Prognostic impact of right ventricular dysfunction following transcatheter mitral valve repair

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Abstract

Background Little is known regarding the impact of right ventricular (RV) function on clinical outcomes following MitraClip therapy. Objectives The aim of this study was to investigate the prognostic impact of RV dysfunction and its cut-off value following MitraClip therapy. Methods Consecutive 77 patients (median 79 years, 33% female) who underwent MitraClip therapy were enrolled. Clinical endpoint was defined as cardiovascular (CV) events, including cardiovascular death and rehospitalization for heart failure (HF). Results and conclusions Twenty-two (29%) patients had primary mitral regurgitation (MR). During follow-up, 5 patients died due to CV events, 8 were hospitalized for HF. On univariate Cox regression analysis, CV events were associated with eGFR (HR; 0.960, 95% CI; 0.926–0.995, p = 0.027), tricuspid annular plane systolic excursion (TAPSE, HR; 0.874, 95% CI; 0.789–0.968, p = 0.010), and significant residual MR (HR; 11.652, 95% CI; 3.257–41.691, p <0.001). On multivariate Cox regression analysis, TAPSE (HR; 0.788, 95% CI; 0.788–0.987, p = 0.029) and significant residual MR (HR; 9.373, 95% CI; 2.581–34.033, p = 0.001) were independently associated with CV events. TAPSE <11 mm was the best cut-off criteria for predicting CV events. RV function was independently associated with clinical outcomes following MitraClip therapy. TAPSE is a simple parameter for predicting CV events in patients with MR who are undergoing MitraClip therapy.

Prognostic impact of right ventricular dysfunction following transcatheter mitral valve repair

Running title: Prognostic impact of TAPSE on MitraClip therapy

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Methods

Consecutive 77 patients (median 79 years, 33% female) who underwent MitraClip therapy were enrolled. Clinical endpoint was defined as cardiovascular (CV) events, including cardiovascular death and rehospitalization for heart failure (HF).

Results and conclusions

Twenty-two (29%) patients had primary mitral regurgitation (MR). During follow-up, 5 patients died due to CV events, 8 were hospitalized for HF. On univariate Cox regression analysis, CV events were associated with eGFR (HR; 0.960, 95% CI; 0.926–0.995, p = 0.027), tricuspid annular plane systolic excursion (TAPSE, HR; 0.874, 95% CI; 0.789–0.968, p = 0.010), and significant residual MR (HR; 11.652, 95% CI; 3.257–41.691, p <0.001). On multivariate Cox regression analysis, TAPSE (HR; 0.788, 95% CI; 0.788–0.987, p = 0.029) and significant residual MR (HR; 9.373, 95% CI; 2.581–34.033, p = 0.001) were independently associated with CV events. TAPSE <11 mm was the best cut-off criteria for predicting CV events.

RV function was independently associated with clinical outcomes following MitraClip therapy. TAPSE is a simple parameter for predicting CV events in patients with MR who are undergoing MitraClip therapy.

Key words: MitraClip therapy, mitral regurgitation, right ventricular function, transcatheter mitral valve repair, heart failure, tricuspid annular plane systolic excursion, cardiovascular events

Introduction

The relationship between right ventricular (RV) function and prognosis has been reported in various cardiac diseases, including mitral regurgitation (MR).(1-6) After transcatheter mitral valve repair (TMVr), patients with RV dysfunction had an increased risk of all-cause mortality.(7) TMVr has the potential to restore RV function, which was shown in early experiences with the MitraClip (Abbott, Abbott Park, IL).(8) To date, only a few reports have provided data regarding RV function during follow-up.(8-10) Further, little is known regarding the impact of RV function and its cut-off value for predicting adverse outcomes following MitraClip therapy. The aim of this study was to investigate the prognostic impact of RV function following TMVr using MitraClip.

Methods

Patient population

We included seventy-seven consecutive patients who underwent TMVr using the MitraClip system at a single center in Asia from April 2018 to November 2019. Indications for TMVr included symptomatic, moderate-to-severe (3+), or severe (4+) MR(11) with a high risk for surgery. An interdisciplinary heart team, which included an interventional cardiologist, a cardiac surgeon, an echocardiologist, and a cardiac anesthetist, discussed each subject's eligibility for TMVr. All patients gave written informed consent in a local registry to be included in the study. The protocol of this study was approved by the ethical committee of St. Marianna University School of Medicine.

