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EDITORIAL

Tricuspid Valve Prosthesis Choice: The Only Railroad to the Truth is to Conduct a Randomised Controlled Trial

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In this issue of *Heart, Lung and Circulation*, Negm et al. report a meta-analysis of outcomes of tricuspid valve replacement (TVR) with mechanical versus bioprosthetic valves [1]. The authors included a total of 23 retrospective studies reported between 2002 and 2019, involving 945 mechanical and 1,332 biological tricuspid valve prostheses. The authors found an equal risk of 30-day and late mortality, reoperation, and 5-year valve failure in patients with mechanical TVR versus biological TVR. This editorial is an effort to shed light on issues affecting their conclusions, and the need to keep an open mind regarding prosthesis choice for tricuspid valve replacement.

The first issue is that several authors have reported conflicting results advocating either the use of mechanical or tissue valve [2,3] — because most patients who require tricuspid valve surgery are members of a very heterogeneous group. Many have undergone previous cardiac surgery; and, in the majority, tricuspid valve surgery is associated with concomitant mitral or aortic valve surgery. These patients are commonly in an advanced stage of multivalvular heart disease, which represents a challenging and high-risk surgical group [4,5].

The second issue is that a meta analysis of retrospective heterogeneous data, with all of the inherent limitations, may only describe the current surgical practice, without the ability to discern or provide undisputed evidence that we can rely on in our decision as to what is the ideal valve in the tricuspid position [6,7].

The choice of valve prostheses is mainly based on the shorter durability of biological prostheses versus the probability of anticoagulation-related complications with mechanical prostheses [8,9]. As a result of the generally limited life expectancy of the patients who receive double or triple valve replacement [10–13], the durability of the prosthesis has a minor influence on the long-term valve survival, which negates the advantages of mechanical valve. On the other hand, many of these patients require anticoagulation therapy for chronic atrial fibrillation, thus losing the potential benefit of tissue valves.

In the mid-1980s, a higher incidence of valve thrombosis after TVR with mechanical prostheses has been reported [14,15]. The type of prosthesis used in most of these studies was the Björk–Shiley tilting disc valve [14]. However, design improvement in mechanical prostheses has reduced this problem significantly [16,17].

Tricuspid valve replacement is an infrequent procedure, because the prevalence of clinically significant tricuspid valve disease is uncommon; and usually, it is amenable to repair [18,19].

Currently, only a few studies with a large number of patients are available to try to answer the question; and, because TVR is infrequent, the question as to whether a bioprosthetic or mechanical valve will lead to a better result will remain unanswered. Thus, valve choice has to depend on the individual patient risk factors and their predicted longevity [20,21].

Current consensus is that tricuspid valve repair is associated with better outcomes in the short and long-term than valve replacement [22–24]. In comparison, tricuspid valve replacement has a high postoperative mortality. Despite recent advances in perioperative care, due to the significant incidence of comorbidity in patients requiring replacement [25], this group has always fared worse compared to the repair group [26]. The incidence of reoperation is low,

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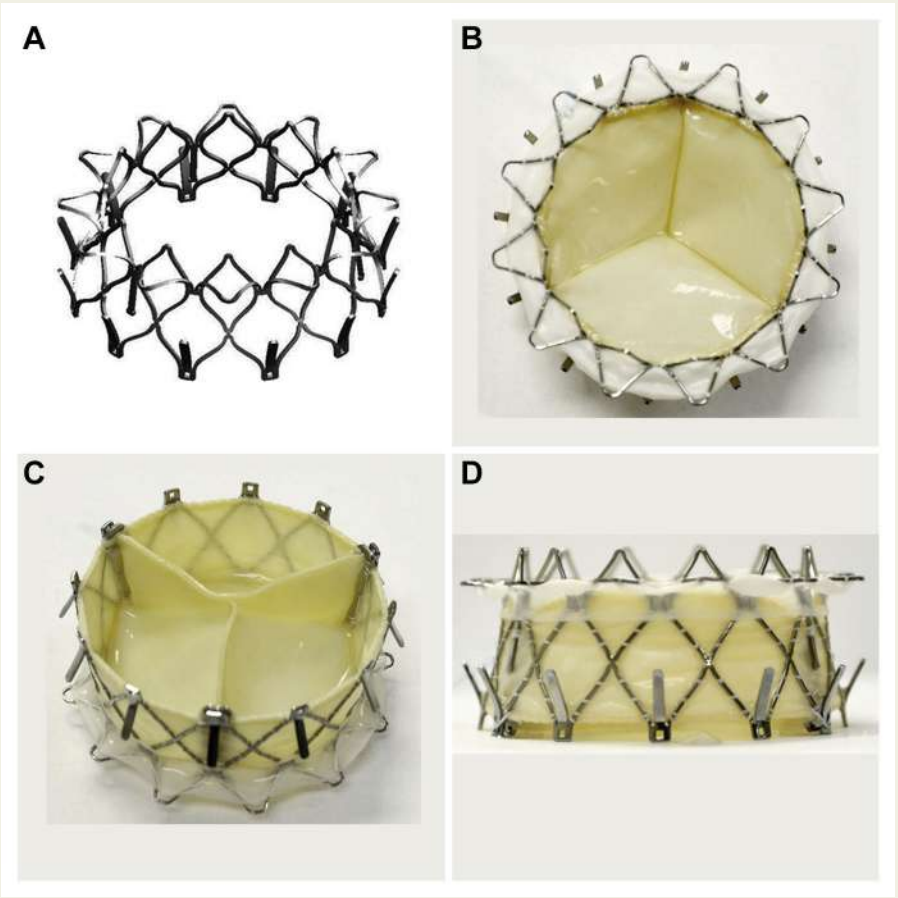

