REVIEW

Tricuspid valve and percutaneous approach: No longer the forgotten valve!

Valve tricuspide et traitements percutanés : décidément plus la valve oubliée !

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Summary Tricuspid valve disease is mainly represented by tricuspid regurgitation (TR), which is a predictor of poor outcome. TR is usually secondary, caused by right ventricle pressure or volume overload, the leading cause being left-sided heart valve diseases. Tricuspid surgery for severe TR is recommended during left valve surgery, and consists of either a valve replacement or, most often, a tricuspid repair with or without prosthetic annuloplasty. When TR persists or worsens after left valvular surgery, redo isolated tricuspid surgery is associated with high mortality. In addition, a sizeable proportion of patients present with tricuspid surgery deterioration over time, and need a reintervention, which is associated with high morbi-mortality rates. In this context, and given the recent major breakthrough in the percutaneous treatment of aortic and mitral valve diseases, the tricuspid valve appears an appealing challenge, although it

Abbreviations: BP, bioprosthesis; CT, computed tomography; IVC, inferior vena cava; NYHA, New York Heart Association; RA, ring annuloplasty; RVP, rapid ventricular pacing; TEE, transoesophageal echocardiography; THV, transcatheter heart valve; TR, tricuspid regurgitation.

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Background

Dysfunction of a native or previously operated tricuspid valve encompasses a variety of situations, which are frequently sources of difficulty in patient management. Tricuspid disease is most often tricuspid regurgitation (TR), which is mainly secondary to left-sided heart valve disease [1]. Tricuspid valve disease has long been ignored, with the belief that TR would improve after surgical correction of left valve disease. A large body of evidence now supports the negative effect of significant TR, and this recognition has led to more frequent indications for combined tricuspid surgery, with the inherent risk of subsequent dysfunction of tricuspid repair or replacement [2,3]. Whatever the clinical context, redo tricuspid valve surgery is often associated with high morbi-mortality rates. Following the recent development of transcatheter therapies for aortic and mitral valve diseases, the possibility of lower-risk tricuspid valve intervention is therefore particularly attractive.

This review presents current status and perspectives regarding transcatheter therapies for tricuspid valve disease, both for bioprosthesis or ring annuloplasty failure and for native valves.

Rationale for percutaneous treatment of tricuspid valve disease

Native tricuspid valve disease can be either stenotic or regurgitant. The extremely rare stenotic lesions, caused mainly by rheumatic fever or carcinoid syndrome, will not be addressed in this paper. The most common disease of the tricuspid valve is regurgitation, which is more often secondary rather than caused by a primary valve lesion, particularly in Western countries [1]. Secondary TR is caused by annular dilatation and increased tricuspid leaflet tethering in relation to right ventricular pressure and/or volume overload [4]. Pressure overload is most often caused by pulmonary hypertension resulting from left-sided heart disease or, less frequently, pulmonary disease, while right ventricular volume overload is observed in left-to-right shunts or intrinsic disease of the right ventricle.

TR has a strong negative effect on outcomes [5–8]. In a study of more than 5200 patients followed for longer than 5 years [5], both moderate and severe TR were associated with increased mortality. Moderate TR may indeed worsen during long-term follow-up after surgery for left-sided valvular disease, and is also associated with decreased
survival [9]. Similarly, residual significant TR after mitral surgery was responsible for a four-fold increase in late mortality in a recent study [10]. However, management of these patients with isolated severe functional TR after previous left-sided valvular surgery is difficult because of the inherent risk of redo interventions. Indeed, operative mortality was 15% in a series of 82 patients undergoing tricuspid surgery, of whom 73% had had previous left-sided heart surgery [11].

