Am J Cardiovasc Dis 2020;10(3):142-149
www.AJCD.us /ISSN:2160-200X/AJCD0115349

Original Article

Unsolved questions in prophylactic tricuspid valve repair and the possible role of transcatheter tricuspid intervention

Ana Paula Tagliari[1,2,3], Diego Vilela Santos[4], Eduardo Keller Saadi[3,5], Maurizio Taramasso[1], Carlos A Mestres[1,6]

[1]University Hospital of Zurich-Clinic for Cardiac Surgery, Zurich, Switzerland; [2]Postgraduate Program in Cardiology and Cardiovascular Sciences, School of Medicine, Universidade Federal do Rio Grande do Sul (UFRGS), Porto Alegre, Brazil; [3]Hospital São Lucas da Pontifícia Universidade Católica do Rio Grande do Sul (PUCRS)-Cardiovascular Surgery Department, Porto Alegre, Brazil; [4]Incor-Instituto do Coração de Natal-Cardiology Department, Natal, Brazil; [5]Hospital de Clínicas de Porto Alegre (HCPA)-Cardiovascular Surgery Department, Porto Alegre, Brazil; [6]The University of The Free State-Department of Cardiothoracic Surgery, Bloemfontein, South Africa

Received May 31, 2020; Accepted June 28, 2020; Epub August 15, 2020; Published August 30, 2020

Abstract: Tricuspid regurgitation progression after left-sided surgery and its correlation with worse postoperative and long-term outcomes is a highly debated topic. Some studies support prophylactic tricuspid repair based on annulus dimension rather than on tricuspid regurgitation severity only, while others are in favor of a more conservative management. Furthermore, the advent of percutaneous tricuspid valve intervention and its promising short-term outcomes has introduced a new factor to be taken into account on the tricuspid intervention decision-making process. We present a review on prophylactic tricuspid valve intervention, covering currently available data, as well as the role of transcatheter tricuspid valve intervention in this equation.

Keywords: Functional tricuspid regurgitation, tricuspid valve repair, transcatheter tricuspid valve intervention

Introduction

The presence of some degree of tricuspid regurgitation (TR) can be considered the most common valvular heart disease, affecting 65-85% of the population [1]. If considered only significant TR (moderate or severe), the condition is estimated to affect up to 1.6 million individuals in the United States [2], with secondary or functional tricuspid regurgitation (FTR) being responsible for almost 90% of the cases [3].

Despite this prevalence, TR was during many years a forgotten and underappreciated disease [4, 5]. One of the reasons behind TR undertreatment was the concept, postulated by Braunwald in 1967 [6] that functional tricuspid regurgitation (FTR) would improve or disappear once the primary left-sided problem was treated. Another reason was the high surgical mortality rate associated with isolated tricuspid valve (TV) intervention, which, unfortunately, remains at least partially correct, since TR carries an impactful surgical mortality (8.8%-9.7%) [7]. However, such high mortality is in part biased by the advanced stage that patients are referred to surgery, with severe right ventricle dysfunction and end-organ damage [8].

Nonetheless, up to 74% of patients submitted to a successful mitral valve (MV) repair will exhibit significant tricuspid regurgitation (TR) over more than a 3-year follow-up [9], and one half will progress by more than two grades in 4.8 years mean follow-up [10]. It is also remarkable that, while isolated TV surgery due to residual TR after MV intervention is associated with high mortality and poor outcomes [7, 11], concomitant TV repair does not increase operative mortality [10, 12].

Based on these arguments and on the fact that FTR is associated with biventricular dysfunction, poor quality of life and, ultimately,