Figure 1 NaviGate stent-valve.

however, with no significant difference whether the tricuspid valve has been repaired or replaced [27]. So, when valve replacement is necessary, it may be that the use of a biological prosthesis, considering the poor long-term survival, is sensible. Currently, the operative outcome can be further improved through improvements in myocardial protection and modified ultrafiltration as well as perioperative care.

It is not wise to delay TVR because of concern about the potential high operative mortality rate [28]. Although there is no general agreement about the optimal timing of TVR, it would seem better to perform TVR early, so as not to develop irreversible right ventricular failure with end-organ failure [28].

Progress in percutaneous valve technology could enable tricuspid valve replacement with lower mortality risk and provide an alternative solution for structural valve deterioration that would eliminate the need for mechanical valve replacement in the tricuspid position — such a development could help settle the argument as to the best valve (and procedure) once and for all.

The innovation of using transcatheter aortic valve implantation (TAVI) in repair of degenerated bioprosthetic valves was first performed with a transfemoral CoreValve system (Medtronic, Minneapolis, MN, USA) and then was followed by Edwards (Edwards Lifesciences, Irvine, CA, USA) [29]. Valve-in-valve has been a progressively attractive procedure, but the data are limited on the percutaneous treatment of severe tricuspid valve (TV) degeneration with the Sapien 3 device [29]. Valve-in-valve therapies have now been reported in the tricuspid as well as the pulmonic, mitral, and aortic positions, with varying results [30].

The novel NaviGate stent-valve (NaviGate Cardiac Structures, Inc, Lake Forest, CA, USA) is a specifically designed valve for the management of tricuspid regurgitation (TR) [31]. It is a self-expanding valved stent, constructed to treat functional tricuspid regurgitation and is offered in a wide range of sizes from 36 to 52 mm (Figures 1 and 2). It comprises a constructed nitinol (nickel titanium) alloy stent, into which is mounted a tri-leaflet valve made from equine pericardium. The outline of the stent is shaped to interlock the TV annulus and TV leaflets from both atrial and ventricular aspects, and maintains a minimal extension into both atrial and ventricular chambers to avoid dynamic flow obstruction; the ventricular diameter is engineered to match the dilated TV annulus typical of functional TR [31].

Rapid progress in transcatheter valve therapies would provide a new platform for treating this challenging group of patients, and to launching a faster vehicle to the core of the truth — what we need is a randomised controlled trial

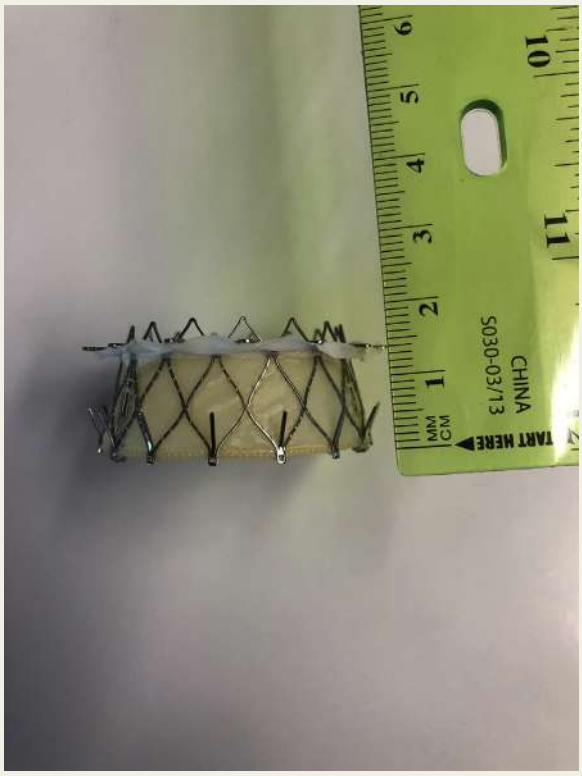

Figure 2 NaviGate - Guide to dimensions.

comparing open tricuspid valve replacement with transcatheter management.

Declaration of Interests

None declared.

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