Transthoracic echocardiographic measurement

Transthoracic echocardiography was performed at baseline (within a week prior to TMVr) and before discharge (shortly after TMVr). MR severity was defined as none or trace (0/4+), mild (1+/4+), moderate (2+/4+), moderate-to-severe (3+/4+), and severe (4+/4+) using the American Society of Echocardiography (ASE) guidelines for an integrative approach.(12,13) Systolic pulmonary artery (PA) pressure was calculated from the peak tricuspid regurgitant (TR) jet velocity using the simplified Bernoulli's equation, with the addition of the right atrial pressure estimated from inferior vena cava diameter.(14) TR quantification, as well as the evaluation of RV dimensions and function, was performed according to the recommendations of the ASE guidelines.(11,14) Briefly, RV function was assessed through tricuspid annular plane systolic excursion (TAPSE) acquired on M-mode tracings through the tricuspid annulus by the RV-focused apical 4-chamber view (Figure1). RV fractional area change (FAC) by the apical 4-chamber view is the area difference between RV end-diastolic and end-systolic areas measured through ideally RV-focused apical view. RV systolic excursion velocity (S') was defined by tissue Doppler echocardiography as a parameter of the longitudinal velocity of the tricuspid annulus.(15)

Clinical follow-up

Clinical outcome was defined as the presence or absence of cardiovascular (CV) events, which included cardiovascular death and hospitalization for heart failure (HF). HF was defined as dyspnea and objective signs consistent with New York Heart Association (NYHA) class II–IV requiring hospitalization and medication. Clinical follow-up data were obtained by review of medical records.

Statistical analysis

Data are expressed as median and interquartile range (IQR) for continuous variables and number and percentage for categorical variables. The t -test was used to determine between-group differences for continuous variables, and the chi-squared test was used to determine between-group differences for categorical variables. We tested the ability of TAPSE to predict CV events by evaluating the area under the curve (AUC) of its receiver operating characteristic (ROC) curve, and compared its AUC with those of FAC and RV S'. Event-free curves were generated using the Kaplan-Meier method. Log-rank tests were used to evaluate the differences between groups. Multivariate cox regression analysis was used to ascertain the relationship between clinical and echocardiographic variables, which could indicate a potential relationship with outcomes. The results of cox regression analysis are given as hazard ratios (HR) with their respective 95% confidence intervals (CIs). A probability value of less than 0.05 was considered to indicate statistical significance. Analysis was conducted using a standard statistical software program (SPSS version 19, IBM Corp., Armonk, NY, USA).

Results

Baseline characteristics are shown in Table 1. The median age of the patients was 79 (74 – 83) years, 33% of patients (n = 25) were female, and the STS SCORE was 11.0 (5.3 – 16.0)%. The mechanism of MR was secondary in 55 (71%) patients and primary in 22 (29%) patients. During a median of 221 (99 – 447) days of follow-up, 13% of patients in the entire cohort had CV events (event group). The event group, compared to the no-event group, had lower estimated glomerular filtration rate (eGFR) (25.2 (IQR: 19.9 – 31.5) mL/min/1.73m^2 vs. 41.7 (IQR: 29.8 – 56.6) mL/min/1.73m^2, p = 0.006), higher N-terminal pro-brain natriuretic peptide (4042 (IQR: 2794 – 7114) pg/mL vs. 1760 (IQR; 870 – 4955) pg/mL, p = 0.039), and lower TAPSE (12 (IQR: 7 – 14) mm vs. 16 (IQR: 13 – 22) mm, p = 0.009).

Procedural and clinical outcomes

One clip was implanted in 44 (57%) patients and two clips were implanted in the remaining patients (Table 2). All patients experienced technical success according to the Mitral Valve Academic Research Consortium (MVARC) criteria.(16) During a median of 221 (99 – 447) days of follow-up after TMVr, 5 patients died due to CV events and 8 patients had HF hospitalization. The event group, compared to the no-event group, had a higher prevalence of moderate residual MR at discharge (p = 0.012) and longer length of hospital stay post-TMVr (p = 0.003) (Table 2). On univariate Cox regression analysis (Table 3), CV events were associated with eGFR (HR: 0.960, 95%CI; 0.926 – 0.995, p = 0.027), TAPSE (HR: 0.874, 95%CI; 0.789 – 0.968, p = 0.010), and significant residual MR (HR: 11.652, 95%CI; 3.257 – 41.691, p <0.001). On multivariate Cox regression analysis, CV events were independently associated with TAPSE (HR: 0.788, 95%CI; 0.788 – 0.987, p = 0.029) and significant residual MR (HR: 9.373, 95%CI; 2.581 – 34.033, p = 0.001). TAPSE did not significantly change mean 4days after the procedure (15 (12 – 22) mm to 16 (12 – 21) mm, p = 0.708). Figure 2 shows the ROC analysis of TAPSE to predict CV events. TAPSE had the largest AUC compared to RV-FAC (0.793 vs. 0.681) and RV-S' (0.793 vs. 0.626). TAPSE <11 mm was the best cut-off value for predicting CV events (Sensitivity 0.839; Specificity 0.556). Kaplan-Meier analysis showed that no RV functional parameters, except for TAPSE, had a significant prognostic power for predicting CV events (Figure 3).

