ORIGINAL ARTICLE

Prognostic value of selected risk scales in patients with end-stage heart failure

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Abstract

Background: Due to the increasing number of patients placed on waiting lists for orthotopic heart transplantation (OHT), the selection of patients with the highest risk of death has become paramount.

Aim: This study aimed to evaluate the predictive value of the Model for End-stage Liver Disease eXcluding INR (MELD-XI) and Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) scales in ambulatory patients awaiting OHT and compare them to the Heart Failure Survival Score (HFSS).

Methods: The study was a retrospective review of 370 adult ambulatory patients with end-stage heart failure, who were added to the OHT waiting list at our institution between 2012 and 2016.

Results: The median age of the patients was 54.0 (46.0–60.0) years, and 324 (87.6%) of them were male. The overall one-year mortality was 27.6%. The areas under the curve (AUCs) for the MAGGIC and HFSS scales were comparable: 0.771 (95% confidence interval [CI] 0.720–0.823); sensitivity 77%, specificity 68% vs. 0.781 (95% CI 0.732–0.829); sensitivity 90%, specificity 58%, respectively. The AUC for the MELD-XI scale was higher than that for the HFSS scale: 0.812 (95% CI 0.769–0.856); sensitivity 91%, specificity 63% vs. 0.781 (95% CI 0.732–0.829) sensitivity 90%, specificity 58%, respectively.

Conclusions: Our study demonstrated that elevated MELD-XI and MAGGIC scores and lowered HFSS scores were associated with an increased risk of death during one-year follow-up. The prognostic utility of the MELD-XI scoring system was better than that of the HFSS scale, while the MAGGIC scale was comparable to the HFSS.

Key words: prognostic scales, end-stage heart failure, heart transplant waiting list

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INTRODUCTION

Heart failure (HF) is a complex clinical syndrome that represents a common final pathway of many cardiovascular diseases and is associated with high morbidity and mortality [1, 2]. In patients with end-stage HF, who remain symptomatic despite optimal medical therapy, orthotopic heart transplantation (OHT) is the treatment of choice [1–3]. Due to the constantly increasing number of patients placed on transplant waiting lists and the global shortage of donor hearts, it is of paramount importance to perform accurate risk-of-death stratification and to allocate organs to those patients who will benefit the most from this form of treatment [3, 4]. Over the years, many prognostic models have been developed to accurately predict the risk of death in patients with end-stage HF, each with their own set of advantages and limitations [1, 5]; however, only the Heart Failure Survival Score (HFSS) was derived from and

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validated in a cohort of ambulatory HF patients referred for OHT [6]. This model is based on HF aetiology, maximal oxygen uptake (VO_2max), resting heart rate, mean arterial blood pressure, serum sodium, left ventricular ejection fraction (LVEF), and interventricular conduction delay [6]. Despite its proven usefulness in the assessment of the risk of death in clinically stable patients with end-stage HF [6–8], the HFSS scoring system has some limitations. Patients with advanced HF often cannot achieve a true peak VO_2 due to leg fatigue, general debilitation, or lack of motivation. In addition, VO_2max depends on many other factors that can significantly influence the test results, such as age, sex, body weight, anaemia, lung diseases, angina, orthopaedic disorders, skeletal muscle strength, and peripheral circulation [9, 10]. It should also be emphasised that the HFSS scale has been validated and developed since the late 1990s, when only a minimal proportion of patients were treated with the use of β-blockers and cardiac resynchronisation therapy or implantable cardioverter-defibrillators [6]. Given the substantial survival benefit conferred by β-blockers and implantable devices, the clinical usefulness of the HFSS scale in the modern HF therapy may be limited. Therefore, the prognostic utility of this scoring system should be tested in current patient populations. Finally, the HFSS scale does not take into consideration the unfavourable prognostic value of liver and kidney dysfunctions, pharmacological treatment, or the presence of other comorbidities [1, 3, 9, 11, 12]. The above parameters constitute the basis of two simple prognostic scales: the Model for End-stage Liver Disease eXcluding INR (MELD-XI) [5, 13] and the Meta-Analysis Global Group in Chronic Heart Failure (MAGGIC) scale, which takes into account easily available clinical and laboratory data, pharmacological treatment, and comorbidities [14]. The main advantage of these prognostic scales is that they include simple, cheap, and routinely assessed laboratory and clinical parameters.

