# External validation of prognostic model of oneyear mortality in patients requiring prolonged mechanical ventilation

Jaiswal S,<sup>1</sup> Sadacharam K,<sup>1</sup> Shrestha RR,<sup>1</sup> Bhatta P,<sup>1</sup> Ghimire RK,<sup>1</sup> Rimal A,<sup>1</sup> Berhane Z,<sup>2</sup> Mirza I,<sup>1</sup> Rather M,<sup>1</sup> Eiser AR,<sup>1</sup> Matchett S<sup>1</sup>

<sup>1</sup>Mercy Catholic Medical Center, Darby, PA, USA, <sup>2</sup>Drexel University, School of Public Health, Philadelphia, PA, USA.

## ABSTRACT

**Background:** External validation of prognostic model for one-year mortality in patients ventilated for 21 days or more. A measure that identifies patients who are at high risk of mortality after prolonged ventilation will help physicians communicate prognoses to patients or surrogate decision makers. Our objective was to validate a prognostic model developed by Carson et al in a different setting.

**Methods:** An observational study was conducted from September 2002 to September 2007 in 30 beds Medical/ Surgical Intensive Care Unit (ICU) at Mercy Fitzgerald Hospital (MFH) and 20 beds Medical/Surgical ICU at Mercy Philadelphia Hospital (MPH). One hundred and fifty medical and surgical patients requiring mechanical ventilation after acute illness for at least 21 days after initial intubation were enrolled.

**Results:** One year mortality was 45.4%. Area under the receiver operating characteristic curve for three month mortality was 0.90 and for one year mortality was 0.92. For identifying patients who had  $\geq$ 90% risk of death at 3 month had sensitivity of 40% and specificity of 95% and risk of death at 1 year had sensitivity of 70% and specificity of 99%. Four predictive variables, requirement of vasopressors, hemodalysis, platelet count  $\leq$  150 x 10 9/L and age  $\geq$ 50 yrs can be used as a simple prognostic score that clearly identifies low-risk patients and high-risk patients.

**Conclusions:** Simple clinical variables measured on day 21 of mechanical ventilation can identify patients at highest and lowest risk of death from prolonged mechanical ventilation.

Keywords: external validation; intensive care unit; prognostic model; prolonged mechanical ventilation.

#### INTRODUCTION

Prolonged mechanical ventilation (PMV) is defined as either  $\ge 21$  days of ventilation or  $\ge 4$  days of ventilation with placement of a tracheostomy after acute illness.<sup>1</sup> Presently, there are > 100,000 new PMV patients annually in the United States, half of whom are Medicare beneficiaries. PMV occurrence rate is increasing more rapidly than that for the mechanical ventilation itself.<sup>2</sup>

Patients requiring PMV consume a disproportionately high amount of healthcare resources both in the intensive care unit and after hospital discharge.<sup>3,4</sup> There short-term and long-term mortality is high, and they experience a very heavy symptom burden for prolonged periods (5). Hospital survivors have a significant degree of functional and cognitive limitations and high readmission rate. Some remain at high risk for death after hospital discharge, but not all (6).

Prolonged hospitalization for patients on PMV who are at high risk of death does not meet current standards of cost-effectiveness (7). Considering the high symptom burden of this population and often poor outcomes, a mortality prediction model that identifies patients on the PMV with the highest and lowest risk for death would be useful to inform discussions of prognoses among clinicians and patients or their surrogate decision makers. Such a model could also standardize illness severity in cohort studies examining outcomes and interventions in this resource-intensive group of patients.

Correspondence: Dr. Suresh Jaiswal, Mercy Catholic Medical Center, Darby, PA, USA. Email: sjkalu@gmail.com.

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Carson et al developed a prognostic model for one-year mortality in patients requiring prolonged mechanical ventilation (8). They conducted a prospective cohort study to develop and validate a mortality prediction model for adult patients meeting the definition of PMV. Independent predictors of mortality included requirement of vasopressors, hemodialysis, platelet count  $\leq 150 \times 10^{9}$ /L and age  $\geq 50$  years. Prolonged Ventilation (ProVent) score variables were measured on day 21 of mechanical ventilation: one point was given to each of the independent predictors of mortality. Sensitivity and specificity of three month mortality and one year mortality were calculated in development and validation set. We are trying to do the external validation of the model at a different institution, in a different cohort of population.

