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Prediction of In-Hospital Mortality in Acute Exacerbations of COPD

Ross Archibald (4th year MBChB, BSc (Hons)), James Chalmers (Clinical Lecturer), Tom Fardon (Consultant Respiratory Physician), Philip Short (Clinical Research Fellow), Pete Williamson (Consultant Respiratory Physician), Joanne Taylor (5th year MBChB), Aran Singanayagam (SpR Respiratory Medicine), Louise Peet (4th year MBChB, BMSc), Muhder Al-Khairalla (Consultant Respiratory Physician) & Stuart Schembri (Consultant Respiratory Physician).

Correspondence to: Ross Archibald : r.z.archibald@dundee.ac.uk

ABSTRACT

Background:
Physicians lack a robust and validated method of measuring severity or predicting poor outcome in patients with acute exacerbation of COPD (AECOPD). Such a predictive tool would allow optimisation of treatment plans for these patients, as well as best use of health care resources.

Objective:
To determine predictors of in-hospital mortality in AECOPD, and develop a predictive scoring system to identify patients at higher risk of in-hospital mortality.

Methods:
Analysis of clinical patient data from the exacerbations of obstructive lung disease managed in UK Secondary care [EXODUS] study database, collected from 11 UK hospitals.

Results:
A total of 1031 patients were included in the validation cohort. The in-hospital mortality rate was 5.2%. Independent predictors of mortality were identified and a new scoring system ("CAUDA70"), for prediction of in-hospital mortality in AECOPD was derived. The score incorporated 6 easily obtained clinical variables: acidosis, albumin, urea, the presence of confusion, MRC dyspnoea score and age. The score displayed strong discrimination, with an area under the receiver operating characteristic (ROC) curve of 0.84. This performance was reproduced in a further validation dataset of 312 patients. The discrimination of the new score exceeds that of existing scores validated for use in AECOPD (CURB65, CRB65 and BAP-65).

Conclusion:
A new scoring system composed of six readily available clinical variables can accurately predict in-hospital mortality in AECOPD.

Key Words:
Respiratory Medicine; Acute Medicine; Predictive Tools; Chronic Obstructive Pulmonary Disease

Introduction

Chronic Obstructive Pulmonary Disease (COPD) represents a significant burden in terms of morbidity and mortality, accounting for nearly 6% of deaths globally in 2008[1]. In the UK, COPD is a leading cause of mortality, accounting for over 29,000 deaths in 2008[2] and ranked as the 5th leading cause of mortality in England and Wales in 2005[3].

At present, there is no established method of predicting mortality risk amongst patients admitted to hospital with acute exacerbation of COPD (AECOPD), and current national guidelines do not recommend the use of a severity tool for this purpose[4]. Forced expiratory volume in one second (FEV_1) is often used to gauge disease severity in COPD, but is not a reliable predictor of mortality[5]. Variables which have been commonly linked to an increased risk of in-hospital mortality in AECOPD have included age[6,7], heart rate[7,8] and serum creatinine[8,9], sodium[8,9] and urea[7,8]. However, one review paper notes that there is a wide variation in prognostic variables between studies[10], which may be related to differences in the characteristics of patient cohorts, clinical variables recorded and the geographical setting of different studies. In addition, although some overlap exists, prediction of post-discharge and in-hospital mortality in AECOPD appears to involve distinct clinical variables[10].

