Evaluating the monitoring of physiological parameters of respiration in patients treated with non-invasive ventilation in the emergency department: A retrospective chart review at Sligo University Hospital in Ireland

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Abbreviations

ABG	Arterial blood gas
ACPE	Acute cardiogenic pulmonary oedema
AECOPD	Acute exacerbation of chronic obstructive pulmonary disease
ARDS	Acute respiratory distress syndrome
ARF	Acute respiratory failure
BPAP	Bilevel positive airway pressure
BTS	British Thoracic Society
CCF	Congestive cardiac failure
COPD	Chronic obstructive pulmonary disease
CPAP	Continuons positive airway pressure
ED	Emergency department
EPAP	Expiratory positive airway pressure
GCS	Glasgow Coma Scale
ICU	Intensive care unit

IMV	Invasive mechanical ventilation
IPAP	Inspiratory positive airway pressure
LOS	Length of stay
NIV	Non-invasive ventilation
PaO2	Arterial partial pressure of oxygen
PaCO2	Arterial partial pressure of carbon dioxide
pCO2	Partial pressure of carbon dioxide
PEEP	Positive end-expiratory pressure
pO2	Partial pressure of oxygen
SpO2	Oxygen saturation using a pulse oximeter
SUH	Sligo University Hospital
VBG	Venous blood gas

Part A

Literature review

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Objectives of the literature review

The aim of the literature review is to identify research that has previously been done on the topic, i.e., the types and patterns of monitoring of respiratory function parameters in patients initiated on non-invasive ventilation (NIV) in the emergency department. It also seeks to review the physiological changes of NIV, and to review types of acute respiratory failure for which NIV is indicated. Lastly, this literature review seeks to review the existing NIV guidelines in the emergency department. Quality research was identified in order to extract and review what we already know about the utilisation of NIV in the emergency department.

Search strategy, including inclusion and exclusion criteria

Medline, OVID, EMBASE, and Google scholar via the Sligo University Hospital library were used as the primary sources of published research. The search was conducted using search terms containing: adult acute respiratory failure, non-invasive ventilation in the emergency department, monitoring of non-invasive ventilation patients in the emergency department, non-invasive ventilation guidelines and protocols in the emergency department. The final search was conducted in December 2020.

Inclusion criteria

Articles on acute respiratory failure in the emergency department
Articles on non-invasive ventilation
Articles on monitoring of patients on non-invasive ventilation
Articles on non-invasive ventilation guidelines and protocols
Articles on adult patients with acute respiratory failure >16 years old
Articles published over the past ten years
Articles published in English

Exclusion criteria

Articles on respiratory failure and non-invasive ventilation in paediatric patients
Non-English articles
Articles older than ten years
Articles on NIV for treatment of COVID-19 patients

Literature reviewed

Background

Spontaneous breathing is initiated when the diaphragm and intercostal muscles contract to create a negative intrathoracic pressure.[1,2] This process is called inhalation, and it is important to get oxygen into the lungs for oxygenation of tissues. Exhalation, which is expulsion of air from the lungs, occurs when the diaphragm and respiratory muscles relax and lead to recoil of the chest wall as a result. This is a passive process which is important for gaseous exchange, i.e., getting rid of the body's excess carbon dioxide.[1,2]

Hypoxaemia, which is defined as a decrease in the partial pressure of oxygen in the blood is different from hypoxia, which occurs as a result of defective tissue oxygenation. Both conditions do not necessarily coexist, and one can occur with or without the other.[3] The most common cause of hypoxaemia is a V/Q mismatch, while other factors such as hypoventilation, and right to left shunt may contribute to this as well.[3] V/Q mismatch is defined as a mismatch between the alveolar ventilation and the alveolar blood flow, represented by the V/Q ratio which is 0.8 in a normal state.[3] Physiologically as a result of regional heterogeneity, VQ ratio is higher at the apex and lower at the base of the lung. A decline in V/Q ratio causes hypoxaemia by decreasing alveolar oxygen content, with a subsequent reduction in in the arterial oxygen content.[3] The A-a gradient, which is a difference between alveolar oxygen content and arterial oxygen content (PAO2- PaO2), informs of the integrity of the alveolocapillary membrane. A wide A-a gradient is caused by V/Q mismatch, and right to left shunt while a normal gradient is caused by hypoventilation.[3]

