Development and Validation of Predictors of Respiratory Insufficiency and Mortality Scores: Simple Bedside Additive Scores for Prediction of Ventilation and In-Hospital Mortality in Acute Cervical Spine Injury

Padmaja Durga, MD, PD, CC*

Barada Prasad Sahu, DNB†

Srinivas Mantha, MD, PD, CC*

Gopinath Ramachandran, FFARCAI*

BACKGROUND: Numerous studies have developed a "severity score" or "risk index" for mechanical ventilation and mortality, but there are few to predict outcomes for cervical spine injury (CSI) patients. Our objective in this study was to develop a simple bedside additive predictive score for requirement for ventilation and early in-hospital mortality for patients with CSI.

METHODS: Multivariate logistic regression analysis of the data obtained from 101 patients (development set) after surgical stabilization of traumatic CSI was performed to identify independent predictors of the need for mechanical ventilation and of early in-hospital mortality. Predictors of respiratory insufficiency and mortality (PRIM) scores were developed separately for ventilation and mortality by using the coefficients of the logistic regression model. The model was validated using the receiver operating characteristics curve to test its discriminatory ability and by comparing the predicted and observed outcomes. Validation was performed on an independent data set of 87 consecutive patients (validation set) with traumatic acute CSI.

RESULTS: Mechanical ventilation was required in 16.8% of the patients, and the in-hospital mortality rate was 17.8% in the development set. Independent risk factors for mechanical ventilation were severe injury (American Spinal Injury Association Impairment Scale Grades A and B), breath-holding time, pulmonary infection, hemodynamic instability, and progressive neurologic deterioration. Scores of 15, 20, 25, 25, and 15 were assigned to these variables, respectively. Independent predictors of death were severe injury (American Spinal Injury Association Impairment Scale Grades A and B), hemodynamic instability, progressive neurologic deterioration, and mechanical ventilation. The scores assigned for each of the variables were 20, 20, 40, and 20, respectively. The PRIM scores for mechanical ventilation and mortality had excellent discrimination (area under receiver operating characteristics curve >0.75). There was good correlation between predicted and observed outcomes in the development set and the validation set.

CONCLUSION: PRIM scores enable accurate prediction of individual patient risk of need for mechanical ventilation and in-hospital mortality in association with acute CSI.
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Cervical spinal cord injury (SCI) is a devastating event for the patient and the family. It has a huge impact on society because of the intensive resources required to manage the patient in both the acute and rehabilitation phases. The risk of mortality associated with cardiorespiratory complications after acute cervical spine injury (ACSI) continues to be distressingly high.[1–3] Prediction of individual patient outcomes can be of particular value in clinical decision making and during discussions with patients and families about the prognosis.

Several models have been developed for prediction of postoperative ventilation based on pulmonary function testing, but application of these models to patients with ACSI is not practical, because these patients remain immobilized in supine position. Therefore, prediction of outcome based on simple bedside variables would be more appropriate. No such risk predictor scoring systems are available for patients with CSI. A simple model incorporating clinical features readily identified at bedside and information that could be collected in a relatively short period would permit

From the Departments of *Anesthesiology and Intensive care, and †Neurosurgery, Nizam's Institute of Medical Sciences, Hyderabad, Andhra Pradesh, India.

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Address correspondence to Padmaja Durga, MD, PD, CC, Department of Anesthesiology and Intensive Care, Nizam's Institute of Medical Sciences, Hyderabad, AP 500082, India. Address e-mail to padmajanims@yahoo.com.

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efficient triage and management without waiting for additional tests or results. The objective of this study was to develop and validate a simple bedside additive predictive score for requirement for ventilation and early in-hospital mortality in patients with ACSI.

METHODS

Hospital ethical committee approval was obtained for the study. The study was performed in 2 stages. Stage I included collection of data and identification of predictors of ventilation and in-hospital mortality in patients after surgical stabilization for cervical spine trauma (development set) and development of a predictor score. Stage II included validation of the score on a separate set of data (validation set).