In addition to identifying prognostic predictors in AECOPD, a number of groups have formulated clinical prediction tools, although as yet, none have been validated in independent cohorts or accepted into clinical practice. One such study of a large cohort of patients with AECOPD developed and validated a risk score for prediction of in-hospital mortality or the need for invasive mechanical ventilation (BAP-65) involving age, heart rate, serum urea and acute onset confusion[7]. A further study identified predictors of risk of in-hospital mortality and the need for post-hospital support in initially non-life threatening AECOPD admissions[6]. These factors were patient age, cyanosis, impaired neurological status, lower limb oedema, asterixis (flapping tremor), use of accessory inspiratory or expiratory muscles, and dyspnoea grade in the stable state. Whilst this study led to derivation of a prediction score with good discrimination, this was done without certain important clinical data (e.g. arterial blood gases), as well as specifically targeting patients admitted to emergency departments within a fairly short time frame[6]. Another study derived a simple equation to predict death and the need for mechanical ventilation in AECOPD[9]. However, the cohort studied was relatively small and drawn from a tertiary referral centre, with a relatively high number of patients with severe disease[9]. Further studies producing outcome prediction models for hospital mortality in AECOPD have only included high-risk patients admitted to ICU/HDU[8,11] or have only predicted survival for an extended period following admission[8,11,12].

Clinical prediction tools have proven useful in other acute respiratory diseases, such as community acquired pneumonia (CAP). The CURB65 score was derived and validated for use in CAP[13] and is a severity score that has been widely adopted in clinical practice[14]. A similar bed-side prognostic tool to CURB65 may be equally useful in AECOPD in order to stratify patients by risk and target their management more effectively, a view recognised by at least two other research groups[15,16]. A retrospective study found that this score also predicted short-term mortality in AECOPD[15]. The simplified version of this score, CRB65, has also been validated for use in AECOPD, showing modest performance as a predictor of short-term mortality[16]. Both studies suggest that these scores have similar efficacy in predicting short-term mortality in AECOPD patient cohorts to CAP cohorts[15,16].

Despite extensive research into important clinical parameters in AECOPD, we still do not have the ability to accurately predict outcomes such as mortality in a hospitalised patient. None of the models developed thus far for this purpose have been recommended by

guidelines, and none having undergone extensive external evaulation[6,7,9], thus making conclusions on whether rules may be clinically useful across different patient populations impossible. It is proposed that the development of a clinically useful prediction tool for in-hospital mortality in AECOPD may allow more effective disease classification on admission, as well as optimisation of subsequent management and resource allocation decisions.

Methods

Study database and data collection

This study uses data collected in EXODUS (Exacerbations of Obstructive Lung Disease managed in UK Secondary care), a prospective observational study of patients with a diagnosis of COPD exacerbation, hospitalised for more than 12 hours in a UK hospital. Patients were enrolled for inclusion in EXODUS using a standard proforma, and anonymous data held on a secure NHS server. Enrolment took place at the following hospitals: Royal Infirmary of Edinburgh, Western General Hospital (Edinburgh), St John's Hospital (Livingston), Borders General Hospital (Melrose), Perth Royal Infirmary, Ninewells Hospital (Dundee), Victoria Hospital (Kirkcaldy), St Mary's Hospital (London), Doncaster Royal Infirmary, Milton Keynes General Hospital and John Radcliffe Hospital (Oxford). The EXODUS study has been approved by the Lothian Research Ethics Committee (LREC), and local Caldicott Guardian approval was obtained for each participating centre.

Patient case selection

This study uses data obtained from patients enrolled in the EXODUS study between November 2009 and January 2012. Selection bias was minimised by ensuring that enrolment occurred in a consecutive manner. Inclusion criteria for the EXODUS database are:

- Age >40 years.
- Presentation to hospital from the community with a primary diagnosis of AECOPD.
- Symptom(s) of exacerbation (e.g. increasing breathlessness) in a patient with known (confirmed by spirometry) COPD, OR:
- Symptom(s) of exacerbation (e.g. increasing breathlessness) in a patient aged >40 years with a history of cigarette smoking in which the diagnosis of COPD can be confirmed by spirometry during or subsequent to the hospitalisation.

