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Original Research

Safety and Efficacy of Pivot-Balloon for Severe Tricuspid Regurgitation: The First-in-Man Experiences

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AUTHOR'S SUMMARY

The management of isolated severe tricuspid regurgitation (TR) remains challenging due to the lack of evidence-based medical treatment and the conflicting result of surgical and interventional outcomes. Transcatheter treatments for severe TR have been actively studied and emerged as a less invasive alternative to surgery. We reported first-in-human experiences of a novel atraumatic vertical spacer, Pivot-balloon. The Pivot-balloon procedure was safe, technically feasible, and effective in reducing TR in patients with isolated severe TR. Further studies are necessary to confirm the long-term efficacy and safety of the spacer system to improve outcomes for patients with severe TR.

ABSTRACT

Background and Objectives: Among various emerging catheter-based treatments for severe tricuspid regurgitation (TR), the spacer device can reduce the regurgitation orifice without manipulating the valve leaflet. However, its clinical application has been hampered by

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Conflict of Interest
Drs. Kim EK and Hahn JY received consulting fees from Tau Medical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Data Sharing Statement
The data generated in this study is available from the corresponding authors upon reasonable request.

traumatic anchoring to the myocardium and the coaxial alignment of the balloon resulting in insufficient TR reduction. This study aimed to evaluate the early-stage safety, technical feasibility, and preliminary efficacy of the novel atraumatic vertical spacer in patients with isolated severe TR.

Methods: All procedures were guided by fluoroscopy and transthoracic echocardiography. The maximum device placement time with an inflated balloon was 24 hours. Changes in the amount of TR, right ventricular function, and patient hemodynamics were measured during balloon deployment.

Results: A total of 7 patients (median age 74), underwent successful device implantation without procedure-related complications. During balloon inflation (median 25 minutes), there were no symptoms or signs indicative of TR intolerance. TR was reduced by 1 grade or greater in all patients, with 2 patients exhibiting a reduction of 3 grades, from torrential TR to a moderate degree. Mild TR after balloon inflation was achieved in 3 patients with baseline severe TR. The TR reduction observed during initial balloon deployment was sustained during the subsequent balloon maintenance period.

Conclusions: The Pivot-balloon procedure was safe, technically feasible, and effective in reducing TR in patients with severe TR. No periprocedural complications or adverse cardiovascular events were reported during device placement with TR reduction observed in all patients. However, longer-term follow-up is needed to confirm safety and treatment effect.

Trial Registration: ClinicalTrials.gov Identifier: NCT05648838

Keywords: Tricuspid regurgitation; Catheter; Therapy

INTRODUCTION

The prevalence of tricuspid regurgitation (TR) increases with age, and the burden of chronic functional TR, which constitutes the majority of clinical cases, requiring therapeutic intervention is also rapidly increasing.[1-3] Especially, functional TR more than a moderate degree is mainly associated with patients with left-heart disease, pulmonary hypertension, or atrial fibrillation (AF) and results in increased mortality and morbidities.[4][5] Regardless of its cause, significant TR leads to right ventricular (RV) dilation and dysfunction, tricuspid annular enlargement, and functional abnormalities of the tricuspid apparatus, further exacerbating TR and contributing to poor clinical outcomes.[1][3] The management of isolated severe TR remains challenging due to the lack of large-scale outcome studies and the conflicting results. Medical therapy, which primarily involves escalating doses of diuretics, is frequently ineffective as patients develop diuretic resistance associated with declining renal function. Due to significant patient comorbidities and poor perioperative outcomes, surgical intervention for isolated severe TR has been limited, with most physicians performing surgery late in the disease process, resulting in excessive morbidity and mortality.[6-8]

Recently, catheter-based treatments for severe TR have been actively studied as a less invasive alternative to surgical interventions, including transcatheter edge-to-edge repair, annuloplasty, heterotopic and orthotopic valve replacement, and spacers.[9] Of these, the spacer system technically reduces the regurgitation orifice without manipulating the valve leaflet. So, unlike other procedures, it rarely causes injury to the leaflet or subvalvular apparatus.[10-12] As the earliest spacer system, the Forma device (Edwards Lifesciences, Irvine, CA, USA) demonstrated TR reduction and improvement of symptoms and quality of life, but

