Validation of the Hematopoietic Cell Transplantation-Specific Comorbidity Index in a retrospective cohort of children and adolescents who received an allogeneic transplantation in Argentina

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ABSTRACT

Introduction. Hematopoietic cell transplantation is a therapy with a risk of transplant-related mortality (TRM), which may vary depending on prior comorbidities. The Hematopoietic Cell Transplantation-Specific Comorbidity Index (HCT-CI) is an instrument developed to measure this risk. There are very few reports on its use in pediatrics. The objective of this study was to validate the HCT-CI in a pediatric cohort of allogeneic hematopoietic-cell transplantation recipients in Argentina.

Population and methods. Retrospective cohort made up of 140 transplant patients at Hospital J. P. Garrahan between 2008 and 2012. Medical records were reviewed to identify patient history and course. The HCT-CI was estimated for each patient, who was classified as having a low (score: 0), intermediate (score: 1-2) or high (score: >3) risk. Survival was estimated for each group using the Kaplan-Meier method and compared with the log-rank test. For malignancies, relapse was considered an event consistent with TRM. A p value <0.05 was considered significant.

Results. The median score in the HCT-CI was 1 (r: 0-6). A score of 0 was observed in 45.7% of patients, 1-2 in 40.7%, and >3 in 13.6%. The most common comorbidities included obesity, infection, pulmonary and liver involvement. TRM was 14.1% among patients with a score of 0; 43.7% with a score of 1-2, and 52.6% with a score >3. Differences were observed among the survival curves of the three groups (p = 0.01).

Conclusion. The HCT-CI demonstrated to be an effective tool to predict the risk of TRM in our setting.

***Key words**: comorbidity, hematopoietic stem cell transplantation, non-relapse mortality, pediatrics.*

http://dx.doi.org/10.5546/aap.2016.eng.337

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Funding:
None.

Conflict of interest:
None.

Received: 12-13-2015
Accepted: 02-10-2016

INTRODUCTION

In spite of advances in support therapy, hematopoietic-cell transplantation (HCT) still presents a high risk of mortality.[1]

Previous organ involvement or a history of infection may increase the likelihood of complications or transplant-related mortality (TRM).[2-5] When a patient has several concurrent risk factors, it becomes difficult to estimate their individual risk. Reducing the level of uncertainty in this regard may help to define a patient's eligibility for HCT, to select a more acceptable conditioning regimen, and to facilitate an adequate consent process.

In 2005, Sorror et al. published the results of the validation of a new instrument to solve such uncertainty, the Hematopoietic Cell Transplantation-Specific Comorbidity Index (HCT-CI),[6] based on the general comorbidity index developed by Charlson.[7] Taking the HCT-CI into account, authors were able to define three TRM risk categories according to comorbidities existing before transplantation. Several subsequent studies, including two multicenter, prospective studies, confirmed the usefulness of the HCT-CI,[8-12] although dissimilar results were reported by some sites.[13,14]

In 2011, Smith et al. described the results of implementing the HCT-CI in a retrospective cohort of 252 pediatric patients followed up at four sites in the USA.[15] In this study, the HCT-CI demonstrated adequate power to predict TRM and overall survival.

The primary objective of this study was to assess HCT-CI effectiveness to predict TRM risk and survival in a retrospective cohort of children and adolescents who received an allogeneic HCT in an Argentinean site. The secondary objectives included exploring TRM causes and the impact of a pre- and post-transplant invasive fungal infection (IFI).

POPULATION AND METHODS

Retrospective cohort made up of a consecutive sample of 140 patients who received an allogeneic HCT between January 1st, 2008 and December 31st, 2012 at the Division of Bone Marrow Transplant of Hospital de Pediatría Prof. Dr. Juan P. Garrahan.

All patients received antibiotic prophylaxis with ciprofloxacin and fluconazole during the neutropenia period, acyclovir prophylaxis for herpes simplex, and trimethoprim-sulfamethoxazole or pentamidine prophylaxis for *Pneumocystis jiroveci*. The management of cytomegalovirus infection consisted of its early treatment, based on viral load surveillance weekly. Low-dose heparin prophylaxis was administered for hepatic veno-occlusive disease. Prevention of graft-versus-host disease (GvHD) consisted in the administration of a calcineurin inhibitor (cyclosporin A for related donor transplants or tacrolimus for unrelated donor transplants) in association with methotrexate for bone marrow or peripheral blood recipients. For umbilical cord blood recipients, GvHD prophylaxis consisted of the combination of a calcineurin inhibitor and methylprednisolone or mycophenolate.

Pre-transplant assessment included lab tests, renal and liver function tests, an echocardiogram, an abdominal ultrasound, chest and sinus computed tomography, and lung function tests as of six years old.

