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## Sutureless, rapid deployment valves and stented bioprosthesis in aortic valve replacement: recommendations of an International Expert Consensus Panel

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### Abstract

**OBJECTIVES:** After a panel process, recommendations on the use of sutureless and rapid deployment valves in aortic valve replacement were given with special respect as an alternative to stented valves.

**METHODS:** Thirty-one international experts in both sutureless, rapid deployment valves and stented bioprostheses constituted the panel. After a thorough literature review, evidence-based recommendations were rated in a three-step modified Delphi approach by the experts.

**RESULTS:** Literature research could identify 67 clinical trials, 4 guidelines and 10 systematic reviews for detailed text analysis to obtain a total of 28 recommendations. After rating by the experts, 12 recommendations were identified and degree of consensus for each was

determined. Proctoring and education are necessary for the introduction of sutureless valves on an institutional basis as well as for the individual training of surgeons. Sutureless and rapid deployment should be considered as the valve prosthesis of first choice for isolated procedures in patients with comorbidities, old age, delicate aortic wall conditions such as calcified root, porcelain aorta or prior implantation of aortic homograft and stentless valves as well as for concomitant procedures and small aortic roots to reduce cross-clamp time. Intraoperative transoesophageal echocardiography is highly recommended, and in case of right anterior thoracotomy, preoperative computer tomography is strongly recommended. Suitable annular sizes are 19–27 mm. There is a contraindication for bicuspid valves only for Type 0 and for annular abscess or destruction due to infective endocarditis. Careful but complete decalcification of the aortic root is recommended to avoid paravalvular leakage; extensive decalcification should be avoided not to create annular defects. Proximal anastomoses of concomitant coronary artery bypass grafting should be placed during a single aortic cross-clamp period or alternatively with careful side clamping. Available evidence suggests that the use of sutureless and rapid deployment valve is associated with (can translate into) reduced early complications such as prolonged ventilation, blood transfusion, atrial fibrillation, pleural effusions and renal replacement therapy, respectively, and may result in reduced intensive care unit and hospital stay in comparison with traditional valves.

**CONCLUSION:** The international experts recommend various benefits of sutureless and rapid deployment technology, which may represent a helpful tool in aortic valve replacement for patients requiring a biological valve. However, further evidence will be needed to reaffirm the benefit of sutureless and rapid deployment valves.

**Keywords:** Aortic valve replacement • Sutureless valve • Rapid deployment valve • Stented aortic valve prosthesis • Recommendations

## INTRODUCTION

Aortic valve stenosis is by far the most frequent valvular pathology leading to surgical or interventional aortic valve replacement [1] due to the poor outcome of conservative treatment in case of symptomatic aortic stenosis [2]. Besides aortic valve reconstruction, the technique of choice for young and active patients suffering from isolated aortic regurgitation [3], mechanical and biological prostheses offer excellent haemodynamic results and long-term durability. However, due to the increase in patient age and comorbidity, mechanical valves are more and more restricted to patients of 60 years or younger; ~80% of prostheses implanted in aortic position in Western societies now are biological valves [4]. Additionally, for high-risk and inoperable patients, transfemoral and transapical aortic valve implantation has emerged in the past 10 years as an alternative to sternotomy and extracorporeal circulation as well as myocardial ischaemia due to cross-clamping of the aorta [5].

However, because the diseased valve is left in place and the current implant technique still has limitations, transcatheter aortic valve implantation (TAVI), both transapical and trans-femoral, still carries drawbacks such as paravalvular leakages, increased pacemaker rates, stroke, vascular complications and migration [6]. Moreover, due to crimping procedure, TAVI technology presents uncertain durability [7]. To provide a curative treatment to patients 'in the gray zone' of intermediate to high risk [8–10] and to fill the gap between TAVI and traditional aortic valve replacement (AVR), sutureless and rapid deployment valves have been introduced to facilitate safe and effective implantation of biological aortic valve prostheses in a rapid fashion using modern deployment techniques [11–16]. Most importantly, this facilitates minimally invasive approaches such as ministernotomy and right anterior minithoracotomy [17–20]. Sutureless valves represent valve prostheses which are anchored in the aortic annulus without surgical sutures by means of a collapsible design. Rapid deployment valves are positioned with three interrupted sutures and anchored with a balloon-inflatable stent. Both types of valves facilitate a quick implantation. In particular, the Perceval sutureless valve (Sorin Group, Saluggia, Italy) [11–14] and the Edwards Intuity Elite (Edwards Lifesciences, Irvine, CA, USA) [16], as well as the former ATS 3f Enable Bioprosthesis (ATS, Minneapolis, MN, USA) [15, 21]

have proved their suitability for both traditional and minimally invasive approaches to reduce aortic cross-clamp and bypass time [21, 22] and thus reducing perioperative risk of the patients [22, 23]. Recently, the ATS 3f Enable Bioprosthesis (ATS) has been withdrawn from the market by the company for reasons of slow market penetration and cautious acceptance by the surgical community. Nevertheless, performance data and expert statements about this prosthesis remain included in this manuscript.