Retrospective record review of patients with blunt CSI who underwent cervical spine surgery under general anesthesia from June 1999 to June 2002 (development set) at our institution (a tertiary referral center with a spinal trauma care facility) was performed. All patients were cared for in the SCI intensive care unit according to the institutional protocols. Data were obtained from the neurosurgical electronic database and anesthesia records, and inconsistencies between the 2 data sources were resolved by hospital record review. Records with incomplete information were excluded from the study. Patients requiring mechanical ventilation or experiencing in-hospital mortality for reasons not related to ACSI were also excluded from analysis. Mortality resulting from refractory spinal shock, respiratory failure, respiratory infections, and deep vein thrombosis (DVT) were considered deaths resulting from SCI. The following data were collected: age, gender, the nature of the injury, the type of cord lesion as seen on magnetic resonance imaging, and the highest level of injury and severity of injury as measured by the American Spinal Injury Association (ASIA) Impairment Scale. Subjects with either motor or sensory neurologic deficits were classified at the highest level of bilateral normal function according to the criteria established by the ASIA Impairment Scale.[4] Other associated severe injuries such as head injury, rib fractures and lung contusion, abdominal injury, long bone injury, and other comorbid diseases were noted. Presence of preoperative hemodynamic instability (bradycardia or hypotension requiring inotropic support) and respiratory infections, defined by clinical (fever, cough, crepitations, or wheeze) and radiological criteria (new infiltrates and effusion), occurring any time during the hospital stay and deterioration in ASIA scale grade or progression of level of injury after admission were noted. Breath-holding time (BHT), measured as the duration for which the patient could hold their breath after a deep inspiration, was noted as a simple bedside pulmonary function test. Timing of surgical intervention, termed early if undertaken within 3 days of injury, was noted. Immediate postoperative outcome (tracheal extubation or ventilation), development of postoperative hemodynamic instability, respiratory infections, respiratory insufficiency, and need for postoperative ventilation were noted. The occurrence of DVT, pulmonary embolism, and the mechanical complications of internal orthopedic devices were also noted. Mechanical ventilation was considered an outcome variable if it was required for more than 48 h. The final outcome of interest was in-hospital death or discharge from the hospital. The 2 dependent variables (primary end points) analyzed were requirement for mechanical ventilation due to respiratory insufficiency and in-hospital mortality.

Statistical Analysis

Statistical analysis was performed using SPSS version 13.0 (SPSS, Chicago, IL). Data are expressed as mean and 95% confidence interval (CI) or as proportions (%). Univariate analysis was performed, and predictors were identified separately for mechanical ventilation and in-hospital mortality. All variables with a P value <0.05 in the initial univariate analysis were considered potential predictors of the study primary end points. The significant variables with multiple responses and continuous variables were redefined to obtain a dichotomous response and analyzed again before being entered into the multivariate logistic model. The discriminatory ability of BHT for requirement of mechanical ventilation was tested using receiver operating characteristics (ROC) analysis. The cutoff value with good sensitivity and specificity was determined, and BHT was dichotomized as above and below the cutoff value.

Independent predictors of ventilation and in-hospital mortality were determined using multivariate logistic regression analysis. A hierarchical method of entry was used to intentionally order the variables to be entered. Variables that cannot be altered by clinical intervention, such as the demographic variables, nature and severity of injury at admission, and neurologic deterioration, were entered first into the model. The variables that are affected by intervention, such as hemodynamic instability, BHT, pulmonary infection, and mechanical ventilation, were entered later. The R^2 of the model, change in R^2 obtained by addition of the variable, and the partial coefficients of each variable at each stage at which the variable is added to the equation were determined. The variable was retained if it contributed to a significant change in R^2 (0.5 or more). The final models for predictors of mechanical ventilation and in-hospital mortality were obtained using the variables with statistically significant contributions ($P < 0.05$). The goodness of fit was tested using Hosmer-Lemeshow statistics. A P value >0.05 was considered as showing that the model fits the data.

