Safety and effectiveness of transcatheter tricuspid valve repair in elderly patients

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SAFETY AND EFFECTIVENESS OF TRANSCATHETER TRICUSPID VALVE REPAIR IN ELDERLY PATIENTS

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LIST OF ABBREVIATIONS

AF – Atrial fibrillation

ALT – Alanine transaminase

AST – Asparate transaminase

AV – Atrioventricular

AVN – Atrioventricular node

BMI – Body mass index

BNP – Brain natiuretic peptide

CO – Cardiac output

COPD – Chronic obstructive pulmonary disease

CDS – Clip delivery system

CVD – Cardiovascular disease

ECG – Electrocardiogram

ESC – European Society of Cardiology

HF – Heart failure

ICU – Intermediate care unit

IVC – Inferior vena cava

ID – Identity document

LSHD – Left-sided heart disease

LVEDD – Left ventricular end-diastolic diameter

LVEF – Left ventricular ejection fraction

MACCE – Major cardiovascular and cerebrovascular event

MI – Myocardial infarction

MR – Mitral regurgitation

MV – Mitral valve

NYHA – New York Heart Association

PAD – Peripheral artery disease

PAH – Pulmonary arterial hypertension

PE – Pericardial erffusion

PTD – Primary tricuspidal disease

PTR – Primary tricupid regurgitation

sPAP – Systolic pulmonary artery pressure

STR – Secondary tricuspid regurgitation

STS – Society of thoracic surgeons

SVC – Superior vena cava

TAPSE – Tricuspid annular plane systolic excursion

TR – Tricuspidal regurgitation

TS – Tricuspidal stenosis

TV – Tricuspid valve

RA – Right atrium

RAAS – Renin-Angiotensin-Aldosterone-System

RV – Right ventricle

1. INTRODUCTION

1.1 Introductory Words

Looking back over recent years, the tricuspid valve (TV) has historically received less attention than any other heart valve (1). It is often referred to as the "forgotten valve". This is because the focus has been on left-sided heart failure (HF).

One possible explanation for this is that left-sided heart disease (LSHD) can cause pulmonary congestion, leading to respiratory distress and high rates of suffocation in patients (2).

On the other hand, right-sided HF is frequently the source of peripheral edema, elevated liver values, and ascites, which are often well apparent and sometimes symptomatic but not connected this high burden of suffocation that LSHD leads to, especially regarding the pulmonary system (3).

More than 90% of patients with clinically significant tricuspid regurgitation (TR) are currently not provided with any treatment. This is primarily due to the common misconception that treating LSHD will consequently improve secondary tricuspidal regurgitation (STR). In fact, the TR's clinical outcome is improved by the MitraClip procedure in most patients, and the focus has shifted more to the mitral valve and its repair mechanisms (4). However, up to 25% of patients will experience progression of TR after open heart surgery for LSHD (5).

With cardiac remodeling, the right ventricle (RV) response to a chronic severe TR volume overload and elevated wall stress. In this disease progression, patients with and without decreased left ventricular ejection fraction (LVEF) experience aggravation of HF symptoms and enhanced mortality (5).

Statistically speaking, 4% of people 75 years or older are affected with clinically significant TR. Only 8–10% of individuals with TV dysfunction have primary TR, which is mainly caused by anatomical abnormalities of the TV system. Secondary TR, on the other hand, is clinically apparent as a source of annular dilatation. A frequent complication of LSHD is pulmonary hypertension (PH) which, if long-standing, can lead to RV enlargement due to pressure overload and TV apparatus (5).

However, a systemic review and meta-analysis published in 2019 showed that moderate and severe TR is linked to higher mortality but seems to be unrelated to pulmonary pressures and RV dysfunction (6).

Another cohort study conducted between 2003 and 2011 had similar results concluding that functional TR had a considerably worse survival in the long-term outcome regardless of baseline characteristics (7).

TV repair mechanisms were limited to surgical procedures until recently, when the percutaneous TV clipping approach was introduced. The TriClip procedure must be conducted by experienced personnel and is often accompanied by the supervision of trained staff from the device company due to the anatomical complexity of the anterior, posterior, and septal leaflets (4). The procedure itself will be discussed in detail later in another section.

The incidence of TV disease among hospitalized patients and those with consequent HF has increased markedly in the last few years, particularly among the elderly and women. Furthermore, one in five for HF has an underlying TV disease (4).

For these reasons, there is a significant public health care problem with excess mortality due to isolated TR exists (8).

Thus, we decided to evaluate the outcome of the TriClip procedure, which is also now being performed in our clinic (Regiomed Klinikum Coburg). We are particularly, this thesis is interested in the age group over 80 years.

1.2 Tricuspid valvular apparatus

The following section focuses on the TV in general, its anatomy, and the mechanisms that cause regurgitation. In addition, the effects of the TR on the heart itself and the body will be described to provide an overview of the importance of repairing and alleviating the symptoms of the diseased valve.

1.2.1 Anatomy

The right atrium (RA), right ventricle (RV), and pulmonary circulation are part of the TV's complex functioning apparatus. The most common TV condition is functional tricuspid regurgitation (TR), caused by tricuspid annulus dilation and tethering of valve leaflets because of right ventricular dilation and dysfunction (1). To outline where the TriClip procedure must be conducted, the anatomy will now be reviewed.

1.2.1.1 Tricuspid valve position

With an average opening area of 7 to 9 cm^2, of the four cardiac valves, the TV is the most apical in position (Figure 1). Due to its vast size and the slight pressure differential between the right atrium (RA) and right ventricle (RV), peak transtricuspid diastolic velocities are normally less than 1 m/s with mean gradients of 2 mmHg. Papillary muscles, leaflets, as well as chordal attachments, and annulus are separated into functional parts, as described in the mitral valve (MV). TV closure during systole depends on the leaflets and how they connect to the papillary muscle and the chordae, but they may also be related to RV function and size. (9).

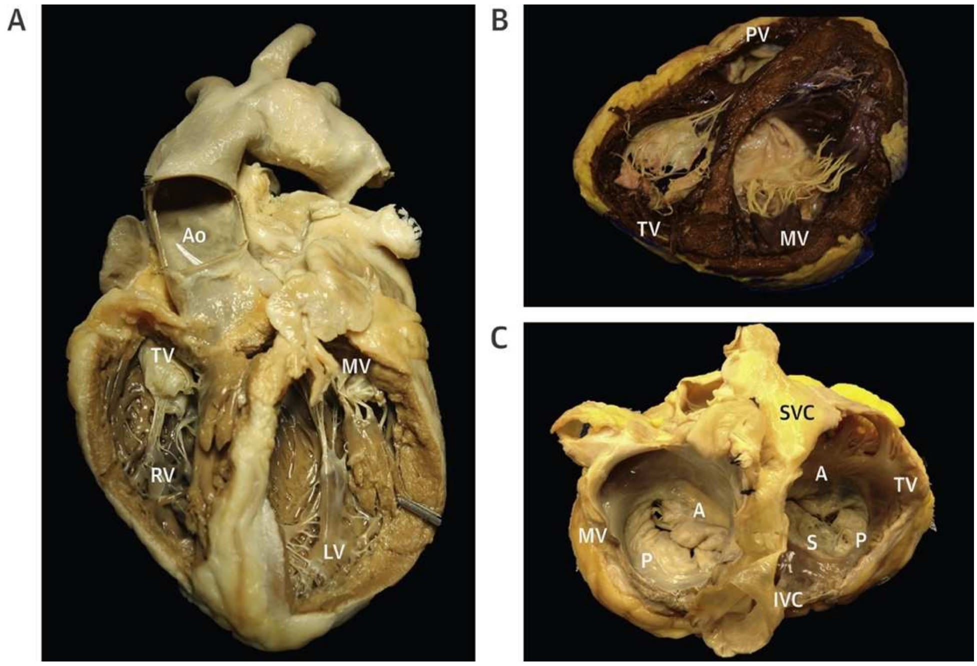

Figure 1: Heart anatomy along with its valves

Dahou A, Levin D, Reisman M, Hahn RT. Anatomy and Physiology of the Tricuspid Valve. JACC Cardiovasc Imaging. 2019;12:458-68.

1.2.1.2 Tricuspid valve composition

Although the TV is typically composed of three leaflets of different diameters, two (biscuspid) or more leaflets may be present as anatomic variations in healthy individuals. The three leaflets are known as the anterior-superior, as well as inferior and septal leaflets in their anatomic locations. However, these described leaflets are commonly simply named the anterior, posterior and septal leaflets. In the radial direction, the anterior leaflet is the longest and largest

, with the widest motion and the most significant area. The posterior leaflet has the shortest circumference and may show numerous scallops. In about 10% of individuals, it may not be easily distinguished from the anterior leaflet (9).

