Prognostic scales in advanced heart failure

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Abstract

Heart transplantation (HT) is the treatment of choice for patients with advanced heart failure (HF) who remain symptomatic despite optimal medical therapy. Due to the shortage of organs for transplantation and constantly increasing number of patients placed on waiting lists, accurate risk stratification is a crucial element of management in this population. Prognostic scales allow one to evaluate the patient prognosis, estimate the potential benefits of therapy and identify those patients most likely to benefit from advanced methods of treatment. In this review, we describe prognostic scales in advanced HF, concentrating on commonly used tools – the Heart Failure Survival Score (HFSS) and Seattle Heart Failure Model (SHFM) – as well as on the new promising scales for evaluating waiting list mortality and post-transplant outcomes.

Key words: prognostic scales, advanced heart failure.

Streszczenie

Transplantacja serca jest uznaną metodą leczenia chorych z zaawansowaną niewydolnością serca, u których wszelkie inne formy terapii nie przyniosły oczekiwanych rezultatów. Ze względu na stale zwiększającą się liczbę pacjentów kwalifikowanych do transplantacji serca oraz znaczny niedobór narządów do przeszczepienia istotnym elementem postępowania w tej grupie chorych jest dokładna ocena rokowania. Ważnymi narzędziami oceniającymi prawdopodobieństwo wystąpienia specyficznych zdarzeń są skale prognostyczne umożliwiające holistyczną ocenę rokowania chorego, oszacowanie potencjalnych korzyści i zagrożeń związanych z terapią oraz identyfikację tych pacjentów, którzy w największym stopniu skorzystają z zaawansowanych metod leczenia. W artykule przedstawiono przegląd aktualnej wiedzy na temat skal prognostycznych w zaawansowanej niewydolności serca, koncentrując się na powszechnie stosowanych narzędziach, takich jak skala HFSS (*Heart Failure Survival Score*) oraz skala SHFM (*Seattle Heart Failure Model*), a także na nowych skalach prognostycznych oceniających rokowanie zarówno w okresie oczekiwania na przeszczep, jak i po operacji.

Słowa kluczowe: skale prognostyczne, zaawansowana niewydolność serca.

Introduction

Heart transplantation (HT) is the treatment of choice for patients with advanced heart failure (HF) who remain symptomatic despite optimal medical therapy. Given that the prognosis of HT candidates is poor due to the small number of donors, the long waiting time, as well as potential perioperative complications, risk stratification is a crucial element of management in this population [1–3]. Over the years, to minimize mortality in patients awaiting HT, allocation policy has prioritized sicker candidates to receive donor hearts. However, not all candidates listed with the same status share similar risk of death while waiting for and after the HT. In addition, patients at the highest risk of waiting list death also present high rates of post-HT mortality [3, 4]. Therefore, optimal selection of HT candidates requires constant considerations of balance between waiting list mortality and post-transplant outcomes [4, 5]. Physicians involved in the care of advanced HF patients often estimate their risk of death incorrectly due to difficulties in assessing the relative weight of each prognostic parameter, personal beliefs, or previous experiences [2, 6]. Therefore, the assessment of prognosis cannot be based on the clinician's knowledge alone, and an in-depth analysis with effective and simple prognostic tools is needed [7–10]. Prognostic scales are important tools for calculating the probability of a specific event; they enable holistic evaluation of the patient, taking into account many important clinical, demographic, and laboratory variables.

Among the available prognostic scales, only the Heart Failure Survival Score (HFSS) and the Seattle Heart Failure Model (SHFM) are used in everyday clinical practice. The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of HT candidates recommend using the HFSS and SHFM scores in the assessment of prognosis of ambulatory patients with advanced HF qualified for HT [1]. However, there are several promising predictive scales such as the Model for End-Stage Liver Disease (MELD) and its modifications, the Index for Mortality Prediction After Cardiac Transplantation (IMPACT) and the RADIAL scale, that may also become valuable tools for risk stratification in the near future.

In this review, we describe the prognostic scales commonly used for advanced HF, namely, the HFSS and SHFM, as well as new promising scales for evaluating waiting list mortality and post-transplant outcomes.