This study aimed to evaluate the predictive value of the MELD-XI and MAGGIC scales in ambulatory patients awaiting OHT, and to compare their usefulness to that of the HFSS scoring system, which is a validated prognostic tool in ambulatory patients with end-stage HF.

METHODS

The study was a retrospective review of the clinical records of 491 ambulatory end-stage HF patients aged 18 years or older, who were placed on the OHT waiting list at our institution between 2012 and 2016. Patients removed from the waiting list because of improvement, deterioration, or withdrawal of consent (n = 81) as well as subjects who underwent OHT (n = 40) during the follow-up period were excluded from the analysis. The resulting study sample comprised 370 participants.

All the included patients were on optimal medical therapy, resynchronisation therapy, and/or a defibrillator, if appropriate, in accordance with the guidelines of the European Society of Cardiology [1].

The basic clinical data and the routinely measured laboratory parameters considered by the evaluated prognostic scales were collected by reviewing the electronic chart data that had been used as the basis for admission to the OHT waiting list. The endpoint was defined as all-cause mortality within 12 months. If a patient failed to attend a scheduled visit, his or her survival status was obtained through a telephone interview with the patient or a family member.

The HFSS score was calculated based on the following equation incorporating seven variables: ([0.0216 × resting heart rhythm] + [–0.0255 × mean arterial blood pressure] + [−0.0464 × LVEF] + [–0.0470 × serum sodium] + [–0.0546 × peak VO_2] + [0.6083 × presence (1) or absence (0) of interventricular conduction defect (QRS duration ≥ 0.12 due to any cause)] + [0.6931 × presence (1) or absence (0) of ischaemic cardiomyopathy]), as described previously [6].

We also calculated the MELD-XI scores using a well-defined formula, where ln — log normal [13]:

MELD-XI = 5.11 × (ln of total bilirubin in mg/dL) +
+ 11.76 × (ln of creatinine in mg/dL) + 9.44.

The lower limit of all variables in the MELD-XI scale was set at 1.0 mg/dL, and the upper limit for creatinine was set at 4.0 mg/dL.

The calculator available at www.heartfailurerisk.org was used to determine the score of the MAGGIC scale developed by Pocock et al. [14]. The scale includes 13 parameters: (1) age, (2) sex, (3) body mass index, (4) systolic blood pressure, (5) creatinine concentration, (6) presence or absence of diabetes mellitus and (7) chronic obstructive pulmonary disease, (8) HF diagnosed within the last 18 months, (9) New York Heart Association (NYHA) class, (10) LVEF, (11) current smoking status, (12) β-blockers, and (13) angiotensin converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs).

Statistical analysis

All statistical analyses were carried out using SAS software, version 9.4 (SAS Institute Inc., Cary, NC, USA). Data were expressed as means and standard deviations or medians and interquartile ranges (continuous variables), or as numbers and percentages (categorical variables). Intergroup differences between continuous variables were tested using Student t test or Mann-Whitney U test, while χ^2 test was used to analyse categorical variables. The receiver operating characteristic (ROC) curve was created to determine the utility of the analysed scales in distinguishing survivors from non-survivors. The prognostic strength of the scales was evaluated by calculating each area under the curve (AUC) from the ROC analysis for one-year motrality. An AUC > 0.7 was considered clinically relevant [15]. AUCs from ROC analysis were compared to identify the scale that had a stronger association with the endpoint. A difference of ≥ 0.025 between the AUCs was considered clinically relevant [16–18]. The optimal cut-off value for the models was determined by using the Youden index.