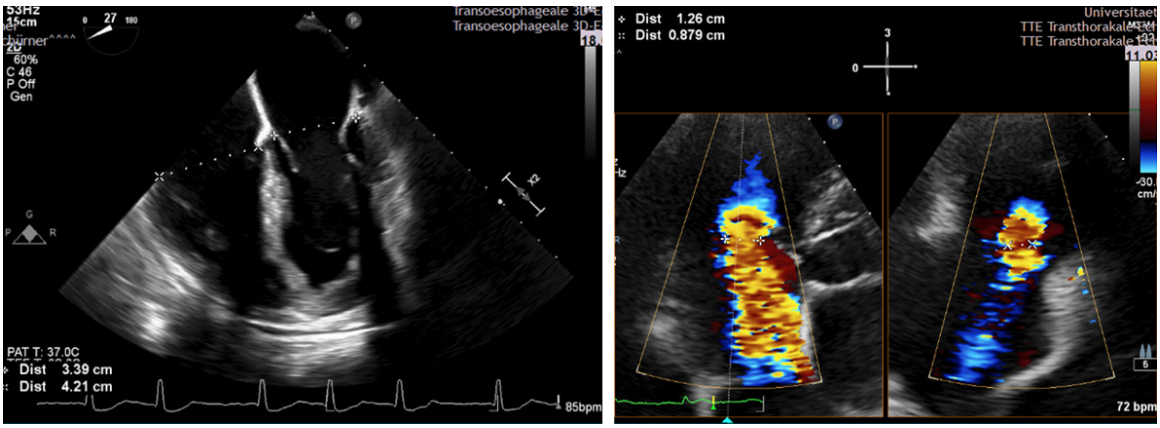

Figure 1. Echocardiographic tricuspid valve evaluation showing annulus dilatation (> 40 mm) and severe tricuspid regurgitation (vena contracta >7 mm).

death [13-15], a more aggressive TR surgical approach was suggested. Hence, the concept of treating TR based on tricuspid annulus diameter rather than TR severity was raised [10].

Prophylactic tricuspid intervention

Carpentier was one of the first authors to recommend tricuspid annular dilation as a more objective parameter to indicate TV repair. His evaluation method consisted in TV surgical exploration, checking the annulus ability to admit three fingerbreadths of the surgeon's hand, in which case TV repair would be indicated [16].

Three decades later, Dreyfus et al. evaluated tricuspid annuloplasty performed concomitantly with MV surgery in the presence of intraoperative tricuspid annular diameter ≥ 70 mm, measured from the anteroseptal commissure to the anteroposterior commissure, regardless the preoperative TR grade. In a 5-year follow-up, TR degree, as well as patients' functional status, was significantly lower in the TV treated group [10].

Regarding echocardiographic measurement, evaluating 50 patients submitted to MV replacement due to rheumatic disease, Colombo et al. suggested that tricuspid annulus diameter > 21 mm/m^2 could be a reliable parameter to indicate concomitant TV repair in this specific patient population [17].

Similarly, using a tricuspid annulus dimension ≥ 40 mm (> 21 mm/m^2) measured preoperatively in transthoracic echocardiography (TTE) 4-chamber view as a cut-off to indicate concomitant TR intervention, Van deVeire et al. demonstrated better reverse right ventricular remodeling and less postoperative TR prevalence, when compared with isolated MV surgery [18]. To illustrate, **Figure 1** shows echocardiographic TV evaluation, and **Figure 2** an TR surgical repair.

In 2012, Benedetto et al. conducted a randomized trial enrolling 44 patients with less-than-severe TR (≤ +2) and annular dilatation (≥ 40 mm) treated at the same time that MV surgery. Early results demonstrated the safety of the combined approach (1 case of 30-day mortality in each group), with just a discreet increase in cardiopulmonary bypass and aortic cross-clamping time. After 12 months, those patients who underwent TV intervention presented significant TR reduction (TR absent in 71% vs. 19%; P=0.001), improvement in functional capacity (6 min walking test: +115 ± 23 m vs. +75 ± 35 m; P=0.008), and right ventricular reverse remodeling [right ventricle long-axis 71 ± 7 mm preoperative vs. 65 ± 8 mm postoperative (P < 0.01), and short-axis 33 ± 4 mm preoperative vs. 27 ± 5 mm postoperative (P=0.01) in TV treated group; right ventricle long-axis 72 ± 6 mm preoperative vs. 70 ± 7 mm postoperative (P=0.08), and short-axis 34 ± 5 mm preoperative vs. 33 ± 5 mm postoperative (P=0.1) in TV non-treated group] [19].