Tricuspid annuloplasty is effective in reducing the severity of functional TR, improves right ventricle geometry and function, and has a favourable effect on mortality [12–18]. Tricuspid valve replacement is usually limited to anatomy unsuitable for repair. Guidelines recommend the consideration of wide indications for combined tricuspid surgery in patients undergoing left-sided heart valve surgery [2,3]. However, a number of patients now present with late prosthetic dysfunction after tricuspid repair or replacement. After previous tricuspid valve surgery, recurrence of moderate or severe TR may be as high as 60% at 5 years [19], and reoperation is necessary in approximately 20% of patients within 10 years after tricuspid valve surgery [20]. While redo surgery is the treatment of choice for a degenerated bioprosthesis (BP) or deterioration of ring annuloplasty (RA), it may be associated with a very high mortality rate [21–24], reaching 35% at 30 days [25], particularly in patients with co-morbidities [16,20].

Uncertainties concerning the risk–benefit ratio of surgery in severe functional TR or dysfunction after tricuspid surgery therefore justify the search for less invasive approaches.

Since its first steps [26], the efficacy of transaortic valve implantation has led over time to transition to valve-in-valve implantation for a failing aortic BP and, more recently, for mitral BP and RA deterioration, with favourable immediate and mid-term outcomes [27,28]. Tricuspid valve-in-valve and valve-in-ring implantation may therefore present a new therapeutic option. More recently, transcatheter repair techniques have been described to correct functional TR in native valves.

Tricuspid bioprosthesis, ring annuloplasty and percutaneous interventions

Transcatheter heart valve (THV) implantation has recently been reported for the treatment of a degenerated tricuspid BP or failure of RA [29–49].

Whereas the technique for valve-in-valve shares features with procedures for aortic or mitral valves, the valve-in-ring implantation presents specific challenges because of the tricuspid position [30].

Tricuspid bioprosthesis failure and valve-in-valve implantation

Prosthesis measurements

One of the main difficulties associated with the procedure is the proper evaluation of prosthesis size. For tricuspid BP, as for aortic or mitral valve-in-valve, the prosthesis size may be derived from an integrated approach, taking into account the manufacturer’s inner diameters and the mean diameter determined by computed tomography (CT), three-dimensional transoesophageal echocardiography (TEE) and fluoroscopy. Whenever possible, the three available techniques should be used systematically in the absence of recommendations for the assessment of prosthesis size (Fig. 1). However, given the round shape of the prostheses, and based on the experience of the centre, a reliable CT scan measurement may be sufficient. Based on our experience, fluoroscopy usually provides the largest dimensions while TEE gives the smallest ones [30].

Transcatheter heart valve implantation procedures

The routes reported so far for tricuspid implantations have been mainly transatrial or transjugular accesses [29,32–34,36,37,40,42,43,46,48,49]. However, the transfemoral route has also provided good results, confirming the technical feasibility of this approach [30,31]. The
avoidance of a thoracotomy, with its potential complications, is deemed desirable given the high-risk profile of the candidates regarding such techniques. In the published transfemoral approach series of the Bichat centre, no technical difficulty was observed [27].

In our institution, transfemoral procedures are performed under general anaesthesia and TEE guidance. After crossing the tricuspid valve, a J-shaped guidewire is placed at the apex of the right ventricle (Fig. 2); then, an Edwards SAPIEN™ XT valve (and more recently the SAPIEN™ 3 valve) (Edwards Lifesciences, Irvine, CA, USA), mounted upside down on the catheter, is deployed by slow balloon inflation under rapid ventricular pacing (RVP) (140–180 beats per minute). RVP is performed using either a temporary lead in the left ventricle or in the coronary sinus, or using a permanent pacemaker implanted before the procedure (Fig. 3). Predilatation of the BP should be avoided as often as possible to prevent the risk of cusp rupture or embolization, although their consequences are less severe than for left-sided valves. The results are assessed in the catheterization

Figure 2. Transcatheter heart valve (THV) implantation in a degenerated bioprosthesis in the tricuspid position. A. After the tricuspid bioprosthesis valve has been crossed with a Judkins right diagnostic catheter or a balloon flotation catheter, a stiff wire is placed at the apex of the right ventricle. B. The THV is placed within the tricuspid valve and inflated using rapid ventricular pacing. Final result after tricuspid valve-in-valve implantation in the catheterization laboratory (C, D) and using computed tomography (E, G) and computed tomography three-dimensional reconstruction (F, H, I).

