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Original Article

A Comparison of Early and Medium-term Results of De Vega Annuloplasty and Ring Annuloplasty Techniques for the Tricuspid Valve Repair in Patients Undergoing Mitral Valve Replacement

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Abstract

Objectives: Tricuspid regurgitation is a pathology that usually occurs secondary to left heart pathologies and affects the daily activities of the patients. The long-term results of tricuspid valve replacement are not very encouraging. Therefore, the primary treatment for tricuspid valve regurgitation is repair. Therefore, which repair method should be used is very critical. The aim of our study is to compare tricuspid valve De Vega annuloplasty (TDVA) and tricuspid valve ring annuloplasty (TRA) methods, which are frequently used in tricuspid regurgitation (TR).

Methods: Patients who underwent TDVA or TRA in addition to mitral valve replacement at our hospital between January 01, 2017, and December 31, 2019 were included in the study. The study was designed retrospectively and was based on hospital database, patient files, and archive records. A total of 125 patients were included in the study. The pre-operative, intraoperative, and post-operative clinical features of the patients were investigated, and their cardiac status at the last follow-up visit to the hospital was investigated.

Results: In the early post-operative and mid-term evaluation, TR was similar in both groups.

Conclusion: There is no difference between TRA and TDVA techniques in terms of the recurrence of tricuspid valve insufficiency in the early and mid-term post-operative period. Both techniques are not perfect, and there is a need for the development of new strategies and techniques.

Keywords: De Vega; mitral valve replacement; ring annuloplasty; tricuspid valve repair.

Mitral Kapak Değişimi Geçiren Hastalarda De Vega Anuloplasti ve Halka Anuloplasti Tekniklerinin Triküspit Kapak Onarımı İçin Erken ve Orta Dönem Sonuçlarının Karşılaştırması

Özet

Amaç: Triküspit yetersizliği genellikle sol kalp patolojilerine ikincil olarak ortaya çıkan ve hastaların günlük aktivitelerini etkileyen bir patolojidir. Triküspit kapak replasmanının uzun vadeli sonuçları pek cesaret verici değildir. Bu nedenle triküspit kapak yetersizliğinin öncelikli tedavisi onarımdır. Bu nedenle hangi onarım yönteminin kullanılması gerektiği oldukça kritiktir. Çalışmamızın amacı, triküspit yetersizliğinde (TR) sıklıkla kullanılan Triküspit kapak De Vega anüloplastisi (TDVA) ile Triküspit kapak Ring Anüloplastisi (TRA) yöntemlerini karşılaştırmaktır.

Gereç ve Yöntem: Çalışmaya 01.01.2017–31.12.2019 tarihleri arasında hastanemizde mitral kapak replasmanına ek olarak TDVA veya TRA uygulanan hastalar dahil edildi. Çalışma retrospektif olarak tasarlandı ve hastane veri tabanı, hasta dosyaları ve arşiv kayıtları esas alındı. Çalışmaya toplam 125 hasta dahil edildi. Hastaların ameliyat öncesi, ameliyat sırası ve ameliyat sonrası klinik özellikleri incelenerek, hastaneye son kontrollerindeki kardiyak durumları araştırıldı.

Bulgular: Ameliyat sonrası erken dönemde ve orta dönem değerlendirmede triküspit yetersizliği her iki grupta da benzerdi.

Sonuç: Erken ve orta dönemde TRA ve TDVA teknikleri arasında trüküspit rekürrensi açısından fark yoktur. Her iki teknik de mükemmel değildir ve yeni strateji ve tekniklerin geliştirilmesine ihtiyaç vardır.

Anahtar sözcükler: De vega; mitral kapak replasmani; ring anüloplasti; triküspit kapak tamiri.

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Introduction

Tricuspid valve De Vega annuloplasty (TDVA) and tricuspid valve ring annuloplasty (TRA) techniques are currently the most widely used techniques in tricuspid valve insufficiency. Although the TDVA technique is used less over time, it still maintains its importance. Indications for surgical intervention in tricuspid valve diseases and which surgical method to use are controversial. The reason for this is that tricuspid valve diseases are relatively less common and generally occur secondary to left heart valve diseases, pulmonary hypertension, and myocardial disease.[1]

In general, tricuspid regurgitation (TR) may decrease somewhat after intervention in left heart valve pathological conditions,[2] but it is not known whether this reduction will be sufficient and whether it will increase over time. Annuloplasty methods are commonly used in TR.