Discussion

We aimed to ascertain whether RV dysfunction was associated with CV events in patients with MR who underwent MitraClip therapy. The main findings of this study are as follows: first, RV dysfunction was independently associated with CV events following MitraClip therapy; second, TAPSE was the best RV functional parameter of conventional echocardiography for predicting adverse events; third, the cut-off value of TAPSE for predicting CV events was 11 mm.

RV function is an important parameter with prognostic value in predicting symptomatic limitation and outcome in different cardiovascular pathologies.(17-22) Several parameters have been developed for the evaluation of RV systolic function, including TAPSE, FAC, and S'. Among them, TAPSE is a commonly utilized single-dimension measure of global RV systolic function. It simply measures the distance of systolic excursion of the RV annular segment along its longitudinal axis. According to the ASE/EACVI guidelines, a TAPSE of <16 mm suggests impaired RV systolic function.(14) In patients with severe MR, RV dysfunction is associated with increased morbidity and mortality.(1,23,24) Our results are in agreement with those of previous studies(7,25,26) in determining the prognostic role of baseline RV function in patients with MR undergoing MitraClip therapy. Our study expands on these previous studies in demonstrating an 11-mm cut-off value of TAPSE for predicting CV events following MitraClip therapy. Atrial fibrillation (AF) could result in pulmonary hypertension, causing RV dysfunction and RA dilation or loss of atrial contraction, which reduces RV filling and could reduce TAPSE.(27) In the present cohort study, 80% of the event group had AF. This might have resulted in a low cut-off value for TAPSE.

Apart from RV dysfunction,(28) pulmonary hypertension is a common complication in HF and predicts the occurrence of adverse outcome.(29,30) Pulmonary hypertension has long been considered a serious complication in patients with significant MR. Elevation of LAP occurs in the transitional and decompensated phases of chronic MR(31) and leads to increased pulmonary arterial pressure, eventually resulting in RV dysfunction.(32)

A number of previous studies have described the impact of RV-PA coupling (TAPSE/PA systolic pressure).(33) Because RV systolic performance is highly dependent on RV afterload,(34) a combination of these coupling parameters would be more important than each parameter in isolation. Combined evaluation (i.e. RV-PA coupling) could be considering right heart hemodynamics.(35) RV-PA coupling ratio was impaired in patients with HF with preserved ejection fraction.(36) Sultan et al. demonstrated that RV-PA coupling is strongly associated with all-cause mortality and its evaluation may be superior to RV or PA alone in predicting worse outcomes in patients undergoing transcatheter aortic valve replacement.(37) In contrast, our

study demonstrated that TAPSE had a larger AUC than RV-PA coupling (0.793 vs. 0.675) to predict CV events (Supplemental figure 1). On multivariate Cox regression sub-analysis, CV events were independently associated with lower TAPSE (HR: 0.873, 95%CI; 0.788 – 0.968, p = 0.010) after adjustment for PA pressure measured by transthoracic echocardiography. According to our results, RV dysfunction (by TAPSE) could independently predict worse outcomes regardless of hemodynamics.

In the present study, we found that residual MR>2+ was also an independent predictor of CV events. Similarly, a previous study reported that MitraClip therapy was effective in reducing MR.(38,39) Since residual MR after MitraClip therapy has been associated with suboptimal outcomes and increased mortality(40), the goal of the procedure is to reduce residual MR as much as possible.

Limitations

Previous studies demonstrated that RV function improved after MitraClip therapy.(41,42) However, there was no mention of periprocedural change of RV function in this study. This was a single-center study and the sample size was small, which limits its generalizability. Further, this study focused on short-term results. Properly designed trials with longer follow-up and more patients are required to confirm our results.

