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Differential prognostic accuracy of right ventricular dysfunction, the Seattle heart failure model and the MAGGIC score in patients with severe mitral regurgitation undergoing the MitraClip® procedure

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ABSTRACT

Background: MitraClip ® (MC) is an established procedure for severe mitral regurgitation (MR) in patients deemed unsuitable for surgery.

Right ventricular dysfunction (RVD) is associated with a higher mortality risk. The prognostic accuracy of heart failure risk scores like the Seattle heart failure model (SHFM) and Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) score in pts undergoing MC with or without RVD has not been investigated so far.

Methods: SHFM and MAGGIC score were calculated retrospectively. RVD was determined as tricuspid annular plane systolic excursion (TAPSE) ≤15 mm. Area under receiver operating curves (AUROC) of SHFM and MAGGIC were performed for one-year all-cause mortality after MC.

Results: N = 103 pts with MR III° (73 ± 11 years, LVEF 37 ± 17%) underwent MC with a reduction of at least I° MR. One-year mortality was 28.2%.

In Kaplan-Meier analysis, one- year mortality was significantly higher in RVD-pts (34.8% vs 2.8%, p = 0.009).

Area under the Receiver Operating Characteristic (AUROC) for SHFM and MAGGIC were comparable for both scores (SHFM: 0.704, MAGGIC: 0.692). In pts without RVD, SHFM displayed a higher AUROC and therefore better diagnostic accuracy (SHFM: 0.776; MAGGIC: 0.551, p < 0.05). In pts with RVD, MAGGIC and SHFM displayed comparable AUROCs.

Conclusion: RVD is an important prognostic marker in pts undergoing MC. SHFM and MAGGIC displayed adequate over-all prognostic power in these pts. Accuracy differed in pts with and without RVD, indicating higher predictive power of the SHFM score in pts without RVD.

1. Introduction

The transcatheter mitral valve edge-to edge repair (TMVR) using the MitraClip device (Abbott, USA) has emerged as therapeutic tool for patients with severe symptomatic mitral regurgitation (MR III°) who are deemed unsuitable for mitral valve surgery by the heart team.

In pivotal trials, TMVR showed similar improvements in clinical outcomes with a superior safety profile compared to conventional surgery in these patients [1].

Several large registries have since demonstrated sustained clinical benefit and echocardiographic improvement of MR severity after the procedure [2–4].

Consensus exists that the presence of mitral regurgitation has a negative impact on prognosis in heart failure patients [5,6]. Moreover, in the COAPT trial, patients with moderate to severe functional MR were randomized to either optimal medical treatment (OMT) alone or additional TMVR [7]. Patients in the interventional group demonstrated lower mortality and fewer heart failure hospitalizations, which held up during long term follow up [8]. However, the Mitra FR trial failed to show a mortality benefit at twelve months [9].

A number of important comorbidities and pathophysiological conditions have been described to attenuate the beneficial effect of TMVR in these selected multimorbid patients, such as depressed

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left atrial systolic function, atrial fibrillation and pulmonary hypertension [10–12]. Proper identification of patients likely to benefit from the procedure would therefore be highly advantageous.

In heart failure patients, prognostic models like the Seattle Heart Failure Model (SHFM) and the Meta-Analysis Global Group in Chronic (MAGGIC) Heart Failure score are widely used [13–16]. However, only limited data exist about the prognostic accuracy of these scores in patients referred for TMVR [17]. Moreover, the prognostic accuracy of these scores in the context of possible interactions with important determinants of prognosis in patients suffering from MR III° such as right heart dysfunction has not been separately described so far in the setting of TMVR.

Therefore, aim of the present study was to describe the prognostic utility of the SHFM and the MAGGIC score in patients with severe mitral regurgitation after TMVR with and without right ventricular dysfunction, as assessed by tricuspid annular plane excursion (TAPSE).

2. Methods

A total number of 103 consecutive patients were included in this retrospective observational analysis after TMVR in our institution. All patients gave their written informed consent to collect, analyze and publish patient-related data prior to data analysis. The study was approved by the local ethics committee (protocol Nr. 512/15) and performed in accordance with the declaration of Helsinki.

2.1. Heart team

As recommended by the ESC guidelines [17], every patient was discussed in detail by a heart team composed of interventional and noninterventional cardiologists, cardiac surgeons and anesthesiologists prior to therapy. If relevant for the individual patient, physicians of other specialties were also consulted. Factors favoring TMVR over a surgical approach included the patient's comorbidities, age, frailty, previous cardiac surgery, anatomy amenable to TMVR and high surgical risk (as determined by the EUROScore II) [18].