In our study, patients who underwent TRA or TDVA for TR in addition to mitral valve replacement will be compared and investigated. We wanted to investigate whether the TRA technique, which has been increasingly preferred in recent years for tricuspid valve repair, is truly superior TDVA.

Materials and Methods

Patient Selection

Our study is a single-center retrospective cohort study. Patients who underwent mitral valve replacement and tricuspid valve repair due to rheumatic heart disease between January 01, 2017, and December 31, 2019 at our hospital were included. The patients were divided into two groups as those who underwent TRA and TDVA. The data of the patients were analyzed retrospectively, and the hospital database, archive records, and patient files were examined.

Patients aged 20–80 years who had undergone mitral valve replacement as well as tricuspid valve repair techniques, TDVA or TRA, were included in the study. Which technique will be applied in patients with tricuspid regurgitation has been decided according to the surgeon's discretion. In the TDVA technique, the annulus measurement was made using the finger technique. The annulus was narrowed so that the thickness of two to three fingers width remained the size of the annulus.[3] In the ring technique, the ring gauge number, in which leaflet coaptation is provided, was used. Contour 3D annuloplasty ring (Medtronic, Minneapolis, MN) has been used for all TRA.

In the study, TR was divided into no-trace, mild, moderate, and severe. The study is basically based on the 2014 and 2017 American Heart Association/American College of Cardiology Guidelines. According to the guidelines; moderate or severe TR after surgery was classified as recurrence/insufficient repair. TR was graded according to the central jet area and vena contracta width and is as follows.

Mild TR; central jet area <5.0 cm^2, Vena contracta width not defined Moderate EN; Central jet area 5–10 cm^2, Vena contracta width not defined but <0.70 cm Severe TR; Central jet area was accepted as >10.0 cm^2 and Vena contracta width >0.7 cm.

Surgical indications were determined according to the following headings.

Class 1. Tricuspid valve surgery is recommended for patients with severe TR undergoing left-sided valve surgery.

Class IIa 1. Tricuspid valve repair can be beneficial for patients with mild, moderate, or greater functional TR at the time of left-sided valve surgery with either (1) tricuspid annular dilation or (2) prior evidence of right heart failure.

Class IIb 1. Tricuspid valve repair may be considered for patients with moderate functional TR and pulmonary artery hypertension at the time of left-sided valve surgery.

Patients with concomitant left ventricular assist device, emergency cases, reoperations, patients who underwent aortic valve replacement or coronary artery bypass grafting (CABG), or carotid endarterectomy were not included in the study. Mitral valve diseases of ischemic and degenerative origin have been excluded from the study. Furthermore, patients with primary tricuspid valve insufficiency were excluded from the study. We aimed to create a more isolated group by excluding these patients, allowing for a clearer comparison of the techniques we wanted to investigate.

A fasting blood glucose level of 126 mg/dL and above was taken as the criterion for diabetes. A fasting blood low-density lipoprotein value of 160 mg/dL and above was taken as the criterion for hyperlipidemia. Renal dysfunction criterion was determined as creatinine value of 1.2 mg/dL and above in female patients and 1.4 mg/dL and above in male patients.

The primary end-point was post-operative tricuspid valve insufficiency. Thirty day mortality was not taken as the primary endpoint due to the small number of patients.

This study has been approved by the Ethics Committee decision numbered 2021/1/414 dated January 12, 2021.

Surgical Method

The patients were operated under general anesthesia with median sternotomy. Aortic arterial and bicaval venous cannulation was performed. Venting was performed through the right superior pulmonary vein. The cross-clamp was applied to the ascending aorta. The heart was arrested with antegrade isothermal blood cardioplegia. Antegrade cardioplegia was given intermittently in every 20 min. Following the vertical left atriotomy incision, the patients underwent mitral valve replacement. The left atrium was closed. Afterward, the tricuspid valve was intervened by right atriotomy. Then, the right atriotomy was closed, the air was evacuated, and the cross-clamp was removed. After separation from cardiopulmonary bypass, drain tubes, and epicardial pacemaker wires were placed. After the bleeding control, the sternum was wired. The skin and subcutaneous tissue were closed in accordance with the procedure. The patients were transferred to the intensive care unit. After the stable intensive care process, the patients were followed up in the service. The patients, whose blood tests, chest X-rays, and echocardiograms were evaluated, were discharged with the knowledge of the responsible physicians.