Author Contributions

Conceptualization: Chon MK, Hahn JY; Data curation: Kim EK, Chon MK, Kim HS, Park YH, Lee SH, Choo KS, Je HG, Kim DH, Kim TO, Kim YS, Lee JH, Choi YJ, Yoon HJ, Hahn JY; Formal analysis: Park JH; Methodology: Kim EK, Chon MK, Park YH, Lee SH, Choo KS, Kim DH, Kim YS, Park JH, Yoon HJ; Supervision: Kim HS, Lee JH, Choi YJ, Shin ES, Lee SW, Hahn JY; Writing - original draft: Kim EK, Chon MK, Hahn JY; Writing - review & editing: Kim EK, Kim HS, Je HG, Shin ES, Lee SW, Hahn JY.

it had safety issues including RV perforation, device dislocation, and late TR recurrence that were poorly tolerated in a highly comorbid population.[10)12)] These shortcomings of the Forma device were mainly due to the coaxial design of the spacer which required the mechanical anchoring at the RV apex as well as center line orientation of the spacer in the tricuspid valve (TV) without proper supporting structure. To overcome these limitations, a novel vertical spacer, Pivot-TR (Tau Medical Inc., Yangsan, Korea), that traverses the TV vertically without myocardial anchoring was developed.[13)14)] The Pivot-TR system was designed to acquire fixation in consideration of the direction of blood flow from the heart and the anatomical structure without the use of any physical device for fixation. Previous animal data showed several promising features of the device; 1) simplicity of the procedure, 2) maintenance of the original position with non-traumatic anchoring, 3) minimal device-related complications, and 4) effective reduction of TR amount. Simulation of computational fluid dynamics showed that the vertical spacer works better than the coaxial spacer in reducing regurgitation of the tricuspid leaflet valve.[15)] Based on these preclinical data, we evaluated the early-stage safety, feasibility, and preliminary efficacy of the Pivot-TR procedure in patients with isolated severe TR by monitoring changes in TV hemodynamics and the morphological changes of the tricuspid annulus.

METHODS

Ethical statement

The protocol was approved by the Korean Food and Drug Administration and by the institutional review boards (IRBs) of the Samsung Medical Center (IRB No. 2022-06-036) and other participating centers. All the patients provided written informed consent for participation and all procedures were conducted in accordance with the Declaration of Helsinki 2013.

Study design and patient enrollment

This study was designed as a multicenter, open-labeled, single-arm, investigator-initiated exploratory pilot trial of the Pivot-TR system in symptomatic patients with chronic severe TR.

Enrolled patients were assessed by the multidisciplinary heart team and were deemed to need surgical intervention due to hemodynamic decompensation despite medical treatment. We included patients over 20 years of age with chronic severe to torrential TR. Exclusion criteria were as follows; 1) patients who had a device such as a pacemaker, cardiac resynchronization treatment, or implantable cardioverter defibrillator in the right heart, 2) congenital TR, 3) left ventricular systolic dysfunction, 4) uncontrolled hyperthyroidism, 5) systolic pulmonary artery pressure ≥60 mmHg, 6) chronic pulmonary disease, 7) recent thromboembolic event, 8) uncorrected coagulopathy or prohibition of anticoagulation, 9) intracardiac mass, and 10) pregnant or lactating or planning to become pregnant during the trial period.

Pivot-balloon system

With consideration for subsequent implantation of the Pivot-TR device or surgical intervention for TR, the Pivot-balloon (Tau Medical Inc.), a preliminary form of the Pivot-TR system, was designed to evaluate the size of the spacer for adequate reduction of TR and to monitor acute hemodynamic change due to TR reduction. The Pivot-balloon consisted of four parts: 1) a distal shaft; a flexible single-lumen tube with an ultraviolet-impermeable material that allows to passage of the guidewire, 2) balloon; a part that can be adjusted to