2.2. TMVR procedure

All patients received TMVR by the MitraClip device under general anesthesia, guided by both fluoroscopy and transesophageal echocardiography as previously described [1]. After femoral transvenous access and atrial transseptal puncture, the device is aligned with the regurgitant jet. Using the delivery system, the arms of the device are opened to grasp and approximate the leaflets. In case of inadequate MR reduction, the device may be moved, or additional Clips may be placed.

2.3. Echocardiography

Comprehensive transthoracic and transesophageal echocardiography was performed before the procedure. Transthoracic echocardiography was done during follow up according to the recommendations of the European Society of Cardiology [19]. The examinations included an assessment of severity, mechanism and suitability for interventional edge- to- edge repair.

Tricuspid annular plane systolic excursion (TAPSE) was measured before TMVR using the lateral tricuspid annulus from the apical 4- chamber view with an M- mode cursor [20,21]. A TAPSE $\leq$15 mm was defined as RVD [22].

Pulmonary artery systolic pressure was estimated using the peak tricuspid regurgitation velocity added to the right atrial pressure which was estimated based on size and collapsibility of the inferior vena cava [23].

2.4. Follow- up and outcome

Follow up was performed by phone calls with the patientś relatives, family physicians, or contacting the local registry office authorities about the patientś vital status.

2.5. Prediction of survival by the Seattle heart failure model

The Seattle Heart Failure Model (SHFM) integrates demographic characteristics, clinical features, laboratory values as well as implemented pharmacological and device treatments to comprehensively asses a heart failure patient's prognosis [24]. It was originally derived in a clinical trial cohort of HF patients with reduced left ventricular ejection fraction (LVEF) <35% and severe symptoms (NYHA class IIIB or IV) with external validation in additional HF cohorts from clinical trials and outpatient settings [25]. It has been used as a predictor of mortality, LVAD placement and to evaluate the benefit of cardiac devices [26].

SHFM scores were calculated using the SHFM webpage (https://depts.washington.edu/shfm).

2.6. Prediction of survival by the MAGGIC score

The Meta- Analysis Global Group in Chronic Heart Failure (MAGGIC) mortality risk model contains the following predictor variables: age, sex, body mass index, systolic blood pressure, LVEF, creatinine, current smoker, diabetes mellitus, chronic obstructive pulmonary disease, New York Heart Association (NYHA) class, HF duration >18 months, beta -blocker use and angiotensin-converting enzyme inhibitor use [27]. It includes patients from 30 cohort studies and includes both heart failure patients with reduced and preserved ejection fraction. It has been shown to predict all- cause mortality in patients undergoing transcatheter aortic valve replacement [13].

MAGGIC scores were calculated using the online calculator (https://www.mdcalc.com/maggic-risk-calculator-heart-failure).

2.7. Statistical analysis

Statistical analysis was performed using SPSS Version 23.0 for Windows. Categorical variables were expressed as counts and percentages, continuous variables with normal distribution as mean ± SD or median and interquartile range after testing for normal distribution. Categorical variables were analyzed by chi-square testing. For continuous variables, the Mann Whitney *U* test was performed.

The Kaplan- Meier method was used to chart event rates, survival curves were compared using the log- rank test.

Using C- statistics ("concordance"), specifically Delong's test for two correlated ROC curves, the receiver operating curves of both scores were compared to differentiate the discriminative ability of the MAGGIC and SHFM scores. The Software R Version 3.5.2 by Revolution Analytics was employed for this purpose.

Multivariate analysis for one-year all-cause mortality was performed using the Cox proportional hazard model.

All testing was performed with two-sided $p < 0.05$ as level of significance.

3. Results

3.1. Baseline characteristics and procedure

Between June 2013 and February 2017, a total number of 103 patients underwent successful TMVR with the MitraClip device in our institution after consensus for TMVR approach by the interdisciplinary heart team. All patients reported heart failure symptoms despite optimal medical treatment according to contemporary guidelines for pharmacotherapy in heart failure at the time of TMVR [19,28].

Right ventricular dysfunction defined as a TAPSE of 15 mm or less was present in 46 (44.6%) of the 103 patients. Patients with RVD demonstrated significantly lower left ventricular ejection fraction and higher NT-proBNP serum levels. Consecutively, mean EuroScore II, MAGGIC Score and SHFM score were higher in these patients (see Table1). Baseline characteristics are depicted in Table 1.