Development of Predictors of Respiratory Insufficiency and Mortality Scores

The predictor scores were developed separately for mechanical ventilation and in-hospital mortality on the development set using those variables that were determined to be significant independent predictors during the multivariate analysis. A score proportional to the *B* values, which represent the relative importance and contribution of the variables in the model, was assigned to each of the variables. The weighted average of the variables in the model was set at 100. The scores were then rounded to the nearest 5. The scores thus obtained were referred to as predictors of respiratory insufficiency and mortality (PRIM) scores. The PRIM scores were calculated separately for respiratory insufficiency requiring mechanical ventilation and mortality, using the simple arithmetic sum of the scores of independent end point predictors present in each patient. The discriminative ability of the PRIM scores for mechanical ventilation and in-hospital mortality was calculated by measuring the area under the ROC curve. An area under the ROC curve >0.75 is considered consistent with a good discrimination ability. The best cutoff value of the score that predicts the primary end point was determined from the ROC curves. Finally, the patients in the development set were stratified according to the presence of the predicted mechanical ventilation and mortality. Predicted outcome (mechanical ventilation or in-hospital mortality) obtained with the PRIM scores and observed outcome were compared using the Pearson χ^2 test (with Fisher's exact test where applicable) and the Spearman correlation. The positive predictive value (PPV), negative predictive value (NPV), and accuracy of the scores were determined.

External Validation

External validation was performed on data obtained from an independent data set of consecutive patients with ACSI admitted between June 2002 and August 2005 (validation set). Predicted probabilities of ventilation and in-hospital death for individual patients in the validation set were calculated using the PRIM scores developed. Model discrimination was assessed by ROC curve analysis. The differences in predicted outcome, PPV, NPV, and accuracy were determined as in the development set.

RESULTS

Retrospective data were obtained from 101 patients who underwent surgical stabilization for blunt traumatic CSI and used to derive PRIM scores for respiratory insufficiency requiring mechanical ventilation and mortality. Data for validation of PRIM scores were collected from 87 patients admitted with ACSI.

The baseline demographic and clinical characteristics of the development and validation sets were compared (Appendix, see Supplemental Digital Content, http://links.lww.com/AA/A40). Age and percentage of patients with ASIA Grade A, respiratory infection, and hemodynamic instability were significantly higher in the validation set. There were no other significant differences between the data sets in terms of demographic and injury characteristics. In the development set, the incidence of respiratory insufficiency requiring ventilation was 16.8%. The overall in-hospital mortality rate was 17.8%. The univariate analysis of variables for prediction of mechanical ventilation and in-hospital mortality is shown in Table 1. Variables associated with requirement for mechanical ventilation and early in-hospital mortality were severity of injury, BHT, hemodynamic instability, pulmonary infection during hospital stay, and progressive neurologic deterioration. In addition, the nature of the injury on magnetic resonance imaging and mechanical ventilation were associated with in-hospital mortality. Age, gender, level of injury, type of injury, associated injuries, and timing of surgery had no correlation with requirement for mechanical ventilation or in-hospital mortality. None of the patients had significant surgery-related complications or comorbid disorders. Complications related to DVT could not be commented on because there was no consistency in monitoring; however, there was no record of deaths attributable to pulmonary thromboembolism. ROC analysis revealed that BHT was a good discriminator for ventilation, and the best cutoff obtained was 12 s (Fig. 1). To obtain a dichotomous response for BHT, patients were categorized as above and below the cutoff. The patients with ASIA Impairment Scale Grades A and B were categorized as severe

Table 1. Variables Assessed to Determine a Need for Mechanical Ventilation and In-Hospital Mortality in the Development Set