Non-invasive ventilation is the strategy of choice for patients who present with cardiogenic pulmonary oedema and COPD exacerbation in the emergency department. [4,5] NIV differs from invasive mechanical ventilation primarily in the of delivery. While invasive mechanical ventilation requires passage of a tracheal tube and sedation to assist with ventilation, NIV refers to the administration of ventilatory support without the use of an invasive ventilatory airway.[4] The key to success of NIV relies in the appropriate patient selection.[5] After elimination of patients with respiratory failure who are candidates for an immediate intubation, indications and contraindications for potential NIV candidates should be reviewed and contingency plans made in terms of escalation/de-escalation of care.[5] The absolute contraindications to NIV are as follows; coma, respiratory arrest, cardiac arrest, and any condition requiring immediate intubation.[6] Other relative

contraindications include shock, inability to protect airway, GI bleeding, and status epilepticus.[6]

Physiological changes of non-invasive ventilation

NIV can be delivered in two different modes, namely continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BPAP).[8] Single pressure in the form of positive end expiratory pressure (PEEP) is applied throughout the entire respiratory cycle during CPAP, and in contrast different inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP) are applied during BPAP.[8] While CPAP is recruited primarily for hypoxic respiratory failure, BPAP can be utilised for both hypercapnic and hypoxic respiratory failure.[8]

It is essential to have a good understanding of the respiratory and cardiovascular changes related to NIV for an effective and safe application of this treatment strategy. NIV decreases the work of breathing by providing PEEP and/or pressure support, which in turn ensures the alveoli do not collapse during the entire phase of the respiratory cycle.[9] Spadaro at al (2016) demonstrated that in patients undergoing both laparotomy and laparoscopic surgery, positive pressure ventilation was able to improve supine position related basal lung V/Q mismatch by improving pulmonary shunt and dynamic compliance of the lungs.

In contrast, positive pressure ventilation is not always consistent with reduced shunt and improved V/Q match.[10] In a study evaluating the changes in shunt, V/Q mismatch, and lung aeration with PEEP in patients with acute respiratory distress syndrome, it was concluded that poorly matched redistributions of ventilation and perfusion between dependent and non-dependent regions of the lungs may explain why some of the patients showed detrimental changes in shunt and V/Q mismatch in response to an increase in PEEP.[10]

Types of acute respiratory failure

Respiratory failure can be classified based on duration as acute or chronic, and acute on chronic which is an acute exacerbation of an existing condition resulting in respiratory failure.[7] Diseases which lead to breathing impairment may cause respiratory failure by affecting the thoracic wall, i.e., muscles and bones, the nerves, and they may also affect the lungs directly. Respiratory failure is caused by conditions which impair oxygenation, and by conditions which cause the retention of carbon dioxide.[7] Respiratory failure, classified as either type 1 acute

respiratory failure or type 2 acute respiratory failure, is classified according to blood gas findings.[11]

In type 1 acute respiratory failure, there is an impairment of gaseous exchange at the level of the alveolar-capillary membrane. This is hypoxaemic respiratory failure where the arterial partial pressure of oxygen (PaO2) level is less than 60 mmHg (8 kPa), with a normal or low arterial partial pressure of carbon dioxide (PaCO2). Conditions such as severe pneumonia, and pulmonary oedema can cause this type of ARF.[11] Type 2 ARF, occurs as a result of carbon dioxide retention. This is a hypercapnic respiratory failure where PaCO2 levels are greater than 50 mmHg (6.5 kPa).[11]