Exclusion criteria for the EXODUS database are:

- Age <40 years.
- Hospitalisation primarily for a reason other than COPD, e.g. pulmonary embolism, congestive cardiac failure, acute myocardial infarction.
- Elective hospitalisations, such as for CT-guided lung biopsy, or intravenous antibiotic eradication of *Pseudomonas aeruginosa.*
- Airways disease primarily due to a cause other than COPD (severe asthma, bronchiectasis, allergic broncho-pulmonary aspergillosis).
- Interstitial lung disease.
- Patients in whom active treatment is not considered appropriate (palliative care). This includes patients not treated with steroids, antibiotics or other active measures. (Patients with DNAR orders, or "not for ICU orders" but who are otherwise actively treated ARE included.)

Selection and measurement of variables

EXODUS collects routinely available demographic, clinical, laboratory, management and outcome data for patients with AECOPD, shown in Table 1. Most of this data was available from standard hospital clerk-in proformas used for new patient admissions. Where possible,

all measurements in the EXODUS database were those first recorded on presentation to hospital, and all clinical variables (e.g. blood pressure, pulse rate) were recorded within 6 hours of admission to hospital. The outcome of interest in this study was in-hospital mortality.

Statistical methods

All data were analysed using SPSS version 13 for Windows. The derivation cohort was made up of consecutive patients from all enrolling hospitals from November 2009 to November 2011. The validation cohort was made up of consecutive patients from Edinburgh and Tayside collected between January 2011 and January 2012.

Table 1 Variables recorded in EXODUS study

Demographics	Age & Gender
	Presenting symptoms
	Co-morbid illness
	Current medication use
COPD background data	FEV1% predicted
	BMI
	Smoking status
	Long term O_2 therapy (LTOT)
	Medical Research Council (MRC) dyspnoea grade when well
	Asthma and bronchiectasis
	Exacerbations in last year
Clinical & Lab Data	Clinical observations
	Blood tests/Chest x-ray abnormalities
Treatment	Treatment prior to admission
	Treatment on admission
Outcomes/Complications	Outcome
	Duration of admission
	Respiratory treatments (e.g. mechanical ventilation)
	Microbiology results
	Complications (e.g. MI, stroke, GI bleed, MRSA/*C.difficile* infection)

Descriptive statistics for demographic and clinical variables are presented as *median (interquartile range)* unless otherwise stated. Demographic, clinical, laboratory and radiographic variables were converted to binary variables, as in previous studies, based on

cut-offs identified in the published literature. The following cut-offs were applied: age >70 years, pulse >100 beats per minute, respiratory rate >30 breaths per minute, systolic blood pressure <90mmHg, temperature >38^{o}C, Hb <11.5g/dL, WCC >12x10^{9}/L, Na <135mmol/L, urea >7mmol/L, pH <7.35, glucose >7mmol/L, albumin <35g/L. Odds ratios were calculated for each variable, presented with 95% confidence intervals in brackets.

The univariate tests used to analyse the categorical and numerical data were the chi-square ($\chi 2$) test and Mann-Whitney U test respectively. For multivariate analysis, statistically significant candidate variables were entered into a multivariate logistic regression model using a backward stepwise approach. The methodology used to develop the regression model is similar to those used to develop other severity scores[6,11].

In clinical practice, simple and easy to use scoring systems are more likely to be used than those based on multiple factors. Therefore, a prediction score was constructed by beginning with several simple scores involving four of the strongest predictors of mortality derived from multivariate analysis. Further mortality predictors were added in sequence to the scores with the best combination of sensitivity and specificity, allowing identification of the simplest scores with the greatest overall predictive accuracy. The area under the receiver operating characteristic curve* (AUC) was then assessed for the best performing scoring systems in order to test discriminatory power. The approach described by Hanley and MacNeil[17] was used to compare the ROC curves.

A 2-tailed p-value of <0.05 was considered statistically significant for each analysis.

Results

A total of 1343 patients were included in the study. 1031 patients (77%) were assigned to the derivation cohort with 312 patients (23%) assigned to the validation cohort. The in-hospital mortality rate was 5.2% (54 deaths). 10.4% of the derivation cohort received assisted ventilation with all but 7 of these patients receiving bi-level ventilation**.