On the other hand, the shortest and least mobile leaflet in the radial direction is the septal leaflet. Numerous third-order chordae, some of which may be directly connected to the interventricular septum, attach to the tricuspid annulus just above the septum. It is located 10 mm apically above the septal insertionbelonging to the anterior mitral leaflet (12).

The commissure, which clearly separates the septal and posterior leaflets, is often seen close to the entrance of the coronary sinus into the RA. The size and form of the annulus has a major impact on the anatomic landmarks for each leaflet (12).

The noncoronary sinus of Valsalva of the aortic root is often closely associated to the commissure between the septal and anterior leaflets. The anterior and septal leaflets are usually the largest in terms of size, hence the anteroseptal commissure is the longest. With a coaptation length of 5 to 10 mm, the TV typically coapts at or slightly below the annulus. As a reserve, this additional coaptation lengths allows for some annulus dilatation prior to malcoaptation (12).

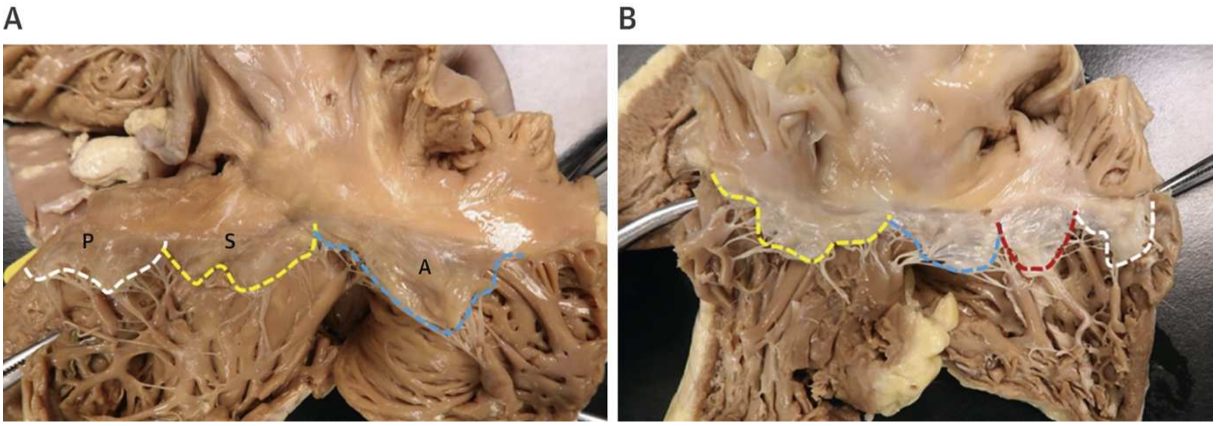

Figure 2: Variable tricuspid leaflets

(A) The most typical anatomy shows a 3-leaflet valve. The P-leaflet is represented by the white color, the S-leaflet by the yellow color, and the A-leaflet by the blue color. A denotes the anterior leaflet, P the posterior, and S the septal leaflet. (B) More than three leaflets are frequently observed. In this quadricuspid valve, the fourth leaflet is additionally visualized by the orange line.

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1.2.1.3 Anatomically Adjacent Structures

The tricuspid valve is surrounded by three key components (Figure 3). Right next to the commissure joining the septal and anterior leaflets is the site of the noncoronary sinus of Valsalva. Transcatheter devices that require anchoring in this location are therefore problematic due to the risk of aortic perforation. The atrioventricular (AV) node as well as the bundle of His cross the attachment of the septal leaflet 3 to 5 mm posterior in regard to the anteroseptal commissure. The heart is also impeded by pressure or perforation of the node. Anatomically, right coronary artery leaves the sinus of Valsalva, travels posteriorly along the right atrioventricular groove until it reaches the apex of the heart, where it makes a sharp bend and enters the posterior interventricular sulcus (9).

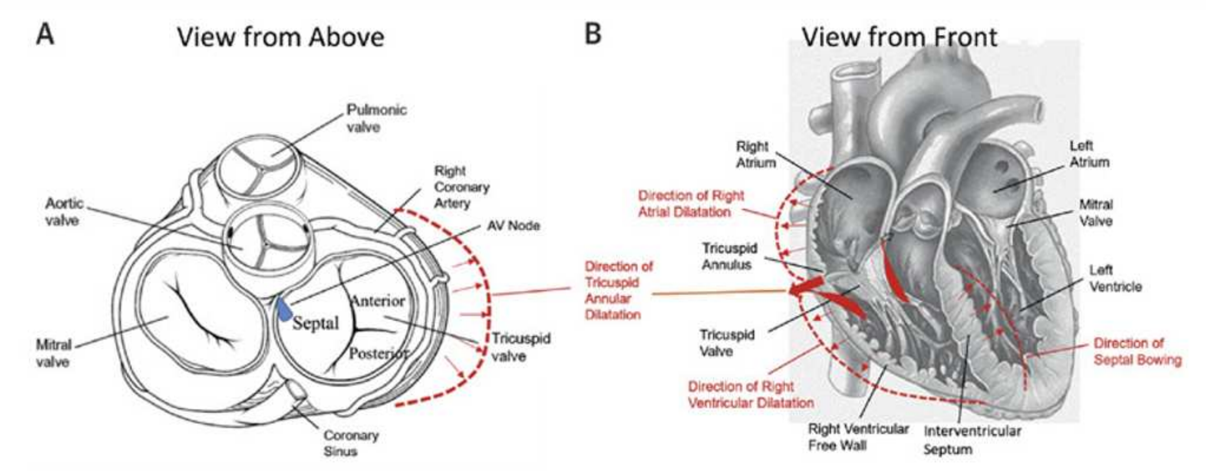

Figure 3: Anatomy of the tricuspidal apparatus and its possible dilation leading to STR
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1.2.2. Etiology of regurgitation

After explaining the TV itself and its anatomical variability, this section will describe the pathophysiology of TR. Unlike tricuspidal stenosis (TS), TR is most commonly the result of secondary etiologies that can cause pronounced dilatation of the tricuspid annulus. Pulmonary arterial hypertension (PAH) can complicate pre-existing RV dilatation, which is very pronounced in a setting of inferior myocardial infarction (MI). MI is a frequent manifestation of advanced stages of HF, often caused by congenital or rheumatic disease ,in which severe PAH (defined as systolic pressure >55 mmHg) has developed. In addition, ischemic and idiopathic dilated cardiomyopathies can also trigger MI. A relief of MI can be achieved by lowering the PAH (3).

Primary causes of regurgitation include rheumatic disease, carcinoid conditions, TV prolapse, RV papillary muscle infarction, trauma, endomyocardial fibrosis, radiation, infective endocarditis, and less commonly, malformations such as Ebstein's anomaly. Another etiology of TR to mention is RV apical pacing which can eventually result in TR (3).

1.2.3. Effects of regurgitation

After looking at the different possible etiologies of TR, we now describe the effects of regurgitation on the body and how they can be identified with medical devices. TR is mainly manifested in systemic venous congestion and a subsequent fall in cardiac output (CO) like in TS. When a patient is developing TR after PAH, pulmonary congestion is alleviated, but also clinical features of right-sided heart failure become more prominent (3).

The first sign might be that the Vena jugularis become distended, and in an haemodynamic studies marked v waves and rapid y descents are visible. Patients with severe disease have very low CO and no x descent during early systole but prominent c-v wave with fast y descent. RA and RV end-diastolic pressures are higher than usual, and AF is additionally a common finding. Characteristics for the enlargement of the ventricle seen in ECG are, for example, an inferior Q-wave MI or right ventricular hypertrophy (3).

Doppler imaging has shown to be very helpful in displaying RV hypertrophy, prolapse, scars, flails, and regurgitation. Furthermore, the continuous wave Doppler of TR velocity can be profiled and used to estimate the PA systolic pressure, which we also used for our study to investigate this parameter in our patients. Then, systolic flow reversal can be seen when severe disease is present in the hepatic vein (3).

Systemic manifestations of TR can be prominent hepatomegaly, ascites, pleural effusion, edema, systolic pulsations of the liver, and a positive hepatojugular reflex. While inspiration, a holosystolic murmur on the lower left sternal margin line will be heard on auscultation louder and expiration or while performing the Valsalva maneuver more quietly.

Pulsation of the RV along the left parasternal region might be another sign of TR. Additionally, RA and RV are usually enlarged on X-ray (3).

In all the above signs and symptoms, a clinical need hasn't been met; thus, something must be done (5).

1.3. Valvular repair

Looking at the effects of regurgitation, we conclude that there is essential to alleviate the symptoms and prevent the progression of the disease.
The following table indicates whether to use the surgical or the transcatheter approach to repair the TV.