Figure 3. Different options for rapid ventricular pacing when implanting a valve-in-valve or valve-in-ring in the tricuspid position: (A) lead in the coronary sinus; (B) lead in the left ventricle; and (C) epicardial pacemaker.
Percutaneous implantation of tricuspid valve diseases

A number of cases and series have also been published using the Edwards SAPIENTM valve [29, 31–34, 36, 39–44, 46, 47, 49]. A recent review of the literature [52] reported eight case reports using the Edwards SAPIENTM valve in patients aged 8–74 years. All procedures had good results without complications, and the valve performance after implantation was good, similar to the results of the series with Melody® valve implantations [45], but the mean reported follow-up was only 3 months.

A recent series of 16 patients implanted between 2008 and 2014 has been published with both the Melody® valve (n = 7) and the Edwards SAPIENTM valves (SAPIENTM XT 26, n = 4; SAPIENTM XT 29, n = 6) [53]. The procedural success reached 100% in this series of young patients (median age 31 years), most of whom had congenital heart disease (14 patients) and only two of whom had an initially acquired tricuspid dysfunction.

In Bichat hospital, we implanted four patients with a BP failure, all of whom had acquired tricuspid dysfunction (three of rheumatic origin and one endocarditis) (unpublished results). This was a very different population compared to patients with congenital heart disease, with a mean age of 56 years, and all patients were implanted with an Edwards SAPIENTM XT valve (26 mm, n = 2; 29 mm, n = 2). Of these four patients, two were already tridux, one was already redux and the last patient had a history of drug use and infective endocarditis. For the degenerated BP, two had stenotic impairment, and two had both regurgitant and stenotic BP failure. The procedural success was 100% with no conversion to surgery. During in-hospital follow-up, two complications occurred: one major gastrointestinal bleeding related to oesophageal ulceration and one severe vascular complication needing surgical management as a result of venous subcutaneous bleeding at the puncture site. No other complication occurred at 30-day follow-up.

Both the Melody® valve and the Edwards SAPIENTM XT valve seem to give good results for THV implantation in the tricuspid position. However, given the small sizes available for the Melody® valve (maximal diameter of 22 mm), it may be less adequate for adult patients with acquired valve disease. In our series, for example, the sizes of the failed BPs were between 25 and 31 mm, which is not compatible with Melody® valve implantation. Moreover, larger studies with a longer follow-up need to be conducted to assess whether the risk of infective endocarditis is really more important with the Melody® valve.

Choice of valve: Melody® or Edwards SAPIENTM?

THV implantation in a degenerated tricuspid BP has been reported using two different valves: the Melody® valve (Medtronic, Minneapolis, MN, USA) and the Edwards SAPIENTM valve.

A series of 15 Melody® valve implantations in bioprosthetic tricuspid valves in patients with a median age of 31.5 years, most of whom had congenital heart disease, reported good results [45]. The valve was successfully placed in all patients and the median follow-up was 4 months. Complications were one death in a patient with preprocedural multiorgan failure, one third-degree atrioventricular block requiring pacemaker implantation and one case of endocarditis 2 months after implantation. However, recent concerns have been raised regarding the increased risk of infective endocarditis in the Melody® valve, although mainly in the pulmonary position [50, 51].

Rapid ventricular pacing: specificities for tricuspid transcatheter heart valve implantation

For THV implantation in the tricuspid position, RVP should not be performed via a temporary right ventricular pacing lead, should the lead be jailed or damaged during the procedure. Several other strategies may be proposed [31, 34, 49].

For patients with a previous permanent pacemaker, RVP may be performed using the latter. Implantation of an additional lead in the coronary sinus may also be discussed to prevent any adverse event.

When the patients do not have a pacemaker, the different options for RVP are either a temporary lead in the coronary sinus.
sinus or in the left ventricle, or direct pacing using the wire at the apex of the right ventricle and crocodile forceps.

In some particular cases, when the risk of pacemaker implantation is very high, a permanent epicardial pacemaker may be proposed before the procedure. These options are feasible without major difficulties and the choice must be individualized to patients’ characteristics (Fig. 3).