Two-years after this publication, Chikwe et al. tested the association of an aggressive concomitant prophylactic TV repair (annular dilatation ≥ 40 mm or ≥ moderate TR) in patients

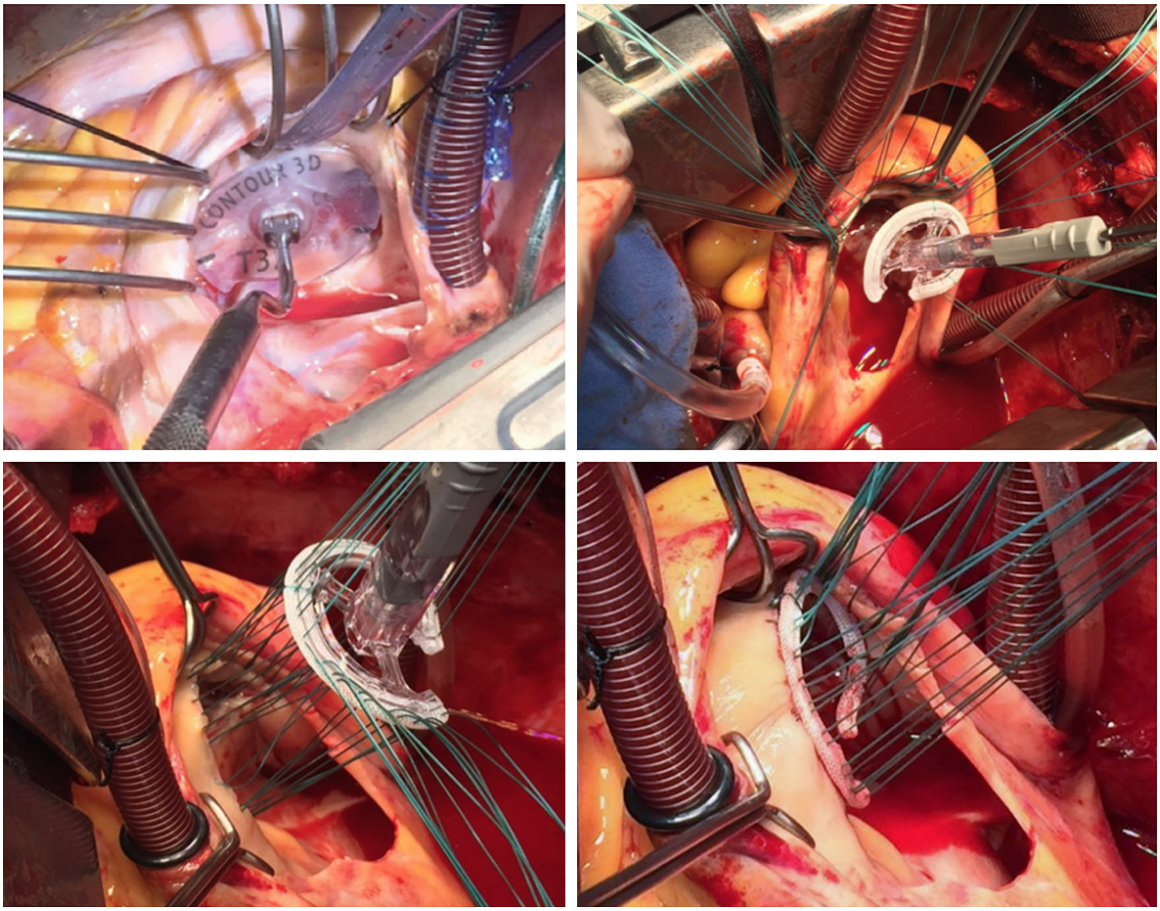

Figure 2. Tricuspid valve repair with an annuloplasty ring.

undergoing MV repair for degenerative diseases. No increased 30-day mortality and morbidity, lower TR progression rate, reduced pulmonary hypertension and improvement in induced right ventricle recovery were observed at 7-year follow-up [20].

Regarding guideline recommendations, the American Heart Association/American College of Cardiology and the European Society of Cardiology/European Association for Cardio-Thoracic Surgery have recommended TR repair concomitant with left-sided surgery in the presence of annular size ≥ 40 mm (> 21 mm/m^2), regardless of TR degree, as a Class IIa of recommendation [21, 22], which still means a low level of evidence.