Patient characteristics

Selected patient characteristics and clinical variables are displayed in Table 2. The median age in the derivation cohort was 74 years old. 33% of patients were current smokers, 7% had long-term oxygen therapy, and 4.1% were resident in a nursing home. In terms of respiratory disability, 63.6% of patients were classified as having a MRC Dyspnoea score of 4 or 5. Significant co-morbidities included ischaemic heart disease (30.7%) and congestive cardiac failure (21.8%).

Clinical and laboratory variables

On initial presentation, confusion was recorded for 12.9% of patients. 14.4% of patients had a heart rate of >125 beats per minute, and 33% had a respiratory rate of >30 breaths per minute. A systolic blood pressure of <90mmHg was seen in 7.3% of the cohort. The median temperature on presentation was 37.1^{o}C.

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* ROC curves graphically represent how well a diagnostic test discriminates, or separates individuals into two classes; in this case, survivors and non-survivors. The maximum value for the AUC is 1.0, indicating a perfect test (i.e. 100% sensitive and 100% specific).

** Also known as bi-level positive airway pressure (BiPAP, this form of mechanical ventilation aids the inspiratory phase of the respiratory cycle by delivering high pressures during inspiration, and lower pressure during expiration. This allows retained carbon dioxide to be expired as a result of the positive end-expiratory pressure 'stenting' the airways open.

Table 2 Characteristics of patients in the derivation cohort

Demographics		COPD background information	
N	1031	FEV1 predicted	Mean 46% (SD# 19%)
Age	74 (IQR* 63-75)	BMI	8.0% <18.5
Gender	529 males (51.3%) 502 females (48.7%)	Smoking status	33.0% current smokers
Co-morbid illness		LTOT	7.0%
IHD	30.7%	MRC dyspnoea grade when well	
Stroke	14.0%	I	16
CCF	21.8%	II	140
Renal failure	7.8%	III	218
Malignancy	9.9%	IV	338
Diabetes	13.9%	V	318
*IQR – interquartile range #SD – standard deviation		Nursing home resident	4.1%

In terms of laboratory findings, 8.6% of patients had a haemoglobin concentration of <10.5g/dL, and 60.3% had a white blood cell count of >12x10^9/L. Sodium levels were found to be <135mmol/L in 26.4% of the cohort, with 52.9% having a blood urea level of >7mmol/L. In 10.5% of patients, blood albumin was recorded as <35g/L, and in 36.3%, blood glucose was >7mmol/L.

Factors associated with in-hospital mortality

Table 3 shows the factors associated with in-hospital mortality on univariate analysis, and the number of surviving and non-surviving patients for whom each variable is positive. Table 4 presents the results of multivariate logistic regression analysis where all statistically significant univariate predictive variables were entered into the model.

Table 3 Factors associated with mortality in the derivation cohort

Predictor	Non-survivors	Survivors	Univariate odds ratio	P-value	Predictor	Non-survivors	Survivors	Univariate odds ratio	P-value
Age >70	75.7 (9.8%)	70.7 (10.7%)	2.44 (95% CI from 1.3 to 5.2)	0.003	Renal failure	10 (18.5%)	70 (7.2%)	2.30 (1.22-4.34)	0.01
Gender (female)	27 (50%)	475 (48.7%)	1.05 (0.61-1.82)	0.8	Malignancy	13 (24.1%)	85 (8.7%)	2.11 (1.04-4.27)	0.03
BMI <18.5	5 (9.3%)	77 (7.9%)	1.19 (0.46-3.08)	0.7	Diabetes	14 (26%)	129 (13.2%)	1.38 (0.67-2.87)	0.4
MRC dyspnoea score	-	-	-	-	Confusion	16 (29.7%)	117 (12%)	3.09 (1.67-5.72)	0.0003
I	0 (0%)	16 (1.6%)	2.56 (1.75-3.75)	<0.0001	Pulse rate	114 (101-125)	100 (90-117)	2.25 (1.29-3.90)	0.006
II	0 (0%)	140 (14.3%)	7.63 (2.73-21.3)	0.0001	Respiratory rate	30 (22-32)	24 (20-30)	1.67 (0.96-2.91)	0.01
III	4 (7.4%)	214 (21.9%)	3.51 (2.00-6.14)	<0.0001	Systolic blood pressure	119 (98-163)	122 (106-140)	3.19 (1.53-6.62)	0.002

