Validation of the Pediatric Index of Mortality 2 (PIM2) in Argentina: a prospective, multicenter, observational study

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ABSTRACT

Introduction. The Pediatric Index of Mortality 2 (PIM2) is one of the most commonly used scoring systems to predict mortality in patients admitted to pediatric intensive care units (PICU) in Argentina. The objective of this study was to validate the PIM2 score in PICUs participating in the Quality of Care Program promoted by the Argentine Society of Intensive Care.

Population and Methods. Multicenter, prospective, observational, cross-sectional study. All patients between 1 month and 16 years old admitted to participating PICUs between January 1st, 2009 and December 31st, 2009 were included. The discrimination and calibration of the PIM2 score were assessed in the entire population and in different subgroups (risk of mortality, age, diagnoses on admission).

Results. Two thousand, eight hundred and thirty-two patients were included. PIM2 predicted 246 deaths; however, 297 patients died ($p < 0.01$). The standardized mortality ratio was 1.20 (95% confidence interval [CI]: 1.01-1.43). The area under the ROC curve was 0.84 (95% CI: 0.82-0.86). Statistically significant differences were detected between the observed and the predicted mortality for the entire population and for the different risk intervals (χ^2: 71.02, df: 8, $p < 0.001$). Statistically significant differences were also found between observed and predicted mortality in adolescent patients (37/22, $p = 0.03$) and in those hospitalized due to respiratory disease (105/81, $p = 0.03$).

Conclusions. The PIM2 score adequately discriminates survivors from non-survivors. However, it underscores the overall risk of death, especially in adolescent patients and those hospitalized due to respiratory disease. It is critical to take such differences into account when interpreting results.

Key words: *pediatric intensive care unit, mortality, pediatrics, benchmarking, disease severity index, PIM2.*

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INTRODUCTION

Worldwide, the quality and access to pediatric intensive care are not equitable due to major differences in terms of resource availability and the different investments made by each region in their healthcare systems. Critical care distribution and quality are not homogeneous within each country either, which leads to differences in results and a likely impact on overall health indicators, such as child mortality rates.[1]

In order to implement any quality improvement initiative, results should be objectively measured. Prognostic scores of mortality in intensive care units (ICU) have been developed to objectively quantify the relationship between the clinical status of critically-ill patients at the time of admission to the ICU and their risk of death.[2-6] These scores use regression models that yield an equation describing the relationship among different predictor variables (physiological, demographic and clinical) and the likelihood of death.[7] Indicators such as the standardized mortality ratio (SMR), which compares observed mortality with that predicted by scores, are useful tools to assess care provided at ICUs. However, when interpreting these indicators, it is necessary to consider whether the score used to predict mortality is reliable and adequate for the studied population. The model should allow to adjust mortality risk based on factors other than care provided, which might have an impact on results.

Since 1999, the Argentine Society of Intensive Care (*Sociedad Argentina de Cuidados Intensivos*, SATI) has implemented a Quality of Care Program called SATI-Q,[8] an initiative aimed at improving care provided at ICUs in Argentina.

Neonatal, pediatric and adult ICUs take part in this program voluntarily. Participating pediatric intensive care units (PICU) are allowed to use one of two mortality prediction models: either the Pediatric Risk of Mortality (PRISM) score[9] or the PIM2 score.[10,11] The latter is the score most commonly used in PICUs. This may be either because the PIM2 is easily calculated, has been widely disseminated in Argentina, or is free, unlike PRISM III, which is the updated version of PRISM. In addition, unlike PRISM and PRISM III, the PIM2 score takes into consideration aspects related to the patient's status prior to PICU admission and is not affected by the treatment provided in the first 24 hours following hospitalization.[12]

Although the PIM2 score can be used in populations different than those participating in the original study, it is fundamental to test its effectiveness in a representative sample of patients in order to confirm whether the model is also an adequate predictor of death at a local level.[3,13,14] The objective of this study is to validate the PIM2 score in Argentine PICUs that are part of the SATI-Q Program.

POPULATION AND METHODS

A multicenter, prospective, observational, cross-sectional study was designed. All PICUs in the SATI-Q Program were invited to participate.

All patients between 1 month and 16 years old and who required intensive care between January 1st, 2009 and December 31st, 2009 were consecutively included in the analysis.

Patients still hospitalized at the end of the data collection period, or referred to another PICU to continue treatment, and those younger than 1 month old were excluded from the analysis. Newborn infants were also excluded because, in Argentina, they are usually managed in neonatal intensive care units.