Conclusions

TAPSE may be one of the independent significant predictors of CV events in patients with MR undergoing MitraClip therapy. TAPSE may be measured prior to MitraClip therapy as a simple and easy parameter of RV function to predict worse outcomes in a MitraClip cohort.

Clinical Perspectives

In patients with severe MR, RV dysfunction is associated with increased adverse outcomes. TAPSE was an independent predictor of CV events following MitraClip therapy. Its cut-off value (11%) may be independently available to predict CV events following MitraClip therapy. The present study comprised a small sample size and focused on short-term results. Properly designed trials with longer follow-up and more patients are required to confirm our results.

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Table 1. Baseline characteristics

Age, yrs
Female, n (%)
Body mass index, kg/m^2
Patient history
Previous congestive heart failure, n (%)
Previous myocardial infarction, n (%)
Previous coronary artery bypass graft, n (%)
Previous percutaneous intervention, n (%)
Previous cerebral disease, n (%)
Comorbidities
Dyslipidemia, n (%)
Hypertension, n (%)
Diabetes mellitus, n (%)
COPD, n (%)
Coronary artery disease, n (%)
Atrial fibrillation, n (%)
Hemoglobin (g/dL)
eGFR (mL/min/1.73m^2)
proBNP (pg/mL)
Patient status
NYHA functional class, n (%)
I, II, III, IV
STS risk score, %
Preprocedural echo data
Degenerative MR, n (%)
MR grade; III, IV, n (%)
MV-EROA, cm^2
LVEF, %
LVEDVi, mL/m^2
LAVi, mL/m^2
RVSP, mmHg
Moderate or severe TR, n (%)
Pulmonary hypertension, n (%)
TAPSE, mm
RV-FAC, %
RV-s', cm/s

Values are n (%) or median (interquartile range). COPD, chronic obstructive pulmonary disease; eGFR, estimated glomeru

Table 2. Postprocedural characteristics

	All patie
Number of clips implanted, n (%)	1 clip, 44
Greater to moderate residual MR at discharge, n (%)	5 (7)
MV mean PG (mmHg)	3.0 (2.1 –
Length of hospital stay after the procedure (days)	7 (5 – 11
Death, n (%)	5 (7)
Re-hospitalization due to HF, n (%)	8 (10)
Values are n (%) or median (interquartile range). HF, heart failure; MR, mitral regurgitation; MV, mitral valve	Values ar

Table 3. Cox Regression according to cardiovascular death or HF rehospitalization

Variables	
NYHA class [?] III	
eGFR	
Logalism of NT-pro BNP	
TR[?]III	
TAPSE	
Residual MR >2+	
, Assessed at discharge; , included eGFR, TR III or IV, TAPSE and Residual MR >2+. CI, confidence interval; eGFR, esti	

Figure Legends

Figure 1.

Title: Transthoracic echocardiographic image of tricuspid annular plane systolic excursion

Legend: Tricuspid annular plane systolic excursion was measured on M-mode tracings through the tricuspid annulus by the RV-focused apical 4-chamber view

RV, right ventricle

Figure 2. (Central Illustration)

Title: ROC curves of TAPSE, RV-FAC, and S' to predict CV events

Legend: The AUC of TAPSE (0.793) was the largest compared to those of RV-FAC (0.681) and S' (0.626).

AUC, area under the curve; CV, cardiovascular; ROC, receiver operating characteristic; TAPSE, tricuspid annular plane systolic excursion

Figure 3.

Title: Kaplan-Meier curves of cardiovascular events according to TAPSE

Legend: Patients with TAPSE <11 mm had a significantly higher rate of CV event ($p = 0.018$ by the log-rank test) compared to those with TAPSE [?]11 mm.