Table 1. Pre-operative characteristics of the groups

	TRA (n=95)		TDVA (n=30)		Total (n=125)		p
	n	%	n	%	n	%	
Age (year), mean±SD	57.11±10.47		52.93±12.07		56.11±10.97		0.069[1]
Gender							
Male	28	29.5	8	26.7	36	28.8	0.948[2]
Female	67	70.5	22	73.3	89	71.2	
Diabetes	30	31.6	10	33.3	40	32.0	1.000[3]
Hyperlipidemia	7	7.4	4	13.3	11	8.8	0.295[4]
Renal disfunction	8	8.4	2	6.7	10	8	1.000[4]
Weight (kg)	74.69±13.06		78.9±12.31		75.7±12.96		0.122
Height (cm)	161.51±8.99		163.17±8.24		161.9±8.81		0.370
BMI (kg/m^2)	28.6±4.57		29.77±5.84		28.88±4.91		0.258

[1]: Student t-test; [2]: Continuity (yates) correction; [3]: Continuity (yates) correction; [4]: Fisher's exact test. TRA: Tricuspid valve ring annuloplasty; TDVA: Tricuspid valve de Vega annuloplasty; SD: Standard deviation; BMI: Body mass index.

Table 2. Evaluation of the groups in terms of pre-operative echocardiographic data

Pre-operative	TRA (n=95)		TDVA (n=30)		Total (n=125)		
	n	Mean±SD (median)	n	Mean±SD (median)	n	Mean±SD (median)	p[1]
LAD (cm)	93	5.04±0.69 (5)	28	5.12±0.73 (5.1)	121	5.06±0.7 (5)	0.642
LVEDD (cm)	95	4.94±1.11 (4.9)	30	4.78±1.78 (5)	125	4.9±1.3 (5)	0.528
LVESD (cm)	92	3.5±0.78 (3.3)	28	3.71±0.97 (3.5)	120	3.55±0.83 (3.3)	0.416
PAP (mmhg)	91	54.48±14.25 (55)	26	51.92±11.8 (50)	118	53.91±13.74 (55)	0.522
EF	95	58.38±8.42 (60)	30	56.33±10.9 (60)	125	57.89±9.07 (60)	0.491
TR n, %							
Mild	1	1.1	2	6.7	3	2.4	0.177[2]
Moderate	42	44.2	14	46.7	56	44.8	
Severe	52	54.7	14	46.7	66	52.8	

[1]: Mann–Whitney U Test; [2]: Fisher Freeman Halton Test. TRA: Tricuspid valve ring annuloplasty; TDVA: Tricuspid valve de Vega annuloplasty; SD: Standard deviation; LAD: Left atrial diameter; LVEDD: Left ventricle end-diastolic diameter; LVESD: Left ventricle end-systolic diameter; PAP: Pulmonary artery pressure; EF: Ejection fraction; TR: Tricuspid regurgitation.

Statistical Methods

While evaluating the findings obtained in the study, the IBM Statistical Packages for the Social Sciences (SPSS) Statistics 22 (IBM SPSS, Istanbul, Türkiye) program was used for statistical analysis. The suitability of the parameters to the normal distribution was evaluated by Kolmogorov–Smirnov and Shapiro–Wilks tests. While evaluating the study data, in addition to descriptive statistical methods (Mean, Standard deviation, Frequency), Student's t-test was used for the comparison of normally distributed parameters between two groups, and Mann–Whitney U test was used for comparisons of non-normally distributed parameters between two groups. Friedman test and post hoc Wilcoxon sign test were used for in-group comparisons of non-normally distributed parameters. Chi-square test, Fisher's Exact Chi-square test, Continuity (Yates) Correction and Fisher Freeman Halton test were used to compare qualitative data. Significance was evaluated at the $p<0.05$ level.

Results

The ages of the patients included in the study ranged from 28 to 78, and it was conducted with a total of 125 cases, 36 (28.8%) male and 89 (71.2%) female. The mean age is 56.11±10.97 years. TRA was applied to 95 (76%) cases and TDVA was applied to 30 (24%) cases.