Annuloplasty rings failure: specificities of valve-in-ring implantation

All the challenges previously described for valve-in-valve implantation also apply to valve-in-ring procedures. Additionally, tricuspid annuloplasty rings present some specific difficulties.

Annulus measurements

Prosthesis sizing is particularly difficult for prosthetic tricuspid rings, which are non-circular, as illustrated in Figs. 1 and 4, and surrounded by valvular tissue that cannot be detected by CT scan or fluoroscopy. In this setting, it is therefore mandatory to systematically use the three available techniques (CT scan, TEE and fluoroscopy) to determine the most appropriate size of prosthesis by using an integrated approach. The aim is to implant the valve with the diameter that is closest to the mean inner diameter of the ring, to avoid over- or under-valve expansion.

Moreover, careful balloon sizing at the beginning of the procedure may be used to help determine the annulus dimension more precisely [54].

Valve-in-ring implantations: mind the gap!

Only three case reports have been published so far with the Edwards SAPIEN™ valve, using the transatrial [42] and transfemoral [55,56] approaches.

A recent series of three valve-in-ring implantations with an Edwards SAPIEN™ XT valve through the transfemoral approach has been published [30]. The sizes of the failed RAs were between 30 and 32 mm, allowing for implantation of three 26 mm Edwards SAPIEN™ XT stents. The authors reported one patient with a moderate-to-severe residual regurgitation immediately after the procedure, in a rigid and incomplete ring (Carpentier-Edwards Classic Ring; Edwards Lifesciences, Irvine, CA, USA). The regurgitation was caused by a paravalvular leak at the level of the open portion of the ring. Another patient had mild post-procedural paravalvular regurgitation, in the same type of rigid and open ring.

In a recent case report, a 22 mm Melody™ valve was implanted in a 26 mm failed RA in a 21-year-old young women [54]. A severe paravalvular leak occurred in the region where the tricuspid ring was incomplete. This case also concerned a Carpentier-Edwards Classic tricuspid annuloplasty ring. The authors report the successful closure of the paravalvular leak using an AMPLATZER™ Vascular Plug II (St. Jude Medical, St. Paul, MN, USA), with only a mild residual leak as the final result [54].

The presence of a prosthetic ring has the advantage of providing the fluoroscopic landmarks and necessary anchoring for a percutaneous valve, but also has the drawback of creating a non-circular landing zone, with the inability to completely seal the open segment with the THV, and inducing underexpansion of the transcatheter valve in the small diameter of the ring. These findings are more likely to appear with the Carpentier-Edwards Classic tricuspid rings, which are rigid, making it difficult to circularize this type of ring (Fig. 4).

Residual TR is, however, probably less clinically relevant than in the mitral or aortic position. Indeed, we reported a sustained improvement in the functional status of the patient with severe paravalvular regurgitation, who was in New York Heart Association (NYHA) class II at 1-year follow-up [30].

THV implantation should, however, be considered with caution in these particular rigid and open rings. In this setting, semirigid or flexible rings are more favourable as they are easier to circularize during prosthesis deployment, which limits paravalvular regurgitations. However, they are used less often in the tricuspid position.

These emerging techniques of valve-in-valve and valve-in-ring interventions are currently limited to extremely high-risk patients; until now, 150 patients have been treated around the world. These new percutaneous treatments have been proposed for two very different populations: young patients with congenital heart diseases who have already been operated on several times, or older patients with co-morbidities and acquired valve disease who are exposed to the risk of a redo surgery at least. In all cases, patients either had a contraindication to surgery or were considered at very high-risk after evaluation by the heart team.

Given the limited experience with THV implantation in the tricuspid position, the patients who benefit from these techniques should have a close follow-up, including at least an annual visit with TEE and CT scan evaluation in the centre where they were implanted. It is mandatory to ensure that the implanted prosthesis remains functional over a number of years, without any deinsertion, deterioration or thrombosis, before considering larger indications in the future.