Degenerative MR was the underlying etiology in 60 (58.3%) of the patients, functional MR in 43 (41.7%) patients. The etiology of MR did not differ significantly between patients with and without RVD, with a higher proportion of degenerative MR in the group with preserved right ventricular function (30.1% versus 28.2% in patients with TVD, p = 0.17).

Compared to patients with degenerative MR, patients with FMR were significantly more often male (81.4 vs 63.3%, p = 0.047), demonstrated more often HFrEF with severely reduced LVEF (mean LVEF 29.8 ± 12.2% versus 41.4 ± 18.9%, p = 0.001) with more pronounced LV remodeling (left ventricular end-diastolic diameter 64.5 ± 10.1 mm vs 59.5 ± 10.2 mm, p = 0.028). Mean TAPSE did not differ between groups (FMR: 16.3 ± 4.2 versus DMR: 17.1 ± 3.9, p = 0.3). RVD defined as TAPSE < 15 mm was present in 28 (65.1%) of FMR-patients and 31 (51.7%) of DMR-patients, p = 0.12.

During the TMVR procedure, a median number of 2 clips (interquartile range (IQR) 1) were implanted. After therapy, a reduction of MR to MR grade 0 or 1 was achieved in 74 (71.8%) patients, 25 pts (24.3%) had residual MR II°, 4 (3.9%) pts MR had residual moderate to severe MR.

Mean duration of follow up was 11.7 ± 11.5 months. No patient was lost to follow up. Within one year after TMVR, a total number of 29 patients died, accounting for an all-cause mortality rate of 28.2%.

3.2. Prognostic value of right ventricular dysfunction after TMVR

Fig. 1 shows the survival curves of patients with and without RVD, with a significantly higher one-year mortality in patients with RVD present at the time of therapy of 34.8% compared to 22.8% in patients without RVD.

To identify the prognostic impact of RVD in the settings of functional and degenerative MR, separate Kaplan Meier survival analyses were applied for the subsets of patients with predominantly functional or degenerative etiology of mitral regurgitation:

Fig. 2 depicts the one-year survival for patients with FMR stratified according to their right ventricular function: FMR-patients with a TAPSE $\leq$15 mm had a significantly higher all- cause mortality one year after TMVR (38.1%) compared to FMR-patients with preserved right ventricular function (9.1%).

In contrast, in patients with degenerative MR, Kaplan Meier estimates did not differ significantly between the subgroups of DMR-patients with preserved or reduced right ventricular function (32% one-year mortality in DMR-patients with RVD versus 34.3% in DMR-patients without RVD), see Fig. 3.

3.3. Differential prognostic utility of the SHFM and MAGGIC score dependent on the presence of RVD

Retrospective application of the SHFM and MAGGIC score revealed moderate over-all sensitivity and specificity for prediction of one-year all-cause mortality in the whole patients collective, with an area under the receiver operating curve value of 0.704 for the SHFM score and 0.692 for the MAGGIC score. Fig. 4 repre-

Table 1
Baseline Characteristics. In case of missing values, the number of available values is denoted in parentheses (n/N). Values are mean ± SD or n (%) unless otherwise specified.