Table 1. Transcatheter or Surgical Intervention considerations regarding Anatomy
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Commissures and Tricuspid Valve	**Considerations in Intervention**
The TV has a mean gradient of 2 mm Hg and a large valve opening (around 9 cm2).	With central orifice devices (such as edge-to-edge repair or spacer devices), stenosis is improbable; nonetheless, mean gradients of more than 2 to 3 mm Hg may be considerable.
Normally has three leaflets, but can have up to six or have deep clefts and folds.	It could be difficult to image the leaflet anatomy.
Transparent leaflets are very slim.	There is a difficulty in displaying leaflet anatomy.
Typically the biggest and most mobile leaflet is the anterior one.	There are suboptimal conditions for anchoring devices and a high amount of stress with increasing movement of leaflets.

Least movable and possibly short in all directions are the septal leaflets.	The maneuver to capture the leaflet is difficult.
Papillary Muscles and Chordae	**Considerations in Intervention**
The greatest papillary muscle, which provides chordal support to the anterior and posterior leaflets, is the anterior papillary muscle.	The anterior papillary muscle is a marker for the leaflets while imaging.
Septal leaflet chordae are inserting by direct way in the septum or with small-sized, multiple papillary muscles.	Secondary TR is frequently brought on by "tenting" or tethering of the septal leaflet, especially if the septum is shifted in the direction of the left ventricle. Catheters and other objects may be affected by chordae.
A mean of 25 straight collagen bundles arranged in different configurations, making them less extensible than mitral chordae.	Right ventricular enlargement or papillary muscle displacement cause significant tethering.
Annulus of Tricuspid Valve	**Considerations in Intervention**
The annulus is flat and curved like a D over the septum.	In disease circumstances, dilation takes place along the annulus' not backed lateral and posterior free walls, which have a more planar, spherical form.

Dynamic changes which are evident in early diastole, as well as in end-systole are detectable easier in atrial systole.	Device design must take into consideration dynamic variations in form.
Perimeter average = 12 $\pm$ 1 cm Area average = 11 $\pm$ 2 cm^2	It may be necessary to use big annular devices in the case of dilatation.
Fatty tissue and muscle heterogeneity have interrupted support of fibrous structures in dilation.	The integrity of annular fastening devices may differ around the annulus' circumference.

Tricuspid Valve Adjacent Structures	**Considerations in Intervention**
In severe illness, the right atrium has a thin wall and is noticeably dilated.	Bigger maneuver area is provided for devices, but it is more challenging for imaging.
SVC: variable in form, maximum diameter of 2 cm, average length of 7 cm	SVC widths and nonlinear form may restrict venous access considerations for innovative devices. Device implantation may be complicated by the intraventricular-annular angle.
Inferior vena cava is the biggest vein in human body (usually <21 mm).	
The commissure between the septal and the posterior leaflet is where the coronary sinus joins the right atrium.	The commissure's inflow of the coronary sinus can be used as anatomic landmark.
There is an interruption between in- and outflow.	Outflow tract obstruction risk is low.
Right coronary artery with a varied transverse distance from the annulus within the atrioventricular groove.	The inferior annulus, which is close to the posterior leaflet, is short (about 3–4 mm) regarding transverse distance.

Three to five millimeters posterior to the anteroseptal commissure, the His bundle at the atrioventricular node passes the septal leaflet attachment.	There is a danger of heart block with devices concerning this particular area.
The superior-anterior annulus, which is defined as the commissure spacing the right coronary, as well as the noncoronary sinuses and the anterior-septal tricuspid leaflet commissure, is bordered by the noncoronary sinus of Valsalva.	There is a possibility of penetration with the devices in this place. The anterior-septal commissure can be identified anatomically by the aortic sinuses of Valsalva.

From this table, we can conclude that the decision of which technique is chosen must be customized to the patient and is a very complex deal.

1.3.1. Surgical approach

While the organic or primary degeneration of the valve is unlikely to be cured completely, the secondary or functional disease has a better situation for repair. Several techniques have been documented over the past 40 years, ranging from straightforward sutures to using different prosthetic rings. The current thesis states that repair is superior to a replacement, especially when annuloplasty is involved. The following section summarizes surgical techniques in use for primary tricuspid regurgitation (PTR) and secondary tricupid regurgitation (STR) (9).

We start describing the treatment of the more common STR, seen upon developing pulmonary
hypertension and associated with left-sided heart disease. Surgery is indicated when the severe disease is diagnosed, and left-heart surgery is planned. Another relative indication would be a septal-anterior diameter of >40mm or >21mm/m2. A reintervention after left-sided heart surgery is indicated if a progressive right ventricular failure or dilation in the absence of right or left ventricle decline or PH is shown in the patient (9).

The first technique to mention is the Kay procedure, described in 1965. The posterior leaflet is sutured with a 1-0 silk placed through the leaflet and the commissures, which excludes it entirely from the orifice, and a functional bicuspid valve is created (more stitches are advised to fix the leaflet safely) (9).

Another procedure introduced in 1972 is the De Vega surgery, which aims to reduce the area of the tricuspid annulus. This prevalent technique uses two 2-0 Micron or 4-0 polypropylene parallel running sutures which start at the postero-septal commissure, continue through the endocardium around the perimeter of the orifice in a counterclockwise fashion to reach the anteroseptal commissure. To finally tie them together, another parallel suture must be done 1-2mm outside the first. Antunes and Girdwood described in 1983 the reinforcement of the annulus by using pledgets due to fragile endothelium not cutting the annulus (9).

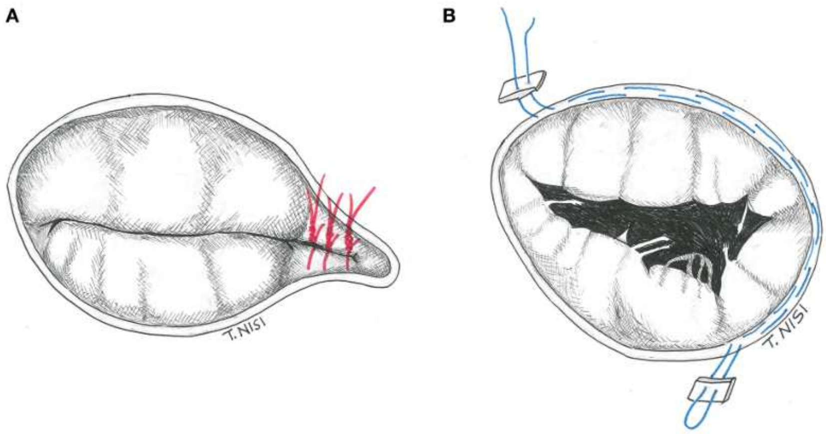

Figure 4 (A) The Kay procedure and the De Vega technique

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Another idea to treat TR was the ring annuloplasty, described by Carpentier in 1971. Thereby the annulus is fixed during systole by a rigid or semi-rigid ring. Flexible ones inhibit annular dilation but fail to restore the 3D morphology. The correct size for the ring must be measured
in advance (e.g., the surface of the anterior leaflet), then the ring is placed by eight to ten 2-0 Ti-cron stitches from posteriorly (midpoint of septal leaflet) and is also running counterclockwise. Attention must be paid to the aortic root, which is close to the septal and anterior leaflet levels. The final stitch is made above the anteroseptal commissure, and the ring is parachuted and fixed (9).

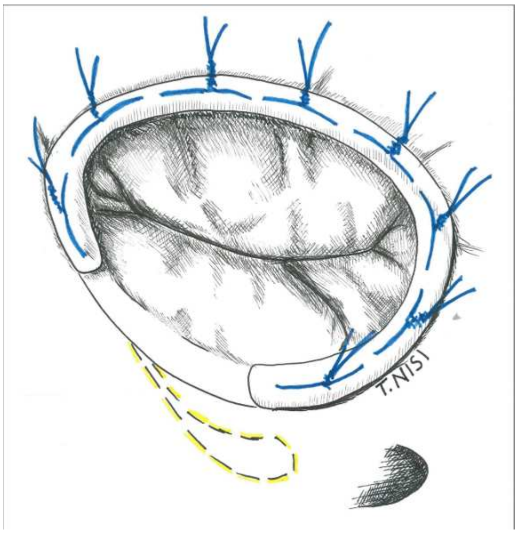

Figure 5 Tricuspid ring annuloplasty

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Furthermore, the enlargement of the anterior leaflet can benefit a TR patient. This is most pronounced in cases of severe tethering where isolated annuloplasty. In 2008 Dreyfus et al. described the removal of the native anterior leaflet, then autologous pericardium was used to patch the annulus, and a semi-rigid annuloplasty ring was implanted. The distance between the anteroseptal and the anteroposterior commissures must be measured in advance (9).

The last procedure to be described for STR is the Clover Technique presented by Alfieri et al. in 2003. It consists of stitching together the middle point of the leaflets using 5.0 polypropylene suture without pledgets and adding a semi-rigid ring. This makes the appearance of a clover. First, this procedure was used for treating post-traumatic TR but later became effective for both STR and PTR (9).