Native tricuspid valve

Valve-in-native valve implantation

Besides tricuspid valve-in-valve and valve-in-ring in failed BP or RA, Kefer et al. reported the first case of THV implantation in a native tricuspid valve [57]. The patient was a 47-year-old woman with congenital heart disease who was already truidx. She had had, in addition to mitral valve replacement and aortic valve replacement, three tricuspid valve repair interventions, but without any RA. Her native tricuspid valve was both stenotic and regurgitant. There was no rigid target zone to anchor the percutaneous valve and no fluoroscopic marker to help THV implantation. Therefore, preseating was performed with two covered 34 mm CP STENTS™ (NuMED, Hopkinton, NY, USA) to create a rigid landing zone. An Edwards SAPIENTM valve (26 mm) was implanted through the transfemoral approach, under general anaesthesia, with fluoroscopic and three-dimensional TEE guidance. Of note, the procedure was performed under extracorporeal membrane oxygenation assistance in anticipation of haemodynamic instability. The patient needed the implantation of a second 26 mm Edwards SAPIENTM valve because the position of the first valve was too low, with
important regurgitation. Finally, the result was good, with no stenosis and only a trivial central leak. At 5-month follow-up, the authors reported persistence of good clinical and haemodynamic results.

This first-in-man implantation is encouraging, but larger studies are needed to confirm the feasibility, safety and durability of this therapy.

**Caval valve implantation against severe tricuspid regurgitation**

A technique involving heterotopic placement of transcatheter aortic valves in the inferior vena cava (IVC) in patients with refractory ascites and lower extremity oedema has been described [58,59]. The aim was to reduce venous hypertension in the hepatorenal system and to protect from the systolic backflow encountered in severe TR, in end-stage patients. Short-term results showed reductions in ascites, hepatic congestion and peripheral oedema, which are encouraging, although long-term follow-up of this palliative treatment is needed. Currently, this therapy is being evaluated in "The Treatment of Severe Secondary Tricuspid Regurgitation in Patients With Advance Heart Failure With Caval Vein Implantation of the Edwards SAPIEN™ XT Valve" (TRICAVAL) study (ClinicalTrials.gov identifier: NCT02387697).

**Bicuspidization techniques: concept and first results**

The Mitralign system™ (Mitralign Inc., Tewksbury, MA, USA) was initially used for functional mitral regurgitation, and has recently been adapted for functional TR. This system mimics the surgical Kay Repair Technique leading to bicuspidization of the tricuspid valve (Fig. 5) [60], by placing pledget sutures through a transjugular venous approach. The final result is a suture supported on both the ventricular and atrial sides of the annulus, with folded pledgets.

A successful procedure was reported in an 89-year-old woman with recurrent heart decompensation caused by isolated TR [61]. The patient’s logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) was 28%, and surgical intervention was deemed too high-risk. The procedure was performed under general anaesthesia with fluoroscopy and two- and three-dimensional TEE guidance. There was a significant reduction in annular area by 57% (from 14.1 cm² to 6.05 cm²) and in effective regurgitant orifice area by 53% (from 1.35 to 0.65 cm²) as measured using three-dimensional TEE. After discharge, the patient needed continuation of her usual aggressive medical therapy, but felt better, with less oedema and improvement in renal function.

Another device, the TriCinch System™ (4TECH Cardio Ltd, Galway, Ireland), also leads to bicuspidization of the tricuspid valve (Fig. 6) [62]. The percutaneous device is specifically dedicated to tricuspid valve remodelling, by means of the fixation of a stainless steel corkscrew close to the anteroposterior commissure of the tricuspid valve. The corkscrew is connected through a Dacron band to a self-expanding nitinol stent implanted in the IVC (Fig. 6). By pulling the system towards the IVC, the anchoring corkscrew reduces the anteroposterior annulus, and the tension is maintained by positioning the stent in the IVC. The stent is available in different sizes (27–43 mm in diameter, 66 mm
in length) to guarantee oversizing in the hepatic region of the IVC.