	Total (N = 103)	TAPSE <= 15 mm (N = 46)	TAPSE > 15 mm (N = 57)	p
Age – y	72.8 ± 10.84	72 ± 11.37	73.8 ± 10.84	0.396
Male sex –n (%)	73 (70.9)	34(33)	39 (37.9)	0.349
Diabetes –n. (%)	38 (36.9)	23 (22.3)	15 (14.6)	0.611
Hypertension -n. (%)	81 (78.6)	36 (35)	45 (43.7)	0.497
Creatinine clearance (ml/ min)	53.3 ± 22	50.6 ± 21	56.8 ± 23.1	0.165
Median NTproBNP (ng/l) (IQR) (83/103)	2540 (1230–4204)	2989 (1583–5361)	1639 (898,3–3790,8)	**0.014**
Medication use				
Antiplatelet agents (100/103)	51 (49.5)	22 (47.8)	29(50.9)	0.859
ACEI/ ARB (100/103)	91 (88.3)	37 (80.4)	54 (94.7)	**0.032**
Beta blocker (100/103)	85 (82.5)	38 (82.6)	47 (82.5)	0.735
MCRA (100/103)	51 (49.5)	26 (56.5)	25 (43.9)	0.151
Diuretic drugs (other than MCRA) (100/103)	87 (84.5)	41 (89.1)	46 (80.7)	0.103
NYHA class – n./ total n. (%)				0.462
II	20 (19.4)	7 (6.8)	13 (12.6)	
III	74 (71.8)	34 (33)	40 (38.8)	
IV	9 (8.7)	5 (4.9)	4 (3.9)	
Left ventricular ejection fraction (%)	36.51 ± 17.31	32.4 ± 16.25	42.2 ± 17.32	**0.004**
LVEDV – ml (99/103)	191.7 ± 82.36	196.1 ± 79.4	185.5 + -87	0.53
EROA, PISA (mm^2) (91/103)	42.15 (14.32)	42.13 ± 14.36	42.16 ± 14.46	0.992
TAPSE (mm)	16.74 ± 4.08	13.28 ± 1.76	19.53 ± 3.03	**<0.001**
Right ventricular systolic pressure (mmHg) (80/103)	52.86 ± 15.31	50.27 ± 15.58	56.19 ± 14.5	0.86
Degenerative MR (%)	60 (58.3)	29 (28.2)	31 (30.1)	0.17
Median EuroSCORE II (IQR)	6.75 (3–11.9)	9.19 (4.84–15)	4.24 (2.47–7.36)	**<0.001**
MAGGIC 1-year mortality (%)	23.77 ± 11.38	25.8 + -12.47	21 ± 9.2	**0.033**
SHFM 1-year mortality (%)	83.74 ± 15.9	81.3 ± 19.2	87.1 ± 9.21	0.07

ACEI = Angiotensin- Converting- Enzyme Inhibitor; ARB = Angiotensin II Receptor Blocker; EROA = Effective Regurgitant Orifice Area; MCRA = Mineralocorticoid Receptor Antagonist; NYHA = New York Heart Association Functional Class); LVEDV = Left Ventricular End- diastolic Volume; MAGGIC = Meta-Analysis Global Group in Chronic Heart Failure; PISA = Proximal Isovelocity Surface Area; SHFM = Seattle Heart Failure Model; TAPSE = Tricuspid Annular Plane Excursion;

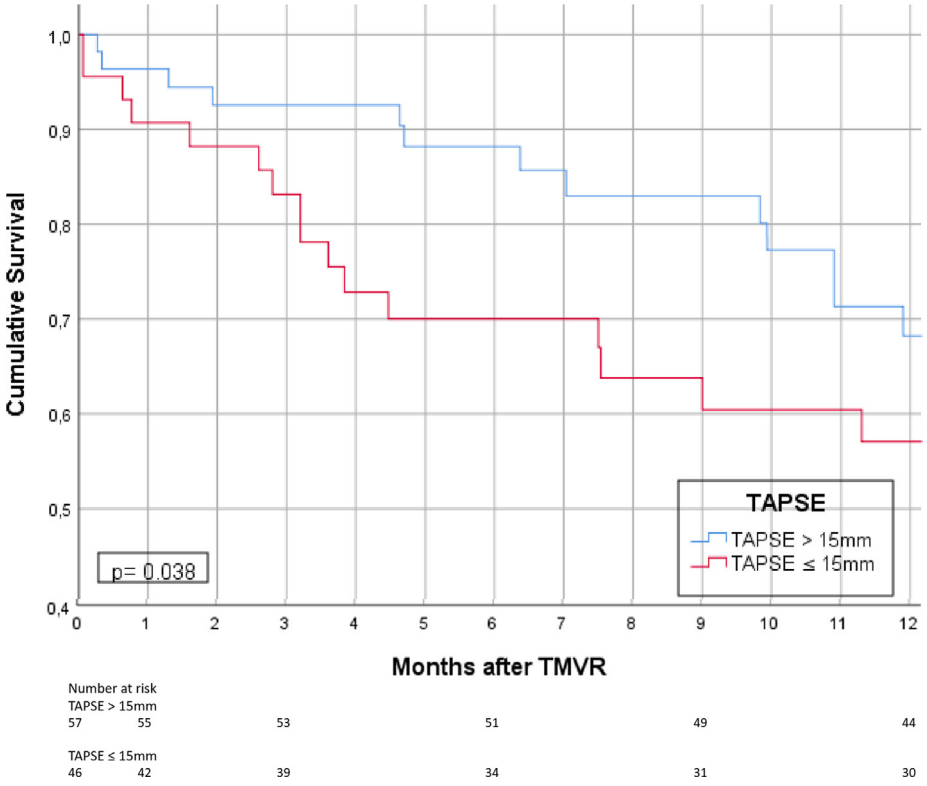

Fig. 1. Kaplan-Meier survival estimates according to tricuspid annular plane systolic excursion (TAPSE).