Controversial information

Despite the accumulated information reported, recent articles have presented opposite results. In a single-center retrospective cohort of 312 patients undergoing MV repair for degenerative diseases, David et al. demonstrated no association between tricuspid annulus size and subsequent FTR development, with a low rate of postoperative TR (at 7 years follow-up) in patients presenting annulus size < 40 mm (6.8%, 95% CI 4.6%-10.4%), but also in those with annulus ≥ 40 mm (6.0%, 95% CI 2.9%-12.2%) [23]. The limitation of this study is that tricuspid annular size was measured intraoperatively, using transesophageal echocardiogram (TEE) under general anesthesia, while the current guidelines are based on TTE or direct intraoperative measurement. Regardless this limitation, TR prevalence was similar to that previously described by Rajbanshi et al., in whose study only 6% of patients developed severe TR at 5-year follow-up after MV repair or replacement [24].

Furthermore, no advantage in terms of TV reoperation rate (HR 0.46; 95% CI 0.10-2.07; P=0.31); congestive heart failure (HR 1.12;

95% CI 0.37-3.36; P=0.84); and death (HR 1.41; 95% CI 0.82-2.42; P=0.22) when mild-to-moderate FTR was concomitantly managed was suggested by Ro et al. [25].

In terms of possible disadvantages of combined procedures, although prophylactic TV repair has not been associated with increased mortality rate, some authors have suggested association with longer operative times [26], higher pacemaker rates [27], and longer hospital length of stay [28].

A single-center prospective randomized trial published in 2019 also showed that prophylactic tricuspid annuloplasty, performed concomitantly to MV repair in patients with less-than-severe FTR, was able to reduce FTR recurrence, but did not affect functional capacity or right ventricular remodeling. Five-year freedom from cardiac-related mortality was similar in TV treated and non-treated patients (94.1 ± 3.2% in treated-group vs. 89.7 ± 4.3% in TV non-treated; P=0.9) [29].

When this new study was included in a meta-analysis, however, the conclusions went in the opposite direction. TV repair was associated with lower cardiovascular mortality, all-cause mortality and TR progression over a median of 5.3 years of follow-up (cardiovascular mortality: RR 0.46, 95% CI 0.28-0.75; P=0.002; all-cause mortality: RR 0.68, 95% CI 0.49-0.96; P=0.03; TR progression: RR 0.26, 95% CI 0.12-0.56; P < 0.001) [30]. Likewise, when the prevalence of TR after MV repair due to leaflet prolapse at a more extended follow-up are evaluated, even David et al. showed numbers that are more concerned. A 20.8% probability of persistent or new moderate or severe TR at 20 years made the author point that maybe a much longer follow-up that those previously reported is needed to observe changes in tricuspid annulus diameter [31].

Transcatheter tricuspid valve intervention

Transcatheter tricuspid valve intervention (TTVI) has emerged as an attractive alternative approach for inoperable or high surgical risk candidates [32] who cannot be submitted to a conventional open cardiac surgery.

Current available devices are designed for different anatomical and functional purposes, as follow (adapted from Curio J et al. and Kolte D et al.) [33, 34]:

1) Leaflet approximation or coaptation [MitraClip in the Tricuspid Position or TriClip (Abbott Vascular, Santa Clara, CA, USA) (**Figure 3**), Pascal system (Edwards Lifesciences Corp., Irvine, CA, USA), TriCinch™ Coil System (4Tech Cardio, Galway, Ireland), Forma™ Repair System (Edwards Lifesciences)]; 2) Annuloplasty [Cardioband® Tricuspid Repair System (Edwards Lifesciences), IRIS Transcatheter Annuloplasty Ring (Millipede Inc., Santa Rosa, CA, USA), Trialign device (Mitralign Inc., Tewksbury, Mass., USA)]; 3) Orthotopic [GATE™ system self-expanding bioprosthesis (NaviGate Cardiac Structures, Lake Forest, CA, USA)] or heterotopic [Heterotopic caval valve implantation using the SAPIEN (Edwards Lifesciences Corp., Irvine, CA, USA), or the TricValve® (P&F Products GmbH, Vienna, Austria) systems].