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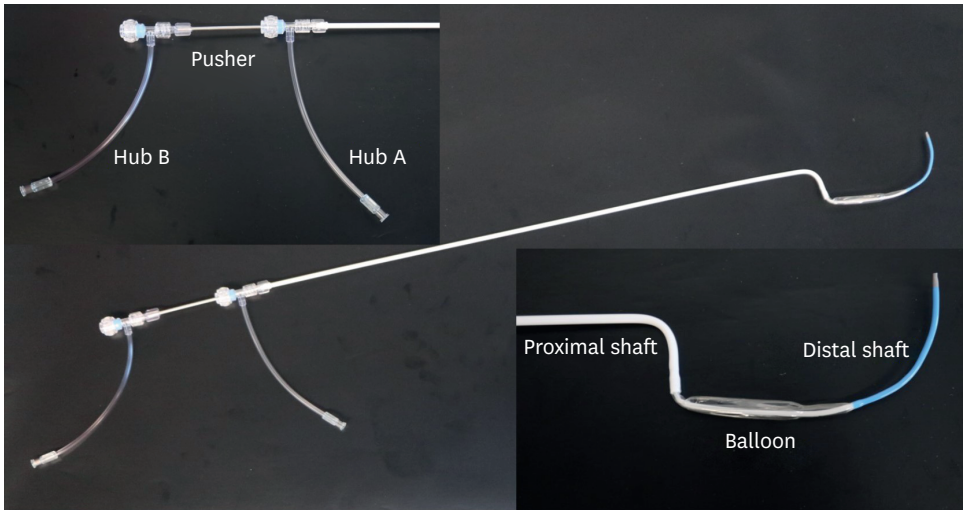

Figure 1. Structure of the Pivot-balloon. The Pivot-balloon, a preliminary form of the Pivot-TR system, is a novel vertical spacer without myocardial anchoring. It consists of four parts: 1) a distal shaft; 2) balloon; 3) proximal shaft; and 4) pusher.

the desired diameter by injecting an appropriate amount of mixture of contrast dye and physiological saline in the TV area, 3) proximal shaft; two single-lumen tubes consisting of an outer shaft for expansion and collapse of the balloon and an inner shaft for support to the distal shaft, and 4) pusher; a part that enables to control of balloon position through bending a distal shaft (**Figure 1**). Unlike the Pivot-TR,[13] the proposed system did not have a distal elephant nose or spiral anchor at the proximal part, and a balloon replaced the 3-dimensional leaflets as a transient insertion device. Six types of different balloon length from 50 mm to 80 mm are available and the size of the Pivot-balloon could be further adjusted with the amount of saline/contrast mix injected into the balloon.

Pivot-balloon procedure

Operators (interventional cardiologists) who completed at least two training programs for the use of investigational devices according to the strategy of the dedicated organization participated in the procedure. All procedures were performed mainly under fluoroscopic guidance (**Figure 2** and **Supplementary Video 1**). Transthoracic echocardiographic (TTE) monitoring was used to guide the position of the balloon system. A 14-F introducer sheath was inserted into the right or left femoral vein. A 5-F curved pigtail was placed in the main pulmonary artery, through which a 0.035-inch guidewire was introduced and subsequently to the right lower pulmonary artery. After removal of the pigtail catheter, a balloon wedge pressure catheter was advanced and withdrawn to exclude the possibility of entanglement with the chordae tendineae. Then, the Pivot-balloon device was delivered along the pre-inserted guide wire so that the collapsed balloon was positioned across the TV. After confirming the proper position of the device using fluoroscopy and TTE, up to 10 ml of diluted contrast agent was slowly injected via the pusher and outer shaft to expand the balloon. The size and position of the balloon were adjusted by the amount of injected solution and the rearrangement of the shaft to most effectively reduce the TR area under TTE monitoring. The maximum device placement time was 24 hours. During device deployment, the patient hemodynamics were continuously monitored in the catheterization laboratory or intensive care unit. Changes in TR, RV systolic function, and chamber size were measured using bedside TTE. The timing of device removal was determined by the physician's

