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EDITORIAL

Tricuspid annuloplasty: a piece of the puzzle or the whole picture?

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Tricuspid regurgitation (TR) is a prevalent disease commonly secondary to left heart disease or longstanding atrial fibrillation. Patients with severe TR suffer from high morbidity and mortality rates, and renal, hepatic and bleeding disorders. The burden of these comorbidities, along with the TR itself, renders these patients at high risk, especially with regard to surgical treatment of TR. In addition, it remains undetermined whether improvement of TR significantly impacts meaningful clinical endpoints such as mortality and heart failure hospitalisation. These uncertainties make high demands on any putative attempt at TR treatment. In an ideal world, such a strategy should (1) carry zero periprocedural mortality and demonstrate high safety, (2) be efficient in TR reduction, (3) be truly minimally invasive with low access site complications, (4) enable early mobilisation and discharge, (5) not increase the already increased bleeding or thromboembolic event rate, (6) leave open future additional treatment options in case of residual or recurrent TR, and (7) address the pathology leading to TR.

Unfortunately, the targeted patient population is highly variable due to changing comorbidities, and the anatomical and functional components leading to and accompanying TR differ substantially between individuals and also within individuals during the course of the disease. A common leading pathology of almost all TR entities, from atrial to ventricular and cardiac implantable electronic device-induced TR, is annular dilation, especially in less advanced cases. At later timepoints, right ventricular dilation and subsequent leaflet tethering mark a more advanced TR state. It is attractive to reason that in the earlier states of TR, when annular dilation is the decisive disorder, an annuloplasty device would be the ideal intervention. By cinching the annulus, leaflet coaptation is restored, thereby diminishing TR without compromising future additional treatment techniques. The so far clinically tested annuloplasty devices are either of a direct nature such as the Cardioband (Edwards Lifesciences) or Millipede (Boston Scientific) or have applied a focal impact on the annulus such as TriCinch (4Tech Cardio) or Trialign (Mitralign). Most of these devices have not achieved clinical approval or a broad application due to insufficient annular reduction and TR reduction, non-eligibility in the frequently presented more advanced cases due to annular size or tethering, proximity to the right coronary artery (RCA), safety issues, high imaging demands or lack of ease of use.

In this issue of EuroIntervention, Zhang et al review the prospective, single-arm, multicentre TriStar study, which evaluated a novel catheter-based device for interventional tricuspid valve indirect annuloplasty, the K-Clip (Huihe Healthcare Technology Co., Ltd.) for a total of 96 patients with relevant and symptomatic secondary tricuspid regurgitation at 11 centres in China[1].

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First and foremost, we wish to congratulate the authors for these encouraging and promising results. The clinical relevance of this topic is high, and development of strategies for interventional tricuspid valve treatment options is a rapidly evolving field.

Pertaining to the quality criteria for transcatheter tricuspid valve repair (TTVr) devices, the periprocedural complication rate in this analysis with a novel device was relatively low, with one pericardial effusion requiring intervention, one case of RCA injury and one case of retroperitoneal haematoma requiring transfusion. The technical success

rate was 98% (94/96), and the procedural success rate was 94%; additionally, the mortality rate was encouraging and comparable to other European Conformity (CE)-certified TTVr devices[2,3] with no periprocedural or short-term deaths and an all-cause mortality rate at one-year follow-up of 5.5% (5/96) – unrelated to the device or procedure but explainable by the patients' comorbidities.

With regard to clinical performance and device efficacy, the K-Clip device showed a marked, persistent and comparable TR reduction at short- and midterm follow-up, significant improvement of functional New York Heart Association Class, 6-minute walk distance and Kansas City Cardiomyopathy Questionnaire scores – no device detachments or embolisations were reported. Furthermore, although the patient characteristics show a rather compensated heart failure with preserved ejection fraction cohort, a right ventricular fractional area change of 41% and mainly atrial functional TR, right atrial and ventricular remodelling and improvement of (semi)quantitative parameters for TR grading were observed during midterm follow-up.