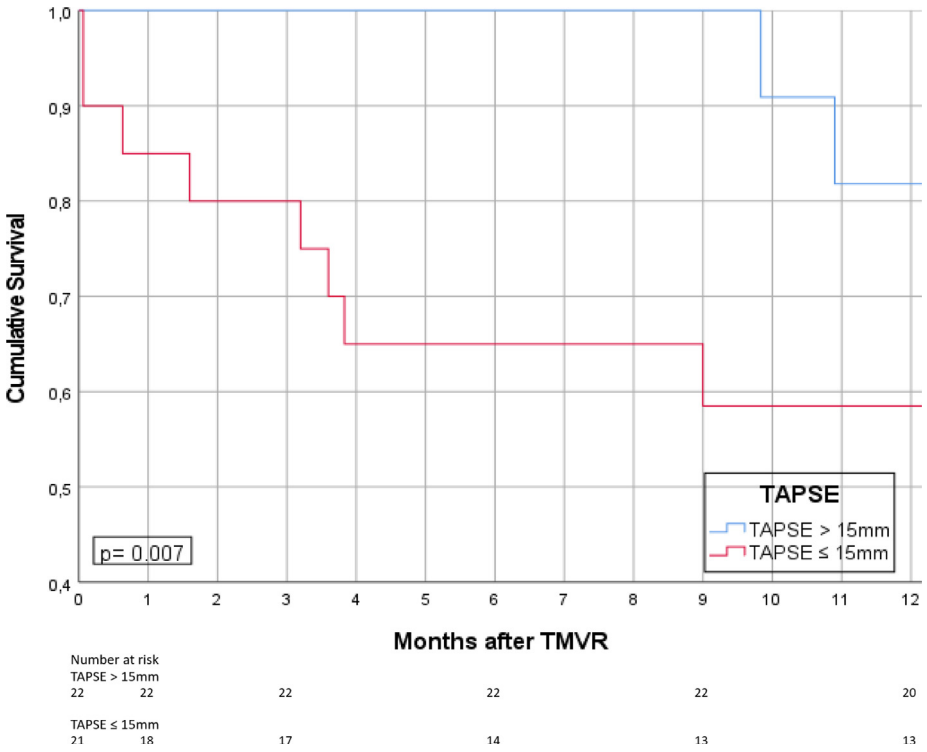

Fig. 2. Survival of FMR-patients with and without RVD after TMVR.

sents the receiver operating curves of the SHFM score and MAGGIC score in these patients.

Also in separate analysis of patients with MR of functional and degenerative origin, SHFM and MAGGIC score displayed corresponding AUROC values (FMR group: 0.696 for SHFM score and 0.722 for the MAGGIC score; DMR group: 0.727 for SHFM and 0.629 for the MAGGIC score).