Table 1. Components of the evaluated scales at the time of listing

Variable	All patients (n = 370)	Survivors (n = 268)	Non-survivors (n = 102)	p
MAGGIC components:				
Age [years]	54 (46–60)	54 (45–59)	54.5 (49–60)	0.64
Male sex	324 (87.6)	234 (87.3)	90 (88.2)	0.81
NYHA class III	263 (71.1)	211 (78.7)	52 (51)	< 0.001
NYHA class IV	107 (28.9)	57 (21.3)	50 (49)	< 0.001
BMI [kg/m^2]	26.0 ± 4.4	25.9 ± 4.4	26.5 ± 4.3	0.17
Resting SBP [mmHg]	110 (90–110)	100 (90–110)	95 (90–101)	0.006
Type 2 diabetes	134 (36.2)	87 (32.5)	47 (46.1)	0.04
COPD	24 (6.5)	15 (5.6)	9 (8.8)	0.40
Current smoker	0 (0)	0 (0)	0 (0)	
HF diagnosed within the last 18 months	0 (0)	0 (0)	0 (0)	
ACEIs/ARBs	343 (92.7)	252 (94.0)	91 (89.2)	0.11
β-blockers	347 (93.8)	253 (94.4)	94 (92.2)	0.61
HFSS components:				
Ischaemic aetiology of HF	164 (44.3)	124 (46.3)	40 (39.3)	0.03
Resting HR [bpm]	77 (69–84)	75 (65–81)	81.5 (74–86)	< 0.001
Resting mean BP [mmHg]	76.7 (70.0–83.3)	76.7 (70–83.3)	73.3 (70–80)	0.01
QRS > 0.12 s	150 (40.5)	101 (37.7)	49 (48.0)	0.07
VO_2 max [mL/kg/min]	12.3 (10.3–14.1)	13.1 (11.4–14.6)	12.3 (10.0–14.6)	0.12
Sodium [mmol/L]	136.0 (133.0–140.0)	137.5 (134.0–141.0)	132.5 (130.0–136.0)	< 0.001
MELD-XI components:				
Total bilirubin [μmol/L]	18.4 (12.10–27.4)	15.9 (11.1–23.1)	27.2 (20.1–37.5)	< 0.001
Common to MELD-XI and MAGGIC:				
Creatinine [μmol/L]	103.0 (85.0–130.0)	94.5 (81.5–118.0)	127.5 (103.0–143.0)	< 0.001
Common to HFSS and MAGGIC:				
LVEF [%]	18.0 (15.0–20.0)	18.0 (15.0–20.0)	17.5 (15.0–20.0)	0.15
Scores:				
HFSS	7.56 (7.04–8.07)	7.82 (7.23–8.25)	7.05 (6.81–7.37)	< 0.001
MELD-XI	12.7 (10.0–15.9)	11.3 (9.4–14.3)	16 (13.7–17.9)	< 0.001
MAGGIC	26 (24–29)	25 (23–27)	28 (27–30)	< 0.001

Data are presented as medians (interquartile range), means (standard deviation) or numbers (percentages) of patients. ACEIs — angiotensin converting enzyme inhibitors; ARBs— angiotensin II receptor blockers; BMI — body mass index; BP — blood pressure; COPD — chronic obstructive pulmonary disease; HF — heart failure; HFSS— Heart Failure Survival Score; HR — heart rhythm; LVEF — left ventricular ejection fraction; MAGGIC — Meta-Analysis Global Group in Chronic Heart Failure; MELD-XI — Model for End-stage Liver Disease eXcluding INR; NYHA — New York Heart Association; SBP — systolic blood pressure; VO2max — maximal oxygen uptake

Each result was presented as the AUC with its 95% confidence interval (CI), sensitivity, and specificity. A p-value < 0.05 was considered statistically significant.