The following data were collected for each patient: diagnosis on admission, date of admission and discharge from the PICU, age, sex, length of stay in days, days on mechanical ventilation (MV), outcome at the time of discharge from the PICU, and every other information necessary to estimate the PIM2 score. The PIM2 equation and other variables are described in *Table 1*.[11]

Data were collected using the SATI-Q software. This is the software used by ICUs participating in the SATI-Q Program to record data related to quality standards.[8]

In order to minimize missing data in the outcome measures of the study, databases were analyzed on a quarterly basis. Every quarter, five randomly selected records were analyzed for each PICU, and the percentage of missing data was assessed. The PIM2 score was also recalculated for analyzed patients considering data obtained from the case history. Data quality was assessed by comparing the likelihood of death estimated for both cases using the Bland-Altman test.[15]

Each participating PICU sent their encrypted database for review via e-mail. In order to maintain data security and protect personal information, all patient identifying data were anonymized. The database has been registered before the National Argentine Department of Personal Data Protection.

Ethical considerations: The ethical and scientific aspects of the protocol were assessed and approved by members of the Pediatric Chapter, the Management, Quality Control and Score Committee, and the Bioethics Committee of SATI. This Committee exempted the need of having an informed consent based on the observational nature of the study, the fact that data were routinely collected at each participating PICU, and that data protection requirements were complied with.

Statistical analysis: Continuous quantitative outcome measures were expressed as mean ± standard deviation or as median and interquartile range (IQR). Discrete quantitative outcome measures were expressed as average and range. Categorical outcome measures were indicated as frequency and percentage. The χ^2 test was used to compare categorical outcome measures, while the Mann-Whitney U test was used to compare continuous outcome measures given their lack of normal distribution. A value of $p < 0.05$ was accepted as statistically significant.

The Mid-P method was used to estimate the SMR and its 95% confidence interval (95% CI).[16]

Calibration or degree of acceptance between the number of predicted and observed events was estimated using Hosmer-Lemeshow goodness-of-fit test for the general population and stratified by risk deciles.[17] Discrimination or the model's capability to differentiate non-survivors from survivors was assessed estimating the area under the receiver operating characteristic (ROC) curve. The sample was stratified by age and diagnosis groups on admission to assess the effectiveness of the score in these subgroups. Age was categorized

using Medline's MeSH category.[18] For a greater precision in the analysis, the MeSH category "infants" was divided into two groups: infants 1 (1-11 months old) and infants 2 (12-23 months old). The group "Adolescents" was censored as of 16 years old. Diagnosis groups on admission were classified into 6 subgroups based on the subgroups used in the original PIM2 study. For each age subgroup and diagnostic category, the area under the ROC curve and the SMR and its corresponding 95% CIs were plotted.

The sample size was estimated based on the N = 10 k/p formula, where χNχis the minimum number of cases to be included, χkχis the number of independent variables included in the PIM2 logistic regression model, and χpχis the lower proportion of positive expected cases in the population (deaths). Considering that the PIM2 score is made up of 10 independent variables and that the proportion of expected deaths was estimated at 10% according to data previously obtained by the SATI-Q Program, the minimum sample size was estimated to be 1000 patients.[19]

The MS Excel XP, MS Access XP and STATA 10 IC software were used for statistical analysis.

RESULTS

The SATI-Q Program includes 15 PICUs; all were invited to participate in the study, and nine accepted. One PICU was excluded because it failed to send data at the end of the study period. The analysis included information recorded by eight PICUs: four general hospitals, and four children hospitals. The average number of beds in participating PICUs was 16 (range: 7-25).

Data from 3152 patients were collected. Three-hundred and twentyrecords were excluded from the analysis: 148 because data corresponding to the variables required for PIM2 calculation were incomplete; 132 because they were out of the study age limits; and 40 because no diagnosis on admission had been recorded.

Data quality was assessed for a randomly selected sample. The bias in likelihood of death, estimated using Bland-Altman's technique and expressed as ratio and 95% CI, was 0.95 (0.91-1.05), similar to that reported by Slater in the original study.