We recently published the first-in-man implantation in a 72-year-old woman, NYHA class III, as a result of severe TR (grade 4), a 9 mm lack of coaptation and a septolateral dimension of 46 mm, according to TEE [63]. She had had a previous aortic valve replacement with a BP. The procedure was performed under general anaesthesia, with fluoroscopy, two- and three-dimensional TEE and intracardiac echocardiographic imaging guidance. The procedure used a transfemoral approach. The tip of the delivery system was successfully steered on the tricuspid annulus, and tension was applied and maintained by implantation of a 43 mm self-expanding nitinol stent in the IVC. TR was reduced from grade 4 to 3, and the septolateral dimension was reduced from 46 mm to 38 mm [63].

The results of three successful implantations performed in Milan and Paris in 2014 were presented at the last EuroPCR meeting in Paris (May 2015) [64]. The final result in one of the patients, with the stent implanted in the IVC and a reduction in tricuspid annular dimension from 41 mm to 34 mm, is illustrated in Fig. 7. Follow-up at 6 months for two patients and 3 months for the third showed improvement of at least one class in terms of functional NYHA evaluation, and a substantial improvement in the 6-minute walk test in the three patients. The reduction in septolateral dimension was maintained and the device was stable in all three patients. There was neither migration nor stent thrombosis. The PREVENT Study (Percutaneous Treatment of the Tricuspid valve Regurgitation with the Tricinch System™; ClinicalTrials.gov identifier NCT02098200) is still ongoing and is aiming to enroll 24 patients for CE marking.

Transcatheter tricuspid valve repair for severe symptomatic functional TR is still in the initial stages of development. Regarding efficacy, these new procedures only resulted in a slight reduction in TR, which may be sufficient

Figure 6. The TriCinch System™ (4TECH Cardio Ltd, Galway Ireland). A. The anchor is attached on the anteroposterior commissure. B. Tension is applied via the Dacron band in order to bicuspidize the tricuspid valve. C. Tension is maintained via a stent implanted in the inferior vena cava. Reproduced with permission from JACC Cardiovasc Interv [62].

Figure 7. Dimensions of the tricuspid annulus (A) before and (B) after the bicuspidization technique, using the TriCinch System™ (4TECH Cardio Ltd, Galway Ireland). The stent implanted in the inferior vena cava is visible on (C) the final computed tomography scan and (D) the three-dimensional reconstruction.
for symptomatic improvement in these patients. There are still many unsolved technical issues. Long-term follow-up is required to assess the durability of the device and its long-term efficacy. More patients are needed to test both the safety and the reproducibility of the procedure before wider use.

Regarding the TriCinch System™, the accurate location of the anchor on the tricuspid annulus is the most difficult step to achieve under echocardiographic guidance (even using both TEE and intracardiac imaging) in order to avoid screwing in the free wall of the right atrium (with the risk of haemopericardium) or in the right coronary artery that surrounds the tricuspid annulus. CT scan analysis before the procedure is crucial to determine the optimal target for the anchor implantation, far from the right coronary artery and the aortic root (Fig. 8).

The future has begun

As for the mitral valve, transcatheter tricuspid intervention is the natural evolution of modern tricuspid valve surgery. Currently based on bicuspidization, new technologies need to be developed to expand the possibilities of transcatheter intervention, such as edge-to-edge repairs or annuloplasty (direct or indirect), specifically dedicated to the anatomy of the tricuspid valve.

For example, the use of the MitraClip® System (Abbott Vascular, Abbott Park, IL, USA) in the tricuspid valve was first reported in one patient with corrected transposition of the great arteries, through a transjugular access [65]. In this case, the patient had an anatomically left-sided tricuspid mitral valve. This technique is currently being explored to attempt leaflet tethering and decrease functional TR in normally right-sided tricuspid valves (B. Maini, personal communication, January 2015). However, there are often wide malcoaptation gaps resulting from the important tricuspid annular dilation in severe secondary TR, and the MitraClip System may thus be a questionable solution.