RESULTS

The final study group consisted of 370 ambulatory patients with advanced HF in NYHA classes III (71.1%) and IV (28.9%) placed on the OHT waiting list. All patients were in profiles 4 to 7 according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) classification. In the overall population, the median age of the participants was 54.0 (46.0–60.0) years; 87.6% of them were male. All patients were receiving resynchronisation or defibrillator therapy (41.1% and 58.9%, respectively). The devices were implanted more often in primary than in secondary prevention of sudden cardiac death (84% vs. 16%, respectively). Overall, the patients were on optimal medical therapy, which included maximum tolerated doses of β-blockers (93.8% of the patients), ACEIs or ARBs (93.2%), aldosterone antagonists (96.8%), as well as diuretics (100%). Table 1 summarises the

Table 2. Complementary characteristics of the patients — comorbidities and treatment

Variable	All patients (n = 370)	Survivors (n = 268)	Non-survivors (n = 102)	p
Comorbidities:				
Arterial hypertension	151 (40.8)	116 (43.3)	35 (34.3)	0.23
Pulmonary hypertension	202 (54.6)	136 (50.7)	68 (66.7)	0.006
Persistent atrial fibrillation	162 (43.8)	117 (43.7)	45 (44.1)	0.94
Hypercholesterolaemia	182 (49.2)	148 (55.2)	34 (33.3)	< 0.001
Medications:				
Loop diuretics	370 (100)	268 (100)	102 (100)	
Thiazide diuretics	120 (32.4)	80 (29.9)	40 (39.2)	0.09
MRA	358 (96.8)	263 (98.1)	95 (93.1)	0.02
Statin	227 (61.4)	177 (66)	50 (49)	0.003
Coumarin derivatives	188 (50.8)	136 (50.7)	52 (51)	0.97
Acetylsalicylic acid	153 (41.1)	113 (42.2)	40 (39.2)	0.61
ICD/CRT-D	370 (100)	268 (100)	102 (100)	

Data are presented as numbers (percentages) of patients. CRT-D — cardiac resynchronisation therapy with defibrillator; ICD — implantable cardioverter-defibrillator; MRA — mineralocorticoid receptor antagonist

Table 3. Summary of receiver operating characteristic curve analyses for all scales

	AUC	95% CI	p	Cut-off	Sensitivity	95% CI	Specificity	95% CI
MELD-IX	0.812	0.769–0.856	< 0.001	> 12.5	0.91	0.84–0.96	0.63	0.57–0.69
HFSS	0.781	0.732–0.829	< 0.001	< 7.67	0.90	0.82–0.94	0.58	0.52–0.64
MAGGIC	0.771	0.720–0.823	< 0.001	> 27	0.77	0.68–0.85	0.68	0.62–0.73

AUC — area under the curve; CI — confidence interval; other abbreviations — see Table 1

components of the evaluated scales at the time of listing. Table 2 includes additional information on comorbidities and treatment of the analysed population.

At the end of the follow-up, there were 102 (27.6%) non-survivors and 268 (72.4%) survivors.

The ROC curves for the MELD-XI, MAGGIC, and HFSS scales for one-year mortality are presented in Figures 1 to 3. All analysed scales displayed significant discriminatory power ($p < 0.001$). Table 3 presents results obtained from the ROC analysis for all analysed scales.

The prognostic value of the MELD-XI scale was higher than that of the HFSS, as indicated by a larger AUC as well as a higher sensitivity and specificity (Table 3). The difference between the calculated AUC for MELD-XI and HFSS amounted to 0.0306, which was considered clinically relevant (≥ 0.025) [16–18]. The prognostic value of the MAGGIC and HFSS scales was comparable: the MAGGIC scale showed slightly worse sensitivity and slightly higher specificity than the HFSS (Table 3). Furthermore, the difference between the calculated AUCs for MAGGIC and HFSS amounted to 0.0106, which was considered clinically non-relevant (< 0.025) [16–18].

DISCUSSION

Based on a single-centre experience, we demonstrated that the HFSS scale continues to provide useful prognostic information in patients with end-stage HF receiving optimal contemporary therapy. Furthermore, our study showed that the MELD-XI and MAGGIC scales are both useful tools for predicting OHT waiting list mortality in the population of ambulatory patients with end-stage HF. Moreover, it should be noted that in terms of prognostic utility the MELD-XI scoring system was better than the HFSS scale, while the MAGGIC scale was comparable to the HFSS scale in our study group.