Non-invasive ventilation guidelines

The use of NIV has dramatically increased in the last two decades, especially so in the acute and emergency setting.[12] While there is sufficient guidance in regard to the use of NIV in the intensive care unit (ICU), not enough guidelines have been published for use by emergency physicians.[13] While it is crucial to initiate NIV as soon as possible in a selection of patients presenting to EDs with ARF, not knowing the exact cause and the potential for complications may lead to delays in administration of this treatment modality.[14] Nonetheless, emergency physicians well trained in the use of NIV can bypass these hurdles if provided with sound and clear departmental NIV guidelines. With emerging evidence, the use of NIV has gone past the traditional usage, primarily in COPD exacerbation and ACPE.[15]

Osadnik et al., conducted a systematic review of 17 clinical trials to assess the impact of NIV in patients presenting with respiratory failure secondary to COPD and determined that the risk of dying was reduced by 46%, while the risk for invasive mechanical ventilation (IMV) was reduced by up to 65%.[16] While the study does not offer insight into which patients with acute exacerbation of chronic obstructive pulmonary disease (AECOPD) are best treated with NIV and which NIV settings are the most appropriate, the review nonetheless convincingly answers the question whether NIV is safe and effective in the management of this disease entity. This Cochrane study offers to date some of the strongest data to support the effectiveness of BPAP in the management of AECOPD. Jayadev et al., went on to further demonstrate that a ‘door to NIV time’ of less than 70 minutes in the emergency department is both achievable and sustainable, and it is associated with improved overall outcomes in terms of in-hospital mortality, need for IMV, ICU

length of stay (LOS), and hospital LOS.[17] This is attributed to a higher awareness of COPD management which is protocol driven.

A Cochrane systematic review and meta-analysis of 24 randomised controlled trials was conducted to determine the safety and efficacy of NIV compared to standard medical treatment alone for treatment in the ED and in-hospital patients with respiratory distress secondary to ACPE. The study concluded that NIV for ACPE reduces hospital mortality, reduces risk of IMV, and does not have any added adverse effects compared to standard medical treatment alone. This recent, high-quality review reiterates the already existing knowledge regarding the use of NIV in ACPE. The review, however, did not confirm the perception that NIV treatment initiated early in the ED for ACPE leads to decreased hospital or ICU length of stay.[18]

While the above two conditions have traditionally been the beneficiaries of NIV in the ED, new research is beginning to widen the scope of indications for NIV in respiratory failure due to other conditions in the ED.[19] There is a dearth of high-quality data regarding the application of NIV for patients presenting with acute severe, and life-threatening asthma who failed medical treatment. This fact is supported by a Cochrane review by Lim et al., which indicated a scarcity of high-quality data to support NIV use in these cases.[20] However, a recent large retrospective review of severe asthma and status asthmaticus conducted in New Zealand determined the effectiveness and safety of NIV in severe asthma, and in some selected status asthmaticus patients.[21] Life-threatening asthma patients with low Glasgow Coma Scale (GCS) scores were only initiated on NIV at the directive of a consultant present, and with resources for intubation readily available should a need arise.[21] The review highlighted the efficacy and safety of NIV for this patient group, whereby only 8 of the 186 patients initiated on NIV went on to require IMV. Out of those with a GCS of 10 or less initiated on NIV, one in 25 patients went on to receive IMV.[21] While the results of this single-centre study show encouraging evidence for NIV utilisation in severe acute asthma/status asthmaticus and in patients with a low GCS, the study's retrospective chart review methodology is fraught with possible misclassification bias as some patients may have wrongly been classified as status asthmaticus and it not possible to verify this information. Randomised controlled trials and systematic reviews may shed light in this matter and provide evidence that is unequivocal.