A total of 2832 patients were analyzed; their characteristics are described in *Table 2*. There were 297 observed deaths (10.5%), while the PIM2 had predicted 246 (8.7%). This was a statistically

TABLE 1. *Variables considered for estimating the Pediatric Index of Mortality 2 and equation used to estimate the likelihood of death*

1. Elective admission(1) to the PICU for monitoring, procedures, mechanical ventilation revision, postoperative period after an elective surgery: yes= 1; no= 0.
2. Pupillary light reflex:(2)>3 mm and fixed= 1; unknown/other= 0.
3. Mechanical ventilation requirement in the first hour following admission to the PICU: yes= 1; no= 0.
   It includes nasal CPAP or CPAP mask and BiPAP.
4. Hospitalization for recovery from surgery or procedure as the main reason for admission to the PICU: yes= 1; no= 0.
5. Admission following coronary artery bypass surgery: yes= 1; no= 0.
6. Low-risk diagnosis as the main cause for admission.(3)
7. Known high-risk diagnosis of any of the following conditions:(4)
8. Systolic blood pressure (mmHg): unknown = 120.
   Record 0 if the patient is in cardiac arrest, and 30 if the patient is in shock or his/her blood pressure is so low it cannot be measured.
9. FiO_2*100/PaO_2: unknown= 0.
10. Base excess in arterial or capillary blood: unknown= 0.

Likelihood of mortality = exp. (r)/(1 + exp. (r))

r= {0.01395 * [abs. (SBP-120)]} + (3.0791 * pupillary reflex) + (0.2888 * (100*FiO2/PaO2)) + {0.104 * [abs. (base excess)]} + (1.3352 * MV in the first hour) - (0.9282 * elective admission) - (1.0244 * recovery from surgery or procedure) + (0.7507* recovery from on-pump cardiovascular surgery) + (1.6829 * high-risk diagnosis) - (1.577 * low-risk diagnosis) - 4.8841.

(1) Admission for elective surgery is defined as a surgery that can be postponed more than 6 hours with no adverse events.
(2) Used as indicator of brain function. Findings are not recorded as abnormal if due to drugs, toxins or local injury.
(3) It includes asthma, bronchiolitis, croup, obstructive sleep apnea, or diabetic ketoacidosis.
(4) It includes cardiac arrest prior to admission to the PICU, severe combined immunodeficiency, leukemia/lymphoma following the first induction,spontaneous brain hemorrhage, cardiomyopathy or myocarditis, hypoplastic left heart syndrome, HIV infection, liver failure as the main reason for admission to the PICU, or presence of neurodegenerative disorder.

PICU: pediatric intensive care unit; CPAP: continuous positive airway pressure; BiPAP: bilevel positive airway pressure.

significant difference ($p < 0.01$).

The SMR for the entire population was 1.20 (95% CI: 1.01-1.43). The death of 21.2% (63/297) patients occurred in the 24 hours following admission to the PICU. The median length of stay of deceased patients was 6 days (IQR: 2-13), while that of survivors was 4 days (IQR: 2-10) ($p = 0.02$).

PIM2 discrimination was adequate, with an area under the ROC curve of 0.84 (95% CI: 0.82-0.86) (*Figure 1*).

Table 3 shows observed and predicted mortality corresponding to the different risk deciles, based on Hosmer-Lemeshow goodness-of-fit test. An inadequate calibration was observed and significant differences (χ^2: 71.02, df: 8, $p < 0.001$) were described for the general population and in most of mortality risk deciles.

Table 4 describes the results of the analysis stratified by age categories and diagnosis groups. Statistically significant differences were observed in the number of observed and predicted deaths in the adolescent group. Thirty-seven deaths were observed, while the PIM2 had predicted 22 ($p= 0.03$). The SMR was 1.66 (95% CI: 1.2-2.29). In the analysis stratified by diagnosis group, the PIM2 correctly predicted the number of deaths, except for patients admitted due to respiratory disease. In this group, there were more observed than predicted deaths (105 versus 81, $p= 0.03$), with an SMR of 1.29 (95% CI: 1.06-1.56).

TABLE 2. *General population characteristics*

Patients (n)	**2832**
Male sex, n (%)	1652 (58,3)
Age in months (median; IQR)	29 (8-101)
Age groups, n (%)	
Infants 1 (1-11 months old)	945 (33,4)
Infants 2 (12-23 months old)	366 (12,9)
Preschool children (2-5 years old)	472 (16,7)
Children (6-12 years old)	671 (23,7)
Adolescents (13-16 years old)	378 (13,3)
Diagnosis group on admission, n (%)	
External cause	357 (12,6)
Cardiac	178 (6,3)
Neurological	283 (10,0)
Respiratory	846 (29,9)
Others	344 (12,1)
Postoperative (no heart surgery)	824 (29,1)
Patients on MV, n (%)	1383 (48,8)
Length of stay in days (median, IQR)	4 (2-10)
Patients with length of stay shorter than 24 h, n (%)	567 (20)

MV: mechanical ventilation.
IQR: interquartile range.