IV	18 (33.3%)	320 (32.8%)	0.77 (0.42-1.41)	0.4	Temperature	37.3 (36.9-38.1)	37.1 (37.0-38.0)	1.16 (0.87-1.55)	0.5
V	32 (59.3%)	286 (29.3%)	2.09 (0.91-4.80)	0.08	Leg oedema	20 (37%)	169 (20.1%)	2.81 (1.58-5.00)	0.0004
Smoking status	15 (27.8%)	325 (33.3%)	0.90 (0.21-3.83)	0.9	Haemoglobin	118 (98-139)	126 (110-141)	3.34 (1.69-6.60)	0.0005
LTOT	7 (13%)	65 (6.7%)	1.36 (0.76-2.43)	0.3	White cell count	14.5 (9.2-17.8)	13.5 (9.9-17.6)	0.81 (0.47-1.41)	0.7
Nursing home resident	2 (3.7%)	40 (4.1%)	0.91 (0.40-2.06)	0.8	Sodium	136 (132-140)	137 (134-140)	2.00 (1.14-3.50)	0.02
IHD	21 (38.9%)	263 (26.7%)	2.62 (1.49-4.60)	0.0008	Urea	11.0 (7.5-15.1)	7.2 (4.9-10.2)	4.17 (2.08-8.38)	<0.0001
Stroke	7 (13%)	137 (14.0%)	2.94 (1.42-6.09)	0.004	Acidosis	45.7 (38.0-60.2)	37 (33.0-42.0)	7.22 (4.10-12.7)	<0.0001
CCF	22 (40.7%)	203 (20.8%)	3.32 (1.71-6.44)	0.0004	Glucose	7.0 (5.3-10.6)	6.7 (5.7.8.1)	1.81 (1.05-3.14)	0.03
Albumin	31.5 (27.3-36. 0)	37 (33.0-40.0)	4.92 (2.69-9.02)	<0.0001					

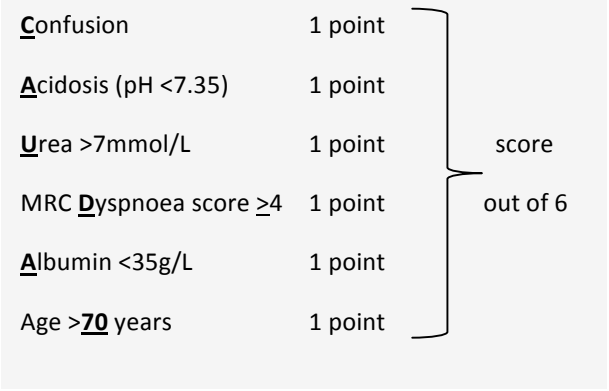
Development of prediction score

Figure 1 describes the predictive score developed using six of the independent predictors of mortality in Table 4. One point was assigned to each variable present, giving a six point scoring system. Table 5 compares the prediction characteristics of the new score against those of existing prediction scores validated for use in prediction of in-hospital mortality in AECOPD. Table 6 presents the mortality and survival for each scoring level of the new prediction score. Mortality strongly increased with increasing prediction score in the derivation cohort. The prediction score showed strong discrimination for in-hospital mortality, with an AUC of 0.84 (Figure 2).