Previous studies had demonstrated the efficacy of NIV for treatment of acute respiratory failure secondary to pneumonia in patients with COPD and in immunocompromised patients with lung infiltrates. However, utilisation of NIV to treat non-hypercapnic and non-immunocompromised respiratory failure patients secondary to pneumonia seems to be widespread in practice.[22,23] Brambilla et al., in an Italian multi-centre prospective observational study, evaluated the scope of NIV outside the ICU in patients with ARF as a result of pneumonia, and risk factors for in-patient mortality. The study demonstrated NIV use was widespread for this purpose in many Italian hospitals, and that CPAP was commonly used for hypoxic ARF patients. The study also concluded that the only risk factor for mortality in admitted patients was a do not attempt resuscitation status as opposed to baseline severity of ARF.[5]

Another interesting group for which NIV is used is that of immunocompromised patients presenting in ARF. The little data available on this topic is mainly of oncology patients in developed countries, while data on immunocompromised patients secondary to human immunodeficiency virus in low- and middle-income countries is very scarce. A study by Huang HB et al., which investigated the effect of NIV compared to oxygen alone in ARF patients with immunocompromise secondary to oncological conditions and organ transplantation, demonstrated that NIV could reduce short-term mortality in this group, but this could be beneficial only in a subgroup of patients which have yet to be identified.[24] However, in an observational cohort study by Coudroy et al., the effect of high-flow nasal cannula (HFNC) compared to NIV was investigated in immunocompromised ARF patients and concluded that the use of NIV in the ICU resulted in higher intubation rates and higher mortality than in the HFNC group.[25]

Other controversial groups of patients for which initiation of NIV could be considered in the ED include patients with reduced mentation and patients with acute respiratory distress syndrome (ARDS). While an altered mental status has traditionally been regarded as an absolute contraindication for initiation of NIV due to fear of aspiration, recent studies are beginning to cast doubt on this practice.[21] As demonstrated above in the study of unconscious patients with status asthmaticus by Bond et al., a subgroup of these patients benefited from NIV and went on to have favourable outcomes.[21] While ARDS is an area of interest for treatment with NIV, this clinical entity is difficult to define in the ED due to the average length of time patients spend in the ED.[26] NIV failure rates for ARDS have traditionally been high, up to 60% in some studies.[27] Potential causes of this failure may include associated sepsis and multi-organ failure, as well as

barotrauma where tidal volumes could not be well controlled to achieve a lung-protective ventilatory strategy.

Monitoring of acute respiratory patients initiated on non-invasive ventilation

The success of NIV treatment is not based solely on the initiation of this treatment, but relies also on adequate monitoring of these patients and subsequent actions taken based on the data derived from this monitoring.[28,29] Most patients initiated on NIV are usually frail and elderly with multiple comorbidities; hence, appropriate monitoring means treatment can be tailored to the specific needs of individual patients as there is no one-size fits all approach.[30] Nonetheless, despite the obvious importance of appropriate monitoring, there is a scarcity of data regard the best monitoring strategies for NIV patients. In addition, there are no studies comparing different levels of monitoring in this situation.[28]

NIV aims to alleviate patients' discomfort by improving gas exchange, thereby decreasing shortness of breath, improving work of breathing, and hopefully avoiding invasive mechanical ventilation.[7] A successful outcome in the first one to two hours of treatment initiation is indicated by a decrease in respiratory rate, improved oxygen saturation, and an improving pH with a dropping PaCO2.[7] A decrease in heart rate towards normal levels and an improvement in mental status are other clinical indicators of a successful outcome.[7]

An observational survey by Roberts et al., which investigated the standard of management of patients with acute exacerbations of COPD came up with surprising results despite the unequivocal proof of efficacy of NIV in this group of patients.[31] The audit demonstrated that these patients initiated on NIV in the acute setting had higher mortality rates compared to patients with the same level of respiratory acidosis who were managed with standard medical therapy alone.[31] While there may have been other factors apart from acidosis which could have determined outcomes, the study was able to demonstrate that factors such as clinicians' experience with NIV use, adequacy of monitoring patients, and appropriate escalation determined the prognosis for these patients.