Heart Failure Survival Score

The HFSS is one of the widely used predictive models; it was developed in the 1990s by Aaronson *et al.* [8]. This scale was derived from the data of 268 ambulatory patients referred for consideration of HT from 1986 to 1991 and was validated in a group of 199 similar patients from 1993 to 1995. Multivariate analysis revealed independent risk factors that were used to create two versions of this scale: an invasive and a non-invasive one. The non-invasive version of the HFSS is calculated from a formula including HF etiology, peak oxygen uptake, mean arterial blood pressure, resting heart rate, serum sodium, left ventricular ejection fraction, and intraventricular conduction delay > 120 ms. In the invasive version, pulmonary capillary wedge pressure is taken into account in addition to the above variables. However, the addition of this catheterization-derived variable did not improve the risk stratification of patients in the final algorithm, so the non-invasive version of the HFSS scale is used more often in clinical practice [8]. The calculated HFSS score is assigned to one of three risk groups: low risk (≥ 8.10), medium risk (7.20 to 8.09), or high risk (≤ 7.19) [8]. According to Aaronson's scale, high-risk patients should be prioritized for HT due to the high risk of death during the 1-year follow-up.

Many studies have confirmed good prognostic strength of the HFSS scale in assessing outcomes of HF patients [7–10]; however, most of them were conducted in the past era of HF therapy, when a minimal percentage of patients were treated with β-blockers, mineralocorticoid receptor antagonists, and implantable devices. Therefore, the prognostic power of the HFSS scale in the current standard of care for HF patients might be limited. The available literature lacks prospective validated studies confirming the prognostic power of the HFSS scale in cohorts of HF patients treated with current medical therapy for HF [11].

Seattle Heart Failure Model

The Seattle Heart Failure Model (SHFM) was derived to predict a composite outcome of death, urgent HT, and ventricular assist device (VAD) implantation in a cohort of 1125 HF patients from the PRAISE I clinical trial database. The scale was then validated prospectively in five additional cohorts including 9942 HF patients from the ELITE2, Val-HeFT, UW, RENAISSANCE, and IN-CHF clinical trial databases [12]. The SHFM incorporates 20 variables representing the patient's clinical characteristics (age, gender, NYHA class, weight, systolic blood pressure, ischemic etiology, left ventricular ejection fraction), laboratory data (serum sodium, hemoglobin, uric acid, total cholesterol, lymphocyte percentage), medications (β-blocker, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, statin, aldosterone blocker, loop diuretic equivalent dose, allopurinol), and device therapy (implantable cardioverter-defibrillator, cardiac resynchronization therapy) [12]. Based on the scores derived from the above variables, the patient can be classified as low-, medium-, or high-risk. The scale provides a good estimate of mean, 1-, 2-, and 3-year survival and allows for the estimation of predictive benefits from adding pharmacological agents or device therapy to the patient's treatment. In 2013, the SHFM was updated to include inotropes, intra-aortic balloon pumping, ventilation, ultrafiltration, and benefits from new VADs in order to enable better risk-of-death stratification in light of more recent guidelines for the management of HF [13]. A calculator for the current SHFM scale is available on the internet (http://depts.washington.edu/shfm). Several other studies have analyzed the accuracy of modified versions of the SHFM scale created by adding new prognostic factors such as renal function, diabetes mellitus, and brain natriuretic peptide [7, 14–17]. Although the SHFM allows an accurate estimation of the risk of death, the multitude of parameters required to calculate the total risk may limit its usefulness in everyday practice.

Model for End-Stage Liver Disease and its modifications

The MELD was originally developed to assess short-term prognosis in patients with cirrhosis undergoing elective placement of transjugular intrahepatic portosystemic shunts. Subsequently, it was adopted for prioritizing liver transplant candidates based on disease severity [18]. Currently, this scoring system provides valuable prognostic information in the population of patients with HF [19].