Among these devices, the MitraClip in tricuspid position is one of the most frequently used. Evaluating its safety and feasibility, Nickenig G et al. reported that, in 64 patients with symptomatic severe TR considered unsuitable for tricuspid conventional surgical intervention, a successful implant (one or more clips implanted with TR reduction by at least one grade) was achieved in 97%. No intraprocedural deaths, cardiac tamponade, emergency surgery, stroke, myocardial infarction or major vascular complications were observed, with an in-hospital mortality of 5% (3 patients) [35]. Two years after this initial study, the multicenter TRILUMINATE trial evaluated the safety and the effectiveness of the TriClip device in patients with moderate or greater TR who remained symptomatic despite optimized medical treatment. Tricuspid regurgitation severity was reduced by at least one grade at 30 days in 86% of patients. No periprocedural death, conversion to open surgery, device embolization, myocardial infarction, or stroke occurred. At 6 months, 4% (3 patients) had a major adverse event, 7% (5 patients) had single leaflet detachment and all-cause mortality was 5% [36].

In a more expanded scenario, Taramasso M et al. presented the results of the TriValve registry (Transcatheter Tricuspid Valve Therapies), the first international registry to collect data of patients undergoing TTVI with the currently available devices. The authors showed that, among 312 high-risk patients with severe TR submitted to a TTVI intervention, procedural success (defined as the device successful implantation and residual TR ≤ 2+) was ob-