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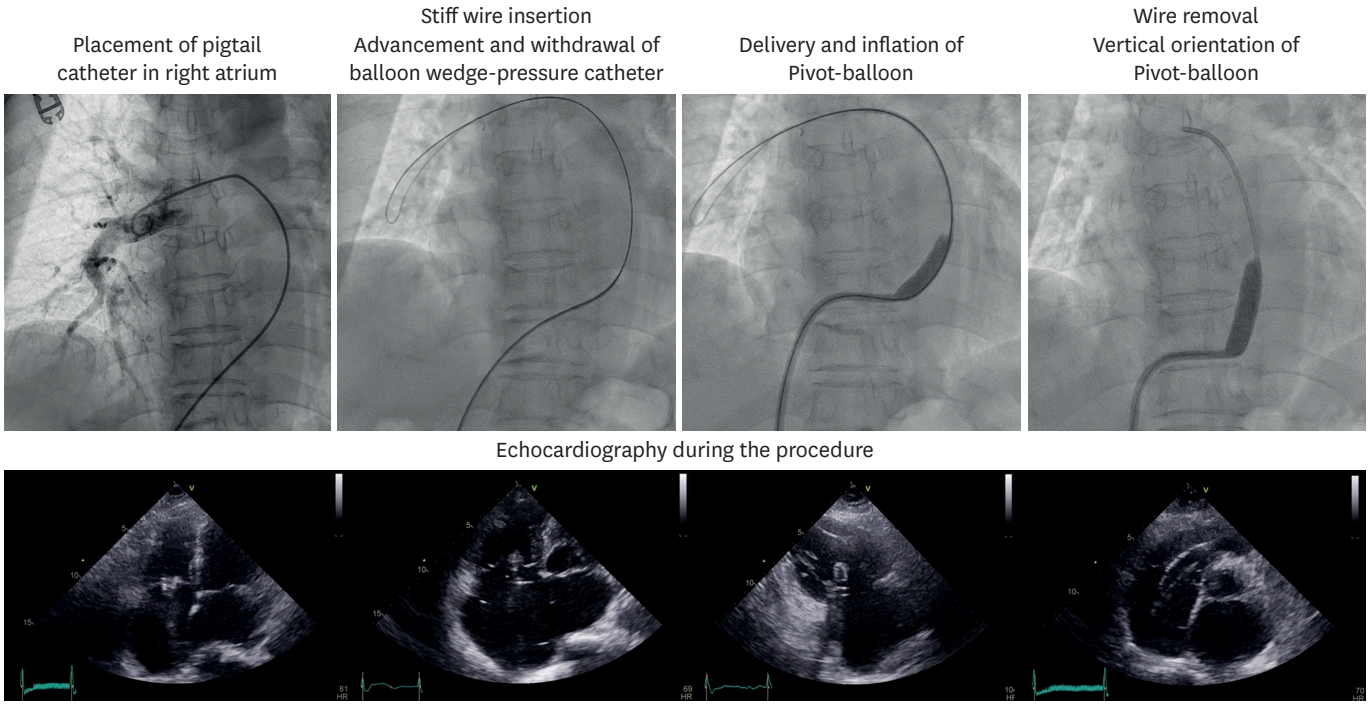

Figure 2. The procedure of the Pivot-balloon. The Pivot-balloon device was delivered along the pre-inserted guide wire so that the collapsed balloon was positioned across the tricuspid valve. After confirming the proper position of the device using fluoroscopy and TTE, the size of the balloon were adjusted and the shaft was rearranged to most effectively reduce the regurgitant area under TTE monitoring.
TTE = transthoracic echocardiography.

discretion. After the deflation of the balloon by withdrawal of the injected contrast agent, the entire system was removed from the body. Anticoagulation during the procedure and device insertion followed the routine cardiac intervention protocol of each institution for the prevention of acute thrombosis.

Echocardiographic analysis

TTE (Vivid E95; GE Medical System, Horten, Norway) was performed by experienced echo specialists before, during, and after the procedure. The severity of TR was graded as mild, moderate, severe, massive, and torrential through a comprehensive assessment of vena contracta width (VCW), jet area, effective regurgitant orifice (ERO), annular diameter, and systolic flow reversal at the hepatic vein according to the current classification guidance.[16] RV size and systolic function were qualitatively and quantitatively evaluated based on multiple views of the RV at short-axis parasternal, lower parasternal RV inflow view, and focused apical four-chamber views. Fractional area change and tricuspid annular systolic plane excursion were measured, and tissue Doppler imaging was performed at the lateral wall at the TV annular plane (S wave). Additionally, we measured the right atrium size and pressure based on the inferior vena cava pattern. During deployment of the Pivot-balloon system, the TR jet was usually split, therefore all possible views were used to obtain the best alignment of the flow center line with the ultrasound beam. Echocardiographic data were digitally stored and transferred to the echocardiography core laboratory. All echocardiographic data were analyzed by an independent imaging specialist who was unaware of the clinical data in the core laboratory.

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Clinical outcomes

The primary safety endpoint was adverse cardiovascular events including death, myocardial infarction, cardiac tamponade, device-related cardiac rupture, stroke, or pulmonary vascular damage during deployment of the Pivot-balloon. For efficacy evaluation, TR reduction and hemodynamic changes of the RV were assessed. Additionally, procedure-related complications such as puncture-site hematoma, infection, aneurysm, or air embolization at the time of retrieval of the device were also collected. We defined TR intolerance as a case in which RV dysfunction was followed by deterioration of vital signs as the amount of TR decreased after device insertion. It was planned to remove the device immediately when TR intolerance occurred during the procedure.

