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**Models of care for non-invasive ventilation in the Acute COPD-
Comparison of three Tertiary hospitals (ACT3) study**

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Summary at a Glance

Although NIV is an established treatment for acute hypercapnic COPD, the optimal model of care is not known. We undertook a comparison of NIV delivery in general, high dependency and intensive care wards and identified

equal efficacy, with considerable financial savings using the general ward model.

Abbreviations:

ABG = arterial blood gas

AECOPD= acute exacerbations of chronic obstructive airways disease.

BAP-65 = Blood urea >9 mmol/L, Altered mental status (GCS <14), Pulse> 109 bpm, age>65); GCS=Glasgow coma scale

HDU= high dependency unit

ICU = intensive care unit

NIV = non-invasive positive pressure ventilation

ABSTRACT

Background and objective: Non-invasive ventilation (NIV) improves clinical outcomes in acute hypercapnic exacerbations of COPD (AECOPD), but the optimal model of care remains unknown.

Methods: We conducted a prospective observational non-inferiority study comparing 3 models of NIV care: general ward (Ward) (1:4 nurse to patient ratio, thrice weekly consultant ward round), a high dependency (HDU) (1:2 ratio, twice daily ward round) and an intensive care unit (ICU) (1:1 ratio, twice daily ward round) model in 3 similar teaching tertiary hospitals. Changes in ABGs and clinical outcomes were compared and corrected for differences in AECOPD severity (BAP-65) and co-morbidities. An economic analysis was also undertaken.

Results: There was no significant difference in age (70 ± 10 yrs), FEV1 (0.84 ± 0.35 L), initial pH (7.29 ± 0.08), PaCO₂ (72 ± 22 mmHg) or BAP-65 scores (2.9 ± 1.01) across the 3 models. The Ward achieved an increase in pH (0.12 ± 0.07) and fall in PaCO₂ (12 ± 18 mmHg) that was equivalent to HDU and ICU. However, the Ward treated more patients (38 vs 28 vs 15, $p<0.001$), for a longer duration in the 1st 24 hours (12.3 ± 4.8 vs 7.9 ± 4.1 vs 8.4 ± 5.3 hrs $p<0.05$) and was more cost effective per treatment day (\$AUD 1231 ± 382 vs 1745 ± 2673 vs 2386 ± 1120 $p<0.05$) than HDU and ICU. ICU had a longer

hospital stay (9 ± 11 vs 7 ± 7 vs 13 ± 28 days, $p<0.002$) compared to the Ward and HDU. There was no significant difference in intubation rate or survival.

Conclusion: In acute hypercapnic COPD patients, the Ward model of NIV care achieved equivalent clinical outcomes, whilst being more cost-effective than HDU or ICU models.

Clinical trial registration: ACTRN12613000011785 at www.anzctr.org.au

Short title: Models of NIV care for acute COPD

Key Words: acidosis, non-invasive ventilation, COPD exacerbations

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) imposes a huge economic burden on health care systems worldwide mainly as a result of acute exacerbations¹. Non-invasive ventilation (NIV) is a proven therapy for acute exacerbations of COPD (AECOPD) complicated by acute hypercapnic respiratory acidosis.^{2,3} Randomised controlled trials^{7,3} and meta-analysis⁴ demonstrate that NIV halves the mortality and intubation rate and reduces hospital length of stay,^{2,3,17} achieving more rapid improvements in physiological parameters compared to standard medical treatment,⁴ such that NIV has now surpassed invasive mechanical ventilation as the initial form of respiratory support in the USA.^{5,6}

The model of NIV service delivery in the acute hospital setting has evolved over the last 20 years. Earlier studies were performed in the emergency department or intensive care unit (ICU) setting (nursing to patient ratio 1:1 and continuous monitoring).⁷ Other studies utilised a high dependency unit (HDU)

setting to deliver NIV (nursing to patient ratio 1:2, continuous monitoring).⁸ However, a pivotal study demonstrated that NIV could be applied successfully to COPD patients on a respiratory or general medical ward (nursing to patient ratio 1:12, no continuous monitoring).³ Furthermore, a subsequent economic analysis of this study demonstrated cost savings for those treated with NIV compared to those who did not.⁹

In clinical practice, NIV service location and protocols may vary according to local resources, particularly the availability of ICU beds. The question of where NIV should be delivered has been much debated in the literature.^{10,11,12} To our knowledge, no direct comparison of NIV models of care (general ward ("Ward"), HDU, ICU) has ever been undertaken. We hypothesised that a Ward-based NIV service would produce equivalent clinical outcomes compared to an HDU or ICU-based model and be more cost-effective, when treating hypercapnic AECOPD. In metropolitan Melbourne, three tertiary hospitals of similar size operated with different models of NIV care (Ward, HDU, ICU) providing an opportunity for comparison.