As tricuspid annular dilation is a common pathophysiological characteristic of functional TR, annuloplasty appears to be a main contributor of successful interventional tricuspid valve repair. In this study, reduction of the tricuspid valve septal-to-lateral annular diameter up to midterm follow-up was 11%, surpassing other TTVr devices such as TriClip (TRILUMINATE: 4% [Abbott]) and Cardioband (TRI-REPAIR: 9%), respectively[4].

A relevant aspect regarding comparability and competitiveness with other TTVr devices is procedural complexity and time. Firstly, the right jugular vein is used for transcatheter access – possibly posing a substantial challenge for both the interventionalist and patient, and requiring precise preprocedural computed tomography (CT) planning. Moreover, and similarly to other annuloplasty devices such as Cardioband, RCA proximity, with a relevant risk for RCA obstruction or injury, also necessitates advanced preprocedural CT planning and analysis – altogether complicating implementation, as the need for dedicated preprocedural CT planning requires significant resources and entails additional administration of contrast agent to a multimorbid patient cohort with a high prevalence of chronic renal impairment.

Additionally, with regard to procedural complexity and the vulnerable patient cohort, procedural time in this study was longer compared to already CE-certified transcatheter edge-to-edge repair (TEER) devices[5,6]; this was firstly due to early experience and a potential learning curve and secondly due to the requirement for RCA protection and implantation of more than one device (39%). However, it was shorter in comparison to the CE-certified Cardioband device for direct annuloplasty (mean procedural time 157±61 min vs 254±93 min, respectively)[7].

Similarly to TEER devices and in contrast to the Cardioband device, the K-Clip is repositionable and fully retrievable up until release, allowing for procedural flexibility as procedural success might not always be completely predictable due to highly variable anatomical circumstances and conditions both between and within individuals. Moreover, with regard to the challenges of treatment strategies in cases of (1) torrential TR with pronounced annular dilation, (2) a potential device failure, or (3) worsening of TR during follow-up, reintervention with other transcatheter TV replacement or repair devices – especially with TEER – is feasible, highlighting its potential concerning staged TR treatment strategies. Nonetheless, this should be evaluated and performed at experienced centres.

Interestingly, in this cohort severe bleeding complications (5/96; 5.5%) – although unrelated to the device or procedure – seem to be an issue at midterm follow-up, emphasising the rather fragile patient cohort under oral anticoagulation (89% atrial fibrillation) at high interventional risk.

The main limitations of this analysis certainly include the single-arm design and the comparatively small patient cohort. As this is the first report outside of a compassionate-use case series, more detailed information regarding long-term performance and comparison to guideline-directed medical therapy and other transcatheter TV repair strategies (especially trancatheter TEER) are mandatory. Moreover, performance analysis in a real-world, multinational setting should provide valuable insight pertaining to comparability and competitiveness with other TV repair strategies.

Putting all given aspects into perspective, the K-Clip device for indirect annuloplasty showed an encouraging profile regarding the main device features, such as procedural safety, efficacy, clinical performance and mortality at midterm follow-up. This preliminary analysis introduces the K-Clip as a viable treatment option, adding more flexibility to the treatment portfolio considering the variability of anatomical preconditions. This is especially true for more advanced patients with larger annuli and perhaps pronounced leaflet tethering in whom a focal annuloplasty may be insufficient.

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Conflict of interest statement

G. Nickenig has the following conflicts of interest to declare: honoraria for lectures or advisory boards: Abbott, Amarin, AstraZeneca, Bayer, Berlin Chemie, BioSensus, Biotronik, BMS, Boehringer Ingelheim, Cardiovalve, Daiichi Sankyo, Edwards Lifesciences, Medtronic, Novartis, Pfizer, and Sanofi Aventis; stock options: Beren, and Cardiovalve; participation in clinical trials: Abbott, AstraZeneca, Bayer, Berlin Chemie, BioSensus, Biotronik, BMS, Boehringer Ingelheim, Cardiovalve, Daiichi Sankyo, Edwards Lifesciences, Medtronic, Novartis, Pfizer, and Sanofi Aventis; research funding: DFG, BMBF, the European Union, Abbott, Bayer, BMS, Boehringer Ingelheim, Edwards Lifesciences, Medtronic, Novartis, and Pfizer. J. Vogelhuber has no conflicts of interest to declare.

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