Accurate risk stratification is a fundamental component of the management strategy for end-stage HF patients awaiting OHT [19]. A valuable method for outcome prediction is constituted by the use of prognostic scales that estimate the risk of death holistically, taking into account many significant factors and allowing for a better evaluation of the prognosis than that enabled by analysing single variables [19, 20]. One of the well-established prognostic tools for the discussed group of patients is the HFSS scale. Its prognostic strength in our analysis was comparable to that reported in the study by Aaronson et al. [6]. It should be noted that our study differed

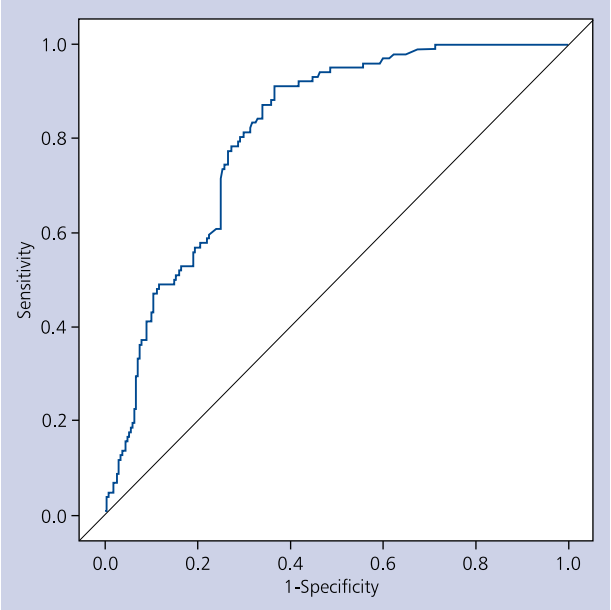

Figure 1. Receiver operating characteristic curve for the Model for End-stage Liver Disease eXcluding INR scale

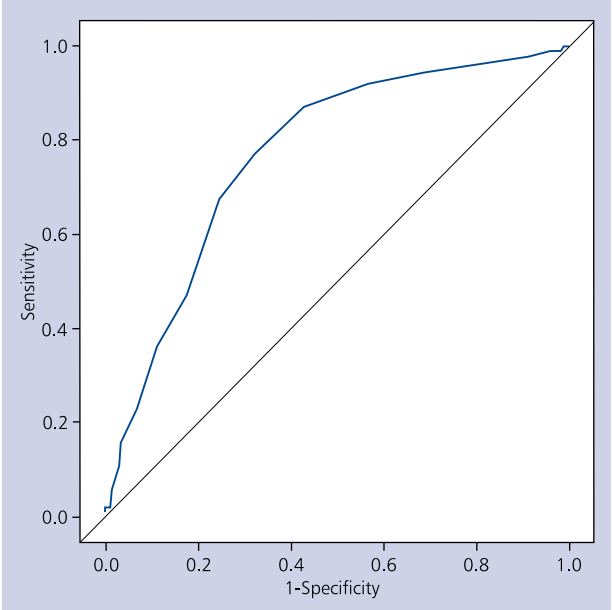

Figure 3. Receiver operating characteristic curve for the Meta-Analysis Global Group in Chronic Heart Failure scale