Statistical analyses

This clinical trial is an investigator-initiated pilot study to evaluate the safety and efficacy of the device, a statistically valid sample size was not estimated. Based on the previous first-in-men studies or early experiences on transcatheter valve therapy, the sample size of the present study was set to 7 patients to obtain generally acceptable clinical results.[10)17)18)] Descriptive data were presented as median with interquartile ranges (25^{th}–75^{th} percentile) for continuous variables and frequency with percentage for categorical variables. To compare changes in echocardiographic parameters before and after the procedure, Wilcoxon test was used. All analyses were conducted with SPSS software version 27.0 (IBM, Armonk, NY, USA).

RESULTS

Baseline characteristics

From July 2022 to January 2023, 7 patients (6 women) were enrolled in this initial experience study. Baseline clinical characteristics are shown in **Table 1**. The median age was 76 (73–81) years, with NYHA class III or IV in 4 patients and class II in 3 patients. Most patients had chronic AF and a normal left ventricular ejection fraction. No patient had a history of prior cardiac surgery, pulmonary arterial hypertension, or chronic lung disease. Chronic renal dysfunction was present in 3 patients, none of whom was on dialysis. Baseline echocardiography confirmed that 4 patients had severe TR and 3 exhibited torrential TR. The mean vena contracta width was 1.0 (0.8–2.1) cm, attributed to poor coaptation resulting from annulus dilatation (4.5 [4.2–5.1] cm) (**Table 2**). The mean maximal ERO area of TR by the 2-dimensional proximal isovelocity surface area (PISA) method was markedly large (64.2 [43.7–104.2] mm^2).

Table 1. Baseline clinical characteristics

Variables	Values (n=7)
Age (years)	74 (73–81)
Female	6 (85.7)
Body mass index (kg/m^2)	22.5 (19.1–23.0)
Body surface area (m^2)	1.4 (1.3–1.6)
NYHA functional class ≥III	4 (57.1)
Chronic obstructive pulmonary disease	-
Chronic atrial fibrillation	6 (85.7)
Chronic kidney dysfunction	3 (42.9)
Estimated glomerular filtration rate, mL/min/1.73 m^2	71.5 (37.7–87.0)
Hypertension	5 (71.4)
Diabetes	2 (28.6)
Liver cirrhosis	2 (28.6)

Values are median (25^{th}–75^{th} percentile) or number (%).
NYHA = New York Heart Association.

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Table 2. Echocardiographic data

Parameters	Before Pivot-balloon	During Pivot-balloon	p value
LV ejection fraction (%)	62.0 (59.4–70.5)	65.0 (60.0–68.0)	0.917
TR grade			-
Mild	-	3 (42.9)	
Moderate	-	3 (42.9)	
Severe TR	4 (57.1)	1 (14.3)	
Massive TR	-	-	
Torrential TR	3 (42.9)	-	
Vena contracta width of TR (cm)	1.0 (0.8–2.1)	0.6 (0.3–0.6)	0.018
TR jet area (cm^2)	21.2 (17.8–23.3)	8.1 (3.4–16.6)	0.018
Effective regurgitant orifice area (mm^2)	64.2 (43.7–104.2)	16.9 (9.7–45.3)	0.043
Fractional area change of RV (%)	44.4 (41.0–45.0)	43.6 (40.8–50.1)	0.345
TAPSE (mm)	16.1 (12.7–20.0)	17.4 (16.0–20.5)	0.043
Tricuspid annulus diameter (cm)	4.5 (4.2–5.1)	4.2 (3.8–4.5)	0.043
RV basal diameter (mm)	49.0 (48.0–54.0)	48.0 (46.4–52.0)	0.028
RA dimension (mm)	66.8 (50.5–68.0)	50.0 (47.0–66.5)	0.043

Values are median (25^{th}–75^{th} percentile) or number (%).
LV = left ventricular; RA = right atrium; RV = right ventricle; TAPSE = tricuspid annular plane systolic excursion; TR = tricuspid regurgitation.

Procedural findings

Table 3 summarizes the procedural results. All patients underwent successful device implantation without procedure-associated complications. The total procedural time from puncture to balloon implantation was 20 (11–20) minutes. The device was deployed at the optimal position where maximal TR reduction was achieved by carefully repositioning the device and gradually inflating the balloon under guidance of TTE.