Strategy: One of the investigators reviewed each patient's medical record, including an assessment record sheet completed at the time of admission to the transplant unit. Sorror's recommendations[16] were followed to record data regarding the HCT-CI.

If necessary, the lab database was also reviewed. In the case of uncertainty regarding a score assignment, a discussion was held among all investigators.

The following data were recorded: sex, age at the time of transplant, diagnosis, date of HCT, date of transplant-related death, date of relapse, date of most recent control, donor type, conditioning type, and source of hematopoietic stem cells. The history of pre-HCT IFI and the following post-transplant events were also recorded: acute GvHD (grade 2-4 and 3-4), chronic GvHD (limited and extensive), IFI, and known TRM risk factors.[1,5]

HCT-CI: The index score is the result of assessing 17 items at the time of patient's admission for HCT, and each result is assigned a specific score, which is the result of its relevance as a risk factor in the original study.[6] The results for each of these items were recorded based on authors' specifications and the index score was estimated for each patient. The same risk categories used in the original study were used here: mild for a score of 0, intermediate for a score of 1-2, and high for a score ≥3.

Statistical analysis: The different outcome measures were summarized as percentage or median and range, as applicable. The rate of acute and chronic GvHD, IFI, and TRM were compared between related and unrelated donor HCT using the Fisher's test. Logistic regression was used to analyze the association between TRM and the following risk factors: grade 2-4 and grade 3-4 acute GvHD, extensive chronic GvHD, and pre- and post-transplant IFI. The association between the HCT-CI risk category and the risk of TRM was assessed by estimating survival of each group using the Kaplan-Meier method, and it was then compared to a log-rank test. For malignancies, relapse was considered an event consistent with TRM. A p value <0.05 was regarded as significant. The statistical software used was Stata 9.

The protocol was assessed and approved by the Research Review Committee and Ethics Committee of the hospital.

RESULTS

Table 1 describes the general characteristics of the sample. As observed, the main indication for HCT was acute leukemia; 45.8% were in second remission, and 2.7%, in third remission.

Also, 55% of patients had grade 2-4 GvHD, and 11.4% grade 3-4 GvHD (8.3% in related donor HCT versus 18.3% in unrelated donor HCT, p= 0.14).

The rate of chronic extensive GvHD was 28.6% (25% in related donor HCT versus 36.4% in unrelated donor HCT, p = 0.23).

A history of pre-HCT IFI was observed in 7.8% of patients while 19.3% had post-transplant IFI (15.3% in related donor HCT versus 27.3% in unrelated donor HCT, p= 0.11).

The TRM was 27.1%, and a worse clinical course was observed in unrelated donor HCT (19.8% in related donor HCT versus 42.8% in unrelated donor HCT, p= 0.007).

The most common causes of TRM were infections (92%), in association with active or corticosteroid-refractory GvHD in 39% of cases. The latter was observed in 21% of GvHD cases.

Table 2 describes the rate of documented infections that caused TRM.

The presence of acute grade 3-4 GvHD (odds ratio [OR]: 7.8, confidence interval [CI]: 2.4-25.1, p= 0.001) and post-HCT IFI (OR: 2.7, CI: 1.1-7, p= 0.039) was associated with a greater TRM. No association was demonstrated between TRM and a history of IFI (OR: 1.4, CI: 0.4-5.9) or the presence of chronic extensive GvHD (OR: 1.1, CI: 0.4-2.3).

Hematopoietic Cell Transplantation-Specific Comorbidity Index

The median score was 1 (r: 0-6). A score of 0 was assigned to 45.7% of patients; of 1-2, to 40.7%; and ≥3 to 13.6%. No significant differences were observed between related and unrelated donor HCT recipients.

Table 3 describes comorbidities observed in the sample. The most common comorbidities included obesity, infection, and pulmonary and liver involvement.

The TRM in patients whose score was 0 was 14.1% (10.6% in related donor HCT versus 23.5% in unrelated donor HCT, p= 0.23); in those whose score was 1-2, 43.7% (27.3% in related donor HCT versus 80% in unrelated donor HCT, p= 0.1); and in those whose score was ≥3, 52.6% (50% in related donor HCT versus 57.1% in unrelated donor HCT).

A score of 0 was associated with a lower risk of TRM in both related donor HCT (OR: 0.30, CI: 0.09-0.9, p= 0.03) and unrelated donor HCT (OR: 0.25, CI: 0.06-0.95, p= 0.04) recipients.

Patients with comorbidities (score >0) tended to have post-transplant IFI more frequently than those without comorbidities (25% versus 12.5%, p= 0.08) and grade 3-4 acute GvHD (15.79 versus 6.25%, p= 0.1).