The standard MELD scale consists of three objective and easily obtainable variables: the international normalized ratio (INR), serum bilirubin, and serum creatinine [19]. Bilirubin is a well-established marker of hepatic metabolic function, while the INR reflects coagulopathy associated with synthetic dysfunction. The third component, i.e., creatinine level, is used to assess the severity of renal dysfunction. Kidney and liver dysfunction is commonly observed in HF patients and is closely correlated with adverse outcomes and increased risk of mortality [19]. Therefore, assessment of cardio-hepatic and cardio-renal interactions using the MELD scale may also improve risk stratification in HF patients [19]. The ability of the MELD score to predict

clinical outcomes has been confirmed in different HF populations [20, 21]. However, the MELD score has one important limitation: it cannot be applied in patients treated with oral anticoagulants due to the distortion of INR values [21]. As an alternative to the traditional MELD system, the modified Model for End-Stage Liver Disease (modMELD) and the MELD excluding INR (MELD-XI) were developed [20–22]. The modMELD is identical to the standard version except for the substitution of the INR component with albumin [20], whereas the MELD-XI score is based on creatinine and bilirubin alone [21]. Given that INR is not used in their calculation, the modifications of the MELD scale remain accurate even if the patient receives oral anticoagulation. For this reason, the MELD-XI and modMELD scales seem to be superior to the standard MELD score, especially in cohorts of patients with advanced HF referred for HT evaluation or undergoing VAD implantation [19, 20, 23, 24].

Interagency Registry For Mechanically Assisted Circulatory Support classification

The most commonly used system for the subjective evaluation of the severity of HF symptoms is the classification of the New York Heart Association (NYHA) [25]. However, it does not allow accurate grading of risk, especially in populations with advanced HF, which prompted the development of the new INTERMACS (Interagency Registry For Mechanically Assisted Circulatory Support) classification. It consists of seven clinical profiles, ranging from patients on the brink of death (INTERMACS level 1), who have little chance of surviving, to patients who are clinically stable and do not currently have indications for urgent interventions (INTERMACS level 7) (Table I) [26]. The INTERMACS profiles were devised during the development of the database from a multicenter registry of VAD to unify the criteria describing the clinical characteristics of advanced HF patients, clarify the target populations for VAD implantation, and present the available treatment alternatives [4, 26, 27]. This scale also provides important prognostic information for HF patients receiving VADs [4, 26, 27]. Patients who do not require inotropic support before VAD implantation (INTERMACS profiles 4–7) have significantly better survival and shorter hospital stays than patients on high doses of inotropes (INTERMACS profiles 1–3) [28]. The INTERMACS profiles are also used to stratify prognosis after urgent HT [4, 29]. The mortality rate among INTERMACS level 1 patients is significantly higher than among INTERMACS level 2–4 patients in the first year after HT. The poor post-HT outcomes in INTERMACS level 1 patients are mostly due to

Table I. INTERMACS (Interagency Registry for Mechanically Assisted Circulatory Support) classification of patients with advanced HF

Profile	NYHA class	Description	Time frame for intervention
INTERMACS 1	IV	Critical cardiogenic shock Patient with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion	Definitive intervention needed within hours
INTERMACS 2	IV	Progressive decline on inotropic support Patient dependent on inotropic support, with progressive deterioration in nutrition, renal function, fluid retention, or other major status indicators	Definitive intervention needed within a few days
INTERMACS 3	IV	Stable but inotrope-dependent Patient with stable blood pressure, organ function, nutrition, and symptoms on continuous intravenous inotropic support, but demonstrating repeated failure to wean from inotropic agents due to symptomatic hypotension, worsening symptoms, or progressive organ dysfunction. Patient can be in the hospital or at home	Definitive elective intervention within a period of weeks/a few months
INTERMACS 4	IV	Resting symptoms in a patient who is at home on oral therapy Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during activities of daily living. Some patients may shuttle between 4 and 5	Definitive elective intervention within a period of weeks/a few months
INTERMACS 5	IV	Exertion intolerant Comfortable at rest and with activities of daily living, but unable to engage in any other activity; living predominantly within the house, frequently with moderate water retention and some level of kidney dysfunction. If underlying nutritional status and organ function are marginal, patient may be more at risk than INTERMACS 4 and require definitive intervention	Variable urgency, depends upon maintenance of nutrition, organ function, and activity
INTERMACS 6	IIIB	Exertion limited Comfortable at rest, without evidence of fluid overload, able to engage in activities of daily living and minor activities outside the home, but experiences fatigue within a few minutes of any meaningful exertion	Variable, depends upon maintenance of nutrition, organ function, and activity level
INTERMACS 7	III	Advanced NYHA class III symptoms Clinically stable with a reasonable level of comfortable activity, without current or recent episodes of decompensation	HT or circulatory support may not currently be indicated

the high incidence of primary graft failure and multiorgan dysfunction. In addition, the patients at INTERMACS level 1 are more likely to require preoperative mechanical circulatory support and greater doses of vasoactive amines; furthermore, dysfunction of the liver and kidneys in such patients is more severe [4, 29]. The main advantage of the INTERMACS classification that makes it useful in evaluating prognosis is its ability to precisely stratify the clinical and hemodynamic condition of candidates for HT or VAD implantation (Table I) [4, 26–29].