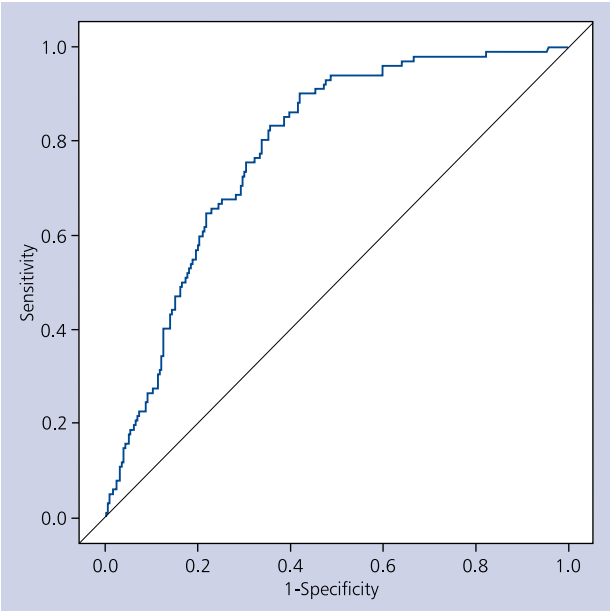

Figure 2. Receiver operating characteristic curve for the Heart Failure Survival Score

from the latter analysis in some aspects. We analysed patients on an OHT waiting list, whereas the population in Aaronson's study included ambulatory patients aged < 70 years with LVEF ≤ 40% referred for OHT evaluation. Furthermore, the AUC in Aaronson's study was calculated from a composite endpoint consisting of death without transplantation, United Network for Organ Sharing (UNOS) status 1, or left ventricular assist device (LVAD) implantation during one-year follow-up. We used one-year mortality as the endpoint for the analysed group of patients. Patients dependent on mechanical support as well as subjects undergoing OHT during the follow-up were excluded from the analysis to increase the homogeneity of the population and to reduce bias associated with the different weight of factors in a composite endpoint. We considered the fact that it is not the clinical status, but the donor-recipient matching in terms of size and blood group that is the main parameter considered when allocating organs to UNOS status 2 heart transplant candidates. Goda et al. [7] assessed a population of 354 patients referred for OHT. The researchers demonstrated that the HFSS scale (AUC = 0.72) provides good risk stratification in HF patients referred for OHT and that combining the HFSS with the Seattle Heart Failure Model improves discriminatory power (AUC = 0.77). However, the above authors also used a composite endpoint defined as death, urgent OHT, or LVAD implantation. Furthermore, the proportion of patients receiving ACEIs/ARBs, aldosterone antagonists, and β-blockers was unsatisfactory [7].

Lund et al. [8] investigated the prognostic value of the HFSS scale in ambulatory patients with advanced HF, who were referred for OHT evaluation. The authors demonstrated that the HFSS can be successfully used for serial assessment of the mortality risk in this group of patients [8]. Although the HFSS incorporates a multitude of variables and can effectively identify patients with poor prognosis, it fails to fully address the impact of liver and kidney dysfunction, which are conditions commonly observed in the advanced stages of HF. Their aetiology in HF has been attributed to haemodynamic

influence: congestion and decreased blood flow resulting from diminished cardiac output. Liver and kidney functions can be accurately assessed using the classic Model for End-stage Liver Disease (MELD) scale, but this scoring system includes international normalised ratio (INR) and, thus, cannot be applied in patients receiving vitamin K antagonists [21]. Therefore, MELD-XI, a modification of this scale that does not consider INR, appears to be an attractive alternative that enables the gathering of prognostic information in patients with INR elevated due to therapeutic anticoagulation with warfarin [11, 13, 22–24].

In our study, we found that the MELD-XI score allows the identification of end-stage HF patients at high risk of death, with excellent sensitivity and good discriminatory power. In the available literature, there are several studies discussing the usefulness of the MELD-XI scale in the assessment of prognosis in patients with advanced HF. Kim et al. [11] evaluated the utility of the MELD-XI scale in a cohort of 260 advanced HF patients referred for OHT evaluation. The researchers found that, among all the analysed MELD scores, the MELD-XI score was the best predictor of one-year endpoints in patients on anticoagulation [11]. The study by Kim et al. [11] had some limitations that could have affected the predictive value of MELD-XI. No echocardiographic or invasive data and no information about the degree of HF were provided; therefore, we cannot be sure whether all patients were indeed in an advanced stage of the disease. The study also used a composite endpoint defined as death/OHT/ventricular assist device requirement, which makes it difficult to determine the true effect of the MELD-XI score on each of these event types. A study by Yang et al. [25] demonstrated that patients with a MELD-XI score > 17 prior to LVAD implantation had a significantly worse overall survival, while a decrease in this score to < 17 during LVAD support improved post-OHT survival. Although the population of that study differed from ours, because it included patients with LVADs, the results corroborate the importance of the MELD-XI score in terms of its prognostic value. Our previous study also showed that an elevated MELD-XI score directly before OHT is an independent risk factor for worse posttransplant prognosis during one-year follow-up [26]. Similar conclusions were reached by Farr et al. [21], who reported that the MELD-XI score calculated at the time of OHT evaluation and immediately before the operation is an independent predictor of death within one year of OHT. Taken together, the above results indicate that liver and renal dysfunctions in patients awaiting OHT are associated with worse survival both before and after the surgery; therefore, these patients should be monitored closely and treated aggressively in order to improve their prognosis.