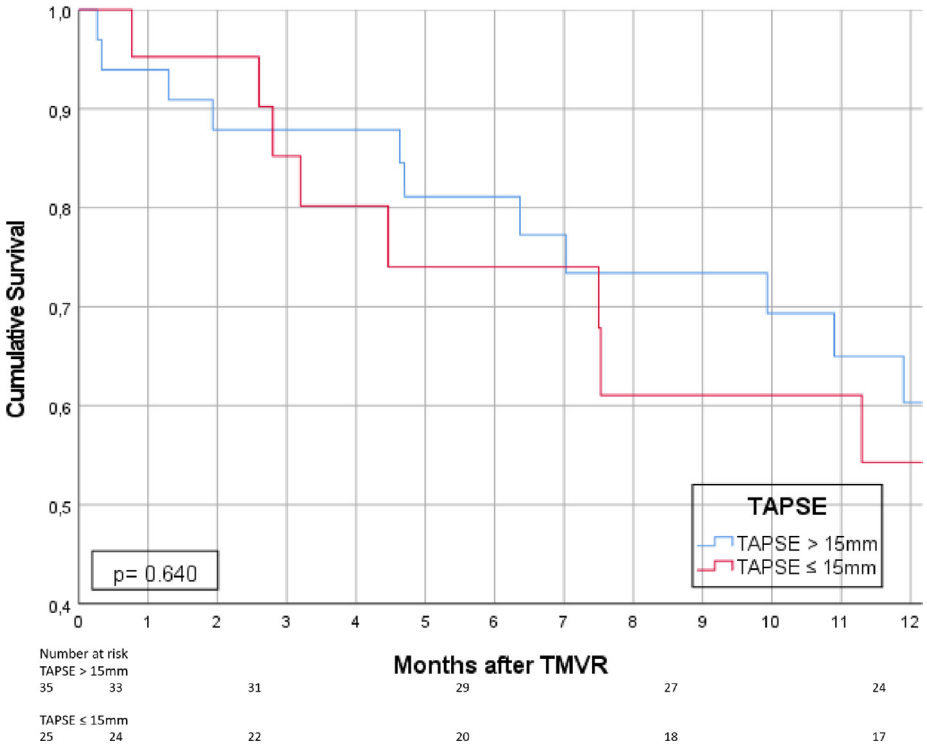

Fig. 3. Survival of DMR-patients with and without RVD after TMVR.

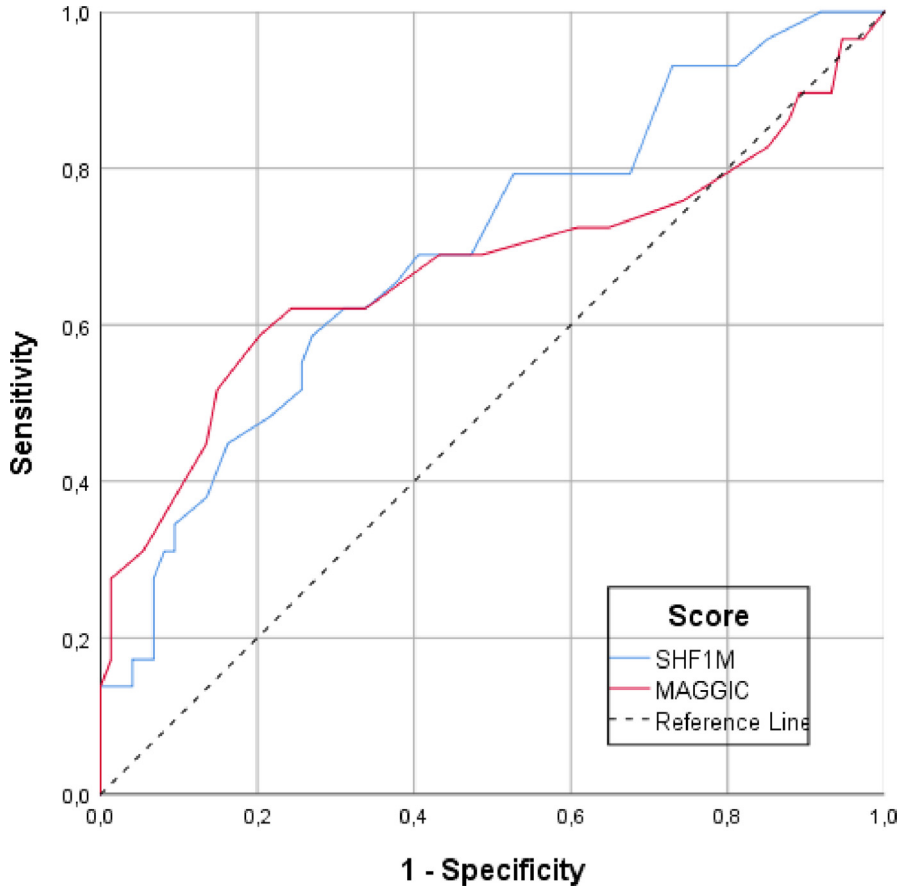

Fig. 4. Comparison of the Receiver-Operating Curve Statistics of the MAGGIC versus SHFM score for one- year mortality SHFM AUROC = 0.695; MAGGIC AUROC = 0.671; *P* > 0.05, DeLong AUROC comparison.

However, after separate analysis of the subsets of patients with preserved and reduced right ventricular function, SHFM and MAGGIC scores displayed differential prognostic performance:

In the subset of patients with RVD present at the time of TMVR, both scoring systems provided modest and comparable prognostic utility with an AUROC value of 0.665 for the SHFM score and 0.788 for the MAGGIC score, see Fig. 5.