METHODS

A prospective observational non-inferiority study was performed in 3 government-funded, tertiary referral, university based, teaching hospitals, each containing 350-500 beds¹³, over a 14 month period (March 2011- May 2012). Ethics approval was obtained from the institutional ethics committee at all three hospitals and the trial was registered with clinical trials registry- ACTRN12613000011785. Each hospital had an established NIV service (greater than 5 years) operating under a Ward, HDU and ICU-based model of care. Information regarding the model was collected for each hospital, including: nurse to patient ratio; registrar, physician and respiratory nurse specialist allocation to service; frequency of physician ward round and NIV equipment. Inclusion criteria were: all patients admitted with a primary

diagnosis of AECOPD (physician diagnosis) complicated by acute hypercapnic respiratory acidosis (arterial pH < 7.35 and PaCO₂ > 45 mmHg) and receiving NIV during their admission. COPD patients receiving NIV post invasive mechanical ventilation were excluded.

A Microsoft Access database was created to record data prospectively in a standardised manner at the three hospitals. Patient demographics, medication, lung function within 12 months, and relevant COPD co-morbidities (eg cardiac, neurological, diabetes, osteoporosis, depression)^{14,15} were collected. BAP-65 scores were calculated based upon Blood urea >9 mmol/L, Altered mental status (GCS <14), Pulse > 109bpm, age > 65) were calculated from initial emergency department evaluations to provide a validated measure of COPD exacerbation severity.¹⁶

The primary outcome measure was the increase in pH and reduction in PaCO₂ with NIV treatment. Secondary outcome measures were: total number of patients treated, hospital length of stay, survival, intubation rate, treatment outcome, NIV machine settings and adherence. Treatment outcomes were classified as: (a) unable to tolerate NIV, (b) improved on NIV and ceased, (c) deteriorated on NIV and intubated, (d) deteriorated but NIV continued for palliation, (e) patient palliated and NIV ceased. A maximum of two admissions per patient were included in the data for analysis.

An economic analysis was performed using direct and indirect costs for each patient admission including medical, nursing, allied health, pharmacy, pathology, radiology and bed costs. These figures were generated by each hospital finance department and used for reimbursement via government funding. Bed day costs were calculated for each centre based on personnel and overhead costs for each bed. Equipment costs were calculated on disposable and non-disposable (capital) equipment.

Statistical Analysis

Results are given as mean $\pm$ standard deviation for normally distributed data. Three-way ANOVA (log conversion) was used to compare means for clinical outcomes and costs between the 3 models. Cost per total admission, per day of admission and per day of NIV treatment were calculated. Chi-square test was used to compare proportions. Sixteen patients were required at each centre to achieve a power of 80% with a 2-sided alpha of 0.05 for the primary outcome variables. Regression analysis was used to construct models for significant findings to correct for the effects of co-morbidities and disease severity (BAP-65).

RESULTS

Models of care

Medical, nursing support and ventilator type for all three models are summarised in Table 1. Patients were admitted via the emergency department and depending on the care model available in the hospital transferred either to the Ward, HDU or ICU. The Ward model included a respiratory nurse specialist with a background in ICU and respiratory nursing and supported by a geographically separate ICU for deteriorating patients. During the study 72% of AECOPD patients were managed on the respiratory ward and 28% on general medical wards. The HDU model also included a respiratory nurse specialist with a background in ICU and respiratory nursing and ICU support was available in a separate location within the hospital. The ICU model managed all NIV patients with 1:1 nursing ratio and twice daily ICU registrar and consultant ward rounds. In all care destinations arterial blood gases were taken at baseline, 1 hour, 4 hours, 24 hours and as clinically

indicated thereafter or until pH >7.35 was achieved. Arterial lines were utilised in some ICU patients. Portable bedside oximetry monitoring was available in the ward model whereas dedicated cardiopulmonary bedside monitors were used in HDU and ICU models.