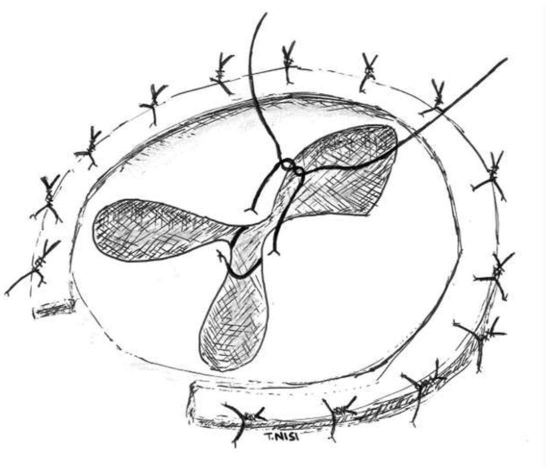

Figure 6 The appearance of the "Clover Technique," where the leaflets are joined together

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The failure rate in the month after surgery in these procedures is between 8 and 15%. Factors that increase the risk of complications comprise the severity of preoperative tricuspid regurgitation, presence of pacemakers, PH, LV dysfunction, increased LV remodeling, severe tethering of the tricuspid leaflets, and the use of sutures rather than ring annuloplasty. Comparing ring and suture procedures, the conclusion can be made that a ring shows a more durable repair, most pronounced when severe tricuspid annular dilation or PH is present. Additionally, better long-term and event-free survival for up to 15 years are evident. The clover technique is especially indicated when there is severe tethering (9).

Now we describe the techniques used for primary tricuspidal disease (PTD). In western countries, the most common etiology of PTD is degenerative valve disease or bacterial endocarditis; in developing countries, the rheumatic disease is the most frequent cause. Regarding the leaflets, excess tissue, thickening, perforation, and tears are present, and for papillary muscles and chordae tendinae, fusion, elongation, and damage can be a finding. However, the main goal of all procedures is the creation of an adequate surface for coaptation and ring annuloplasty (9).

We start with describing interventions on the leaflets. Triangular resection is done if the extending segment is less than one-tenth of the leaflet surface area, and in addition, the chordal rupture is only minor. The leafet synthesis is then achieved using 5-0 polypropylene running or interrupted stitches. When endocarditis is also present, annular plication with the optional addition of a pericardial patch is advisable (9).

Ruptured chordae can be repaired using chordal transposition and artificial chordae implantation as used in mitral valve repair.

For damaged papillary muscles, the best choice is a sliding papillary muscle plasty technique. The elongated papillary muscles or the underlying elongated chordae are lowered to an appropriate level and attached to the fixed power by 5-0 polypropylene interrupted stitches (9).

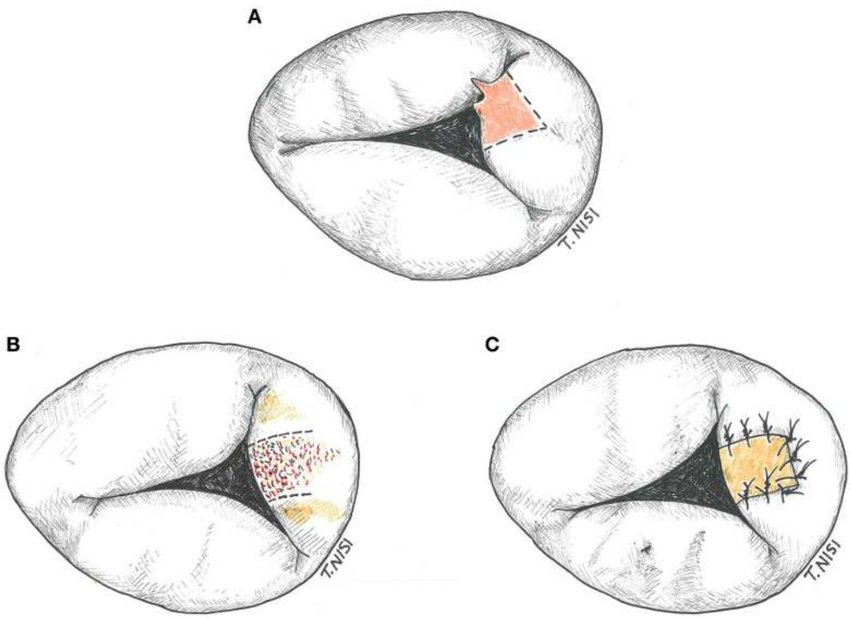

Figure 7 (A) Triangular resection on tricuspid valve (B) Resection of a leaflet following bacterial endocarditis (C) Restored gap by autologous pericardial patch

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Due to rheumatic disease, fused commissures (sometimes in addition to underlying chordae), commissurotomy with an 11-blade under direct visualization is the method of choice.

Suppose the valve is fulminantly compromised, like in endocarditis, carcinoid syndrome, and radiation-induced disorder, and repair mechanisms seem to have no significant benefit on the patient. In that case, tricuspid valve replacement must be considered. The procedure can be done under cardioplegia or with a beating heart, depending on the surgeons' skills. A combination of both cans is also possible (9).

The challenging part is the choice of the device, which is made between mechanical or biological valves. It must be recalled that right-heart low-pressure chambers and lower levels of prostacyclins may increase the risk of valve thrombosis. In addition, mechanical devices can be contraindicated when a pacemaker is needed in the future. Biological prostheses in the right heart provide a lower rate of re-operations compared to mitral valve bio-prosthetic valves, which can be due to lower pressure and life expectancy. In the case of a minor or young patient, automatic valve selection can be superior, but a definitive choice should be tailored to a patient's profile individually (9).

Generally, the native leaflets are resected or fenestrated to leave a 2 to 3-mm fringe of tissue covering the annulus, the chordal attachments are resected, and the septal leaflet is kept in situ. 2-0 or 3-0 pledged Ticron stitch suture is performed along the circumference of the annulus following atrial to the ventricular side of the valve, starting anteriorly and continuing clockwise. Optimal sizing is essential to avoid obstruction and lesions. The bioprosthetic valve has stent posts at 12, 4, and 8 o'clock positions which must be proper to prevent outflow obstruction. After slipping down the prosthesis, the sutures are finally secured, starting from the septal leaflets (9).

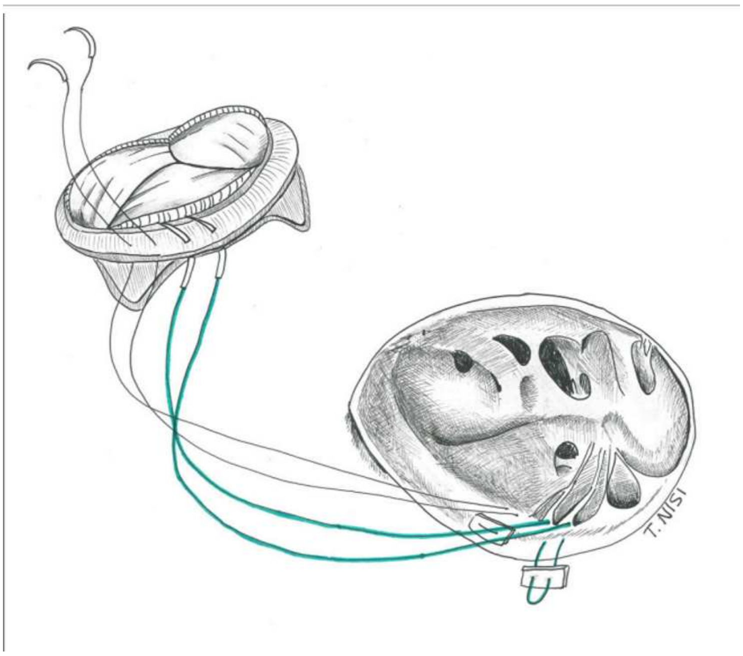

Figure 8 Replacement of TV for bio-prosthesis

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Regarding procedural safety, a high operative mortality and complication rate is evident.

Operative mortality of 18% is stated in some studies. Factors including the New York heart association (NYHA) class, female gender, bilirubin level, preoperative diuretic dose, and preoperative hemoglobin levels are all considered to increase the operative mortality rate. Beating heart technique without aortic cross-clamping in redo cases shows acceptable acute mortality, especially in the absence of ascites, PH, and RVD (9).

Functional TR is mostly not eliminated sufficiently by suture or ring annuloplasty. The severity of preoperative TR, PH, the presence of pacemakers, LVD increased left ventricular remodeling, severe tethering of the tricuspid leaflets, and the use of suture rather than staples have all been linked to the recurrence rate of significant TI of around 8-15%. Ring annuloplasty repairs are more durable than suture annuloplasty, especially in patients with substantial tricuspid annular dilatation or PH, which is suggested by most published research (15).