	Mechanical ventilation		Mortality	
Variable	Correlation coefficient	*P*	Correlation coefficient	*P*
Age	0.04	0.34	0.07	0.24
Gender	0.18	0.03*	0.08	0.21
Nature of injury	0.10	0.15	0.28	0.00*
Head injury	0.05	0.31	0.06	0.27
Long bone injury	0.04	0.33	0.95	0.17
Smoking	0.40	0.34	0.05	0.30
ASIA grade	0.36	0.00*	0.32	0.00*
Severe injury	0.43	0.00*	0.34	0.00*
Level of injury	0.07	0.23	0.11	0.13
Hemodynamic instability	0.60	0.00*	0.49	0.00*
BHT	0.36	0.00*	0.28	0.00*
BHT (<12 s)	0.44	0.00*	0.27	0.00*
Timing of surgery	0.07	0.27	0.67	0.25
Respiratory infections	0.66	0.00*	0.56	0.00*
Neurological deterioration	0.46	0.00*	0.59	0.00*
Mechanical ventilation	—	—	0.69	0.00*

BHT = breath-holding time; ASIA = American Spinal Injury Association.

* Significant correlation between variable and outcome measure.

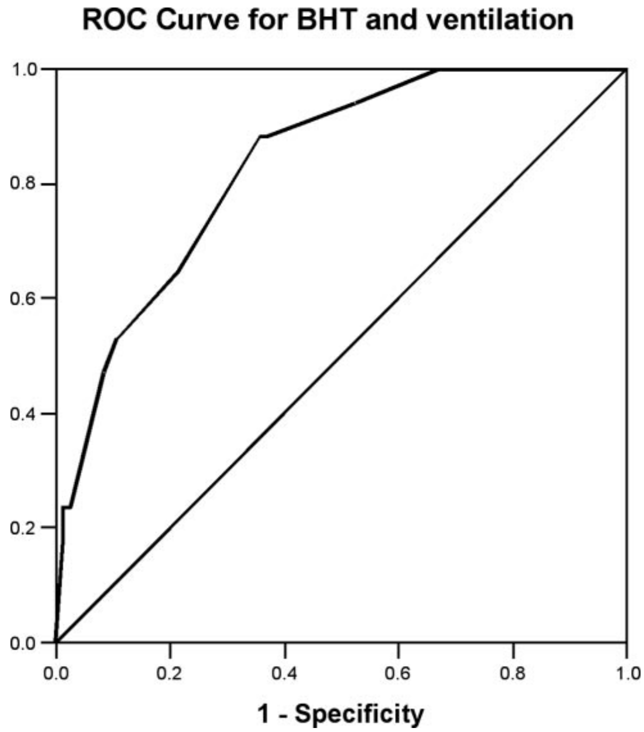

Figure 1. Receiver operating characteristics of breath-holding time (BHT) and need for mechanical ventilation. Area under the curve was 0.83 (95% CI: 0.74–0.93), indicating good discriminatory ability of BHT for ventilation ($P = 0.000$). The best cutoff for BHT for requirement of ventilation was 12 s, with a sensitivity of 0.9 and a 1 − specificity of 0.3.

injury and the remaining patients as absence of severe injury.

Table 2 shows the final model for the independent predictors of ventilation identified on multivariate analysis. The R^2 of the model was 0.734 ($P = 0.000$). The Hosmer-Lemeshow statistic (which tests the null hypothesis that the model fits the data) was not significant ($P = 0.166$). There was no significant correlation between the variables. A predictor score developed using the regression coefficients of these variables is shown in Table 2. The area under the ROC curve for PRIM score for prediction of mechanical ventilation was 0.95 (95% bias-corrected CI: 0.87–1.00), which indicates excellent model discrimination. The best cutoff score for prediction of ventilation was 45 (sensitivity 0.76 and 1 − specificity 0.03). Internal

Table 3. Internal and External Validation of the PRIM Score for Prediction of Mechanical Ventilation in Cervical Spine Injury

	Predicted ventilation					
	Development set (n = 101)			Validation set (n = 87)		
Observed ventilation	No	Yes	Total	No	Yes	Total
No	81 (80.1%)	4 (4%)	85	63 (72.4%)	5 (5.7%)	68
Yes	3 (3%)	13 (12.8%)	16	2 (2.3%)	17 (19.5%)	19
Total	84	17	101	76	9	87

PRIM = Predictors of Respiratory Insufficiency and Mortality.

