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# Comparison of Beating-Heart Technique Versus Aortic Cross-Clamping in Tricuspid Valve Surgery

Triküspit Kapak Cerrahisinde Atan Kalp ve Aortik Kros Klemp Tekniklerinin Karşılaştırılması

#### ABSTRACT

**Objective:** Tricuspid valve surgery can be performed on a beating heart or on an arrested heart. We aimed to compare the outcomes of tricuspid valve surgery using these two different approaches.

**Methods:** Between January 2015 and February 2020, 204 patients who underwent tricuspid valve surgery along with concomitant cardiac surgical procedures were included in the study. Techniques of cross-clamping and beating-heart tricuspid surgery were applied to 103 and 101 patients, respectively. Concomitant valvular and/or coronary interventions were performed under cross clamping in both groups. Results from the preoperative period, immediate postoperative period, and six-month postoperative interval were compared between the groups.

**Results:** There were no differences in demographic characteristics or preoperative grades of tricuspid valve regurgitation between the groups. Duration of mechanical ventilation, and stays in the intensive care unit and hospital were significantly shorter in patients operated on using the beating-heart technique. Additionally, re-exploration surgery and mortality rates were significantly lower in the beating-heart group. Postoperative six-month echocardiography findings related to tricuspid valve regurgitation, maximum and minimum gradients of the tricuspid valve, and pulmonary arterial pressure were also lower in the beating-heart group.

**Conclusion:** Beating-heart tricuspid valve surgery may be preferable to the cross-clamping technique to avoid clamp-induced ischemia, which can lead to worsened postoperative outcomes.

**Keywords:** Arrested heart, beating heart, tricuspid valve disease, tricuspid regurgitation, tricuspid valve repair

#### ÖZET

**Amaç:** Triküspit kapak cerrahisi atan kalpte ya da arrest halindeki kalpte yapılabilir. Bu çalışmada triküspit kapak cerrahisinin sonuçlarının iki farklı yaklaşım temelinde karşılaştırmayı amaçladık.

**Yöntem:** Ocak 2015-Şubat 2020 tarihleri arasında triküspit kapak cerrahisi ve ek kardiyak cerrahi prosedür uygulanan 204 hasta çalışmaya dahil edildi. Sırasıyla 103 ve 101 hastaya arrest halindeki kalp ve atan kalpte triküspit ameliyatı teknikleri uygulandı. Her iki grupta da eşlik eden valvüler ve/veya koroner işlemler kros klemp altında yapıldı. Grupların preoperatif, postoperatif erken dönem ve postoperatif 6. ay sonuçları karşılaştırıldı.

**Bulgular:** Gruplar arasında demografik özellikler ve ameliyat öncesi triküspit kapak yetersizliği derecesi açısından fark yoktu. Atan kalp tekniği ile ameliyat edilen hastalarda mekanik ventilasyon, yoğun bakım ve hastanede yatış süreleri anlamlı olarak daha düşüktü. Yeniden eksplorasyon cerrahisi ve ölüm oranları da atan kalp grubunda önemli ölçüde daha düşüktü. Triküspit kapak yetmezliği, triküspit kapağın maksimum ve minimum gradiyentleri ve pulmoner arter basıncı ile ilgili postoperatif altıncı ay ekokardiyografi bulguları atan kalp grubunda daha düşüktü.

**Sonuç:** Ameliyat sonrası olumsuz klinik bulgulara neden olabilecek kros klemp kaynaklı iskemiden kaçınmak için atan kalpte triküspit kapak cerrahisi arreste kalp tekniğine tercih edilebilir.

**Anahtar Kelimeler:** Arreste kalp, atan kalp, triküspit kapak hastalığı, triküspit yetmezliği, triküspit kapak tamiri



## ORIGINAL ARTICLE KLİNİK CALISMA

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Tricuspid valve (TV) disease is one of the main disorders in valvular heart lesions. Annular dilatation and increased tricuspid leaflet tethering lead to functional or secondary tricuspid regurgitation (TR).<sup>1</sup> Additionally, combined aortic and/ or mitral valve surgery is often required for patients with TR.<sup>2.3</sup> The incidence of endocarditis in patients with tricuspid valve disease related to central venous catheters or pacemaker leads is higher compared to patients with other heart valve diseases. A history of long-term intravenous drug abuse, hemodialysis, and intracardiac devices is markedly common in this group.<sup>4</sup>