Table 4 Independent predictors of mortality in the derivation cohort

Prognostic factor	Multivariate odds ratio	P-value
Acidosis	5.09 (2.69 – 9.61)	<0.0001
Age >70	3.06 (1.24 – 7.55)	0.02
Confusion	2.41 (1.19 – 4.89)	0.01
MRC dyspnoea ≥4	2.61 (1.08 – 7.16)	0.03
Albumin <35g/L	2.43 (1.17 – 5.05)	0.02
Urea >7mmol/L	2.15 (1.01 – 4.57)	0.05
Leg oedema	2.77 (1.45 – 5.32)	0.002
Glucose >7mmol/L	2.04 (1.11 – 3.99)	0.03
Sodium <135mmol/L	2.11 (1.11 – 3.99)	0.02
Heart rate >125/min	2.11 (1.10 – 4.03)	0.02
Hb <10.5g/dL	2.25 (1.02 – 4.96)	0.04

Figure 1 Breakdown of new prediction score "CAUDA70"



Validation of prediction score

When tested in the validation cohort of 312 patients, the new scoring system reproduced a similar performance as in the derivation cohort, with a sensitivity of 89.3%, a specificity of 59.7% (using a predictive score of 3 or greater for a positive result), and an AUC of 0.84 (95% C.I. 0.80 – 0.89).

Table 5 Performance of CAUDA70 score in derivation cohort versus existing prediction scores

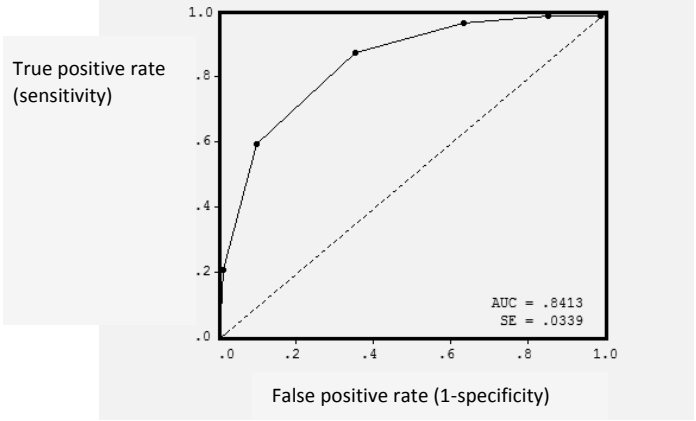
	Prediction score		
	New score	CURB-65	BAP65
Sensitivity* %	87.04	55.56	53.70
Specificity* %	64.38	81.15	83.66
Positive predictive value %*	12.57	14.78	16.20
Negative predictive value %*	98.83	96.88	96.85
Area under the ROC curve (AUC)	0.84	0.71	0.73

*using score >= 3 for positive result, and score <= 2 for negative result

Table 6 Mortality and survival at each scoring level of CAUDA70 score

Score	Number of in-hospital deaths (% mortality)	Number alive at discharge (% surviving)	Score	Number of in-hospital deaths (% mortality)	Number alive at discharge (% surviving)
0	0 (0%)	13 (100%)	4	21 (20%)	84 (80%)
1	2 (1%)	203 (99%)	5	9 (53%)	8 (47%)
2	5 (2%)	255 (98%)	6	2 (100%)	0 (0%)
3	15 (6%)	235 (94%)			

Figure 2 ROC curve for CAUDA70 score



Discussion

The principal result of the present study is the identification of strong predictors of in-hospital mortality in patients admitted with AECOPD. In addition, the study allowed derivation of a predictive scoring system based on these factors. To our knowledge, this prediction tool has the highest level of discrimination of any scoring system yet produced for prediction of in-hospital mortality in AECOPD. These findings should help in determining which patients are at high risk of in-hospital death, and whether they should be managed as an in-patient or at home with early supported discharge.