[a] Development set—Good correlation between predicted and observed mechanical ventilation (Spearman correlation 0.74 [P, 0.000]), no statistically significant difference between predicted and observed ventilation.

[b] Validation set—Spearman correlation 0.78 (P, 0.000), no statistically significant difference between predicted and observed outcomes.

cross-validation of the PRIM score for ventilation (Table 3) shows good correlation and no statistically significant difference between predicted and observed outcomes. The odds ratio of mechanical ventilation with predicted ventilation was 87.75 (95% CI: 17.5–437) with a PPV of 81%, an NPV of 95%, and an accuracy of 93% for predicted ventilation.

Table 4 shows the independent predictors of in-hospital mortality identified on multivariate logistic regression analysis. The R^2 of the model was 0.718 ($P = 0.000$). The goodness of fit assessed with the Hosmer-Lemeshow statistic ($P = 0.54$) indicates that the model fits the data well. A predictor score developed based on the regression coefficients of the independent predictor variables is shown in Table 4. The area under the ROC curve for the PRIM score for prediction of in-hospital mortality in CSI was 0.96 (95% bias-corrected CI: 0.92–1.00), which indicates excellent model discrimination of the score. The best cutoff score for prediction of mortality was 50 at a sensitivity of 0.83 and a 1 − specificity of 0.02. There was no statistically significant difference between predicted and observed mortality (Table 5). The predicted outcome using the PRIM score for in-hospital mortality had an odds ratio of 105.3 (95% CI: 18.4–600.7), a PPV of 86.7%, an NPV of 94.2%, and an accuracy of 93.1%.

External Validation of PRIM Scores

The area under the ROC curve for the PRIM score for prediction of mechanical ventilation in the validation set was 0.97 (95% bias-corrected CI: 0.95–1.0) and

Table 2. Development of PRIM Score for Prediction of Mechanical Ventilation in Acute Cervical Spine Injury

Variables included in model	B	SE	Wald	P	Exp (B)	Score
Severe injury (ASIA impairment Scales A and B)	2.10	1.08	3.80	0.051	8.16	15
Hemodynamic instability	3.11	1.47	4.49	0.034	22.52	25
BHT <12 s	2.80	1.20	5.46	0.020	16.48	20
Pulmonary infection	3.66	1.15	10.14	0.001	38.85	25
Neurological deterioration	2.18	1.10	3.91	0.048	8.87	15

Wald is the statistic used; the ratio of B to SE, squared, equals the Wald statistic. If the Wald statistic is significant (i.e., $P < 0.05$) then the parameter is useful to the model.

BHT = breath-holding time; ASIA = American Spinal Injury Association; PRIM = predictors of respiratory insufficiency and mortality; B = the beta coefficient for the variable in the model; SE = the standard error for beta.

[a] The score of an individual patient is the sum of the scores of the variables present.

[b] A total score of 45 and more predicts requirement for mechanical ventilation.

Table 4. Development of PRIM Score for Prediction of In-Hospital Mortality in Cervical Spine Injury

Variables included in model	B	SE	Wald	P	Exp (B)	Score
Severe injury (ASIA impairment Scales A and B)	2.69	1.345	3.99	0.05	14.74	20
Hemodynamic instability	2.72	1.45	3.53	0.05	15.18	20
Neurological deterioration	4.26	1.59	7.12	0.01	70.51	40
Mechanical ventilation	2.56	0.96	7.10	0.01	12.88	20

Wald is the statistic used; the ratio of *B* to SE, squared, equals the Wald statistic. If the Wald statistic is significant (i.e., $P < 0.05$) then the parameter is useful to the model.

PRIM = predictors of respiratory insufficiency and mortality; ASIA = American Spinal Injury Association; *B* = the beta value for the variable in the model; SE = the standard error for beta.