Yet no recommendations exist to define which patients might take additional profit from sutureless and rapid deployment valves. The aim of the project was to gain evidence-based consensus on the use of both sutureless and rapid deployment valve types in isolated and combined aortic valve replacement.

## METHODS

Two approved—one of them recently withdrawn from the market—sutureless valves and one rapid deployment valve with specific features of design and implantation techniques were included in the literature search and the panel process. Table 1 gives an overview over the specific properties of the three respective prostheses used.

### Perceval sutureless valve

The Perceval sutureless valve comprises a biological component of bovine pericardium treated to reduce the risk of calcification, and a self-expanding and elastic nitinol alloy stent, covered by a thin coating of Carbofilm™ to improve biocompatibility. The stent consists of two rings, as well as nine connecting struts, with the dual task of supporting the valve and holding it in place with no need for any permanent suture. The design of the stent copies the anatomy of the aorta and, due to its flexibility follows its movements to relieve stress from the leaflets. For implantation, the valve is collapsed with an atraumatic device, assuring that the valve leaflets are not affected. Perceval is until the correct position while collapsed, enhancing direct visualization and then self-expands back to its original diameter. Ballooning is recommended by the manufacturer to optimize adherence to the native aortic wall.

**Table 1:** Overview table of the three available technologies

| Name                  | Perceval, Sorin Group  | Intuity, Edwards   | 3f Enable, Medtronic                    |
|-----------------------|--|--|---|
| CE mark               | January 2011   | February 2012  | December 2009                           |
| Withdrawal            |  |  | September 2015                          |
| Annular sizes covered | S (19–21 mm), M (21–23 mm),<br>L (23–25 mm), XL (25–27 mm)           | 19, 21, 23, 25, 27 mm  | 19, 21, 23, 25, 27 mm                   |
| Materials             | Bovine pericardium and super elastic<br>Ni-Ti stent                  | Bovine pericardium, cobalt-chromium<br>alloy stent, stainless steel skirt            | Equine pericardium and Ni-Ti stent      |
| Tissue fixation       | Glutaraldehyde based treatment                                       | Glutaraldehyde based treatment   | Glutaraldehyde based treatment          |
| Tissue treatments     | HAT, No rinsing required   | ThermaFiX process (thermal<br>treatment, ethanol and surfactant)<br>rinsing required | No treatment rinsing required           |
| Type                  | Sutureless valve   | Rapid deployment valve   | Sutureless valve                        |
| Collapsibility        | Radially collapsible at room<br>temperature with dedicated tools     | Not collapsible  | Manually foldable with iced<br>solution |
| Repositioning         | Retrievable at room temperature (not<br>recommended by manufacturer) | Not repositionable   | Re-foldable with iced solution          |

HAT: homocysteic acid treatment.

## Edwards Intuity

The Edwards Intuity valve is a stented trileaflet bovine pericardial bioprosthesis with a balloon-expandable, cloth-covered skirt frame at the inflow aspect. The valve component itself is identical to the Magna Ease conventional valve. For implantation, three equidistant simple or mattress guiding sutures are placed through the annulus at the nadir of each sinus and then passed through the corresponding black marks on the nadir portion of the valve suture ring. The valve is positioned into the aortic annulus by the use of these guide sutures and three tourniquets, with the stent and polyester sealing cloth being seated directly below the aortic annulus. Once the valve is properly seated, the balloon-expandable frame is deployed with short balloon inflation. The guiding sutures are finally tied.

## ATS 3f Enable Bioprosthesis

The 3f Enable Model 6000 valve is made with a stentless valve of three equal sections of equine pericardial tissue sewn in a self-expanding nitinol support frame. The nitinol frame is intended to maintain the tissue valve geometry and eliminates the potential for misplaced attachment of the commissural tabs. The properties of nitinol and the flexibility of the equine pericardial leaflets allow the device to be folded in chilled water intraoperatively and positioned in the root accordingly. On deployment, its shape and size return to the preset dimensions and the outward radial forces keep the valve fixed at the target position. For implantation, because of some cases of valve migration, two permanent sutures were recently recommended to support placement and fixation of the valve at the level of the annulus. The polyester flange at the inflow aspect promotes tissue ingrowth, thus contributing to the long-term stabilization of the valve.