Various surgical techniques for TV disease have been described in the literature. TV replacement remains the standard treatment for patients with organic TV diseases involving leaflet destruction. Alternatively, TV repair using several methods, including DeVega, Kay, and ring annuloplasty, are viable options for patients with functional TV regurgitation.<sup>5-7</sup> Operations are performed with cardiopulmonary bypass, with or without clamping of the ascending aorta. The beating-heart technique, which avoids clamping the ascending aorta, offers several advantages: it eliminates myocardial ischemic time, reduces the risk of systemic embolization related to aortic clamping, and allows for early recognition of atrio-ventricular (AV) node damage by detecting AV block.<sup>8</sup> Consequently, the beating-heart technique has become an appealing choice for many surgeons.

In this study, we aimed to compare the clinical outcomes of beating heart versus cross-clamping TV surgery performed in our clinic. Additional valvular and/or coronary interventions performed under cross clamping in both groups but TV surgery was performed with or without cross clamping.

#### Materials and Methods

Between January 2015 and February 2020, 204 patients who underwent tricuspid valve surgery with concomitant cardiac surgical procedures were included in the study. Written informed consent was obtained from all participants, and this singlecenter retrospective study was approved by Necmettin Erbakan University Non-Pharmaceutical and Non-Medical Device Research Ethics Committee (Approval Number: 2021/3033, Date: 22/01/2021), complying with the Declaration of Helsinki.

The indications for preoperative surgery were discussed and determined by the council of cardiology and cardiovascular surgery, as the cases involved combined operations. Surgical decisions were made based on coronary angiography for coronary artery disease and echocardiography for valvular issues. Specifically for the tricuspid valve, decisions were influenced by the degree of insufficiency, tricuspid annulus diameter, pulmonary artery pressure, and signs of right heart failure (right ventricular functions). Annuloplasty techniques were employed in cases of functional tricuspid regurgitation. Echocardiographic leaflet pathologies (leaflet thickness, flail status, and

# **ABBREVIATIONS**

AF	Atrial fibrillation
AV	Atrioventricular
PAP	Pulmonary artery pressure
TR	Tricuspid regurgitation

TV Tricuspid valve

commissural fusion) were assessed to differentiate between types of regurgitation. Additionally, an intraoperative water test, where the right ventricle was filled with water to assess valve status, was performed to evaluate valve structure and degree of leakage.

Patients were divided into two groups. Group 1 consisted of 103 subjects who underwent cross-clamping TV surgery, and Group 2 comprised 101 subjects who underwent beating heart TV surgery. Patient data, including demographic characteristics (age, gender), smoking status, comorbidities (hypertension, chronic obstructive pulmonary disease, diabetes mellitus, and cerebrovascular disease), presence of preoperative atrial fibrillation, preoperative grade of TV regurgitation, TV annulus diameter, pulmonary artery pressure (PAP), duration of mechanical ventilation, stays in the intensive care unit, total hospitalization time, requirements for erythrocyte suspension, whole blood, platelet suspension, fresh frozen plasma, type of surgery, additional valvular and/or coronary interventions, need for re-exploration surgery, postoperative heart block occurrences, including atrioventricular complete block, right bundle branch block, left bundle branch block, and pacemaker requirements, were collected from hospital records and compared between the groups. Additional valvular and/or coronary interventions were performed using a cardiopulmonary bypass pump. Additional valvular and/or coronary interventions were performed by using aortic cross clamping but interventions to TV was performed with aortic cross clamping (Group 1) or without aortic cross clamping (Group 2). The grade of TV regurgitation was evaluated from 1° to 4° based on echocardiography results, with 1° being mild and 4° severe.

Patients were followed up for six months, and values of PAP, the grade of tricuspid valve regurgitation, and levels of maximum and minimum TV gradients were noted and compared between the groups. Death within 30 days post-surgery was defined as operative mortality. Pregnant individuals and patients diagnosed with any type of neoplasia were excluded from the study.