TABLE 1. *General characteristics of patients*

	n (%)
Total number of patients	140
Age, *median (range)*	9 años (0.2-18)
Boys	87 (62)
Diagnosis:	
Acute leukemia	75 (53.6)
Myelodysplastic syndrome	15 (10.7)
Aplastic anemia	14 (10)
Wiskott-Aldrich syndrome	4 (2.9)
Mucopolisacaridosis tipo I	4 (2.9)
Fanconi anemia	4 (2.9)
Severe combined immunodeficiency	3 (2.1)
Other severe immunodeficiencies	5 (3.6)
Juvenile myelomonocytic leukemia	3 (2.1)
Chronic myeloid leukemia	2 (1.4)
Lymphoma	2 (1.4)
Hemophagocytic lymphohistiocytosis	2 (1.4)
Adrenoleukodystrophy	2 (1.4)
Erythroblastopenia	2 (1.4)
Others*	3 (2.1)
Donor type:	
Related identical donor	96 (68.6)
Unrelated identical donor	44 (31.4)
Hematopoietic cell source:	
Bone marrow	88 (62.9)
Peripheral blood	29 (20.7)
Umbilical cord blood	23 (16.4)
Conditioning:	
Myeloablative	124 (88.6)
Non-myeloablative	16 (11.4)

* Thalassemia, Shwachman–Diamond syndrome, paroxysmal nocturnal hemoglobinuria.

TABLE 2. *Infections documented as a cause of mortality related to hematopoietic cell transplantation*

Infections	n
Virus	15
Cytomegalovirus	8
Adenovirus	5
Community-acquired respiratory infection	2
Bacteria	6
Gram-negative bacilli	5
Mycoplasma pneumoniae	1
Invasive fungal infections	4
Aspergillus	3
Candida glabrata	1
Pneumocystis jiroveci	2
Toxoplasmosis	1

TABLE 3. *Rate of comorbidities evaluated with the Hematopoietic Cell Transplantation-Specific Comorbidity Index*

Comorbidity	n (%)
Arrhythmia	1 (0.71)
Valvular heart disease	0
Other heart diseases	0
Peptic ulcer disease	0
Prior solid tumor	0
Psychiatric disorders	5 (3.57)
Obesity	28 (20)
Infection	25 (17.86)
Moderate/severe kidney disease	0
Rheumatic disease	0
Diabetes	0
Moderate pulmonary involvement	7 (5)
Severe pulmonary involvement	19 (13.57)
Moderate/severe liver involvement	8 (5.71)
Mild liver involvement	13 (9.9)
Cerebrovascular disease	4 (2.86)
Inflammatory bowel disease	1 (0.71)

Figure 1 shows survival curves with significant differences among groups (p= 0.01)

DISCUSSION

The study findings show that the HCT-CI predicts the risk of TRM in pediatric patients seen in our setting.

The possibility of unrelated donors, advances made in support management, and diversified conditioning regimens have allowed widening the base of HCT-eligible patients.[17] This results in HCT candidates being more heterogeneous and in the inclusion of patients with a more significant organ involvement prior to transplant, so it becomes more difficult to compare different groups and to make individual predictions regarding the likelihood of survival and risk of TRM.

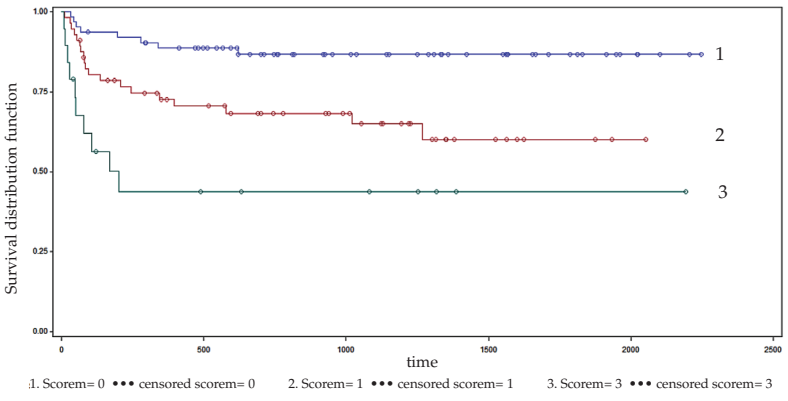
The Charlson Comorbidity Index, which is used to measure different diseases, was combined with the performance status and demonstrated an adequate predictive power for TRM, but its sensitivity to detect comorbidities in HCT candidates was limited.[18] Based on the index developed by Charlson, Sorror et al. designed a new indicator, the HCT-CI, which includes common comorbidities in HCT recipients, such as infections and psychiatric disorders, and demonstrated a higher sensitivity and predictive power.[6]