The major limitation of valvular repair is the amount of excess pliable tissue. Furthermore, their interaction must be assessed before the intervention when more than one lesion is present. Surgical expertise and valve anatomy contribute mainly to whether repair or replacement must be considered (14). Ring annuloplasty is more durable when isolated annulus dilation is present than suture annuloplasty. More procedures must be introduced or combined in cases with marked leaflet tethering (15).

In conclusion, reviewing all these techniques, the repair is the safer procedure, and replacement is reserved for severe cases (9). Despite advancements in surgical methods and post-operative care, isolated tricuspid valve surgery is known to be a high-risk procedure with a 10% in-hospital death rate that has stayed constant throughout research and time (17).

1.3.2. Clipping approach

The TriClip system used in our study is a technical variant of the MitraClip method. The MitraClip procedure is a popular tool for treating MR and is used worldwide. The device is similar in both techniques, but the TriClip system has optimized alterations regarding the guide and the steering handling (10).

As a leaflet repair system to cure TR, the PASCAL repair system just acquired CE-mark approval. The implant comprises a central spacer that fills the TV's regurgitant aperture. The spacer is then joined to two wide paddles by clasps that may be moved simultaneously or separately for the best leaflet catch (16).

The TriClip system design utilized for the study consisted of two components: a steerable guide catheter with a dilator and a steerable clip delivery system (CDS) with an implanted clip (TriClip device, size NT) (13).

Then the CDS inserted and moved the implanted clip to be correctly positioned and placed on the TV leaflets. The CDS deploys the implant gradually over several steps, ensuring the device is administered safely. To access the TV, the steerable guide is set along with the catheter, and a steerable sleeve is used to place the clip about the valve. The clip will then be delivered and set via the delivery catheter (13). Two knobs for steering movements, in contrast to the traditional MitraClip system, are included in the TriClip design. The distal curve of the steerable sleeve has a smaller radius and only one knob for tip deflection. These TriClip system revisions make it easier to perform bending and directing actions in the RA (9).

The procedure starts with gaining access to the femoral vein, and the guide is placed at the junction of the inferior vena cava and right atrium. The TriClip delivery system is positioned correctly above the tricuspid valve after being put into the guide. During the procedure, two- or three-dimensional transoesophageal echocardiography guided by fluoroscopy was utilized to visualize the device, the vasculature, and the architecture of the heart and the valves (13).

TriClip is inserted into the RA using the SDC. Using the control knobs on the handles, the catheter tip is advanced in the RA until the clip is positioned correctly perpendicular to the line of coaptation of the TV leaflets. Then the clip is engaged, put into the ventricle across the TV, and pulled back to catch the leaflets. To evaluate leaflet insertion, clip location, and TR severity, color flow Doppler imaging and two-or three-dimensional transoesophageal echocardiography (or both) are performed. Additional grasping should be attempted if the clip is not correctly positioned or TR has not been sufficiently minimized. In the next step, the clip is secured and released from the SDC after successful implantation. Additional clips were inserted to minimize TR further if the placement of one clip did not reduce TR to a level considered satisfactory by the surgeon. The final step is to pull out the patient's catheter (9). To maintain an active clotting time of at least 250 seconds, heparin was given intraprocedural. For 30 days following surgery, patients received oral aspirin 81 mg/day as short-term antiplatelet medication or anticoagulant therapy (16).

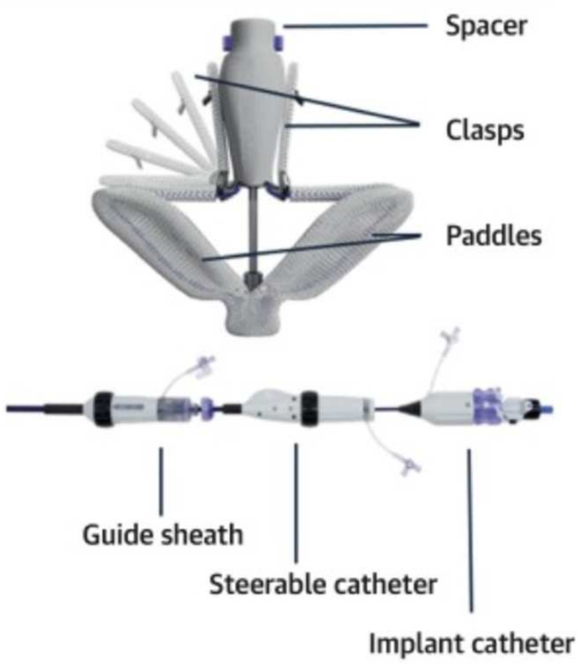


Figure 9: PASCAL device composition

Kodali S, Hahn RT, Eleid MF, Kipperman R, Smith R, Lim DS, Gray WA, et al. Feasibility Study of the Transcatheter Valve Repair System for Severe Tricuspid Regurgitation. J Am Coll Cardiol. 2021;2;77:345-56.

The best timing for the TR treatment is still being discussed. Long-term outcomes might benefit from an earlier treatment before the TR becomes torrential. Further studies need to be conducted to prove this theory (10).

2. OBJECTIVES

This study's main aim was to evaluate effectiveness and safety of the TriClip procedure in patients over 80 years. We defined parameters to compare pre-and post-procedural clinical and laboratory values. In addition, safety intervals were included to demark the safety of the TriClip procedure for elderly patients.

Hypotheses:

1. TR severity will be reduced
2. sPAP mmHg will be reduced
3. NYHA class will be improved
4. Safety parameters of the procedure are within safety intervals
    a. Post-procedural blood transfusions in <5 patients needed
    b. Post-procedural emergency unit days in <5 patients needed
    c. Postprocedural infection in <5 patients
    d. No MI after the procedure
    e. Post-procedural pericardial effusion (PE) in <5 patients
    f. No related procedural death

3. SUBJECTS AND METHODS

3.1. Subjects and ethical considerations

In this cross-sectional study, we enrolled thirty-three consecutive patients older than 80 years (84.45 ±3.12 years), 14 men and 19 women with acute TR, which we all treated with TriClip percutaneous procedure.

They all received treatment according to the latest guidelines of the European Society of Cardiology (ESC) (34). No exclusion criteria were defined except for patients outside the reviewed age range.

This study was conducted in the period between 26.11.2019 and 28.01.2022 at the Regiomed Hospital in Coburg in the department of cardiology. All ethical guidelines of the Declaration of Helsinki were fulfilled, and every included patient was informed about performed measurements in the study, after which informed consent was obtained.

3.2. Clinical and laboratory measurements

The basic information about the patients included the hospital identity document (ID) number of the investigated person and the name, date of birth, age, gender, and body mass index (BMI).

We also estimated the TR etiology and the duration of RV failure symptoms at the moment of the treatment, previous Euroscore (in %), prior society of thoracic surgeon (STS) score (in %), last REDO (which means if an earlier valve surgery has taken place or is planned again), previous acute MI, previous left heart valve intervention, previous rhythm (sinus rhythm, atrial fibrillation, paced, other), a previous-existing pacemaker or intracardial device, interference of pacemaker lead contributing to TR, pre-existing extracardiac arthropathy (distinguished in none, acute cardiac ischemia (ACI), peripheral artery disease (PAD)), pre-existing cardiovascular disease (CVD), pre-existing chronic obstructive pulmonary disease (COPD), pre-existing diabetes and admission for RV failure.

To compare the success and effectiveness of our procedure, the following values were gathered before the procedure:

Effective glomerular filtration rate (eGFR) (in ml/min), hemoglobin in g/dl, aspartate transaminase (AST), alanine transaminase (ALT), Gamma-Glutamyltransferase (GGT), dialysis, hemodynamic instability, mechanical ventilation, PRE pro-brain natriuretic peptide (BNP) in pg.ml, NYHA class, ascites, peripheral edema (graded from 1-3), Torasemide (mg/day), Furosemide (mg/day), anti-renin-angiotensin-aldosterone-system (RAAS) medication (Angiotensin-converting enzyme (ACE) -Hemmer, Ramipril, Valsartan, Candesartan, etc.), Betablocker medication, anti aldosterone treatment, left ventricular end-diastolic diameter (LVEDD), left atrium volume (in ml), left ventricular ejection fraction (LVEF) (in %), TR severity (1+ to 4+), MR severity (0+ to 4+), tricuspid annular diameter in 4 chamber view (in mm), trans tricuspid gradient (mean mmHg), systolic pulmonary artery pressure (sPAP) (in mmHg), Inferior vena cava diameter (in mm)

The postprocedural gathered were: TR severity (0+ to 4+), TR <3, Procedural Success (device successfully implanted with TR reduction to ≤2+), lower eGFR (in ml/min), LVEDD (in mm), right atrium volume (in ml), post-LVEF (in %), TR severity (1+ to 4+), MR severity (0+ to 4+), TR main location (1= central; 2=anteroseptal; 3=anteroposterior; 4= posteroseptal), TR vena contracta width (in cm), RV tricuspid annular plane systolic excursion (TAPSE) (in mm), sPAP (in mmHg), 30-day NYHA class, 30-day ascitis, 30-day peripheral edema, 30-day furosemide (mg/day), 30-day torasemide (mg/day).