#### Surgical Procedure

The surgery was performed under general anesthesia following a sternotomy, with aortic cannulation and bicaval venous cannulation. In patients undergoing tricuspid procedures on a beating heart, the surgical approach initially involved cardioplegia for other cardiac pathologies, such as mitral valve replacement (MVR), aortic valve replacement (AVR), and coronary artery bypass grafting (CABG). Subsequently, the cross-clamp was removed, and the tricuspid valve was addressed after the heart resumed beating. A transseptal approach was used in patients undergoing mitral valve surgery. In patients undergoing CABG, distal anastomoses were performed under cross-clamping, while proximal anastomoses were performed on the beating heart. Cannulations were terminated after the completion of the surgical procedures.

### Statistical Analyses

Data were analyzed using SPSS version 24.0 (Statistical Package for the Social Sciences 24, IBM SPSS Statistics, NY, USA). In the statistical analysis, the conformity of the data to a normal distribution was evaluated using the Kolmogorov-Smirnov test. Chi-square or Fisher's Exact test was utilized to compare nominal

	Cross-clamping (n = 103) X±SD n (%)	Beating Heart (n = 101) X±SD n (%)	P
Age, years	62.37 ± 13.20	61.05 ± 15.56	0.534
Gender			
Female	68 (66.0)	62 (61.4)	0.491
Male	35 (34.0)	39 (38.6)	
Smoking			
No	74 (71.8)	59 (58.4)	0.044
Yes	29 (28.2)	42 (41.6)	
Comorbidity			
Absent	29 (28.2)	36 (35.6)	0.251
Present	74 (71.8)	65 (64.4)	
Preoperative AF			
Absent	56 (54.4)	52 (51.5)	0.382
Present	47 (45.6)	49 (48.5)	
Preoperative Grade of TV Regurgitation	2.90 ± 0.66	2.89 ± 0.66	0.899
Preoperative TV Annulus Diameter (cm)	3.67 ± 0.51	3.74 ± 0.53	0.335
Preoperative PAP (mmHg)	51.24 ± 11.72	51.86 ± 13.65	0.729

data, alongside descriptive statistics (percentage, frequency, mean, standard deviation) for evaluating the data obtained in the study. Independent Samples t-test was used to compare the normally distributed independent variables, and the Mann-Whitney U test was used to compare the independent variables that did not show normal distribution. The significance level was set at P < 0.05. According to the study conducted by Jacob Cohen (A power primer, Psychological Bulltein, 1992, 112/1, 155-159) correlation coefficients expressed as low (0.1-0.29), moderate (0.3-0.49) and high (>1.00).

## Results

TV surgery using the cross-clamping technique was performed on 103 patients (mean age: 62.37 ± 13.20 years; male: 35, female: 68), and beating heart surgery was performed on 101 patients (mean age: 61.05 ± 15.56 years; male: 39, female: 62). There was no statistically significant difference in the terms of age, gender, smoking, comorbidity, critical preoperative condition, preoperative atrial fibrillation, preoperative grade of TV regurgitation, TV annulus diameter, and PAP (P > 0.05) (Table 1).

Other surgical procedures accompanying tricuspid valve surgery included mitral valve replacement, coronary bypass surgery, and aortic valve replacement. Details of these accompanying surgical procedures and their frequencies are provided in Table 2.

The duration of mechanical ventilation, time spent in the intensive care unit and hospital, cross clamping and cardiopulmonary bypass, requirements for erythrocyte suspension and fresh frozen plasma, necessity for re-exploration surgery, and incidence of postoperative atrial fibrillation showed statistically significant differences between the groups (P < 0.05). Mortality rates were significantly lower in patients undergoing beating heart TV surgery (P < 0.05). There were no differences in the need for whole blood and platelet suspension, type of surgery, additional



valve regurgitation of the groups. TR, Tricuspid regurgitation.

valvular or coronary interventions, and the requirement for a postoperative pacemaker (P > 0.05) (Table 2).

Values of PAP, the grade of tricuspid valve regurgitation, and levels of maximum and minimum TV gradients at the postoperative sixth month were compared between the groups and significant differences were observed (P < 0.05) (Table 3, Figure 1).

Correlation values between postoperative 6th month outcomes of the groups were given in Table 4. There was a strong correlation between postoperative 6th month TV regurgitation and postoperative 6th month maximum gradient, minimum gradient and PAP in cross clamping group, whereas moderate correlation in beating heart group.