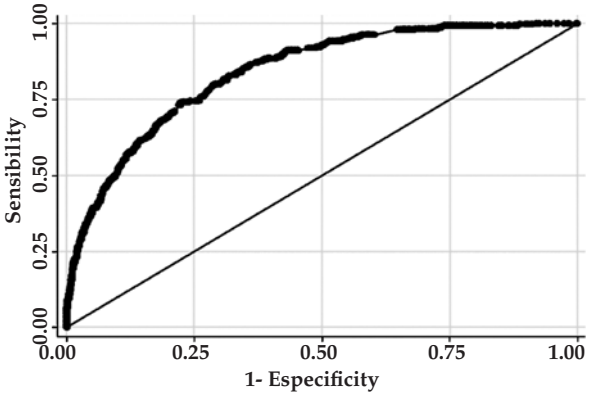
DISCUSSION

This study assessed the performance of the PIM2 score at the PICUs participating in the Argentine SATI-Q Program.

Results show that the PIM2 score adequately discriminates survivors from non-survivors: the area under the ROC curve was 0.84, compared to the 0.90 value observed in the original population.[11] However, the model did not show an adequate calibration. There were more observed deaths than predicted deaths in most risk intervals.

The lack of calibration showed by the PIM2 score in the studied population may be interpreted based on our patients' specific characteristics and clinical course. On the one side, the different international studies that validated the PIM2[14] described that approximately 40% of deaths occurred in the first 24 hours of hospitalization. In our population, only 21.2% of patients died in this period, and their length of stay was significantly longer than that of survivors. Although the different versions of the PIM and PRISM were designed to predict death, their predictive capability and adjustment declines as the patient's stay in the PICU extends. Visser, et al.[20] assessed the functioning of different versions of both scores in a multicenter study conducted in Denmark and found that all models showed an adequate calibration for patients discharged from the PICU in the first six days. However, observed mortality was significantly higher than predicted mortality (SMR > 1) in patients with a longer stay. Based on these data, the lack of calibration observed in our population may be partially explained by the fact that patients did not die in the first hours or

FIGURE 1. *Area under the ROC curve*



Area under the ROC curve= 0.8392.

days of hospitalization, but later during their stay in the PICU. Probably, our patients' risk factors are different from those considered to estimate the PIM2, such as other comorbidities that may be related to late mortality during hospitalization in the PICU.

In the subgroup analysis, the PIM2 score demonstrated to function similarly as in the general population. The main differences observed between our results and those reported in the original PIM2 study are summarized in *Table 5*. Although discrimination was adequate in all age groups, calibration was inadequate in adolescent patients. More deaths were observed than those estimated by the model (37 versus 22, $p = 0.03$). There might be an explanation for such difference because age is not a variable included in the score estimation even though adolescents are different in many aspects compared to adults or pre-adolescents.[21,22]

In the analysis of the performance of the PIM2 score stratified by diagnosis group on admission, an adequate discrimination for all categories was observed, except for patients with a diagnosis of a respiratory disease on admission. The calibration also evidenced significant differences between observed and predicted deaths in this group (105 versus 81, $p = 0.03$). In our population, patients with a respiratory disease had a more severe status than those included in the original

TABLE 3. *Hosmer-Lemeshow goodness-of-fit test for mortality risk deciles: χ^2: 71.02. df: 8. $p < 0.001$*

Risk group	Likelihood	n	Observed deaths	Predicted deaths	Observed survivors	Predicted survivors
1	0.002	285	1	0.4	284	284.6
2	0.004	283	1	0.8	282	282.2
3	0.009	286	4	1.8	282	284.2
4	0.013	282	8	2.9	274	279.1
5	0.020	282	12	4.7	270	277.3
6	0.043	282	18	8.9	264	273.1
7	0.070	294	32	16.7	262	277.3
8	0.11	282	38	24.8	244	257.2
9	0.23	273	61	43.0	212	230
10	0.99	283	122	142.0	161	141

Likelihood: maximum likelihood for the risk interval.

TABLE 4. *Model calibration and discrimination stratified by age and diagnosis group on admission*