The last check-up included these values: NYHA class, ascites, furosemide (in mg/day), torasemide (in mg/day), eGFR (in ml/min), AST, ALT, GGT, LVEED (in mm), Left Atrium volume (in ml), Right Atrium volume (in ml), LVEF (in %), TR severity (1+ to 4+), MR severity (0+ to 4+), TR main location (1= central; 2=anteroseptal; 3=anteroposterior; 4= posteroseptal), TR vena contracta width (cm), trans tricuspid gradient (mean mmHg), RV TAPSE (in mm), sPAP (mmHg), Inferior vena cava diameter (in cm), also here the PE was tracked.

We added additional information, such as loss of follow-up, death, and clip dislocation.

Also, the dates of pre-, postprocedural, and last echocardiography, as well as the procedure and follow-up dates with censored CV event, death, rehospitalization, recurrent TR > 3+, tricuspid surgery, and composite endpoint, were included.

For the procedure itself, we used the following values: previous TR main location (1= central;

2=anteroseptal; 3=anteroposterior; 4= posteroseptal), type of transcatheter repair (1= mitraclip; 2= trialign; 3=tricinch; 4= CAVI; 5= Forma; 6= Cardioband; 7= other; 8 = Pascal), in case of TriClip: specific clip location, Duration of the procedure (in min)

The safety values were the following: Pulmonary catheterism performed (1.0), blood transfusion, Emergency care unit days (in days), acute kidney failure, dialysis, conversion to surgery, PE, low CO syndrome, new atrial fibrillation (AF) onset, infection, stroke, acute MI, mechanical ventilation duration (in hours), intermediate care unit (ICU) stay (in days), clinical days until discharge, in-hospital death, cause of in-hospital death, 30-day mortality, cause of 30-day mortality (cardiac and non-cardiac), 30 days major cardiovascular and cerebrovascular event (MACCE) complications, the definition of MACCE.

3.3. Statistical analysis

Statistical analysis was performed using IBM-SPSS version 23. Normal continuous variables were determined with the Kolmogorov Smirnov test and are presented as mean ± standard deviations. Linear regression analysis was used to study univariate and multivariate statistical associations between fibrosis and other clinical variables, and 95% confidence intervals were added. P-values of less than 0.05 were considered statistically significant.

4. RESULTS

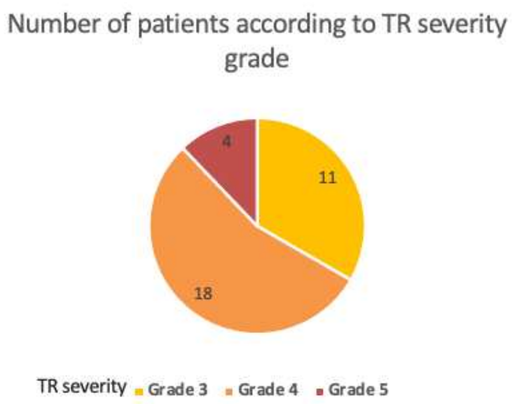
A total of thirty-three patients older than 80 (84.45 ±3.12, 14 men and 19 women, who received transcatheter TR repair between September 2021 and January 2022 treated in the Regiomed Klinikum Coburg were enrolled. Ninetine of them were female which made up a slight majority. The mean age of all patients was 84.45 ±3.12. Approximately 70 percent of patients were overweight with a BMI over twenty-five. Three patients have experienced a MI before the procedure and thirteen patients already received a left heart valve intervention in the past. Atrial fibrillation was already present in 28 patients, but no patient had a valvular surgery before the TriClip procedure. Five participants had a pacemaker and two suffered extracardiac artheropathy. Cardiovascular disease (CAD) was present in approximately half of the patients and seven patients had diagnosed COPD. Two patients needed regular hemodylasis and one patient was hemodymanically instable. Another comorbidity in the participants was diabetes which was diagnosed in five patients. Signs of right heart failure were seen as ascites in five patients and peripheral edema showed in 27 participants. A prior pericardial effusion showed up upon examination in four patients. The overall gathered baseline information about the enrolled patients are displayed below.

Table 2. Baseline characteristics of the enrolled patients

Characteristics	n=33
Female sex – no. (%)	19 (57.6%)
Age – years mean (SD)	84.45 ±3.12
BMI > 25	23 (69.7%)
MI	3 (9.1%)
Left heart valve intervention	13 (39.4%)
AF	28 (84.8%)
Valve surgery	0 (0%)
Pacemaker	5 (15.2%)
Extracardiac artheropathy	2 (6.1%)
Cardiovascular disease	17 (51.5%)
COPD	7 (21.2%)
Dialysis	2 (6.1%)
Hemodynamic instability	1 (3.0%)
Mechanical ventilation	1 (3.0%)
Diabetes	5 (15.2%)
Ascites	7 (21.2%)

Peripheral edema	27 (81.8%)
Pericardial effusion	4 (12.1%)

Procedural success, defined as reducing the TR to grad I-II, was achieved in 97 % of the patients (3.79±0.65 vs. 1.55±0.56, P = 0.011). Prior the severity grade five was shown in four patients, the fourth grade was seen in eighteen participants and the grade three in eleven patients. Postprocedurally the severity grades of the investigated persons were lowered to grades one and two in all cases. 22 patients showed the second severity grade after the exam and the first degree was achieved by eleven patients as shown in the diagrams below.



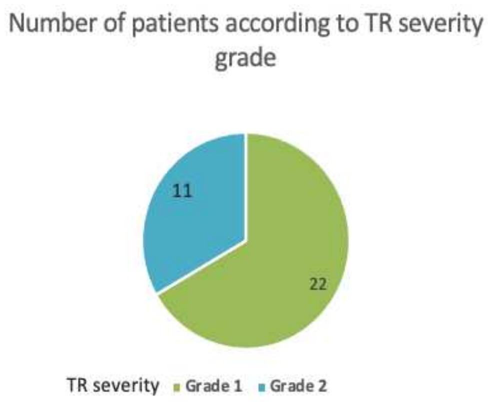


Figure 10: pre-and postprocedural severity of tricuspid regurgitation; left: preprocedural; right: postprocedural

We found preprocedural peak sPAP pressures of 70 mmHg. Most patients achieved lower pressures during the treatment, and the lowest pressure found was 22 mmHg. 7 out of 19 post-procedurally evaluated patients (36,84%) had an sPAP under 36mmHg, which is considered a normal value. The diagrams below show the development of sPAP from the preprocedural state, the postprocedural evaluation and the last estimated values of the patients.