Prolonged Ventilation (PorVent) Score can facilitate communication of likely health outcomes and help maximize PMV value. External validation of the ProVent score could facilitate earlier and more definitive discussions between clinicians and patients or surrogates regarding appropriate goals of care.

#### **METHODS**

An observational study was conducted from September 2002 to September 2007 in 30 beds Medical/Surgical Intensive Care Unit (ICU) at Mercy Fitzgerald Hospital (MFH) and 20 beds Medical/Surgical ICU at Mercy Philadelphia Hospital (MPH). One hundred and fifty medical and surgical patients requiring mechanical ventilation after acute illness for at least 21 days after initial intubation were enrolled, following approval by the Institutional Review Board (IRB) at Mercy Fitzgerald Hospital/ Mercy Philadelphia Hospital, Drexel University College of Medicine, Philadelphia, USA. Total of 150 charts were pulled out during the study period. Retrospective review of the medical records of patients requiring mechanical ventilation after acute illness for at least 21 days after initial intubation, admitted to MFH ICU and MPH ICU were included in the study. If patients were extubated within the initial 21 days period but needed reintubation, were also included in the study if the period of spontaneous breathing was  $\leq$  72 hrs. Exclusion criteria included age <18 yrs, severe burns, chronic neuromuscular diseases, chronic mechanical ventilation before admission.

Demographic, diagnoses, comorbidities, length of stay and outcome data were collected on one hundred and fifty patients. ProVent score was calculated on each patient, one point for each independent risk factor; requirement of vasopressors, platelet count  $\leq$ 150 x 10 <sup>9</sup>/L, requirement of hemodilaysis, age  $\geq$ 50 years. Each patient outcome was followed for one year by review of medical records, National Death Index or contact to the patients residence or their surrogates. Outcome of each patient was calculated as observed 3 month mortality or observed one year mortality.

Summary analysis were performed on demographic and physiological variables and expressed as mean ± SD for normally distributed data and median, interqartile range for non-normal data. Area under the receiver operating characteristic curve, sensitivity and specificity were calculated. Calibration of the study was assessed using Pearson's chi-square goodness-of-fit (GoF) test. Similar analysis was performed using 3-month mortality as the primary outcome. The results are compared with the study done by Carson et al at University of North Carolina Hospital. Statistical analysis was done by computer software SPSS 16.0 and STATA 10 software.

#### RESULTS

The study included 150 patients with age range from 29 to 96 years. Distribution of patient demographics and outcomes and prognosis of the ventilation score were Age  $\geq$ 50 = 1point, Vasopressor = 1 point, Platelets  $\leq$ 150 x 10<sup>9</sup>/L = 1 point, Requiring hemodialysis = 1 point (Table 1-4).

Table 1. Demographics of study pop	ulation.
Variable	Values
	N= 150
Age, mean ± SD	64.93 ± 14.73
Age, median (IQR)	64 (41-67)
Sex, No.	(%)
Male	63 (42)
Female	87 (58)
Race	No. (%)
White	45 (30)
African American	99 (66)
Hispanic	1 (0.7)
Asian	3 (2)
Residence	No. (%)
Home	95 (63.3)
Assisted living facility	35 (23.3)
Skilled nursing facility	20 (13.3)
Service	No. (%)
Medicine	134 (89.3)
General surgery	9 (6)
Cardiac surgery	3 (2)
Neurosurgery	4 (2.7)
Specific comorbidities	No. (%)
Congestive heart failure	73 (48.7)
COPD	38 (25.3)
Diabetes	68 (45.3)
Chronic vascular disease	66 (44)
Tracheostomy, No. (%)	150 (100)
Days to tracheostomy, mean $\pm$ SD	12.95 ± 6.5
Pressors, No. (%)	97 (64.7)
Platelet < 150 x 10 9/L, No. (%)	74 (49.3)
Hemodialysis, No. (%)	63 (42)
Age > 50 yrs, No. (%	123 (82)

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Table 2. Outcomes of the patients.	
Variable	Values
Hospital disposition, No. (%)	
Died	56 (37.3)
Hospice	6 (4)
Long-term acute care	65 (43.3)
Rehabilitation	5 (3.3)
Skilled nursing facility	12 (8)
Home	6 (4)
Ventilator days, mean ± SD	34.59 ± 19.37
ICU length of stay, mean $\pm$ SD	35.17 ± 15.46
Hospital length of stay, mean ± SD	42.09 ± 23.28
Mortality	No. (%)
Three months	49 (32.7)
One year	68 (45.4)