[a] The score of an individual patient is the sum of the scores of the variables present.

[b] A total score of 50 and more predicts early in-hospital mortality.

Table 5. Internal and External Validation of PRIM Score for Prediction of In-Hospital Mortality in Cervical Spine Injury

	Predicted mortality					
	Development set (n = 101)			Validation set (n = 87)		
Observed mortality	No	Yes	Total	No	Yes	Total
No	81 (81.2%)	2 (2%)	83	66 (57.5%)	6 (5.2%)	72
Yes	5 (5.1%)	13 (13.1%)	18	0 (0%)	15 (13.1%)	15
Total	86	15	101	66	18	87

PRIM = predictors of respiratory insufficiency and mortality.

[a] Development set—good correlation between predicted and observed in-hospital mortality (Spearman correlation 0.761 [*P*, 0.000]), no statistically significant difference between predicted and observed ventilation.

[b] Validation set—Spearman correlation 0.835 (*P*, 0.000), no statistically significant difference between predicted and observed outcomes.

0.98 (95% bias-corrected CI: 0.97–1.0) for in-hospital mortality, consistent with excellent model discrimination. A good correlation was seen between predicted end points and observed ventilation requirement and in-hospital mortality rates (Tables 3 and 5). The odds ratio for requiring mechanical ventilation in patients with predicted ventilation was 107.1 (95% CI: 19–601.2), and the predicted ventilation using the PRIM score for ventilation had a PPV of 77.3%, an NPV of 96.9%, and an overall accuracy of 91.9%. The PRIM score for in-hospital mortality applied to the validation set had an odds ratio of 165 for in-hospital mortality, a PPV of 71.4%, an NPV of 100%, and an overall accuracy of 93.1%. Surgical stabilization was deferred because of adverse predicted outcome in 16 patients in the validation set. The mortality was 81.3% in these patients. In the operated patients, the mortality was 2.1%, with a PPV of 66% and an NPV of 100%. In nonoperated patients, the PPV was 86.6% and the NPV was 100%.

DISCUSSION

In this study, independent predictors of ventilation and in-hospital mortality in patients with traumatic ACSI were identified, and a simple bedside risk prediction score, the PRIM score, was developed. The score performed well on both internal and external validation.

Recent stabilization techniques and pharmacological advancements have resulted in a substantial reduction of risk of death and major complications for patients with ACSI. However, the presence of complete injury, respiratory insufficiency, and hemodynamic instability is still associated with an increased risk of mortality, which is inherent in the natural history of the disease itself.[3,5,6] Thus, precise prediction of individual patient outcome has particular importance during discussions with patients and families regarding prognosis or for clinical decision making.

The mortality rate due to traumatic ACSI observed in the population studied was relatively high compared with mortality rates previously reported in other series,[6–8] which reflects the high percentage of patients with severe injury (ASIA Impairment Scale Grades A and B) and hemodynamic instability in this series. In agreement with findings from other studies, higher mortality rates were observed in patients who were hemodynamically unstable.[3,9] Most patients had cervical injury at C4-5, consistent with other studies.[8,10,11] In contrast to several other studies, level of injury was not an independent variable predicting mechanical ventilation or mortality. CSI is a dynamic process, and the level of cord injury is not restricted to the initial level of injury. Moreover, the severity of injury and the physiological consequences of injury, such as hemodynamic compromise and respiratory compromise resulting from autonomic and motor involvement, determine the outcome. Given the heterogeneous nature of involvement and the dynamic nature of the disease, the aforementioned consequences would determine the outcome rather than the level of injury. A similar observation has been made by Winslow et al.[12] The neurologic deterioration due to secondary injury was an important predictor of mechanical ventilation and mortality, emphasizing the need for early referral to specialized centers and intensive care to initiate measures for reduction of secondary injury. Secondary deterioration occurred in both operated and conservatively managed patients and was not attributable to any specific management event.