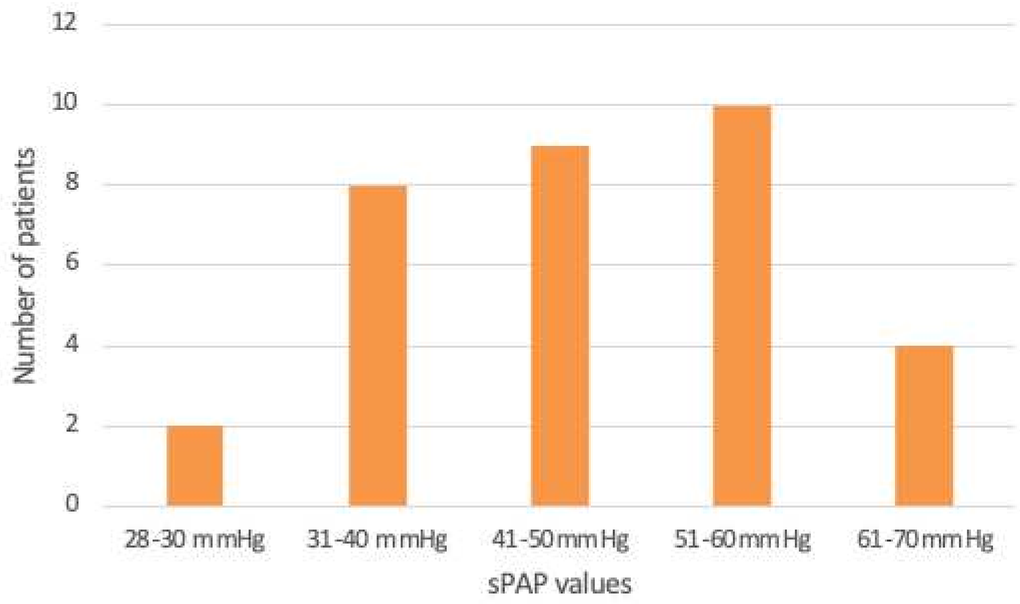


Figure 11: Preprocedural systolic pulmonary artery pressure values

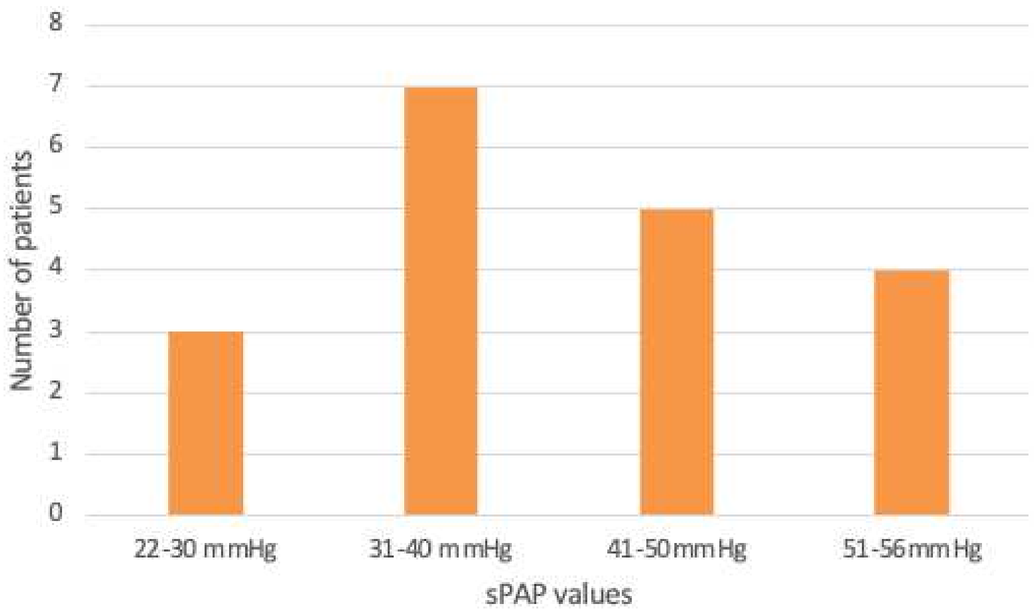


Figure 12: Postprocedural systolic pulmonary artery pressure values

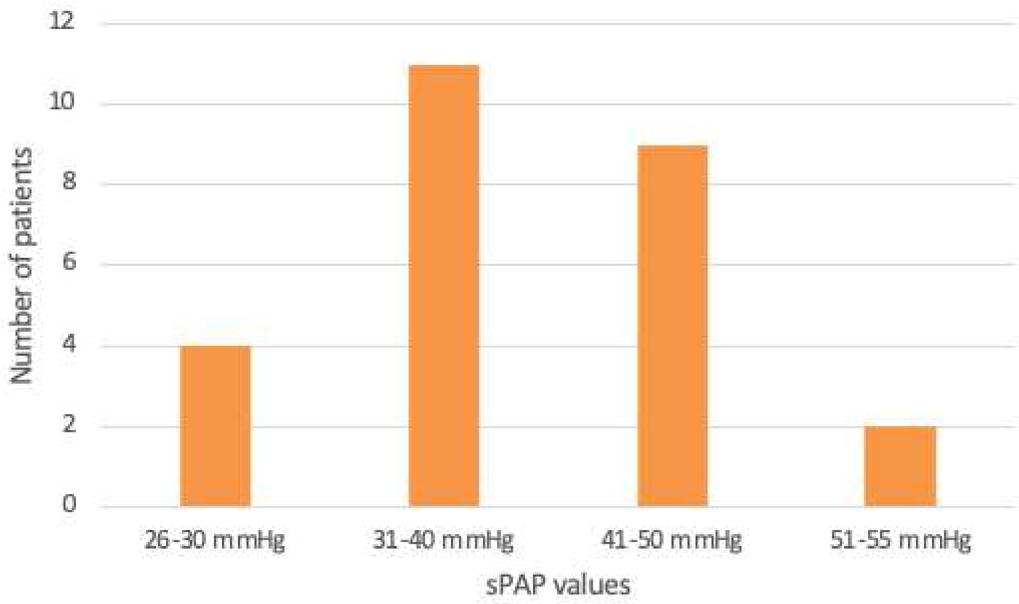


Figure 13: Latest estimated systolic pulmonary artery pressure values

Before the intervention three patients suffered a NYHA class four which is comprised of a high disease burden, NYHA class three was determined in 22 participants and eight patients showed NYHA class two in advance. All patients improved in the NYHA class (2.85±0.50 vs. 1.39±0.056 30 days after the intervention). Which means that most of them achieved at least a two step better class seen in the follow-up after 30 days. One patient was still experiencing symptoms belonging to NYHA class three. Ten participants were classified postprocedurally in NYHA class two and 20 patients achieved NYHA class one. The development from pre- to postprocedural NYHA class in enrolled patients is displayed in the diagrams below.

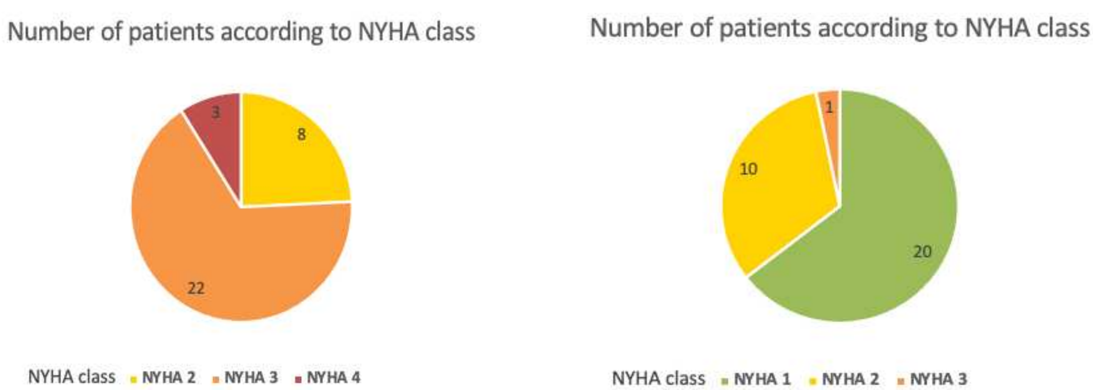


Figure 14: New York Heart Association class preprocedural and after 30 days; left: preprocedural; right: 30-day postprocedural outcome.

No procedure-related death was registered. 87.9 % (n=29) survival rate was achieved three months after the intervention.

Regarding the safety parameters, we found only three patients receiving blood transfusions (9,09%), and three were spending six emergency unit days (9,09%). We found two patients growing an infection post procedurally. (6,06%) No MI was identified after the intervention, and two patients experienced PE (6,06%). The most important safety value is death directly related to the conducted procedure, and we found no directly connected death.

5. DISCUSSION

The main aim of our treatment was to reduce the severity of TR. We found this goal achieved in all of our patients. 97% of the participants reached the TR severity grades 1 and 2, which are the lowest on the scale we used. The aforementioned grading includes categories from 1 to 5, and a comprehensive definition is now required (19). Until recently, the 2017 American Society of Echocardiography recommendations were used to define TR severity in conjunction with qualitative and semiquantitative criteria, but new evidence from 3D echocardiography and MRI provide more precise measures of TR severity (20).

In all of our patients, the desired outcome of the procedure was a narrowing of the tricuspid regurgitant area. The logical consequence was the reduction of TR. However, a potential problem has already been described for mitral regurgitation (MR). Velocity, voracity, and Reynolds shear stress were increased in treated patients as demonstrated by particle image velocimetry (21). In reality, the ideal outcome of minimizing regurgitation and maintaining adequate space for forward flow is impossible. The outcome is likely to be optimized by steadily gaining experience and increasing the frequency of the procedure.

A reduction in sPAP is associated with the reduction in TR and restoration of valve function. Our preliminary post-procedure results show that the highest sPAP was 50 mmHg in four patients (12%) and sPAP between 31-40 mmHg was achieved in 11 patients (36%). PAH was measured by right heart catheterization. In addition, precapillary PAH is defined by a mean PAP >25 mmHg and a normal pulmonary artery wedge pressure of 15 mmHg (30). The decreased percentage of sPAP in patients post-procedurally can be explained by the decreased volume load on the vessel due to an increase in forward flow and a reduction in backflow.

Furthermore, HF risk stratification is mainly based on the NYHA classification, which establishes clinical trial candidacy and eligibility for medications and devices (18). All of our patients improved in NYHA class but still transesophageal visualization, and transthoracic guidance for the categorization are challenging and require trained staff (22).

However, display through the esophagus bears the risk of mucosal and muscular damage. In 3.1% of patients undergoing percutaneous TriClip procedures, complications were observed (23). The procedure has certain risk factors, beginning with anesthetics and increase up with invasive visualization and device-related internal damage. Conversely, our results conducting the procedure raised the hypothesis that the benefit outweighs the potential risk factors. To prove this consideration, we defined parameters for the intervention.