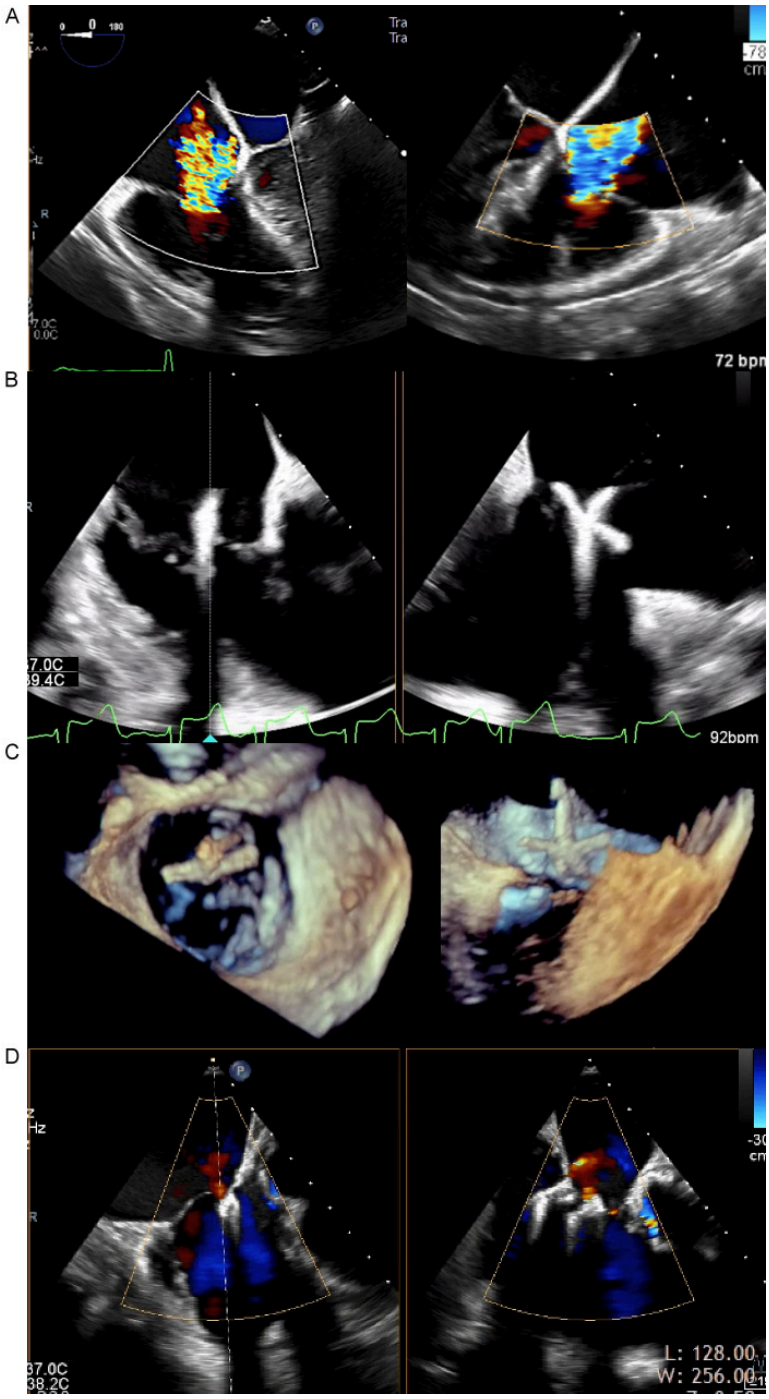

Figure 3. Tricuspid valve percutaneous repair using the TriClip system. A. Preoperative tricuspid regurgitation. B. Intraprocedural transesophageal echocardiogram right ventricle inflow-outflow view showing Clip trajectory. C. Intraprocedural transesophageal echocardiogram 3D view showing Clip orientation between the anterior and the septal tricuspid leaflets. D. Trace residual tricuspid regurgitation after 2 XTR Clip implantation.

tained in 72.8%. The overall 30-day mortality was 3.6%, and it was significantly lower in patients who had procedural success, compared to those who did not (1.9% vs. 6.9%; P=0.04). Actuarial survival at 1.5 years follow-up was 82.8 ± 4%, and it was also significantly better among patients who had procedural success [37]. These same authors recently reported an important benefit in terms of survival and rehospitalization rates when TTVI was compared with medical therapy [(1-year mortality: 23 ± 3% vs. 36 ± 3%, in TTVI vs. control group, respectively; P=0.001; 1-year rehospitalization: 26 ± 3% vs. 47 ± 3%, in TTVI versus control group, respectively; P < 0.0001)] [38].

Discussion

The recent growing development of transcatheter tricuspid valve therapies made the prior forgotten valve a new focus of interventional interest, thus bringing up the debate about prophylactic tricuspid intervention.

Due to the complex nature and interaction between TR progression and clinical outcomes impairment, the question if early TR intervention may change natural disease course and improve clinical outcomes remains to be answered.

Considering the information presented above, the following are meant to be discussion points:

1. Because TV annulus dilation as predictor of TR progression and criteria to indicate concomitant surgery is still nowadays controversial, is there a significant benefit of unrestricted prophylactic TV intervention? Or a watch-and-wait strategy with subsequent intervention, if nec-

essary, could be a valuable alternative in some subgroup of patients? What patients' profiles could benefit from a more conservative approach? 2. Once one of the reasons to indicate concomitant TV repair is the assumption that a future reoperation would be associated with high surgical risk and poor outcomes, in a hypothetical scenario of TTVI providing significantly lower procedural mortality, should this argument be reviewed? 3. If the indication of tricuspid prophylactic intervention based on annulus dilation is valid, might be combined TTVI also considered in inoperable or high-risk patients based on annular dilation rather than on TR grade?

Conclusion

The comments in this document do not presume of answering the questions presented above, but rather to bring these questions into the debate and to stimulate a more in-depth discussion.

Tricuspid annular dilatation seems to play an important role as predictor of early and late outcomes after left-sided surgery, especially if other parameter such as leaflet coaptation and tethering are also present. However, controversial data regarding the role of prophylactic tricuspid valve repair concomitant with left-sided intervention make this procedure not as widespread as it could be. Nonetheless, with the advent of percutaneous tricuspid valve interventions, it turned into an interesting alternative approach in selected patients.

The decision-making process should be based on individual factors such as patient desire, clinical symptoms, response to medical management, quality of life, and life expectancy, as well as tricuspid valve morphology, currently available devices and procedural risks.

Disclosure of conflict of interest

Dr. Tagliari scientific research is supported by the Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (Capes) - Finance Code 001. Dr. Taramasso is a consultant for Abbott Vascular, Boston Scientific, and 4tech; and has received fees from Edwards Lifesciences, CoreMedic, Swissvortex, and Mitraltech.

Abbreviations

FTR, Functional tricuspid regurgitation; MV, mitral valve; TR, tricuspid regurgitation; TV, tricuspid valve; TTVI, transcatheter tricuspid valve intervention; TEE, transesophageal echocardiogram; TTE, transthoracic echocardiography.

Address correspondence to: Ana Paula Tagliari, University Hospital of Zurich, Cardiovascular Surgery Department, Rämistrasse 100, Zurich 8091, Switzerland. Tel: +41442552303; E-mail: anapaula.tagliari@usz.ch

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