#### Table 2. Comparison of Postoperative Data Between Groups

	Cross-clamping (n = 103)	Beating Heart (n = 101)	Р	
	Х±SD n (%)	Х±SD n (%)		
Duration of Hospitalization (days)	11.57 ± 6.05	9.50 ± 4.24	0.005	
Duration of Intensive Care Unit Stay (days)	3.53 ± 2.26	2.68 ± 1.69	0.002	
Duration of Mechanical Ventilation (hours)	15.15 ± 9.32	12.04 ± 5.13	0.004	
ES	2.78 ± 1.22	2.02 ± 1.14	<0.001	
Whole Blood	1.75 ± 0.77	1.46 ± 0.58	0.060	
PS	2.50 ± 2.12	1.00 ± 0.29	0.117	
FFP	2.84 ± 1.70	1.69 ± 1.01	0.007	
Discharge/Exitus				
Discharged	94 (91.3)	96 (95.1)	0.077	
Exitus	9 (8.7)	5 (4.9)	0.037	
Additional Surgical Interventions				
TRA + MVR	32 (31)	34 (33.6)	0.814	
TVR + MVR	8 (7.7)	9 (8.9)	0.722	
TRA + CABG	12 (11.6)	13 (12.8)	0.634	
TVR + CABG	5 (4.8)	4 (3.9)	0.645	
TRA + AVR	4 (3.8)	3 (2.9)	0.467	
TVR + AVR	2 (1.9)	3 (2.9)	0.586	
TVR + AVR + CABG	12 (11.6)	10 (9.9)	0.75	
TRA + AVR + CABG	10 (9.7)	10 (9.9)	1	
TVR + MVR + CABG	8 (7.7)	7 (6.9)	0.611	
TRA + MVR + CABG	10 (9.7)	8 (7.9)	0.565	
Re-exploration Surgery				
Absent	79 (76.7)	89 (88.1)	0.134	
Present	24 (23.3)	12 (11.9)	0.032	
Heart Block				
None	81 (78.6)	84 (83.1)		
AV Complete Block	6 (5.8)	4 (3.9)	0.770	
Left Bundle Branch Block	9 (8.7)	5 (4.9)	0.779	
Right Bundle Branch Block	7 (6.7)	4 (3.9)		
Pacemaker Requirement				
Absent	90 (87.3)	89 (88.1)		
Present	13 (12.7)	12 (11.9)	0.988	
Postoperative AF				
Absent	46 (45.5)	65 (63.1)	0.040	
Present	55 (54.5)	38 (36.9)	0.012	

AF, Atrial Fibrillation; AV, Atrioventricular; AVR, Aortic Valve Replacement; CABG, Coronary Artery Bypass Graft; ES, Erythrocyte Suspension; FFP, Fresh Frozen Plasma; SD, Standard Deviation; MVR, Mitral Valve Replacement; PS, Platelet Suspension; TRA, Tricuspid Ring Annuloplasty; TVR, Tricuspid Valve Replacement;  $\tilde{X}$ , Mean.

#### Discussion

Tricuspid regurgitation or insufficiency is the more common form of tricuspid valve disease, leading to backward leakage of blood into the right atrium due to inadequate closure of the valve. Additionally, narrowed and stiff valves impede the flow of blood from the right atrium to the right ventricle, a condition known as tricuspid stenosis.<sup>9</sup> Tricuspid valve diseases, especially tricuspid regurgitation, have a complex pathophysiology and are

	Cross-clamping (n = 103) X±SD	Beating Heart (n = 101) X±SD	Р
Postoperative 6-Month TV Regurgitation	0.92 ± 0.55	0.61 ± 0.59	<0.001
Postoperative 6-Month Maximum Gradient	6.87 ± 4.46	3.88 ± 2.75	<0.001
Postoperative 6-Month Minimum Gradient	3.67 ± 2.55	2.91 ± 2.60	0.036
Postoperative 6-Month PAP (mmHg)	29.13 ± 15.07	24.17 ± 15.14	0.020
PAP, Pulmonary Artery Pressure; SD, Standard Deviation; TV,	Tricuspid Valve; X̄, Mean.		