## Literature search strategy and selection criteria

As a first step, a thorough literature search was performed from May to November 2014. To be eligible for the review, studies

had to evaluate the use of sutureless, rapid deployment valves or stented bioprostheses in isolated or combined aortic valve replacement. Articles were identified via an electronic search on PubMed, EMBASE and Cochrane Library. The search started from the articles inception and ended on October 2014, with subsequent hand search throughout December 2014. The following search terms were used as keywords: 'aortic valve replacement' and 'stented bioprosthesis' or 'sutureless' or 'rapid deployment'. Additional manual search for articles was performed in the reference sections of articles identified by systematic search. We only searched the studies that were published in English. Abstracts and unpublished studies were excluded, as well as expert opinions or case reports. If the author reported results that were obtained on the same patient population in several studies, we would use the most recent or complete study. Besides clinical studies, relevant guidelines published since 2006 with their latest version if they had undergone substantial revision were included.

Full-text analysis was performed by two independent scientists with the emphasis on selection of main topics to represent possible recommendations on the use of stented bioprostheses or sutureless, rapid deployment valves in isolated and combined aortic valve replacement in general and the indications, benefits, possible pitfalls, contraindications, perioperative conditions, complications and their treatment, outcome and follow-up criteria for the use of the respective techniques. These selected main topics represented the basic material for the first round of the modified Delphi process.

## Panel of experts

The selection of panel experts should reflect the population of cardiac surgeons involved in the use of both sutureless, rapid deployment valves and stented biological valve prostheses for use in aortic position. Selection of participants started in 2013 and, for this purpose, a 'snowball sampling' approach was used, starting with a preliminary list of possible experts, defined by credibility to the target audience of cardiac surgeons considering the use of sutureless valves and rapid deployment valves in aortic valve replacement. Possible credibility was defined by recent activities

on the mentioned topics by (i) publishing scientific papers (studies, reviews) with frequent citations, (ii) playing an active role in guidelines committees and (iii) representing speaker on recent congresses of relevant scientific societies, respectively. Additional possible experts were included to the preliminary list if recommended by one of the final experts.

From the preliminary list, experts were contacted for further participation according to their current clinical expertise. Only experts were chosen with an experience of at least 100 cases undergoing stented biological aortic valve replacement and at least 50 cases using sutureless, rapid deployment aortic valve prostheses until the end of 2013. Final constitution of the panel was finished by March 2014 to organize the panel process. All experts had to declare any conflicts of interest prior to final constitution of the panel.

Outcomes had to be reported according to the recommendations of the American Association for Thoracic Surgery, Society of Thoracic Surgeons and the European Association for Cardio-Thoracic Surgery [24] and the Valve Academic Research Consortium [25], respectively.

### Panel process

The panel process was planned and maintained as a modified Delphi panel in three rounds: after the selection of experts by March 2014, in a first round they were asked to rate the main topics to be included in the consensus selected from the literature review. Experts were asked to discard topics that were not considered or add new topics to give further details on each main topic to prepare panel discussion during the second round. The first round was performed from August to November 2014 electronically. Main topics were included if mentioned to be relevant by at least one of the experts and excluded if discarded by all experts. The second round represented a meeting of the expert panel that took place 27 November 2014. Each main topic found to be relevant during the first round was presented with evidence-based recommendations and major clinical results if published, and then intensively discussed in terms of their eligibility as general recommendations for cardiac surgeons to give decision criteria for the use of sutureless, rapid deployment valves or stented bioprostheses in isolated or combined aortic valve replacement. The recommendations were classified in terms of level of evidence and strength of recommendations according to the code used by all major cardiovascular scientific societies (e.g. European Society of cardiology: [esccardio.org/static\\_file/Escardio/Guidelines/about/ESC\\_Guidelines\\_for\\_Guidelines\\_Updates\\_2012\\_for\\_web.pdf](http://esccardio.org/static_file/Escardio/Guidelines/about/ESC_Guidelines_for_Guidelines_Updates_2012_for_web.pdf)). A writing

committee prepared the recommendations for final discussion in a third, electronic round and finally wrote the manuscript.