Table 3. Evaluation of the groups in terms of intraoperative data

	TRA (n=95) Mean±SD	TDVA (n=30) Mean±SD	Total (n=125) Mean±SD	p
ACC (min)	99.61±33.3	105.37±27.74	100.99±32.04	0.393
TPT (min)	142.8±40.73	146.97±39.76	143.8±40.38	0.624

Student t-test. SD: Standard deviation; TRA: Tricuspid Valve ring annuloplasty; TDVA: Tricuspid Valve De Vega annuloplasty; ACC: Aortic cross-clamp time; TPT: Total perfusion time.

Table 1 there was no statistically significant difference between the groups in terms of demographic characteristics and health status ($p>0.05$).

Table 2 there was no statistically significant difference between the groups in terms of echocardiographic evaluation ($p>0.05$).

Table 3 there was no statistically significant difference between the groups in terms of the mean duration of aortic cross clamp (ACC) and total perfusion times (TPT) ($p>0.05$).

Table 4 there was no statistically significant difference between the groups in terms of pulmonary artery pressures (PAP) and TR levels in the post-operative 1st week ($p>0.05$).

There was a statistically significant difference between the groups in terms of post-operative 1st week ejection fraction (EF) levels ($p=0.031$; $p<0.05$). The post-operative EF level of the patients who underwent the TRA was significantly higher than the patients who underwent TDVA.

Table 4. Evaluation of the groups in terms of echocardiographic data in the post-operative 1st week

Post-operative	TRA		TDVA		Total		
	n	Mean±SD (median)	n	Mean±SD (median)	n	Mean±SD (median)	p[1]
PAP (mmhg)	47	39.87±11.07 (40)	16	36.56±10.76 (37.5)	63	39.03±11 (40)	0.571
EF	93	54.03±10.35 (55)	30	49.33±11.28 (50)	123	52.89±10.73 (55)	0.031*
TR n, %							
None	17	19.5	9	33.3	26	22.8	0.199[2]
Mild	38	43.7	6	22.2	44	38.6	
Moderate	25	28.7	10	37.0	35	30.7	
Severe	7	8.0	2	7.4	9	7.9	

[1]: Mann–Whitney U Test; [2]: Ki-kare test; *: p<0.05. TRA: Tricuspid Valve ring annuloplasty; TDVA: Tricuspid Valve De Vega annuloplasty; SD: Standard deviation; PAP: Pulmonary artery pressure, EF: Ejection fraction; TR: Tricuspid regurgitation.

Table 5. Evaluation of groups in terms of intensive care follow-up data

Follow-up data	TRA (n=95)		TDVA (n=30)		Total (n=125)		
	n	%	n	%	n	%	p
Revision	8	8.4	5	16.7	13	10.4	0.300
Prolonged intubation	5	5.3	3	10	8	6.4	0.397
Tracheostomy	2	2.1	1	3.3	3	2.4	0.564
IABP	7	7.4	5	16.7	12	9.6	0.158
ECMO	1	1.1	1	3.3	2	11.6	0.424
New onset dialysis	9	9.5	3	10	12	9.6	1.000
30-day mortality	2	2.1	5	16.7	7	5.6	0.009*

Fisher's exact test. *: p<0.05. TRA: Tricuspid Valve ring annuloplasty; TDVA: Tricuspid Valve De Vega annuloplasty; IABP: Intra-aortic balloon pump; ECMO: Extracorporeal membrane oxygenator.

Table 5 taking into consideration of rates of revision for bleeding control, prolonged intubation, tracheostomy, intra-aortic balloon pump, extracorporeal membrane oxygenator, and new-onset dialysis, there was no statistically significant difference between the groups (p>0.05). The 30-day mortality rate (16.7%) in TDVA patients was statistically significantly higher than in TRA (2.1%) patients (p=0.009; p<0.05).

Table 6 there was no statistically significant difference between the groups in terms of length of stay in the intensive care unit (p>0.05).

Table 7 in the medium term, there was no statistically significant difference between the groups in terms of the time between surgery and the last control, PAP levels, EF levels, and TR levels (p>0.05). In the medium term, while there is no TR in 17.7% of cases with TRA applied, it is mild in 40.3%, moderate in 37.1%, and severe in 4.8%. While there is no TR in 12.5% of TDVA applied cases, it is mild in 31.3%, moderate in 37.5%, and severe in 18.8%.