Table 3. Comparison of Six-Month Postoperative Data Between Groups

associated with long-term adverse outcomes. Between 65% and 85% of the global population are affected by some degree of tricuspid regurgitation.<sup>10</sup> Surgery is still the gold standard treatment for tricuspid regurgitation. Indications for surgical treatment of tricuspid regurgitation depend on the underlying cause of the disorder, the severity of the pathology, and the impact of the regurgitation on right ventricular function.<sup>11</sup> In addition, increasing TR grades were related to an increased risk of mortality in non-surgical populations, regardless of ejection fraction or pulmonary hypertension or whereas isolated moderate or severe TR was associated with an increased risk of mortality, regardless of cardiovascular or comorbid conditions. Concomitant valvular procedures also carry increased risk and operative mortality.<sup>12</sup>

Surgical options for tricuspid valve disease include valve repair or replacement. Several repair techniques for TV regurgitation have been described, such as Kay repair, De Vega suture annuloplasty, pericardial or band strip annuloplasty, annuloplasty with a flexible ring, edge-to-edge suture (suturing the free edges of the leaflet), augmenting leaflets with a pericardial patch, and annuloplasty with a rigid ring.<sup>13</sup> However, TV replacement is required for patients with evident tethering, left and right ventricle dysfunction, compromised valve structure, and severe pulmonary hypertension.<sup>14</sup> Moreover, valve replacement is considered reasonable for severe tricuspid regurgitation secondary to disease or abnormal tricuspid valve leaflets not amenable to annuloplasty or repair.15 In our study, 66% of the patients in the crossclamping group and 67% of the patients in the beating heart group underwent tricuspid ring annuloplasty.

Concomitant procedures are generally performed with surgical interventions for TV such as other valve and/or coronary interventions and correction of severe TR while performing CABG is recommended.<sup>16</sup> Consistent with the literature, in our study, TV surgery was always performed with accompanying conditions, and there were no cases of isolated TV replacement.

Multiple advantages of the beating heart technique in TV surgery have been reported in the literature. These include shortened cross-clamp and cardiopulmonary bypass times, which minimize the deleterious effects of the systemic inflammatory response and extracorporeal circulation that may lead to morbidity and mortality.<sup>17</sup> Our study found that postoperative mortality rates are lower in the beating heart group than in the cross-clamping group. Additionally, the absence of a need for cardioplegic arrest, which can cause electrolyte imbalances, malnutrition, and myocardial hypoxemia, is particularly important for patients with preoperative poor ventricular functions and myocardial hypertrophy, who require longer aortic cross-clamp durations.<sup>1</sup>

Anatomically, the close proximity of the TV to the atrioventricular node can cause bradyarrhythmias related to the surgery. Several studies have emphasized an increased risk of requiring a cardiac pacemaker after TV surgery.<sup>18</sup> For instance, a study conducted by Jokinen et al.,<sup>19</sup> found that the need for pacemaker implantation after TV surgery was higher than after other valve interventions. Although it was not statistically significant, the development of postoperative heart block and pacemaker requirement was lower in the beating heart group in our study. According to our study, postoperative heart block was observed in 21.2% of patients in the cross-clamping group and 12.6% of patients in the beating heart group. The main disorder was the left bundle branch block in both groups. The requirement for a temporary pacemaker was 11.9% in the beating heart group and 12.7% in the crossclamping group. This data aligns with literature indicating that prolonged cardiac ischemia may cause ischemic injury to the conduction system, leading to heart blocks following cardiac surgery. Additionally, continuous monitoring of heart rhythm during the beating heart technique of TV surgery allows for adjustments to sutures passed through the septal part of the tricuspid annulus, preventing damage to the heart's conduction system.18

The relationship between atrial fibrillation (AF) and right atrium and tricuspid annulus dilatation has been emphasized in previous studies, thus AF is considered to be associated with severe tricuspid regurgitation.<sup>20</sup> Yamasaki et al.<sup>21</sup> reported that patients with severe tricuspid regurgitation and AF exhibited significant right atrium and severe annular dilatation. The probable mechanism underlying this clinical situation can be explained as follows: atrial fibrillation leads to progressive atrial remodeling, resulting in atrial dilation. This dilation of the right atrium causes a larger TV annulus and loss of systolic coaptation, which allows for tricuspid regurgitation.<sup>22</sup> In our study, 45.6% of the patients in the cross-clamping group and 48.6% of the patients in the beating heart group had preoperative atrial fibrillation. Contrarily, postoperative AF rates were significantly lower in the beating heart group. This finding correlates with data indicating that lesser administration of cardioplegic solution and shortened duration of aortic crossclamping may prevent postoperative AF, and that beating heart cardiac surgery has advantages over arrested heart cardiac surgery in terms of developing postoperative AF.23

Re-exploration for bleeding is one of the most significant complications of cardiac surgery, with incidence rates ranging from 2% to 6%. Several recognized risk factors for re-exploration due to bleeding include on-pump bypass surgery and prolonged aortic cross-clamp times.<sup>24</sup> The rate of re-exploration for bleeding was statistically significantly lower in the beating heart group according to our findings.