Patient demographics

Patient demographics, BAP-65 scores and co morbidities are summarised in Table 2. There was no significant difference in patient age, gender, FEV₁, BMI, baseline pH and PaCO₂, BAP-65 score or COPD co-morbidities between the 3 models of care.

Primary outcomes

All three models of care demonstrated a significant improvement in ABG parameters with an increase in pH (0.11 ± 0.08 vs 0.10 ± 0.1 vs 0.09 ± 0.10 , $p=0.85$) (Figure 1a) and fall in PaCO₂ (14 ± 19 vs 13 ± 18 vs 10 ± 19 mmHg, $p=0.88$) (Figure 1b) for the Ward, HDU and ICU models respectively. The Ward model was non-inferior to HDU and ICU models ($p=0.2$, 0.6 respectively) including after correction for BAP-65 and co-morbidities. There was no significant difference in the mean number of days between the first and last ABG across the three models (3.2 ± 5.4 vs 3.4 ± 5.8 vs 3.7 ± 3.3 , $p=0.926$) for the Ward, HDU and ICU models respectively.

Secondary Outcomes

A total of 81 patients were managed during 92 encounters with NIV (11 patients admitted twice across the 3 hospitals). The Ward model managed significantly more NIV encounters than HDU and ICU including when adjusted for hospital size (Figure 2). Patients in the Ward model received significantly more hours of NIV during the first 24 hours of admission than the HDU and ICU models (12.3 ± 4.8 vs 7.9 ± 4.1 vs 8.4 ± 5.3 hrs, $p=0.006$). Hospital length of

stay was shorter for patients receiving NIV in the Ward and HDU when compared with ICU model. (9 ± 11 vs 7 ± 7 vs 13 ± 28 days, $p < 0.002$) (Figure 3).

NIV ceased in the majority of patients because of clinical improvement in each model (76 vs 77 vs 75%, $p = 0.38$) in the Ward vs HDU or ICU models. There was no significant difference in intubation rates (2 vs 0 vs 12.5%, $p = 0.11$) or mortality rates (11 vs 3 vs 6%, $p = 0.59$) between the 3 models, nor were there differences in relation to “unable to tolerate NIV” (4 vs 3 vs 0 % $p > 0.05$) or NIV used for palliation (9 vs 3 vs 6% $p > 0.05$), even when corrected for the effects of BAP-65 and co-morbidities

NIV settings.

The Ward used the Synchrony (Respironics, Murrysville, USA), HDU the Carina (Dräger, Lubeck, Germany) and ICU the Evita XL (Dräger, Lubeck, Germany) for NIV. Starting pressures were as per each institution’s guidelines with pressures adjusted depending on comfort, arterial blood gases and clinical response. A full face mask was used in all three hospitals. Oxygen was added to maintain SpO₂ 88-92%. No significant difference was found in the final IPAP settings (15 ± 1 vs 17 ± 1 vs 14 ± 1 cmH₂O, $p = 0.06$) or the back-up respiratory rate (8 ± 1 vs 12 ± 1 vs 7 ± 3 breaths/ min, $p = 0.009$) for the Ward, HDU or ICU models. However the final EPAP setting (7 ± 2 vs 8 ± 3 vs 5 ± 2 cmH₂O, $p = 0.02$) was lower in the ICU when compared to the Ward and HDU models.

Economic analysis

Total costs for the Ward and HDU models were significantly less than ICU when analysed for total hospital admission (\$AUD 9,002 $\pm$ 5,982 vs

9,213±5,303 vs 27,485±11,654, $p<0.001$) and per day of hospital admission (\$AUD 1,231±382 vs 1,745±2,673 vs 2,386±1,121, $p<0.001$). These differences remained significant when corrected for the effects of BAP-65 and co-morbidities. Total costs for the Ward model were significantly less than HDU model when analysed per day spent on NIV (\$AUD 1,400±917 vs 2,754±2,810, $p<0.001$) and remained significant after correction for BAP-65 and co-morbidities (regression model $p<0.001$).