Table 6. Evaluation of groups in terms of intensive care unit length of stay

	Intensive care unit length of stay (day)			
	n	Mean±SD	Median	p
TRA	95	5.21±7.75	3	
TDVA	30	4.57±4.09	2.5	0.911
Total	125	5.06±7.03	3	

Mann–Whitney U test. SD: Standard deviation; TRA: Tricuspid Valve Ring annuloplasty; TDVA: Tricuspid Valve De Vega annuloplasty.

Discussion

TR is more common in women.[4] We obtained similar results with literature studies in terms of mean age[5] and gender. TRA has been preferred more in recent years, and the number of tricuspid TDVA performed today has decreased[6] as similar to our study.

The patients participating in the study were tried to be homogenized as much as possible, and only those who had mitral valve replacement as well as TRA or TDVA were included. Some studies in the literature included patients who underwent concomitant CABG or aortic valve surgery.[6,7] On

Table 7. Evaluation of the groups in terms of echocardiographic data at the post-operative 10th month

Post-operative control	TRA		TDVA		Total		
	n	Mean±SD (median)	n	Mean±SD (median)	n	Mean±SD (median)	p[1]
Time between surgery and last control (month)	65	9.33±8.76 (6)	16	12.25±11.81 (8.5)	81	9.91±9.43 (6)	0.634
PAP (mmhg)	48	37.81±10.03 (37.5)	13	40.23±8.56 (38)	61	38.33±9.72 (38)	0.345
EF	65	53.54±11.31 (55)	16	50.25±11.21 (50)	81	52.89±11.30 (55)	0.202
TR n, %							
None	11	17.7	2	12.5	13	16.7	0.326[2]
Mild	25	40.3	5	31.3	30	38.5	
Moderate	23	37.1	6	37.5	29	37.2	
Severe	3	4.8	3	18.8	6	7.7	

[1]: Mann–Whitney U Test; [2]: Fisher Freeman Halton Exact test. TRA: Tricuspid Valve ring annuloplasty; TDVA: Tricuspid Valve De Vega annuloplasty; SD: Standard deviation; PAP: Pulmonary artery pressure; EF: Ejection fraction; TR: Tricuspid regurgitation.

the other hand, excessive homogenization was reflected to us as a decrease in the number of patients.

We think that our study will yield reliable results in the evaluation of the effectiveness of the investigated TRA and TDVA techniques, as there was no significant difference between the groups in pre-operative parameters.

In literature, ACC and TPT times were reported to be longer in patients who underwent TRA[8,9] than TDVA. In our study, unlike the literature, there was no difference between the groups in terms of the mean duration of intraoperative ACC and TPT.

Mild TR had more surgical intervention in the TDVA group. Mild tricuspid valve regurgitation may also require intervention, for example, in some centers, regardless of the degree of tricuspid valve insufficiency, an annulus of the tricuspid valve >21 mm on echocardiography is a surgical indication.[10] In some centers, an intraoperative tricuspid valve anterior leaflet length of 70 mm or more is accepted as the surgical margin.[11]

A decrease in PAP is expected due to the reduction in pulmonary congestion after mitral valve replacement and tricuspid annuloplasty. In the study of Rivera et al.,[12] a decrease was found in PAP after tricuspid valve annuloplasty. In addition, the relative increase in EF secondary to mitral regurgitation appears as a decrease in the EF level after the operation. In addition, we expect a decrease in TR with tricuspid annuloplasty.