## RESULTS

### Literature search

The search model could retrieve a total of 1331 publications covering a wide range of medical fields. After title and abstract screening and final full-text analysis, a total of 80 papers covering 66 clinical trials, 4 guidelines and 10 systematic reviews were identified (Table 2). However, no guidelines or recommendations on the use of sutureless, rapid deployment valves in isolated aortic valve replacement could be identified as presumed. Additional 36 papers describing the results of clinical studies were included from a manual search. All clinical papers except one [26] covered non-randomized, single or multicentre studies.

### Results of modified Delphi panel and expert panel discussion

The panel consisted of 31 international renowned experts on both sutureless, rapid deployment valves and biological stented valves in aortic valve replacement. For the first panel round, a total of 28 possible recommendations were prepared. After discussion in the second and third round, a total of 12 recommendations were finally identified by the panel experts and thus discussed in the consensus paper (Table 3).

## DISCUSSION

The panel identified a number of topics with respect to the use of sutureless, rapid deployment valves as an alternative to biological stented valves in isolated and combined aortic valve replacement. Most of these topics have been found to be not affected by the surgical approach. However, since numerous benefits of the combination of sutureless and rapid deployment valves together with modern minimally invasive approaches could be identified, this has to be discussed by a different panel with expertise on minimally invasive approaches and therefore has to be discussed in a separate consensus paper.

Three approved sutureless and rapid deployment valves with specific features of design and implantation techniques were included in the literature search and the panel process: the

**Table 2:** Results of literature search

|                              | Clinical trials | Guidelines | Systematic review | All  |
|------------------------------|-----------------|------------|-------------------|------|
| Search terms                 |                 |            |                   |      |
| Aortic valve replacement (A) | 991             | 18         | 16                | 1025 |
| Stented bioprosthesis (B)    | 86              | 4          | 12                | 98   |
| Sutureless (C)               | 141             | -          | 19                | 160  |
| Rapid deployment (D)         | 27              | -          | 21                | 48   |
| Total                        | 1245            | 18         | 68                | 1331 |
| Search model                 |                 |            |                   |      |
| Terms A AND (B OR C OR D)    | 66              | 4          | 10                | 80   |

**Table 3:** Consensus recommendations of experts for the implantation of sutureless and rapid deployment valves in comparison to stented biological valve prostheses after second and third round (2 of 31 were not in the position to respond, questions about bicuspid valves are off-label use in some sutureless valves, so there the responders number is not 29) of the panel process

| Consensus recommendations of experts   | Level of evidence | Strength of recommendation | % strongly agree | % agree | % neutral | % disagree | % strongly disagree | Number of responders |
|--|-------------------|----------------------------|------------------|---------|-----------|------------|---------------------|----------------------|
| Proctoring and education are necessary for the introduction of sutureless valves on an institutional basis as well as for the individual training of surgeons  | C                 | I                          | 90               | 10      | 0         | 0          | 0                   | 29                   |
| Consider sutureless or rapid deployment as an alternative to stented valves in patients requiring aortic replacement with a biological valve, especially for redo or delicate aortic wall conditions as calcified root, porcelain aorta or prior implantation of aortic homografts of stentless valves | C                 | IIa                        | 83               | 14      | 3         | 0          | 0                   | 29                   |
| Consider sutureless and rapid deployment as the valve prosthesis of first choice in cases requiring concomitant procedures and in case of small aortic annulus to reduce cross-clamp time  | B                 | IIa                        | 55               | 38      | 3         | 3          | 0                   | 29                   |
| Preoperative CT scan recommended   | C                 | I                          | 14               | 7       | 62        | 14         | 3                   | 29                   |
| Intraoperative transoesophageal echocardiography recommended   | C                 | I                          | 86               | 14      | 0         | 0          | 0                   | 29                   |
| Suitable annular sizes (after decalcification) 19–27 mm  | C                 | I                          | 59               | 41      | 0         | 0          | 0                   | 29                   |
| Oversizing with sutureless valves is not beneficial and can have negative impact   | C                 | I                          | 78               | 22      | 0         | 0          | 0                   | 27                   |
| Contraindication for bicuspid valve type 0   |                   |                            | 18               | 32      | 14        | 36         | 0                   | 28                   |
| Implantation possible in bicuspid valves type 1 and 2 if coronary ostia do not have 180° position, annulus round   | C                 | IIa                        | 38               | 54      | 4         | 4          | 0                   | 24                   |
| uniform height of the commissures (Type 2)   |                   |                            | 28               | 45      | 21        | 7          | 0                   | 29                   |
|  |                   |                            | 34               | 52      | 14        | 0          | 0                   | 29                   |
|  |                   |                            | 38               | 41      | 10        | 10         | 0                   | 29                   |
| Contraindication for annular abscess or destruction due to infective endocarditis  | C                 | III                        | 45               | 24      | 14        | 17         | 0                   | 29                   |
| Careful but complete decalcification of the aortic root is recommended to avoid paravalvular leakage; extensive decalcification should be avoided not to create annular defects  | C                 | I                          | 79               | 17      | 3         | 0          | 0                   | 29                   |
| Recommendation of proximal anastomoses of concomitant CABG during single aortic cross-clamp period   | C                 | I                          | 52               | 17      | 31        | 0          | 0                   | 29                   |

CT: computer tomography; CABG: coronary artery bypass grafting.