DISCUSSION

In this study of hypercapnic AECOPD, a ward based model of NIV care achieved equivalent clinical outcomes (ie improvements in pH and PaCO₂) compared to HDU and ICU models whilst also being more cost-effective. Moreover, the Ward model treated significantly more patients than ICU, with a trend compared to HDU adjusted for hospital size. The Ward model also delivered more hours of NIV during the first 24 hours of admission and was more cost-effective (per admission, per hospital day and per hospital day on NIV) than the HDU and ICU models. Conversely, the ICU model had a longer hospital length of stay despite the intubation and mortality rates not differing across the 3 models. Importantly, all of these differences remained significant after correcting for COPD exacerbation severity (BAP-65) and co-morbidities. To our knowledge, this is the first study to demonstrate the equivalence of three NIV models of care, but with the Ward model treating a greater number of patients more cost-effectively.

Many findings in the current study are comparable to the two largest randomised controlled studies of NIV in COPD, conducted in the ICU⁷ and ward^{3,24}. The range of initial pH (7.27-7.31) and PaCO₂ (65-77mmHg) were similar across all 3 studies. In the current study, pH increased by 0.1 and PaCO₂ fell by 12 mmHg over a mean of 3 days across the Ward, HDU and

ICU. This compares to an increase in pH of 0.03-0.04 and fall in PaCO₂ of 2-4 mmHg after 1-4 hours in the previous studies.^{7,3} NIV was administered for a mean of 8-12 hours during the first 24 hours compared to 6-8 hours in prior studies.^{7,3,17} Hospital length of stay was 8-14 days, dependent on location, compared to 10 to 14 days in the previous ward-based study.^{3,24} The mortality rate in the current study varied between 0 and 11% across the 3 groups compared to 9 to 10% to 23% in the previous studies.^{7,3,24} The mortality rate for the ward model reflected one patient who received a transplant and died during the admission whilst the other 4 patients used NIV as a ceiling of treatment for palliation. The rate of intubation in the ICU group was 20% as compared to 15-26% in the previous studies.^{7,3} However, there were some significant differences. The intubation rate in the current Ward and HDU models (0-2%) was lower. This may be explained by a greater emphasis on palliation with NIV outside the ICU as a ceiling of care. Selection bias may also have resulted in patients less likely to require intubation being admitted to the general ward and HDU models, however, the equivalent markers of disease severity across the 3 models argues against this.

The study findings have several potential clinical implications. Firstly, a Ward model of care may offer greater availability of NIV to COPD patients without compromising clinical outcomes. Under-utilisation of NIV has been reported in the acute hospital setting.¹⁸ British Thoracic Society guidelines suggest NIV should be available 24 hours a day for all hospitals likely to admit such patients. Presumably, greater bed capacity on a respiratory and general medical ward would allow treatment to be offered to more patients. Furthermore, this could free up ICU beds for the most complex patients, particularly those requiring invasive mechanical ventilation.

Secondly, we observed NIV delivery to be more cost effective in the Ward model. Part of this effect was due to a shorter length of stay compared to ICU and lower daily costs compared to ICU and HDU respectively. General ward model of NIV care for AECOPD is already recognised as cost-saving compared to standard therapy due to a reduction in ICU admissions.³ The current results extend these findings by demonstrating that a ward or HDU model with ICU support as required, are more cost-effective than an exclusive ICU model. Several countries have already implemented Ward or HDU models of care to cope with the demand.²⁰ This study supports the appropriateness of these models of care from a clinical and cost-effectiveness point of view.

Thirdly, managing these patients in ICU may result in a longer length of stay than on the ward. In our study, the Ward model delivered more hours of NIV during the critical first 24 hours which may have contributed to the shorter hospital length of stay. The ICU model patients may be thought to be more unwell than the general ward or HDU model cohort to explain the longer length of stay. However, baseline physiological parameters, BAP-65 score and co-morbidities did not differ between the groups making this unlikely. Anecdotally, patients in the ICU model cohort ceased NIV and then underwent a period of observation to ensure stability before being discharged to the ward. This could increase hospital length of stay. Discharge planning may be more streamlined in the general ward model for COPD patients with earlier mobilisation and less sleep deprivation than in ICU.^{22,23} However, we can only speculate on the underlying reasons as they were not formally assessed in this study.