Performing TV surgery with cross-clamping technique results in hemodiluted blood and an increased requirement for blood transfusions.<sup>25</sup> In a study conducted by Atilgan et al.,<sup>26</sup> the postoperative requirement for erythrocyte suspension and fresh frozen plasma transfusions was lower in patients who underwent off-pump TV surgery. Although there were no differences in terms of the postoperative requirement for whole blood and platelet suspension, we detected a statistically significant difference in the need for postoperative erythrocyte suspension and fresh frozen plasma transfusion amounts between the groups. Lower amounts of erythrocyte suspension and fresh frozen plasma were administered in the beating heart group in our study.

Cardiac surgery is associated with lung damage. An aggravated inflammatory response involving complement, cytokines, neutrophils, platelets, monocytes, and activated endothelial cells is one of the main causes of this clinical situation. Chemotactic agents and the release of oxygen free radicals and specific enzymes lead to the sequestration of neutrophils in the lung, resulting in pulmonary injury.<sup>27</sup> Prolonged cardiopulmonary bypass and aortic cross-clamp time were also found to be related to worsened pulmonary functions, which result in prolonged mechanical ventilation. Moreover, prolonged mechanical ventilation was associated with higher mortality rates in patients who underwent TV surgery.<sup>28</sup> A meta-analysis conducted by Nadeem et al.<sup>29</sup> found that cardiopulmonary bypass time was the variable most strongly correlated with prolonged mechanical ventilation, and it was suggested that avoiding or minimizing cardiopulmonary bypass may decrease mechanical ventilation time. In our study, the duration of mechanical ventilation was statistically significantly lower in the beating heart group.

The increased length of intensive care unit and hospital stays has been associated with variables including the duration of cardiopulmonary bypass. Wang et al.<sup>30</sup> reported that prolonged cardiopulmonary bypass time had a negative effect on the length of intensive care unit and hospital stays in patients who underwent cardiac valve surgery. Reduced rates of transfusion, re-exploration for postoperative bleeding, respiratory complications, and acute kidney injury, which may delay discharge from the intensive care unit and hospital, were reported to be significantly lower in the off-pump technique.<sup>31</sup> Length of intensive care unit and hospital stay was statistically significantly lower in the beating heart group according to our study.

Reoperations for recurrent or residual tricuspid valve regurgitation have higher mortality rates, so few patients are offered reoperation.<sup>15</sup> Similarly, Jeganathan et al.<sup>32</sup> reported that redo TV surgery is associated with high operation morbidity and mortality. These findings underscore the importance of postoperative outcomes of TV surgery in terms of postoperative recurrence of TV regurgitation. Postoperative six-month results of beating heart TV surgery also showed superiority over TV surgery with cross-clamping in terms of TV regurgitation, maximum and minimum gradients of the TV, and PAP in our study. All the values mentioned above were statistically significantly lower in the beating heart group.

There was a strong correlation between postoperative 6<sup>th</sup>-month tricuspid valve (TV) regurgitation and postoperative 6<sup>th</sup>-month maximum gradient, minimum gradient, and pulmonary artery pressure (PAP) in the cross-clamping group, whereas a moderate correlation was observed in the beating heart group. This indicates that as TV regurgitation increases, the maximum gradient, minimum gradient, and PAP also increase, but the rates are lower in the beating heart group. This may be a result of decreased reperfusion injury in the beating heart group. Additionally, postoperative gradient and PAP values are related to different variables such as drug use and comorbidities, which may be a limitation of our study.

#### Conclusion

In conclusion, TV surgery performed via the beating heart technique after the correction of accompanied valvular and/ or coronary disorders under cross-clamping, prevents the unfavorable outcomes associated with clamp-induced ischemia and enables the assessment of TV coaptation in an easy, reliable, and reproducible way. However, further prospective, randomized studies consisting of larger patient groups are needed to support these findings.

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