Models for prediction of mechanical ventilation in postoperative and intensive care unit settings are usually based on spirometric pulmonary function tests or laboratory values of adequacy of oxygenation ($Pa{O_2}$, $F{IO_2}/Pa{O_2}$, and alveolar-arterial difference in oxygen tension). Patients with ACSI are immobilized in supine position, and their performance of spirometry could be difficult. Early detection of mechanical respiratory failure that results from motor weakness in these patients is not possible or reliable with the blood gas analysis. Thus, BHT was used as a simple bedside pulmonary function test to assess the adequacy of vital capacity, which is the first to be affected in CSI.[13,14] Because there were no cutoff values established in the literature for the use of BHT in patients with CSI, ROC analysis was used to determine the best cutoff. BHT had good discriminatory power to identify patients requiring mechanical ventilation (area under ROC curve 0.8, with the best cutoff value at 12 s). The test of BHT requires no equipment, is simple to interpret, understand, and perform, and has good reliability. However, its limitations, including the necessity for the patient to understand and cooperate, and the inability of chest-injured and unconscious patients to perform the test, have to be considered.

The scores were derived for patients who underwent surgical stabilization of the cervical spine in a tertiary referral center, which could have resulted in referral and selection bias. Hemodynamic instability and respiratory infection were higher in the validation set. Overall mortality was comparable between the sets. Validation of PRIM scores on the validation set yielded a lower PPV for both ventilation and mortality than validation on the development set. This could have resulted from patients with higher scores and poor predicted outcome receiving more intensive management. There was a considerable emphasis on early surgical stabilization during the period when the development set of data was collected, which resulted in surgery being performed on patients with suboptimal hemodynamic and respiratory stabilization. Analysis of the development set of data showed no significant difference in neurologic deterioration between patients who underwent early surgery and delayed surgery. Complications such as postoperative hemodynamic instability and respiratory insufficiency were higher with early surgical stabilization (not shown in the results), as observed by authors earlier.[15,16] During the period of validation of score, surgery was undertaken after hemodynamic and respiratory stabilization. For 16 of the 87 patients in the validation set, surgical stabilization was not performed because of a predicted high risk of mortality, and they were managed conservatively. The mortality in these patients was 81.3%. The operative mortality was 17.8% in the development set compared with 2.3% in the validation set. There were 6.9% of operated patients who required mechanical ventilation compared with 16.8% in the development set. The application of the PRIM scores contributed to effective triaging of patients for surgery and aggressive optimization of identified predictors of mechanical ventilation and mortality.

Limitations

The total sample size was modest ($n = 188$); no formal power calculation was done for this study. The intent of the study was to use these data to better estimate the primary outcome rates in a representative population of patients. Although there was excellent correlation between observed and predicted need for mechanical ventilation and early in-hospital mortality rates, and validation of the model was performed on the independent data set, additional validation in other subgroups with larger samples might be needed. The independent validation data set was obtained from the same institution that developed the initial model. Validation of the score with data obtained from other institutions is required, because this diversity would lead to stronger external validity. Predictive accuracy is expected to vary with external validation in other multicenter registries. Therefore, one should be cautious when generalizing these findings until the score has been widely tested.

The score includes variables that are amenable to optimization, such as hemodynamic instability and respiratory infection. Another potential concern is incorrect prediction. Because the family of the patient is likely to decide against expensive interventions such as surgery when mortality is forecast, incorrect prediction of survival would result in futile expenditure. However, this tool should not be used to deny care to high-risk patients, but rather to help patients make decisions that are more informed and to reassure low-risk patients that their low-risk estimate is based on a tested mathematical model. This enables family members to realize that aggressive management is likely to result, nonetheless, in an adverse outcome and to accept a decision to reduce or withhold care.

CONCLUSION

PRIM scores were developed based on simple bedside tests (e.g., the BHT) and readily available clinical variables. These are simple to obtain and do not require complex mathematical calculations. Application of these scores results in fairly accurate prediction of a requirement for mechanical ventilation and of in-hospital mortality in patients with ACSI.

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