The balloon was inflated up to 9 mm in 6 patients and up to 12 mm in 1 patient with a large coaptation gap. Considering the size of the right cardiac chamber, annulus diameter, and distance to the cavotricuspid isthmus (CTI), a 70 mm-length balloon was deployed in 3 patients, while an 80 mm balloon was used in 4 patients. During the median 25 (20–30) minutes of balloon inflation, no symptoms or signs indicative of TR intolerance, such as an unstable vital signs, worsening dyspnea, or RV dysfunction on TTE, were observed in any of the cases. In all patients, the balloon was successfully deflated and retrieved without leaflet injury or increase in TR severity compared with baseline TTE findings.

Table 3. Procedural data

Variables	Values (n=7)
Successful device implantation	7 (100)
Cardiac tamponade	-
Access site complication	-
Procedural time, min	20 (11–20)
Device information	
Balloon length	
70 mm	3 (42.9)
80 mm	4 (57.1)
Balloon diameter, mm	9 (9–9)
Ballooning time, min	25 (20–30)
Post-procedure complication	
Pneumonia	-
Pulmonary embolism	-

Values are median (25^{th}–75^{th} percentile) or number (%).

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Tricuspid regurgitation reduction and clinical outcomes

Figure 3 and **Supplementary Video 2** illustrate representative fluoroscopic and echocardiographic findings of enrolled patients. During balloon inflation, the degree of TR was reduced by 1 grade or greater in all patients, with 2 patients exhibiting a reduction of 3 grades from torrential TR to a moderate degree. Even one patient with initially torrential TR, whose TV was 4-leaflet configuration showed a 2 grade reduction of TR after Pivot deployment (**Supplementary Video 3**). Mild TR after balloon inflation was achieved in 3 patients with

