid of other specialists. AS, aortic stenosis; GP, general practitioner; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement; OMT, optimal medical therapy.

practitioner, who is often familiar with the physical and mental capabilities and daily activities of the specific TAVR candidate.

Another aspect to be taken into consideration is how and when to involve the patient in the treatment decisions. This could be done when the patient is referred to the cardiologist, or a patient could be informed about the therapeutic options after the Heart Team meeting. It is clear that patient preference and decision will ultimately be crucial in deciding which alternative therapeutic approach is to be undertaken.

Finally, although MDM has some clear advantages over solitary decision making, it is time-consuming and as it might be difficult to gather the Heart Team participants, meetings can become less efficient. Thus, it is important to promote Heart Team meetings by scheduling them in the agendas of specialists, but also by reimbursing Heart Team meetings or the treatments that are discussed in Heart Team meetings. In the Netherlands, for instance, Heart Team meetings are reimbursed by health insurances. In many countries, TAVR procedures are only reimbursed if they are discussed in a Heart Team.[22]

Conclusion

With an increasing number of therapeutic options available in the management of valvular heart disease, multidisciplinary decision making is becoming increasingly important. Not only because of the complexity of treatment options in older patients with significant comorbidities, but also due to the fact that predictive risk scores have limited accuracy. The role of the Heart Team is crucial, since it can comprehensively discuss the accuracy of surgical risk scores, additional unaccounted for comorbidities, frailty, perform a risk-benefit analysis and include other factors that are not necessarily caught in standard procedures or protocols.

Nevertheless, there is an urgent need for more accurate risk scores, incorporating frailty and other non-traditional risk factors, specifically for patients with severe AS undergoing TAVR. Although this review focused mainly on the role of the Heart Team in the treatment of severe AS, similar challenges lie ahead for the multiple therapeutic options being developed for the treatment of mitral and tricuspid regurgitation.

Disclosure statements

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