In contrast, in patients with preserved right ventricular function at TMVR, SHFM score as well demonstrated an adequate AUROC value of 0.755, whereas the MAGGIC score provided only poor prognostic utility in the subset of patients without RVD with an AUROC value of 0.511, p = 0.019 (see Fig. 6).

By multivariate analysis including RVD as well as MAGGIC and SHFM score, only a high SHFM score persisted as independent predictor of one-year all-cause mortality in these patients with a hazard ratio of 1.03, 95% confidence interval 1.013–1.046, p < 0.001.

4. Discussion

The present study investigates the prognostic utility of right ventricular dysfunction, the MAGGIC score and Seattle Heart Failure model in a non-selected all-comers population with severe mitral regurgitation of functional and degenerative origin after TMVR. Whereas both right ventricular dysfunction and the examined scoring systems represent validated tools for the prediction of survival in heart failure patients also after TMVR [17,29–31], their utility in the growing number of patients undergoing TMVR for severe MR has not been investigated comparatively so far. In

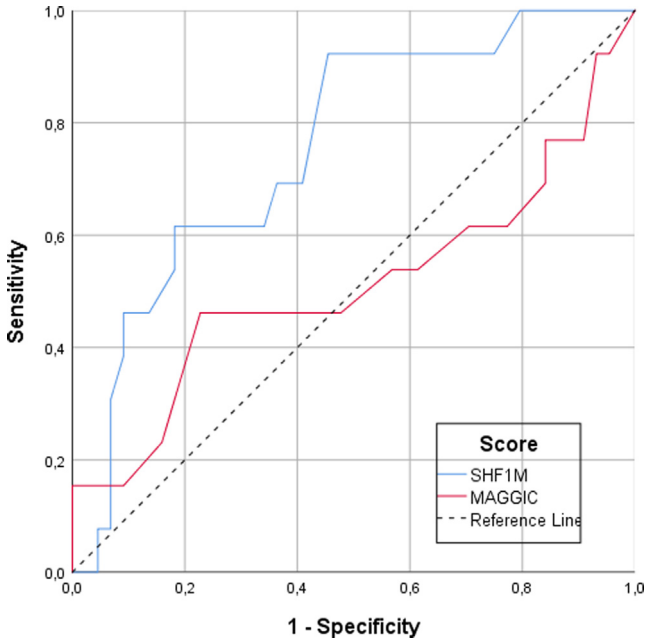

Fig. 6. Comparison of the Receiver-Operating Curve Statistics of the MAGGIC versus SHFM score for one-year mortality in patients without right ventricular dysfunction (RVD). SHFM AUROC = 0.755; MAGGIC AUROC = 0.511; *P* < 0.019, DeLong AUROC comparison.