Perceval sutureless valve, the ATS 3f Enable Bioprosthesis and the Edwards Intuity valve.

## Recommendations on programmes for sutureless and rapid deployment valves

Generally, the experts identified recommendations for the adoption of sutureless and rapid deployment of valves in a pre-existing cardiac surgery programme as well as for the education of young surgeons. All sutureless valves require some special preparation steps prior to implant such as, for example, washing procedures, assembling or even crimping into delivery systems. Proper training of all members of the surgical team therefore is necessary (Level C, Strength I). Furthermore, on an institutional basis, a short learning curve has to be taken into account [27, 28]. Since additionally specific features of the three available valves have to be respected in terms of the indication, valve choice, sizing, height and type of aortotomy, the experts recommend proper education and proctoring by experienced surgeons for the introduction of a sutureless valve programme to avoid complications (Level C, Strength I). Since sutureless valves require surgical access to the aortic root with resection of the aortic valve and decalcification, extracorporeal circulation and in all of the cases also aortic cross-clamping have to be performed. In terms of a teaching policy, since sutureless valves guarantee the implantation of prosthesis with a short cross-clamp time [29–31], these valves should be considered as valves of choice to teach young surgeons, but of course they should be versatile to implant traditional valves prior to this procedure (Level C, Strength IIa).

## Indication and contraindication

The indication and contraindication for sutureless and rapid deployment valves first of all follow the general recommendations for the choice of biological stented prostheses in aortic valve replacement, according to the current guidelines [1, 31]. Since current recommendations focus on patients at an age of 65 years or older to be candidates for biological valve replacement, the experts also recommend to consider sutureless and rapid deployment valves for patients older than 65 years. All concepts in aortic valve replacement, which include resection of diseased valves and decalcification of the aortic annulus, require extracorporeal circulation, aortic cross-clamping and myocardial protection. Compared with trans-femoral and transapical TAVI, the main benefits of sutureless and rapid deployment valves can be found in creating a round, smooth annulus to safely fix a valve prosthesis with maximal orifice area, almost without the risk of paravalvular leakage, migration or damage to conduction system and coronary ostia. Conventional approaches carry certain risks of myocardial infarction due to insufficient myocardial protection and systemic inflammatory response syndrome due to the extracorporeal circulation system. Consequently, reduced cross-clamp and extracorporeal circulation times may lower both risks [32]. Sutureless valves have definitely proved to be able to shorten cross-clamp time to less than 20 min [11] in experienced hands while, in a recent systematic review, pooled CPB and cross-clamp duration for isolated AVR was 56.7 and 46.5 min, respectively [33]. Likewise, when compared with those for conventional aortic valve replacement, aortic cross-clamp and cardiopulmonary bypass times were reduced with the rapid deployment valve in the CE-mark study [16]. Furthermore, the Edwards Intuity rapid deployment valve by the minimally invasive surgery setting was associated with

significantly reduced myocardial ischaemic time and better valvular haemodynamic function than full-sternotomy aortic valve replacement with a conventional stented bioprosthesis in a randomized controlled trial [26].

Different non-randomized studies could demonstrate significantly shorter procedural times when compared with conventional stented valve prostheses in both conventional [29–31] and minimally invasive [34] surgical approaches.

On the basis of recent results from publications comparing sutureless valves with stented valves [20, 26, 29, 30, 35] and on their expert opinions, the panel recommends to use sutureless and rapid deployment valves as an alternative to stented valve prostheses for isolated procedures in patients with comorbidities, delicate aortic wall conditions as calcified root, porcelain aorta or prior implantation of aortic homograft and stentless valves (Level C, Strength IIa) as well as for concomitant procedures and small aortic ‘roots’ (Level B, Strength IIa). In particular, in the presence of concomitant procedures [15, 21, 31, 36–39], sutureless valves should be considered as the prosthesis of first choice to reduce complications and morbidity associated with the duration of extracorporeal circulation and cross-clamp time (Level B, Strength IIa).