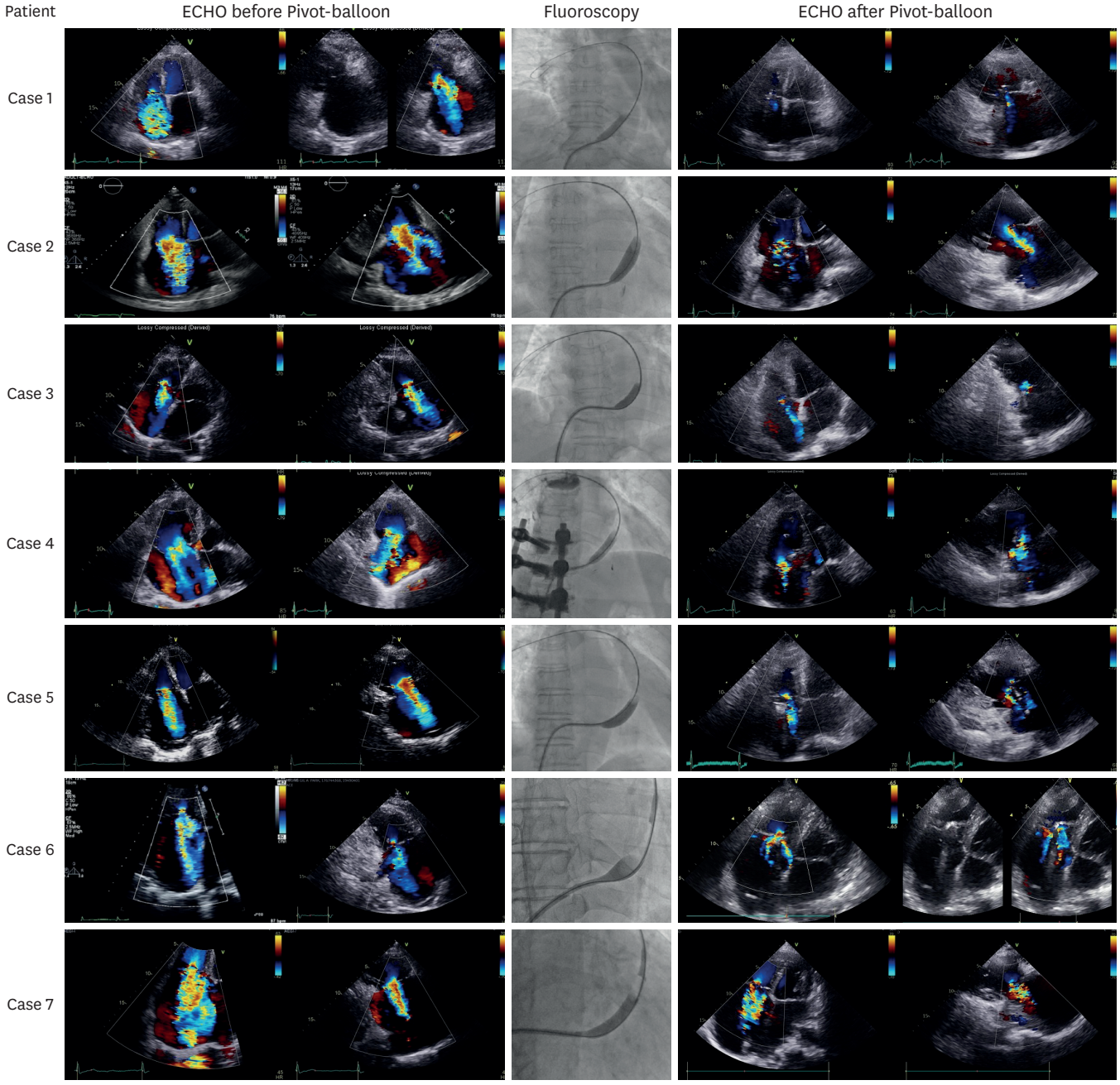

Figure 3. Changes in tricuspid regurgitation before and during the Pivot-balloon. Echocardiographic and fluoroscopic findings representing changes in tricuspid regurgitation before and after the Pivot-balloon. Given the variation in location and direction of the residual TR during balloon inflation, jets were traced in various windows where represented the maximal degree of TR within the mid-to late systolic frame.
TR = tricuspid regurgitation.

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baseline severe TR. Importantly, the observed TR reduction at initial balloon deployment was sustained without any increase during the subsequent period of balloon maintenance. On color Doppler analysis, TV inflow obstruction did not occur in any patients. The mean VCW and maximal ERO area decreased to 0.6 (0.3–0.6) cm and 16.9 (9.7–45.3) mm^2, respectively. RV systolic function and dimension were not compromised following Pivot balloon inflation (**Table 2**). There was no adverse cardiovascular event during deployment of Pivot-balloon or up until 30 days. Procedure-related complications such as puncture-site hematoma, injury to the pulmonary vasculature, or IVC did not occur. Of the 7 patients enrolled, 3 underwent TV repair and 4 were stabilized by meticulous medical treatment during the hospitalization.

DISCUSSION

Herein we describe the first-in-man device experience with transient implementation of a novel vertical spacer, focusing on the safety, feasibility, and preliminary efficacy in reducing TR. The Pivot-balloon system was successfully deployed at the optimal position to mitigate the amount of TR, which remained stable without displacement over time in all patients. The procedure was easily performed in a relatively short time frame under fluoroscopic and TTE guidance. No adverse events were observed during the procedure or after device retrieval. With the Pivot balloon, the average reduction in TR was 2 grades, and no TR intolerance was observed in any of the patients.

The Pivot-balloon system has unique features as a promising treatment option for TR in terms of procedural and anatomical aspects. Procedurally, it did not require general anesthesia as complex imaging guidance such as transesophageal echocardiography or intracardiac echocardiography was not necessary. All patients enrolled in the study underwent the procedure with alert consciousness, except for local anesthesia at the femoral puncture site. Most of all, simple passage of the cardiac structure of the device minimizes injury to the RV, IVC, TV, and pulmonary artery, and atraumatic anchoring contributes to procedural safety. The procedure time was short, and the procedure was relatively simple, suggesting that the learning curve is brief and this procedure does not require acquisition on novel technical skills. Additionally, the entire device could be retrieved for a certain period.

The Pivot-balloon was shaped to cross the annular plane of the TV with a vertical and oblique orientation. Although a coaxial spacer like the Forma device is more intuitive than a vertical spacer, the Pivot-balloon effectively reduced TR in the present study. In terms of biomechanics, vertical traversal of the Pivot-balloon seems to be suitable for the 3-dimensional filling of the regurgitant orifice.[15] Especially in secondary TR, where the annulus is significantly dilated and the regurgitant orifice is not circular, the Pivot spacer's vertical and oblique axes in the direction of the regurgitant jet, can effectively reduce the elliptical regurgitation orifice. The optimal device size could be tailored to minimize TR according to size of the right atrium, non-coaptation gap, and CTI length using preprocedural chest computed tomography and TTE. In the present study, except for 1 patient whose TR was extremely torrential, TR reduction was sufficient with the 9 mm balloon.