Although the sample used to develop and validate the HCT-CI included pediatric patients (authors described that the age ranged from 0.8 to 72.7 years old), the median age of patients was 44 years old, and children and adolescents were not assessed as a sub-group. In 2011, Smith et al. published the only study we could find using the HCT-CI exclusively in a population of children and adolescents.[15] Authors described, with variations among the different participating sites, that 55% of patients had a score of 0, 21% a score of 1-2, and 24% a score of 3 or more. The percentage of patients without comorbidities in that sample was higher than that observed in the original study conducted to validate the HCT-CI, where the percentage of patients with a score of 0 was 38%, and that with a score of 3 or more was also 38%.[6]

In our sample, the percentage of patients with a score of 0 was 46%, which is an intermediate value; however, the percentage of patients with a high risk was smaller than that observed in the above-mentioned studies.

A question arises from these data: do pediatric HCT recipients have fewer comorbidities than older patients and/or do they have specific comorbidities undetected by the HCT-CI? Even though comorbidity prevalence increases with age,[19] some factors may lessen the HCT-CI's sensitivity in pediatric patients. Firstly, some pediatric conditions which are an indication for HCT, such as inborn errors of metabolism or constitutional bone marrow failure syndrome, are associated with comorbidities, such as developmental disorders or malformations not recorded by the HCT-CI. Secondly, a 2 mg/dl limit for blood creatinine (which at our site is considered an exclusion criterion for transplant eligibility) to define severe kidney involvement may undervalue significant reductions in glomerular filtration rate in toddlers whose creatinine values are lower. Estimating glomerular filtration rate by combining blood creatinine values with correction factors that account for age

FIGURE 1. *Survival curves by risk group according to the Hematopoietic Cell Transplantation-Specific Comorbidity Index*



and/or anthropometric data is common practice in pediatrics, but should be assessed in future studies.[20] Performing pulmonary function tests in preschoolers is difficult, and this may be another reason why pulmonary involvement is under-recorded in this age group. Implementing new pulmonary function test techniques in infants and preschoolers, which are now being used more and more to follow-up patients with a significant clinical history in clinical practice, may improve this aspect of the assessment.[21]

Pulmonary and liver involvement, together with infections, were the most common comorbidities observed in the pediatric cohort studied by Smith et al.[15] In our cohort, these comorbidities were less common than obesity, which reached a prevalence of 20% and was the most common. This percentage is much higher than that referred in the sample studied by Smith et al., where obesity is somewhat above 1.1%, but such difference may be due to methodological aspects. While in the study by Smith et al. obesity was defined as a body mass index of 35 kg/m^2 or more, criterion used for adults, in our study we set the limit at the 95th percentile for age in accordance with the recommendations later published by Sorror.[16] As per this criterion, obesity prevalence in our sample is even lower than that observed by other authors, such as White et al.[22]

Infections, either associated with GvHD or not, were the main cause of TRM in our sample. This is consistent with previous studies on TRM.[23] Data obtained from the literature are useful to understand the relationship between pre-HCT comorbidities and these events. Sorror et al. reported, in a recent multicenter study, an association between HCT-CI and the risk for more severe forms of GvHD,[24] consistent with the trend observed in our sample. In addition, Bayraktar et al. observed that the HCT-CI was associated with a higher TRM among HCT recipients who were admitted to the intensive care unit.[25] Given that severe GvHD is a risk factor for infections,[26] it is logical to consider that the most common association between comorbidities and TRM in pediatric patients is the result, in most cases, of multiple organ failure secondary to an interaction between GvHD and infections rather than the primary multiple organ failure caused by conditioning regimens.

The rate of TRM in our sample shows a significant difference between related and unrelated donor HCT recipients. Although studies conducted in sites with major experience in unrelated donor transplants have reported similar survival rates with both donor types,[27] other studies have found differences in TRM by donor type, a difference that has tended to reduce over the past years.[28]

During the study period, the median time at our site, since the start of the search for an unrelated donor and transplantation was six months. Such delay exposes patients with malignancies to higher cumulative chemotherapy doses, and those with hematologic failure or immunodeficiencies, to a higher risk for infections or iron overload. However, in our study, such delay was not observed to be reflected in a higher HCT-CI score among recipients of unrelated donor transplants. This may be either due to the reduced number of unrelated donor HCT recipients in our sample or is a limitation of the HCT-CI's sensitivity.

In this regard, it is worth noting a recently published study by Vaughn et al., which shows that combining the HCT-CI with biological markers, such as ferritin, albumin, and platelet count, increases the instrument's discriminating power.[29]

In conclusion, according to our study, the HCT-CI is a useful tool to predict survival and assess the mortality risk among children and adolescents who received an HCT in our setting. Its use in clinical practice and research may help to improve consent processes and decision-making in planning and managing transplants.[30] ■

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