In our study; compared to the pre-operative period, significant decreases were detected in PAP, EF, and TR levels in both groups at post-operative 1st week. There was no difference between the groups in PAP and TR levels at post-operative 1st week. This shows us that TRA and TDVA are equally effective in eliminating TR in the early post-operative period. The patients in the TRA group with pre-operative moderate or severe TR presented with 36.7% of moderate or severe TR at the post-operative 1st week. In addition, the patients in the TDVA group who were operated for moderate or severe TR were encountered with 44.4% of moderate or severe TR post-operatively. In the light of this information, there is a significant early post-operative recurrence of tricuspid valve regurgitation in both techniques. In Sohn et al.[13] study, mitral valve replacement was identified as an independent risk factor for the recurrence of TR. The recurrence of such valve insufficiency in our patients may be related to this finding. There is a significant risk of recurrent regurgitation after tricuspid valve repair.[1,14,15] As a matter of fact, in our study, these conditions were found to be compatible. The recurrence rate of significant TR after tricuspid annuloplasty was stated as the severity of pre-operative TR, pulmonary hypertension, presence of a pacemaker, left ventricular dysfunction, increased left ventricular remodeling, retraction of the tricuspid leaflets by the severely enlarged ventricle, and the use of sutures instead of ring annuloplasty.[14–16] In the study of Matsuyama et al.,[17] post-operative TR was found to be 45% in the De Vega group, which supports our study. In the same study, this rate seems to be 6% in the TRA group. In a number of studies, TRA was found to be superior in reducing TR recurrence.[7,12,15,17–21,22] In a study conducted by McCarthy et al.,[14] it was found that TR increased significantly over time after TDVA. In a study by Peltola et al.,[23] it was emphasized that TDVA is effective in mild and moderate TR, but TRA should be performed in severe TR. In the study of Shinn et al.,[24] no difference was found between long-term TR recurrences between TRA and TDVA. In Wang's literature review, it is noted that TR persisted in all cases following tricuspid annuloplasty and that it did not completely resolve in any of the cases.[3]

In patients who underwent TRA, EF levels were found to be higher at post-operative 1st week compared to those who underwent TDVA. In addition, we think that the preservation of EF seen in TRA contributes to a lower 30-day hospital mortality compared to TDVA. As we look at the literature, in the study by Türkmen et al.,[9] comparing the TRA and TDVA techniques, the 30-day mortality was found to be higher in the TDVA group. In the study of Ren et al.,[20] no difference was found between TRA and TDVA in terms of hospital mortality. When we look at the intensive care follow-ups among the groups; there was no difference except early mortality. In the study of Tang et al.,[7] post-operative low cardiac output is more common in patients who underwent TRA. In the study by Lafci et al.,[25] the need for post-operative inotropic support, duration of mechanical ventilation, and length of hospital and intensive care unit stays were found to be higher in the TDVA group. Sohn et al.[13] also found a higher incidence of low cardiac output syndrome and respiratory complications in the TDVA group.

After our patients were discharged, the results of the last echocardiography that they had done at the hospital were evaluated. There was no statistically significant difference between the groups in terms of the time between the surgery and the last date they came for control ($p>0.05$). The last control of the patients was at the mean 10th month postoperatively. No difference was found between PAP, EF, and TR levels in the echocardiograms of the controls at the mean 10th month postoperatively. From this, we can say that there is no difference between TDVA and TRA in terms of cardiac functions in the medium-long term.

According to the guidelines, moderate or severe TR after surgery is classified as recurrence/insufficient repair. Significant recurrence of tricuspid valve insufficiency is seen significantly in both the early post-operative period and in the medium-long term in both techniques. It seems that neither technique is effectively preventing tricuspid insufficiency to the desired level. The mid-term results of both techniques are similar, and no significant difference that would favor one over the other has been observed.

Limitations

This study was a retrospective observational study performed at a single institution. Our study covered a period of 3 years and the number of patients was 125 and thus results might be biased. Study time interval and low number of patients may adversely affect the study. In addition, a certain part of the patients came to the clinic at the last hospital control, only the data of these patients could be examined. Futhermore, tricuspid annulus and tricuspid annular plane systolic excursion values were not measured preoperatively and postoperatively in most echocardiographic examinations. This has caused us to have less information of the right heart.

The techniques applied to the patients were applied by different surgeons, and differences in experience may have affected the success of the techniques adversely. Homogeneity between the teams could not be achieved because the number of patients did not allow this.

Conclusion

Although the need for intervention in tricuspid valve insufficiency secondary to left heart valve diseases has been clarified, which method to use is a matter of debate.

Current studies mostly argue that the TRA method is superior to the TDVA method.

Considering the data of our study; there is no difference between TRA and TDVA techniques in terms of recurrence of tricuspid valve insufficiency in the medium term. The mid-term results of both techniques are similar, and no significant difference that would favor one over the other has been observed. In patients with TR, both techniques can be applied. Both techniques are not perfect, and the rates of recurrent TR are very high. There is an urgent need for the development of new strategies and techniques.

Disclosures

Ethics Committee Approval: The study was approved by the Koşuyolu High Training and Research Hospital Clinical Research Ethics Committee (no: 2021/1/414, date: 12/01/2021).

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