Limited access may be a problem in case of redo procedures since extensive adhesions may lead to distortion of cardiac structures. Same conditions may occur in patients with extensive calcification of the ascending aorta not eligible to be candidates for TAVI due to calcification of the femoral vessels, high risk of embolization or other conditions. Such complications, together with possible technical problems in myocardial protection, result in a well-known increased risk of redo valve surgery when compared with primary surgery, both including prior aortic valve and coronary artery surgery [40–42]. Various reports have been published to demonstrate the feasibility and the clinical benefit of the use of sutureless and rapid deployment valves as a redo procedure after previous aortic valve replacement or coronary artery bypass grafting [43] or as a valve-in-valve procedure in calcified aortic homografts [44, 45]. The expert panel, therefore, recommends sutureless and rapid deployment valves in case of redo operations due to prior aortic valve replacement, coronary artery bypass grafting or delicate aortic wall conditions as calcified root and porcelain aorta [46, 47] (Level C, Strength IIa). TAVI recently has been established for the treatment of failed bioprostheses in aortic position as a valve-in-valve procedure [48–50]. However, the procedures are challenging and requiring special measures for appropriate planning [51]. In case of previous implantation of aortic homografts of stentless valves [52], the use of sutureless valves as a special ‘valve in valve’ fashion may be a life saving procedure. Sutureless and rapid deployment valves may even be chosen as a rescue procedure in cases with failed TAVI. Yet in the contrary setting, only case reports are available on valve-in-valve procedures in previously performed sutureless or rapid deployment valves [52, 53].

Special considerations have to be taken into account for the use of minimally invasive approaches in aortic valve replacement. A separate panel of dedicated experts resulting in a different consensus paper has addressed these considerations.

The experts identified annulus sizes of less than 19 mm as too small for the implantation of sutureless and rapid deployment valves since annulus enlargement procedures would be necessary, due to size limits of the current available prostheses (Level C, Strength III). However, since these procedures may be time-consuming and the implantation of patch material in the aortic annulus may result in less stability to anchor a self-expanding

valve, root enlargement procedures should be avoided if sutureless or rapid deployment valves are considered. On the other hand, since available prostheses are limited to an annular size of 27 mm, and since no suture material on the annular level might reduce annulus size, the use of sutureless and rapid deployment valves is currently limited to annular sizes of 19–27 mm. In case of degenerative aortic regurgitation with annuloaortic ectasia, the experts recommend not to use a sutureless or rapid deployment valve to prevent valve migration (Level C, Strength III). However, since sutureless valves demonstrated to reduce the risk of patient-prosthesis mismatch after aortic valve replacement in a recent prospective cohort study [54], these valves should be chosen as an alternative to stented valves in case of small aortic annulus. Also the contraindications follow general recommendations of the current guidelines in terms of aortic valve replacement in general and the implantation of biological prostheses in particular [1, 32]. The experts generally recommend sutureless and rapid deployment valves to provide a more curative treatment to patients 'in the gray zone' of intermediate to high risk [8–10] and to fill the gap between TAVI and traditional AVR.

Additionally, there are some specific considerations for sutureless and rapid deployment valves depending on specific implantation features:

- (i) The Edwards Intuity Elite Valve requires an aortotomy that usually crosses the sinotubular junction down in the non-coronary sinus; this enables a good access to the annulus with easy excision of the valve and appropriate (defensive) decalcification of the annulus. As the fixation of the valve is in the sub-annular region, the aortic wall around the aortotomy remains flexible enough to facilitate easy closure. Repositioning of the valve is not recommended by the company but is principally possible.
- (ii) The Perceval sutureless valve requires a transverse aortotomy ~1 cm above the sinotubular junction—and thus slightly higher, compared with traditional valve techniques. The prosthesis can be collapsed for implantation, resulting in good visibility of the annulus during valve positioning especially in smaller aortic roots. Additionally, repositioning is easily possible, even if the manufacturer does not recommend it.
- (iii) The ATS 3f Enable Bioprosthesis requires even a much higher aortotomy and positioning may be tricky and unpredictable, which is not user-friendly. While some surgeons have reported excellent implant results with this prosthesis, the lack of reproducibility of good positioning among the broader cardiac surgical community might have contributed to the withdrawal of the 3f Enable Bioprosthesis from the market recently. Also, the ATS 3f Enable Bioprosthesis could be repositioned during implantation procedure.