To the best of our knowledge, this is the first study supporting the use of the MAGGIC scale as a prognostic tool in a cohort of patients with advanced HF. We found that the MAGGIC scale had good discriminatory power in terms of predicting one-year mortality in ambulatory patients awaiting OHT. The MAGGIC scale was originally developed by Pocock et al. [14] based on the data of 39,372 patients with HF (NYHA classes I–IV), and it can provide useful information about the risk of one- and three-year all-cause mortality. We identified only one more publication discussing the use of the MAGGIC scale in patients with HF. Sartipy et al. [27] assessed the population of 51,043 patients from the national Swedish Heart Failure Registry. The authors of this study demonstrated that the MAGGIC scale has good discriminatory power in assessing one-year survival in HF patients with NYHA classes I–IV [27]. Unfortunately, in the above studies [14, 27], the percentage of patients with NYHA classes III and IV was low, which makes it difficult to make reliable comparisons with our results. Our study is the first to demonstrate that the MAGGIC scale can also provide accurate risk stratification in advanced HF patients placed on transplant waiting lists. The MAGGIC scale can become a very attractive prognostic tool in the near future because it allows the estimation of mortality risk based on simple and routinely gathered clinical data that are generally available for all HF patients.

Several limitations apply to our study. Firstly, it was a single-centre, retrospective analysis and the sample size was relatively small. Therefore, larger, multicentre, and prospective studies are needed to further confirm the reliability and clinical utility of the scales discussed above. Secondly, all the scores were calculated only at the time of placement on the OHT waiting list, so further studies are needed to determine whether serial use of these scales can improve their prognostic value in terms of one-year risk of death. Furthermore, our study was not sufficiently powered to comment on the mode of death, and we have limited our analysis to all-cause mortality.

In conclusion, this single-centre, retrospective study analysed the prognostic effectiveness of three scoring systems (MELD-XI, MAGGIC, and HFSS) in ambulatory patients with end-stage HF awaiting OHT. Elevated MELD-XI and MAGGIC scores and lowered HFSS scores were associated with an increased risk of death during one-year follow-up. Moreover, it should be noted that the prognostic utility of the MELD-XI scoring system was better than that of the HFSS, while the MAGGIC scale was comparable to the HFSS in this respect. The use of these scoring systems might complement and enhance the current OHT evaluation models for ambulatory patients with end-stage HF.

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WHAT IS NEW?

This single-centre, retrospective study analysed the prognostic effectiveness of three scoring systems: MELD-XI, MAGGIC, and HFSS in ambulatory patients with end-stage heart failure (HF) awaiting orthotopic heart transplantation (OHT). We demonstrated that the HFSS scale continues to provide useful prognostic information in patients with end-stage HF receiving optimal contemporary therapy. Furthermore, our study showed that the MELD-XI and MAGGIC scales are both useful tools for predicting heart transplant waiting list mortality in the population of ambulatory patients with end-stage HF. Moreover, in terms of prognostic utility the MELD-XI scoring system was better than the HFSS, while the MAGGIC scale was comparable to the HFSS. The use of these scoring systems might complement and enhance the current OHT evaluation models for ambulatory patients with end-stage HF.