Predictors of in-hospital mortality

Only a small number of studies have previously derived predictive scoring systems for in-hospital mortality in AECOPD[6-9,11]. The number of subjects used in these ranges from 151[8] – 88,074[7]. The predictive ability of the scoring systems derived also varies with AUC values of 0.718[8], 0.72[7], 0.73[9] and 0.79[6] respectively. Of these studies, one did not perform multivariate analysis[7] and one was carried out with ICU/HDU patients alone[8]. None of these studies have been independently validated, subject to an impact analysis or implemented into clinical practice[6-9,11].

It is useful to consider possible reasons why the six variables in the new prediction score correlate with in-hospital mortality in AECOPD. It is likely that the majority of these variables represent significant organ dysfunction. For example, confusion, (which is also an important marker of poor outcome in community acquired pneumonia[13]), can arise in AECOPD due to hypercapnia, and may act as an indicator of the body's response to underlying pathophysiological processes. Similarly, urea has also previously appeared as an important predictor of poor outcome in respiratory disease[7,8,13]. This may reflect acute kidney injury resulting from volume depletion due to hyperventilation or poor oral fluid intake prior to admission. It should also be noted that it was the pathophysiological markers of disease, rather than underlying co-morbid conditions themselves, which were the strongest predictors of in-hospital mortality in AECOPD.

Development of prediction score

During development of the predictive score, the cut-off value separating a positive and negative result (i.e. high or low risk of in-hospital mortality) was varied. As expected, when a score of greater than or equal to 2 was taken as a positive result, this resulted in a slightly higher sensitivity (96.3%) and much lower specificity (36.6%) than for a cut-off of greater than or equal to 3 (Table 5). As a result, the latter was deemed to have better clinical utility, owing to a better balance between sensitivity and specificity.

In the single-point scoring system described in Figure 1, patients with a score of 0-1 are at low risk of death and are likely to be safely managed at home. Patients with a score of 2 are also at low risk but will need to be hospitalised if they are confused or acidotic. Scores of 3 or more indicate that a patient is at high risk of in-hospital mortality, as the mortality at this level climbs to 14%.

Scoring systems were tested which allocated two points each for confusion and acidosis, and one point for all other clinical variables. This was done as these factors, when present, are absolute indications for hospital admission. It was noted that mortality was very low in the group of patients scoring 0 or 1 point with the new predictive scoring system in Figure 1. It was supposed that if confusion or acidosis were instead scored with 2 points each, this might allow a further degree of certainty that any patient who scored 0 or 1 point (i.e. confusion or acidosis not present), was low risk and could be managed at home with early supported discharge. This more complex scoring system performed slightly better than the chosen scoring system, with an AUC of 0.85 (as opposed to 0.84). However, despite its slightly increased level of discrimination and a slightly lower mortality rate at low prediction scores, these were not deemed to be significant enough to outweigh the ease of use of the chosen single-point scoring system.

Limitations of present study

Lung function tests results are commonly used to quantify the severity of COPD, and these could potentially be of interest in the assessment of mortality risk. However, the lung function test data collected in the EXODUS study were not used in the development of this predictive scoring system as this information is often unavailable to clinicians when a patient is admitted with AECOPD.

As previously described, the conditions for measurement of arterial blood gases were kept consistent by using the first results available after admission to hospital. However, some degree of heterogeneity may have been introduced by variable use of supplemental oxygen across the patient group. This may in turn have influenced the predictive potential of variables dependent on this, such as acidosis.

Although data from the EXODUS study is available for 90 day and 6-month mortality, the present study does not assess the performance of the new scoring system in prediction of post-hospital mortality. This would be required to more fully assess the ability of the new predictive score to quantify mortality risk, as well as the validity of subsequent management decisions such as the use early supported discharge. In addition, a large prospective study is required to externally validate the new scoring system.

Conclusions

This study presents a new scoring system (CAUDA70), predictive of in-hospital mortality in patients presenting with acute exacerbation of COPD. The six variables included in the score are all easily obtainable clinically, and are very simple to translate to an overall severity score. Following external validation, this new scoring system may be useful in decisions on patient admission, discharge management and health care resource allocation.

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