Recently, initial experience with the FORMA repair system (Edwards Lifesciences, Irvine, CA, USA) has been reported at congresses (unpublished data). This new technology is designed to restore leaflet coaptation in patients with functional TR. The device consists of a spacer and a rail. The spacer is positioned into the regurgitant orifice and creates a platform for leaflet coaptation, and the rail tracks the spacer into position. Until now, the device has been implanted in seven patients with functional TR. The use of this device was associated with a mild-to-moderate reduction in TR, diuretic dose and peripheral oedema, and an improvement in quality of life. However, these results, although encouraging, are preliminary. The ongoing “Early Feasibility Study of the Edwards Tricuspid Transcatheter Repair System” (ClinicalTrials.gov identifier NCT02471807) will determine the feasibility, safety and efficacy of this new technology.

Different devices for the tricuspid valve are currently under development in preclinical trials.

The Millipede™ system (Millipede, LLC, Ann Arbor, Michigan, USA) involves the placement of a tricuspid annular ring with an attachment system via percutaneous methods to restore the native tricuspid annular shape and diameter. This device could be repositioned before deployment and may offer simpler device delivery [66].

A novel transcatheter tricuspid annuloplasty technique using transatrial pericardial access has also been published (the TRAIPTA system) [67]. This device has been successfully implanted in 16 swine, including four with secondary severe TR. Under general anaesthesia and mechanical ventilation, the TRAIPTA system is introduced through the femoral vein and pericardial access is gained via puncture of the right atrial appendage. The TRAIPTA device is then deployed circumferentially in the pericardial space to encircle the heart along the atrioventricular groove, under the guidance of pericardial contrast infusion. The contrast product is then washed out, the right atrial appendage puncture is closed and the TRAIPTA implant is then left in place permanently. No complication occurred except for moderate pericardial effusion. The dimensions of the tricuspid annulus have been significantly reduced (from 49% in the septolateral dimension and from 31% in the anteroposterior diameter). During a follow-up of 7 to 14 days, the TRAIPTA device stayed in a proper position and the pericardial effusion decreased without any drainage. So, this preclinical study shows that TRAIPTA device may be successfully positioned in the atrioventricular groove through a right atrial appendage puncture, and leads to a significant decrease in annular dimensions.

These results are encouraging, but challenges remain to be overcome before its use in humans, such as the need for a prophylactic pericardial drain and the risk of coronary compression.

The ultimate goal of transcatheter therapy is total transcatheter tricuspid valve replacement. However, the first attempts with the mitral valve highlight the numerous and specific difficulties encountered in atrioventricular valves [68]. This treatment would be applicable to patients with previous left-sided heart valve surgery who require an extremely high-risk redo isolated tricuspid surgery, but might also be feasible during transaortic valve implantation or percutaneous mitral valve implantation, to be in keeping with surgical guidelines.

Figure 8. Computed tomography scan tricuspid valve (TV) analysis with the expected ideal target for the anchoring system of the TriCinch System™ (4TECH Cardio Ltd, Galway Ireland). APC: anteroposterior commissure; ASC: anteroseptal commissure; MV: mitral valve; PSC: posteriosuperior commissure; RCA: right coronary artery.
Conclusions

In recent years, the tricuspid valve has been recognized as a challenge for new percutaneous treatments, given the combination of high-risk dedicated surgery and deterioration of surgical results over time. THV implantation is feasible in failed tricuspid surgical valves, and may improve haemodynamic and functional status. The differences in reported approaches show that there is no consensus for the best strategy in these complex procedures. Larger series and long-term follow-up are needed to better assess the role of this technique in the future. Moreover, whereas results for valve-in-valve procedures are good, paravalvular leaks occurring with rigid annuloplasty rings are a source of concern. This issue may improve in the near future with dedicated devices, which should offer longer covered lengths.

For the native tricuspid valve, preliminary results with the two bicuspidization techniques validate their feasibility. More experience is needed to assess their clinical benefit and define the best candidates. Finally, a number of other devices are in preclinical development, and there is no doubt that the next decade will see the full recognition of the tricuspid valve in the field of transcatheter treatments.

Disclosure of interest


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References


Percutaneous treatment of tricuspid valve diseases


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