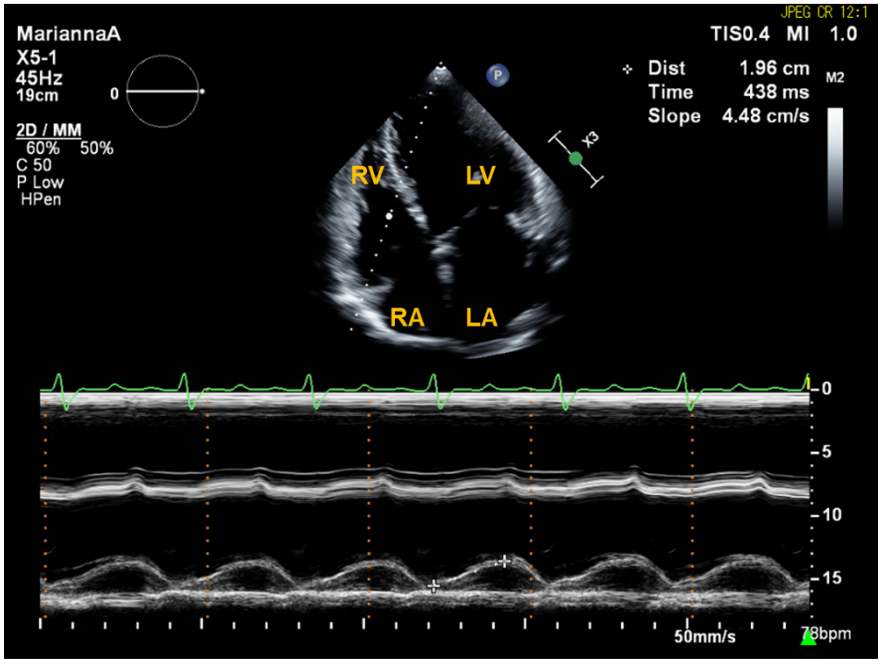
CV, cardiovascular; TAPSE, tricuspid annular plane systolic excursion

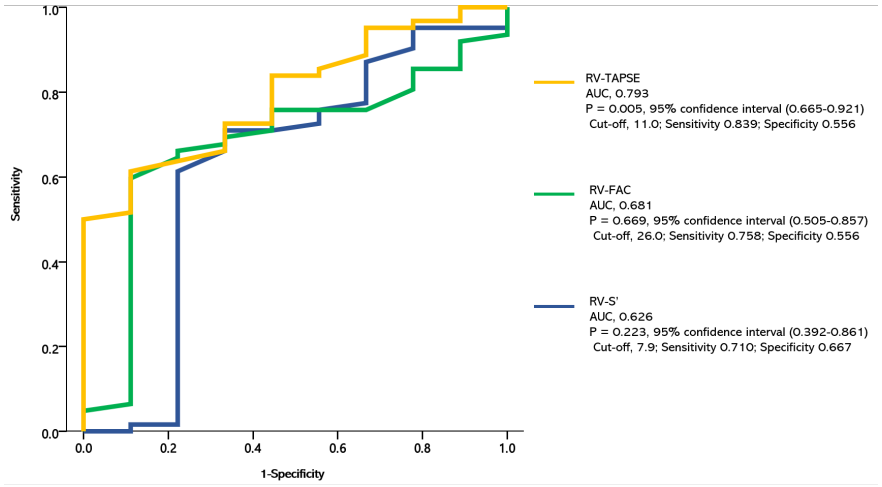
Table Legends

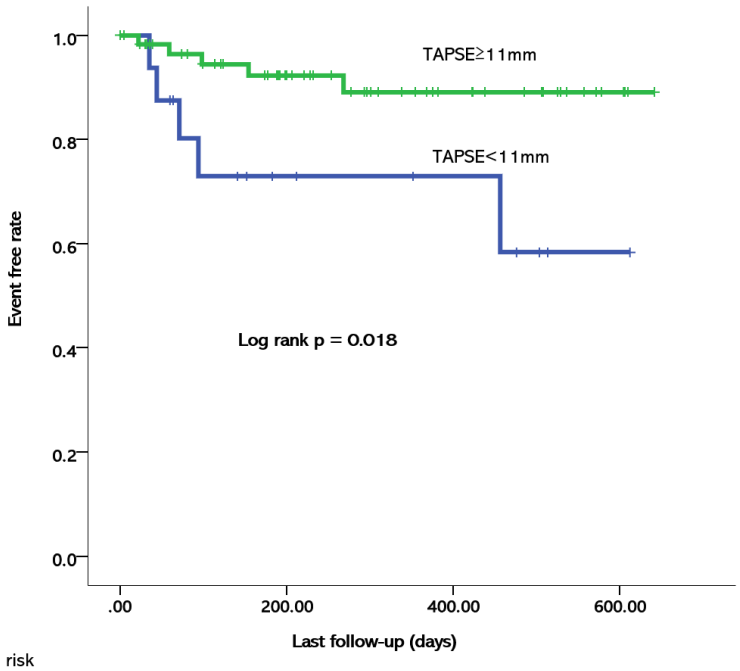
Table 1. Baseline characteristics

Table 2. Postprocedural characteristics

Table 3. Cox Regression according to cardiovascular death or HF rehospitalization







Number at risk

TAPSE≥11mm	58	35	17	4
TAPSE<11mm	15	7	5	1