Table 3. Prognosis for Prolonged Ventilation (ProVent).				
ProVent	N (%)	Observed 3-	Observed 1-Year	
Score		Month Mortality	Mortality	
0	6 (4)	0	0	
1	27 (18)	0.19	0.48	
2	49 (32.6)	0.67	0.88	
3	43 (28.6)	0.97	1	
4	25 (16.6)	1	1	

Performance of the 4-point prognostic scoring system (Prognosis for Prolonged Ventilation [ProVent] score is shown in Table 3. Patients with score of 1, representing one risk factor (n=27 [18]), had three-mortality rate of 19% and one-year mortality rate of 48%. Patients with three or four risk factors had three month mortality of 97% and one-year mortality of 100%. The area under the ROC curve for three-month mortality is 0.90 and for one-year mortality is 0.91 (Figure 1).



The sensitivity for identifying patients at  $\geq 50$  % risk of death in three month was 0.90 and in one year was 0.99 and specificity for three month mortality was 0.60 and for one year mortality was 0.40 (Figure 2). The logistic model for three month mortality and one year mortality had good fit based on its nonsignificant GoF test x<sup>2</sup>= 6.36, p =0.78; x<sup>2</sup>= 5.21, p=0.87 respectively.

Table 4. Logistic regression model performance.					
Variable	Three-Month Mortality OR (95% CI)	p Value	One-Year Mortality OR (95% CI)	p Value	
Vasopressor	14.47 (4.71, 44.42)	0.000	11.73 (2.70, 50.94)	0.001	
Platelets≤ 150x 10 °/L	11.31 (3.51, 36.40)	0.000	13.38 (2.44, 73.17)	0.003	
Age ≥ 50 years	11.45 (2.62, 50.01)	0.001	62.87 (7.40, 534.14)	0.000	
Requiring hemodialysis	11.74 (3.04, 45.35)	0.001	26.89 (2.98, 242.24)	0.003	

Model	Three-Month Mortality	One-Year Mortality
Area under ROC	0.90	0.91
Sensitivity*	0.40	0.70
Specificity*	0.95	0.99

\*sensitivity and specificity determined for 90% risk of death



mortality and one year mortality

### DISCUSSION

Prediction of mortality by clinicians using clinical probability of ICU survival is not accurate and that actual ICU survival rates are higher than the clinical predictors (9). Care in the ICU varies considerably and that individual physician practice style is related to the intensity of care and willingness to forego life support more than the prognosis of the patients (10-12). Four easily measured variables recorded at day 21 of the ventilation can identify patients who are at high risk or low risk of mortality during prolonged mechanical ventilation. This simple prognostic model could enhance communication of prognosis to these patients and their surrogates.

In our study mean age of the patient was 64.93 years as compared to 55.5 years in the study of Carson et al (8). Our study population includes more of African American patients 66% and 23.3% from assisted living facility as compared to Carson et al study which included more of White patients 61% and 93% from home. Even though our study included mostly medical patients 89.3% as compared to Carson et al which included medical 46% and surgical/trauma patients 26% the ProVent score was still predictive.

Comparison of the specificity and area under the receiver operating characteristic curve was similar in both studies. Patients with three or four risk factors had three month mortality of 97% and one-year mortality of 100%, which was comparable with Carson et al study. Thus our study validates Carson et al prolonged ventilation (ProVent) score in a different institution and in a different cohort of patients.

The prognostic score is simple to understand and can be assessed by clinician at the bedside within seconds rather than relying on an intermediary with a complicated formula. This simple prognostic model could enhance communication of prognosis to patients and their surrogates by providing objective estimates of the outcome. Both clinicians and surrogates may be more likely to accept a change in the course of care when poor outcomes are expected despite weeks of maximal treatment.

ProVent score should not change physician practice in isolation and should not be used to replace clinician judgment regarding likely outcome (13,14). However, we can use it as a tool to explain to our patients and their families regarding likely outcome.

#### CONCLUSION

Our study externally validates the prognostic scoring system developed by Carson et al. ProVent score is easy to use and can facilitate earlier and more definitive discussions between clinicians and patients or surrogates regarding appropriate goals of care.

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