Owing to the design of the prostheses, the Perceval sutureless valve and the ATS 3f Enable bioprosthesis should not be chosen if there is a severe discrepancy of annular dimensions and sinotubular junction. To enable proper planning, the experts identified a high standard of preoperative imaging as a central precondition for proper patient selection and procedure planning which should be applied the same way as for TAVI procedures. Therefore, a preoperative thoracic aortic computer tomography (CT) scan is generally beneficial besides the classical diagnostics such as trans-thoracic echocardiography and coronary angiography used to verify the indication (Level C, Strength I). This way the ascending aorta can be displayed and a proper planning of aortotomy with

respect to annular diameter can be performed [54–57], as well as a proper size estimate and a closer analysis of the extent of calcification of the ascending aorta [58]. Additionally, CT scan is useful for the location of coronary ostia, the definition of the aortic root geometry, especially with respect to the relationship between aortic annulus and sinotubular junction, as well as for the identification of the type of bicuspid valve, if present.

Bicuspid valves, however, do not represent a contraindication in all cases. Bicuspid valves are contraindicated if no raphe (Type 0 according to Sievers *et al.*) is present [59] revealing a Level C, Strength III recommendation. In case of Type 1 bicuspid valve with one raphe, sutureless and rapid deployment valves can be used; likewise, Type 2 bicuspid valve with two raphe is indicated if the two commissures have approximately the same height (Level C, Strength IIa).

Despite occasional reports on the use of sutureless and rapid deployment valves [45, 60] and according to the recommendations of current guidelines [1, 32], the panel experts do not recommend the use of sutureless valves in endocarditis with annular abscess or destruction since usually defects in the aortic root or annulus remain even after proper debridement of the infected structures (Level C, Strength III).

Intraoperative transoesophageal echocardiography (TOE) is useful in all cases of sutureless and rapid deployment valves to verify proper systolic and diastolic function of the implanted valve, and to verify left ventricular wall motility reflecting unchanged coronary perfusion, regardless of the nature of valve disease and the personal experience, also according to the current recommendations for TAVI [61]. TOE should be started prior to the induction of cardiopulmonary bypass with documentation of valve pathology, ventricular function and associated valve pathologies, and must be performed both during weaning from cardiopulmonary bypass and at the end of the operation [62] (Level C, Strength I).

## Aspects of operative technique

The experts identified several recommendations based on specific surgical aspects to be addressed when planning the implantation of a sutureless or rapid deployment valve when compared with the procedure in case of the implantation of stented valves.

Decalcification of the aortic annulus should be performed completely to avoid paravalvular leakage; sutureless valves have proved their superiority in terms of the occurrence of paravalvular leakages when compared with TAVI especially due to the resection of deposits of calcium on the annular level [8, 63, 64]. However, as in stented valve prostheses, extensive decalcification is not recommended to avoid postoperative annular ruptures with the risk of bleeding (Level C, Strength III).

Sizing is a crucial step in the management of sutureless and rapid deployment valves to avoid paravalvular leakages, central aortic regurgitation, dislodgement and valve migration as well as annular rupture. Therefore, oversizing is neither necessary nor recommended (Level C, Strength III). Adequate valve placement has already shown excellent haemodynamic results in short [23, 37, 38] and medium-term study [64] and improved haemodynamics when compared with stented valve prostheses [29]. Additionally, sutureless valves have demonstrated to reduce patient-prosthesis mismatch [54]. Intraoperative sizing is necessary after decalcification to verify annulus size, as well as the assessment of the proportion of the aortic annulus versus the sinotubular junction when the

Perceval sutureless valve and ATS 3f Enable Bioprosthesis [21] are chosen.

The exact evaluation of the aortic root with respect to the proportion of aortic annulus and sinotubular junction has implications for the planning of concomitant procedures. Owing to the specific requirements for the aortotomy especially in terms of sizing and anchoring, and to avoid partial clamping of the often delicate aortic wall, the experts recommend to perform proximal anastomoses of concomitant coronary artery bypass grafts during the same aortic cross-clamping period. However, this increases cross-clamp time, so in cases, when anatomically possible and surgically necessary, side clamping is also justified based on the individual operative situation (Level C, Strength IIa).

In fact, the use of sutureless valves and rapid deployment valves in case of combined procedures has shown to have positive impact on the reduction of cross-clamp time and consequently on the risk of comorbidity and mortality [21, 36]. In case of multiple valve procedures, since retractors used for mitral valve reconstruction or replacement may result in distortion or malpositioning of a sutureless or rapid deployment valve, the experts recommend to remove the native aortic valve prior to the mitral procedure and to implant the sutureless aortic valve after reconstruction of the mitral valve. In case of replacement of the mitral valve, the subannular region has to be rechecked. Owing to the short subannular section of the currently available sutureless and rapid deployment valves, the implantation is possible in experienced hands [36, 65–67]. Also triple valve surgery is possible.