Despite the apparent benefits of a ward model of NIV care there are several caveats that need to be considered before implementing this particular model of care. Patient selection is critical. COPD patients with a mild to moderate

acidosis were included in the current study and the study by Plant et al.³ Highly trained and experienced staff including a specialist respiratory physician, dedicated respiratory registrar and specialist respiratory nurse were included in the general ward model. The general ward and HDU models did not function in isolation: they were supported by an ICU team with clinical pathways in case of clinical deterioration.

This study has several strengths. As far as we are aware it is the first to directly compare three different models of NIV care (general ward, HDU and ICU) including baseline characteristics, clinical outcomes and cost-effectiveness. Data was collected prospectively in a “real world” setting with the three tertiary metropolitan hospitals offering ideal conditions for a natural experiment.

The limitations of the study include the observational design without randomisation. Variability in COPD admission and management practices across the three centres could explain some of the results. However, recognising this constraint, all three groups had similar baseline characteristics and any differences were controlled for during statistical analysis. A randomised controlled study could not realistically be performed in a single centre due to overlap in patient treatment across general ward, HDU and ICU. These results may not be generalizable across other health systems which may, for instance, have different costings for resources. However, the cost savings in the current study are considerable (eg \$AUD1155 per day of admission for Ward versus ICU) and reflect ICU staffing costs, so are likely to be reproducible at other centres. Indeed, further work by our group has demonstrated that converting from an ICU to a Ward model of care has resulted in increased availability of NIV treatment with considerable cost savings.²¹

In summary, this study demonstrates that, a ward model of NIV care produces equivalent clinical outcomes in hypercapnic AECOPD compared to HDU and ICU whilst being more cost-effective.

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FIGURE LEGENDS

Figure 1: Change in pH (figure 1a) and PaCO₂ (figure 1b) with each of the three NIV models of care from baseline to follow-up were not significantly different (p=0.85 and 0.88 respectively)

Figure 2: Total number of NIV encounters in each of the 3 hospitals (adjusted for hospital size). Note * indicates a significant difference between Ward and ICU models (p=0.035)

Figure 3: Hospital length of stay for each of the 3 models of care. Note no difference between Ward and HDU models, however ICU model differs from Ward and HDU models as indicated by the * (p<0.002)

Table 1: Descriptions of NIV models of care

	Ward	HDU	ICU
Consultant round	Thrice weekly	Twice daily	Twice daily
Registrar round	Daily	Daily	Daily
Nurse: Patient Ratio	1:4 (Daytime) 1:8 (Overnight)	1:2	1:1
Ventilator	Respironics (Synchrony)	Drager (Carina)	Drager (Evita XL)

Table 2. Patient Demographics, Severity of illness score (BAP-65) and co morbidities.

	Ward	HDU	ICU	P
Number of patients (n)	38	28	15	0.04*
Number of encounters	46	30	16	>0.05
FEV ₁ (L)	0.9 (0.4)	0.9 (0.3)	0.7 (0.4)	0.6
Age (yr)	68 (11)	73 (10)	72 (6)	0.07
Gender Male (%)	41	70	62	0.04
BMI (kg/m ²)	27 (9)	27 (8)	26 (7)	0.97
Baseline PaCO ₂ (mmHg)	77 (21)	72 (16)	65 (25)	0.09
Baseline pH	7.28 (0.06)	7.29 (0.08)	7.31 (0.10)	0.36
BAP- 65	2.91 (1.11)	2.77 (0.94)	3.25 (0.77)	0.4
Co morbidities				
Cardiovascular disease	70% (0.5)	77% (0.4)	63% (0.5)	0.81
Diabetes	22% (0.4)	23% (0.4)	19% (0.4)	0.55
Mental Health	83% (0.4)	40% (0.5)	31% (0.5)	0.9
Osteoporosis	22% (0.4)	17% (0.4)	13% (0.3)	0.87
Renal Failure	17% (0.4)	3% (0.2)	0	0.83
Stroke	1% (0.3)	3% (0.2)	1% (0.3)	0.71
Other respiratory diseases	3% (0.4)	1% (0.3)	2% (0.4)	0.15

All results are reported as mean (SD) except for number of patients (n) and gender (proportion). FEV₁ (n= 31, 29, 9 for the ward, HDU, ICU respectively), *adjusted for hospital size

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