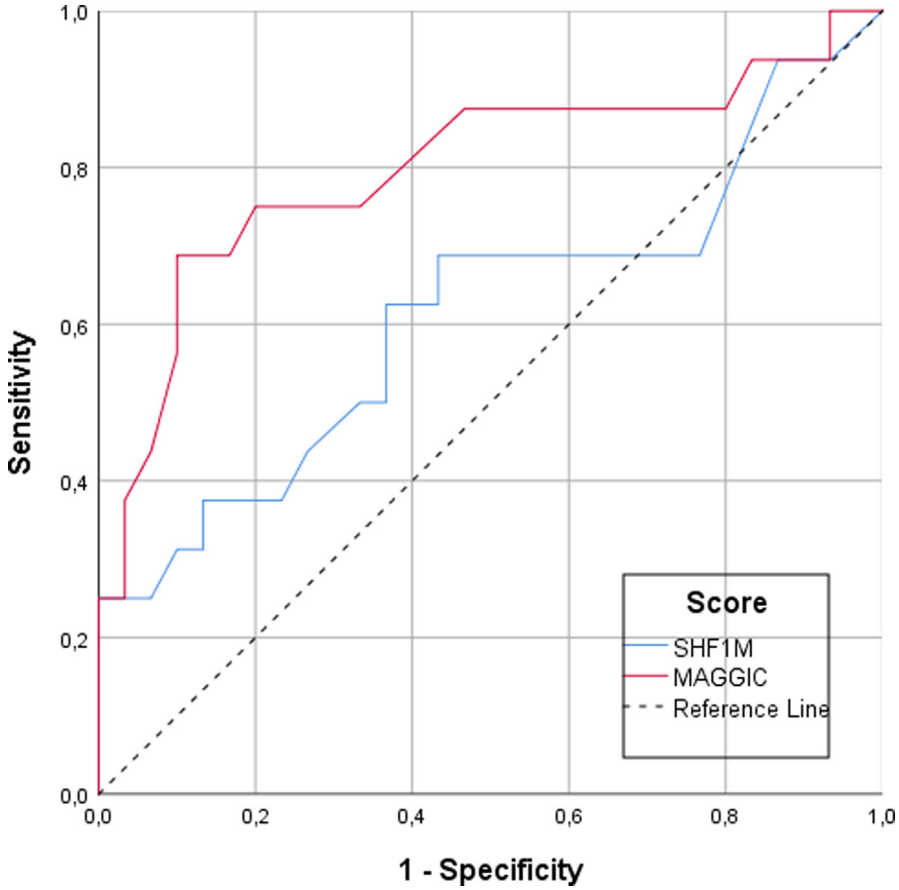

Fig. 5. Comparison of the Receiver-Operating Curve Statistics of MAGGIC versus SHFM for one- year mortality in patients with right ventricular dysfunction (RVD) SHFM AUROC = 0.615; MAGGIC AUROC = 0.799; p= >0.05.

recent large register reports, the impact of right ventricular failure has only been reflected indirectly by severe tricuspid insufficiency [4,32].

One key finding of this study is that the negative prognostic impact of RVD on outcome in FMR-patients after TMVR can also be assessed by the easily obtainable measurement of TAPSE as described by Kaneko et al. [22] and is not dependent on the more complex tissue doppler imaging [33].

In general, echocardiographic assessment of right ventricular failure should comprise several parameters [34–36]. The present study investigates only one of them: TAPSE may be variable depending on different concomitant factors [37] and represents only the longitudinal right ventricular excursion with minor informative value of the free RV wall motion capacity. However, TAPSE showed good correlation with RVEF measured in radionuclide studies [21]. It has to be pointed out that a more detailed analysis of RV function might have augmented the prognostic value of RVD in this study.

Both heart failure scores examined in this study provide moderate overall sensitivity and specificity for one-year mortality in these patients. The application of scoring systems initially designed for other entities is common and feasible [17,38]. Our findings stand in good accordance to the paper of Schau et al. [17] regarding applicability of the SHFM and MAGGIC score also to MC patients.

However, as right heart failure has a well described negative prognostic impact also in TMVR-patients [22,33], we felt that the generalizability of these common heart failure scores in heterogenous groups of FMR and DMR with and without right heart failure should be confirmed separately. Indeed, the key finding of this study is that the prognostic value of the MAGGIC score is dependent on the presence or absence of RVD.

In contrast, the SHFM score provided moderate predictive power also in this subset of patients and persisted as independent significant predictor of adverse outcome in this study.

The interpretation of this finding appears complex. The SHFM and MAGGIC score are based on different parameters and different derivation cohorts, with a presumed minority of patients with severe MR. Further, we only can speculate that the populations used for developing the MAGGIC score with both HFrEF and HFpEF [27] mainly consisted of patients with concomitant RVD, whereas the SHFM patients included a broader spectrum of both right ventricular function and baseline parameters reflecting the patientś characteristics in this study more precisely.

A more detailed stratification of patients by SHFM level and RVD did not provide additional information (data not shown), most probably due to the limited number of data.

Our study bears a number of limitations to be considered when interpreting these findings:

The retrospective design of the study did not allow to calculate and consider further echocardiographic parameters like strain imaging. Due to the lack of complete follow ups, further associations of baseline right heart function and clinical effects could not be performed. The limited number of patients; including those first to be treated in this institution might explain the higher 1-year mortality than expected from contemporary TMVR trials [7,9].

5. Conclusion

Both, right ventricular dysfunction defined by TAPSE and the Seattle Heart Failure model have predictive power for prediction of survival in patients with severe mitral regurgitation undergoing TMVR. Whereas TAPSE as a standardized and easily measurable echocardiographic parameter should be evaluated in every patient screened for TMVR, the more elaborate calculation of the SHFM score gives additional prognostic information irrespective of concomitant right heart dysfunction.

As a substantial number of heart failure patients develops advanced MR during the course of disease, our findings might contribute to a more personalized evaluation of prognosis and therapeutic approach in heart failure patients with MR undergoing TMVR.

Declaration of Competing Interest

The authors report no relationships that could be construed as a conflict of interest.

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