### Short- and medium-term results

The experts found evidence for reduced intensive care unit (ICU) and hospital stay [30] after the use of sutureless valves from propensity-matched score analysis when compared with stented aortic valve prostheses or TAVI [68]. Since postoperative complications contribute to prolongation of both ICU and hospital stay, the experts identified reduced ventilation times, reduced blood transfusion rates, lower incidence of atrial fibrillation and pleural effusions [30], as possible reasons for improved overall outcome. However compared with standard valve bioprosthesis replacement, there is an increased incidence in pacemaker with the Perceval valve (8%) [69].

Studies evaluating TAVI showed an increased rate of paravalvular aortic insufficiency when compared with sutureless and rapid deployment valves [8]. Multivariate analysis showed sutureless aortic valve replacement to have statistically less significant aortic regurgitation, pacemaker implantation and renal replacement therapy compared with transapical TAVI [64]. At a 24-month follow-up, overall survival free from major adverse cardiac and cerebrovascular events and prosthetic regurgitation was significantly better ( $P < 0.05$ ) after sutureless valve implantation ( $91.6 \pm 3.8\%$ ,  $n = 53$ ) than after TAVI ( $70.5 \pm 7.6\%$ ,  $n = 55$ ) [70]. A multicentre study with retrospective analysis of 314 patients demonstrated 1-year survival of 90.5%, and freedom from valve-related mortality, stroke, endocarditis and reoperation of 99.0, 98.1, 99.2 and 98.3%, respectively [71]. Owing to the lack of long-term studies, no recommendation for late outcome with respect to valve durability may be given yet. So far, 5-year data of the ATS 3f Enable Bioprosthesis and of the Perceval sutureless valve have showed excellent results in terms of haemodynamics, freedom from structural valve deterioration and valve-related reoperation. For ATS 3f Enable Bioprosthesis in 141 patients at 5 years [72] and for Perceval in a cohort of over 700

patients with 5-year follow-up coming from three consecutive clinical trials recently presented by Shrestha *et al.* [69] during the EACTS Annual Meeting in 2014, freedom from structural valve deterioration reported was 100%. The longest published follow-up for the Edwards Intuity valve to date is of 3 years, in a cohort of 287 patients [70] with no cases of structural valve deteriorations reported. As the valvular component of the Intuity valve is identical to the Magna valve a comparable excellent durability can also be expected for this prosthesis.

The experts recommend the use of sutureless and rapid deployment valves to reduce perioperative and medium-term morbidity (Level B, Strength IIa). Owing to reduced morbidity, it was shown that the use of Perceval sutureless valve was also associated with shortened postoperative ICU and total hospital stay, with relevant reduced hospital costs by ~25% [30].

Regarding mortality, some evidences have shown how the use of sutureless and rapid deployment valves can be associated with excellent early survival, especially in high-risk patients [71] (Level B, Strength IIb). The experts found no evidence and could therefore give no recommendation for the effect of sutureless and rapid deployment valves in terms of prosthetic valve endocarditis, or other hospital-acquired infections. The experts did not give specific recommendations on the use of anticoagulation or antiplatelet therapy after the implantation of sutureless and rapid deployment valves. The institutional protocol on bioprosthetic valves should be followed.

### CONCLUSIONS

In conclusion, sutureless and rapid deployment valves represent an alternative to stented valves in isolated and combined aortic valve replacement for aortic stenosis, based on the published information available by December 2014. With a short learning curve, which has to be taken into account when starting a programme, the implantation of sutureless and rapid deployment valves is an easy, reproducible and safe procedure. Moreover, since these valve prostheses have been introduced to facilitate safe and effective implantation of aortic biological valve prostheses in a rapid fashion using modern deployment techniques, their use provides an almost curative treatment to patients with intermediate to high risk and is suitable to fill the gap between TAVI and traditional AVR. It provides excellent haemodynamic results together with reduced morbidity resulting in shortening of hospital stay, and even reduction of costs depending on the reimbursement system. The international experts recommend various aspects of sutureless and rapid deployment technology, which may represent a further step forward in aortic valve replacement for patients requiring a biological valve. However, prospective randomized studies and large-scale registries with high data quality and appropriate long-term follow-up will have to confirm the benefit of sutureless and rapid deployment valves with subsequent update of the given recommendations.

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