Index for Mortality Prediction After Cardiac Transplantation

The Index for Mortality Prediction After Cardiac Transplantation (IMPACT) was recently derived and internally validated to predict the likelihood of 1-year mortality after HT in a cohort of 21 378 patients from the United Network for Organ Sharing (UNOS) data [5]. The 50-point IMPACT risk score incorporates 12 preoperative recipient-specific variables with appropriate point values: age, serum bilirubin level, creatinine clearance, dialysis between listing and transplant, female sex, HF etiology, recent infection, intraaortic balloon pump, mechanical ventilation before orthotopic heart transplantation, race, temporary circulatory support, VAD. According to the IMPACT scale, the rate of one-year survival deteriorates in patients achieving higher scores as follows: 0 to 2 points: 92.5%; 3 to 5 points: 89.9%; 7 to 9 points: 86.3%; and 10 or more points: 74.9%. Furthermore, the postoperative one-year mortality rate in patients with preoperative IMPACT scores of 20 or more exceeds 50% [5]. The IMPACT score as a predictor of short-term and long-term mortality after HT was also validated externally by Kilic *et al.* using data from the ISHLT [30]. However, the IMPACT score from the ISHLT cohort differs slightly from the original UNOS cohort [5, 30]. In the ISHLT cohort, the proportion of ischemic heart disease was lower, the average creatinine clearance and 1-year mortality risk after HeartMate II implantation was higher, and no information about the patient's race was included [30]. Nevertheless, the ability of the IMPACT score to estimate one-year survival was comparable in the two cohorts [5, 30]. It seems that the IMPACT score can serve to drive clinical decisions regarding organ allocation and may prove especially useful in view of the increasing population of potential recipients and the significant shortage of donors. In the near future, the IMPACT scale may also become a valuable tool for facilitating discussions with patients and their families regarding prognosis after HT.

RADIAL Scale

The RADIAL scale was derived and validated to predict the development of primary graft failure (PGF), which is an important cause of early death and need for re-transplantation among HT recipients [31, 32]. This scale incorporates 4 recipient variables (right atrial pressure ≥ 10 mm Hg, age ≥ 60 years, diabetes mellitus, preoperative inotrope dependence), 1 donor variable (age ≥ 30 years), and 1 procedural

variable (length of ischemic time ≥ 240 min). The RADIAL score is calculated by adding 1 point when a variable is present and 0 when it is absent, which results in a maximum of 6 and a minimum of 0 points [31]. The obtained score is then assigned to one of the risk strata: low (RADIAL < 2, PGF 12.1%), intermediate (RADIAL = 2, PGF risk 19.1%), or high (RADIAL > 2 PGF risk 27.5%) [32]. The scale is a promising tool for optimizing donor-recipient matching because it considers the interactions between factors associated with the recipient, donor, procedure, and HT duration. Importantly, this is the only scale that estimates the risk of PGF, which may be useful for implementing preventive or early therapeutic measures for PGF and may perhaps help reduce early mortality after HT. However, further prospective studies are needed to substantiate the usefulness of the RADIAL scale in everyday clinical practice.

Conclusions

The application of prognostic scales should be an essential component of the process of qualifying patients for advanced forms of therapy such as HT and VAD implantation. They enable accurate risk stratification and estimation of the potential benefits and threats associated with the therapy. Among the prognostic scales described in this paper, currently only HFSS, SHFM and INTERMACS are applied in everyday clinical practice. According to the ISHLT guidelines, the HFSS and SHFM scales are used to assess the prognosis of ambulatory patients with advanced HF qualified for HT, while the INTERMACS is commonly used in patients receiving VAD.

Disclosure

The authors report no conflict of interest.

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