The conventional indication for blood transfusions is a low hemoglobin value following blood loss intra- or post-procedurally (26). Cardiac surgery is always associated with a high risk of complications, significant trauma, and an extended post-operative recovery (24). Also, even minor trauma to vessels and heart tissue can cause significant bleeding in patients with anticoagulant medications (25). Out of our 33 patients, we found three receiving transfusion postprocedural within the defined safety interval below five patients. Also, with increasing usage of the procedure, the safety of the intervention is likely to enhance even more regarding the routine gained in the guidance of the wire.

Furthermore, a study conducted in 2014 dealing with MitraClip found a high number of patients with long hospital days. 46% of 41 patients stayed longer than seven days in the hospital. Additionally, only 88% displayed procedural success, whereas, in our study, 98% achieved the defined aim (27). However, in our study, only three patients spent time in the ICU for a total of six days which is significantly lower than in the MitraClip study, which can be explained by the possible worse initial condition of the patients or the less experienced staff conducting the procedure. To conclude, if the TriClip procedure is safer than the MitraClip method, insufficient data is available, and further studies must be conducted.

The routes of infection upon percutaneous clipping procedure can be through improper skin disinfection before inserting the surgical instruments, by the cabinet stuff, or by the devices themselves. Also, preexisting microbiota in the bloodstream can manifest in severed tissue. The worse possible outcome might be the manifestation of infective endocarditis. This is rare but reported in a few cases in the literature. Despite medical and surgical interventions, the mortality rate is as high as 41%. The cure for infective endocarditis remains challenging due to the blood constantly channeling through the heart, leaving little time for the antibiotic to act on the endothelium. Also, the surgical approach can deliver new bacteria to the circulation and weaken the patient's immune system (28). Our results showed that only two patients grew a postprocedural infection, and no infective endocarditis was found under these. They were cured effectively with antibiotic therapy. Therefore a good hygiene culture in the surgical cabinet is crucial, and postsurgical wound treatment and infection prophylaxis must be provided to guarantee an optimal result after the intervention. Communication between the nursing staff and doctors and documentation are essential to discover early signs of infections in patients (29). Our finding was satisfactory regarding our goal to achieve less than five postinterventional infections.

Another important safety factor is the postprocedural incidence of MI. No MI was identified after the intervention in our patients. However, a case of a 76-year-old woman in 2021 was reported who developed a femoral vein embolism one month after the TriClip procedure. Even though the intervention achieved the TR reduction from grade 4 to grade 1, no complications were identified. The TriClip embolized the patient and received anticoagulant therapy before and after the intervention. Finally, the embolus was removed endovascularly after the patient declined direct surgical extirpation (31). This report shows the importance of follow-up and the need to be aware of possible clotting.

PE was identified in two of our participants (6 %) in follow-up. The etiology can be bruising of cardiac tissue or the nearby vessels leading to the filling of the pericardial sac (32). This can lead to ventricular outflow tract obstruction and is to be identified by ultrasound and ECG changes as well as in more pronounced volume in the change of well-being of the patient (33). However, in our patients PE was minor and necessitated just transthoracical echogradiographic control. The patients did not need any puncture or opertation and the PE was hemodynamically not important.

Furthermore, the most critical safety value is death related to the conducted procedure, and we found no directly connected death. Two patients died within the study timeframe, but the events were not connected directly to the procedure we carried out.

Additionally, with a higher number of repetitions of the TriClip method, the safety of the procedure is likely to enhance even more.

According to our results, we found the TriClip method for repairing safe and effective regarding TR treatment and its associated complications. For the unwanted outcomes we defined parameteres such as: performed pulmonary catheterism, blood transfusion needed after the intervention, emergency care unit days needed, postprocedural acute kidney failure, dialysis, conversion to surgery, PE, low CO syndrome, new AF onset, infection, stroke, acute MI, mechanical ventilation duration, prolonged intermediate care unit stay, postprocedural in-hospital death, and 30 days MACCE. As evaluated above, all patients in our study suffering postprocedural complications recovered and the number of unwanted outcomes was still in the defined safety intervalls.

The biggest limitation of the study is the small patient number. However, our hospital gathered thirty-three TriClip-procedures. A bigger sample would probably result in more follow-up deaths unrelated to the TriClip-procedure itself. Also, as mentioned above, with increased experience, more critical patients would be considered for the approach.

Another limitation of our study may be the comparison of outcomes with respect to the prior comorbidities of the participants. By dividing the patients in groups with similar conditions, a better conclusion could be drawn regarding the safety and effectiveness of our procedure.

Additionally, different operators conducted the procedure, so the trend of the outcome can not be surely established. Lastely, the postprocedural patient care after the hospital stay was another important limitation. It is possible that better health care and recovery conditions, while others did not receive the same care. This may have biased the postprocedural data.

6. CONCLUSIONS

Our results suggest that transcatheter tricuspid valve repair is a safe and effective therapeutic option in elderly and very elderly patients with severe TR and high surgical risk. Therefore, despite age and comorbidities, this therapy should be considered for effective symptomatic treatment in this cohort.

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8. SUMMARY

Background: Symptomatic tricuspid regurgitation (TR) is associated with high mortality rates and HF-related hospitalization. Symptomatic therapy in elderly and very elderly patients remains weak in controlling severe TR. Patients with an increased risk of surgical repair of the TR seemed to benefit from transcatheter tricuspid valve repair procedures.

Methods: Elderly patients with severe and symptomatic TR were presented and evaluated in the heart team. Patients with high surgical risks underwent transcatheter tricuspid valve repair procedures in our center. Post-procedural transthoracic echocardiography (TTE) technique was performed to determine the TR grade and exclude procedure-related complications.

Results: Thirty-three consecutive patients older than 80 years (84.45 ±3.12, 14 men and 19 women, who received transcatheter TR repair between September 2021 and January 2022 were enrolled. The baseline characteristics are presented in table 1. Procedural success, defined as reducing the TR to grad I-II, was achieved in 97 % of the patients (3.79±0.65 vs. 1.55±0.56, p= 0.011). All patients improved in the New York Heart Association functional class (2.85±0.50 vs. 1.39±0.056 30 days after the intervention). No procedure-related death was registered. 87.9 % (n=29) survival rate was achieved three months after the intervention. No clip embolization was detected in 3 months of echocardiography control.

Conclusions: Our results indicate that transcatheter tricuspid valve repair procedures are a safe and effective therapeutic option in elderly and very elderly patients with severe TR and high surgical risks. Therefore, this therapy should be considered despite age and comorbidities for effective symptomatic treatment in this cohort.

9. CROATIAN SUMMARY

Naslov: Safety and effectiveness of triclip procedure in eldery and very elderly

Ciljevi: simptomatska trikuspidna regurgitacija je povezana sa visokom stopom smrtnosti i visokom stopom hospitalizacija koje su povezane sa zatajenjem srca. Simptomatska terapija u starijih i izrazito starijih pacijenata još uvijek je slaba u kontroli teških oblika TR. Smatra se da pacijenti koji su pod povećanim rizikom za kirurški zahvat imaju koristi od transkateterskih zahvata na trikuspidnom zalisku.

Metode: stariji pacijenti sa teškom i simptomatskom TR su prezentirani i evaluirani od strane kardiološkog tima. Oni koji su imali viski operacijski rizik podvrgnuti su transkateterskoj zamjeni trikuspinog zaliska u našem centru. Nakon postupka im je napravljena transtorakalna ehokardiografija da se ustanovi stupanj TR i isključe komplikacije povezane sa samim postupkom.

Rezultati: 33 pacijenta, starija od 80 godina (84.45 ±3.12, 14 muškaraca i 19 žena koji su bili podvrgnuti transkateterskom popravku TR između rujna 2021 i siječnja 2022). Osnovne karakteristike su prikazane u tablici 1. uspjeh postupka, definiran kao redukcija TR na gradus 1-2, bio je postignut u 97% pacijenata (3.79 ±0.65 vs. 1.55±0.56, P= 0.011). Svim se pacijentima poboljšao NYHA score (2.85±0.50 vs. 1.39 ±0.056 30 dana nakon intervencije). Nisu zabilježeni smrtni slučaji povezani sa intervencijom. U prva 3 mjeseca kontrole ehokardiografijom nije detektirana embolizacija spojnica.

Zaključak: naši rezultati indiciraju da je transkateterska zamjena trikuspidnog zaliska sigurna i efektivna terapijska opcija u starijih i jako starijih pacijenata sa teškom TR i visokim rizikom za kirurški zahvat. Prema tome, ova terapija bi se trebala uzeti u obzir usprkos dobi i komorbiditetima za uspješno simptomatsko liječenje u ovoj kohorti.