The Pivot-TR system can be useful in the following clinical situations: 1) Excessive diuresis undertaken to optimize volume status prior to TR can potentially exacerbate renal function or lead to systemic hypoperfusion, thereby contributing to unfavorable perioperative outcomes.[19] However, employing a non-invasive spacer system as a bridging

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strategy before surgical or interventional repair to mechanically reduce TR could offer a valuable means of volume optimization without compromising systemic circulation or exacerbating renal function deterioration.; 2) Before repair or replacement of intractable TR, bridging implantation of the Pivot-TR system might be helpful in predicting the potential development of RV failure after surgical or interventional TR correction. Monitoring changes in RV function and TR-related symptoms/signs during temporary spacer application may provide more intuitive information on the reversibility of RV remodeling than right heart catheterization.; and 3) Despite evolving surgical and interventional techniques for TR including edge-to-edge repair and transcatheter TV implantation, many patients are not indicated for surgical or interventional repair of TR owing to excessive annular dilation, huge leaflet coaptation gaps, advanced RV dysfunction, or multiple comorbidities. These patients are also excluded from most clinical trials regarding recent interventional approaches. The Pivot-TR system might play a role as a palliative treatment in some cases whose TV anatomy is unsuitable, but there is a clinically compelling indication for intervention. The present study was meaningful because human data confirmed the safety and feasibility of the Pivot-TR device demonstrated in a previous animal TR model.[14] To support the above potential indications, the next trial which maintains the Pivot-TR system (Pivot-bridge) for a longer duration (maximum 7 days) is ongoing based on this initial clinical experience (ClinicalTrials.gov number, NCT05854095). Moreover, the device for permanent implantation (Pivot-extend) is under development and the first-in-human trial will soon start.

This study has several limitations. First, the sample size was small to demostrate the efficacy of the device. However, this was the first application in humans, and we focused on the safety referencing to a previous trial using a spacer system.[10] Second, because echocardiography was performed in a supine position during the procedure, imaging acquisition was limited for accurate measurements of the 3-dimensional ERO area or TV annulus area. Even though we tried to show the maximal residual jet within the mid-to-late systolic frame to avoid overestimation of TR reduction, a direct comparison of TR from the same frame and window as the baseline echocardiography was challenging. Nevertheless, we classified the severity of TR as accurately as possible according to current guidelines using VCW, ERO area by the 2-dimensional PISA method, and flow reversal from the hepatic vein in all patients. To overcome this limitation observed in this pilot trial, future trials investigating the durable efficacy and safety of the Pivot system will address changes in TR with more comprehensive evaluations, including assessments of forward stroke volume, regurgitant fraction using quantified Doppler methods, and three-dimensional assessment. Lastly, the duration of device implantation was relatively short (less than 1 hour). Since this study was the first human trial and the primary objective was to evaluate the safety of the device and procedure, we maintained the device for a short time to minimize patient discomfort or potential risk. To confirm potential applicability in TR reduction and subsequent RV reverse remodelling, additional large data with long-term placement of the device are warranted.

Our initial experience suggested that the Pivot-TR system is safe, technically feasible, and effective for TR reduction. The easy delivery system, which did not require a traumatic invasive anchor, facilitated a simple and safe procedure. TR reduction was observed in all patients without development of the TR intolerance. There was no periprocedural complication or adverse cardiovascular event during the implantation of the device. The next trial which maintains the Pivot-TR system for a longer duration (maximum 7 days) is ongoing based on this initial clinical experience to confirm safety and treatment effect and the device for permanent implantation is under development.

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SUPPLEMENTARY MATERIALS

Supplementary Video 1

Fluoroscopic findings during the procedure. (A) Placement of pigtail catheter in the right pulmonary artery. (B) Stiff wire insertion and balloon wedge-pressure catheter test. (C) Delivery and inflation of Pivot-balloon. (D) Wire removal and vertical orientation of Pivot-balloon.

Supplementary Video 2

The 2-dimensional transthoracic echocardiography of Case 1 before (A) and after (B) the Pivot-balloon.

Supplementary Video 3

The 2-dimensional transthoracic echocardiography of Case 4 before (A) and after (B) the Pivot-balloon. The 3-dimensional transthoracic echocardiography shows quadricuspid tricuspid valve (C).

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