	n	Observed deaths n (%)	Predicted deaths n (%)	SMR (95% CI)	ROC AUC (95% CI)	p
Age group						
Infants 1	945	112 (11.9)	102 (10.8)	1.10 (0.9-1.36)	0.76 (0.72-0.81)	0.32
Infants 2	366	33 (9.0)	31 (8.6)	1.06 (0.74-1.47)	0.80 (0.72-0.87)	0.72
Pre-school children	472	53 (11.2)	43 (9.2)	1.23 (0.93-1.6)	0.88 (0.83-0.92)	0.13
Children	671	62 (9.2)	48 (7.1)	1.29 (0.87-1.92)	0.89 (0.86-0.93)	0.09
Adolescents	378	37 (9.8)	22 (5.9)	1.66 (1.20-2.29)	0.87 (0.82-0.92)	0.001
Diagnosis group on admission						
External cause	357	31 (8.6)	34 (9.5)	0.91 (0.63-1.27)	0.90 (0.83-0.97)	0.60
Cardiac	178	36 (20.2)	29 (16.3)	1.24 (0.88-1.70)	0.81 (0.74-0.88)	0.19
Neurological	283	40 (14.1)	31 (11.3)	1.29 (0.93-1.74)	0.78 (0.70-0.86)	0.10
Respiratory	846	105 (12.4)	81 (9.2)	1.29 (1.06-1.56)	0.69 (0.64-0.75)	0.007
Others	344	68 (19.7)	56 (16.3)	1.20 (0.55-1.53)	0.83 (0.78-0.88)	0.10
Postoperative period (no heart surgery)	824	17 (2.1)	15 (1.7)	1.13 (0.68-1.77)	0.90 (0.85-0.95)	0.60

SMR: standardized mortality ratio; ROC AUC: area under the ROC curve; CI: confidence interval.
p: p value corresponding to χ^2 test estimated as (Observed - Predicted) 2/Predicted with a degree of freedom.

sample (predicted mortality of 9.2% versus 3.9%).[11] This characteristic was also observed in subsequent years, as shown by the benchmarking analysis conducted for SATI-Q in 2010,[23]. This analysis indicates the same observed mortality for patients in the respiratory disease group as reported in 2009 (12%). Although a more severe condition upon admission does not account for the lack of score calibration, it should be considered when describing the studied population. It is likely that patients admitted because of a respiratory disease in our population have characteristics that differentiate them from the original population and have comorbidities which have not been included in the PIM2 estimation. In this context, the diagnosis of bronchiolitis, which is considered as low risk in Australian and English patients, may have a different risk in our setting and therefore, imply a higher mortality.

In our population, there were 51 more deaths than those predicted by the model. The SMR was 1.20 (95% CI: 1.01-1.43). A likely interpretation for this would be to consider that the PIM2 score is not acceptable for our population given its inadequate calibration and the significant differences found between the observed and the predicted mortality. The PIM2 calibration may be improved by generating new local coefficients for the logistic regression model. Such modification would allow the score to have a better predictive capability in our setting; however, it would affect the comparison to international standards. In addition, it is not possible to leave out the fact that the quality of critical care provided at Argentine PICUs may be less effective than that provided at the units where the PIM2 score was developed given the degree of investment made in the health sector and the limited access to human and technological resources. In this regard, two prior studies conducted in Argentina at individual PICUs also reported an inadequate PIM2 calibration.[24,25] Based on a classification by intensive care resource availability,[26] Argentina may be considered a developing industrial country capable of providing equipment-driven care, including ventilators, central venous lines or infusion pumps, to every critically-ill child (category C). The original PIM2 score was developed in category D countries, which have an organized transport system and the ability to deliver extracorporeal therapies. Such differences in resource availability and health systems between both settings may also account for the ineffective performance of the score.

One of the limitations of this study is that it does not include all Argentine PICUs; however, the sample is representative to validate the PIM2 score in our setting because it includes PICUs that receive national and provincial referrals and are located at the different children and general teaching hospitals of various country regions.

In addition, although there are more recently published mortality risk scores, such as the PIM3,[27] their use has not been implemented in Argentina yet and requires to be validated in settings different from the original population.

CONCLUSIONS

The PIM2 score has been assessed in Argentina. Although the degree of agreement between observed and predicted mortality was not adequate, the capability of the model to discriminate survivors from non-survivors was good. The PIM2 score may be used in Argentina, but the interpretation of its results requires to consider the local SMR, since the model underscores the risk of death in our overall population, especially in those admitted due to respiratory disease and adolescents. ■

TABLE 5. *Primary outcome measures in this study (n: 2832) compared to the original sample used for the Pediatric Index of Mortality 2 (n: 20 787)*

	This study	Original PIM2 sample[11]
Mortality		
n (%)	297 (10.5)	1104 (5.3)
SMR (95% CI)	1.2 (1.01-1.43)	1.00 (0.95-1.05)
Respiratory diagnosis group		
n (%)	846 (30)	4480 (21)
SMR (95% CI)	1.29 (1.06-1.56)	0.90 (0.60-1.20)
Adolescent group		
n (%)	378 (13.3)	3110 (14.9)
SMR (95% CI)	1.66 (1.2-2.29)	1.17 (0.77–1.56)

PIM2: Pediatric Index of Mortality 2; SMR: standardized mortality ratio; CI: confidence interval.

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