Monitoring of clinical parameters

A full clinical assessment is essential for ARF patients initiated on NIV, and of utmost importance is the monitoring of dyspnoea, respiratory rate, patient's comfort, mental alertness, and gastric distension.[32]

While it is evident that one of the main aims of NIV is to relieve dyspnoea, it is important to recognise that NIV itself can inadvertently exacerbate dyspnoea under

certain circumstances.[33] The two-way causal relationship between anxiety and dyspnoea is well documented and treating one can directly relieve the other.[33] If conditions permit, clearly explaining to the patient what NIV treatment entails and what to expect during treatment can on its own help relieve anxiety.[33] Mild sedation may be necessary to help relieve anxiety, and subsequently alleviate dyspnoea.[34] Other factors such as ventilator-patient asynchrony, leaks, and inappropriate ventilator settings may exacerbate dyspnoea during NIV and these should be actively investigated and corrected in patients whose dyspnoea does not improve.[33]

ARF can lead to a depressed level of consciousness, either in the form of hypercapnic or non-hypercapnic encephalopathy.[35] Traditionally, a decreased level of consciousness was a contraindication for NIV treatment in ARF due to fear of inability to protect the airway and possible aspiration.[35] Recent data demonstrates the usefulness of NIV in patients with a depressed sensorium, especially in those with hypercapnic encephalopathy.[35] In these cases an improving level of consciousness with NIV treatment may suggest treatment success, while a deteriorating or not improving level of consciousness may signal poor response to treatment.[28] The GCS is used clinically to assess the level of consciousness, but the six-point Kelly-Matthay Score is deemed more appropriate to monitor level of consciousness in ventilated patients in an ICU setting.[35]

Monitoring of gas exchange

The British Thoracic Society (BTS)/Intensive Care Society (ICS) recommends continuous monitoring of oxygen saturation during NIV treatment, and it also recommends intermittent monitoring of ventilation parameters via ABG.[36]

Pulse oximetry is routinely used to guide the management of patients in EDs, and its utilisation is undisputable in clinical care.[37] Non-invasive monitoring and continuously monitored data derived from pulse oximetry help clinicians try to maintain patients' oxygen saturation above hypoxaemic levels.[37] Target oxygen saturation differs between type 1 and type 2 ARF, with target SpO_2 >94% in type 1 ARF and 88–92% in type 2 ARF. However, despite its ease of accessibility, continuous monitoring, and non-invasive nature, pulse oximetry does have its limitations. The main limitation of pulse oximetry is its inability to detect the adequacy of ventilation by measuring $PaCO_2$ in ventilated patients.[38] Patient's hemodynamic status may also affect accuracy of pulse oximetry, especially in critically-ill patients with poor peripheral perfusion.[28]

ABG is considered a gold standard mode of monitoring for assessing a patient's oxygenation, ventilation, and acid-base status adequacy of ventilation in ARF.[39] In the ED setting, it may be challenging to do serial ABGs to monitor response to treatment due to factors such as patient discomfort and clinician's skill with the procedure.[40] For these reasons, studies evaluating comparability between ABG and VBG have found little difference in pH, while the venous and arterial PCO2 were not comparable.[40] Data also shows poor comparability between venous and arterial PO2.[40] These differences are sufficiently large to be of clinical significance.[40] ABG should be performed at baseline prior to initiation of NIV, and again 1-2 hours post NIV initiation.[36] PCO2 decrease by 3 mmHg and pH increase of 0.03 is deemed a good response to treatment.[28] In cases where NIV treatment has been modified from baseline, ABG should be repeated within 30 minutes of the modification.[41]

Despite its demonstrated efficacy in monitoring the adequacy of ventilation in ARF patients, arterial puncture is a painful procedure and can also subject patients to limb threatening complications.[28] This has led some to investigate the adequacy of non-invasive measures such as transcutaneous CO2 and end-tidal CO2 in patients receiving NIV treatment. While end-tidal CO2 is widely regarded as underestimating the true CO2 in spontaneously breathing patients, transcutaneous CO2 monitoring has found a place in NIV monitoring either as a concurrent supplement of ABG, or in helping decide which patients to wean without having to repeat ABG.[42,43]

Monitoring of side effects

Despite the documented benefits of NIV, it is important to mention that NIV is associated with frequent minor, and even life-threatening major side effects.[44] It is important to thoroughly screen patients who are candidates for NIV to minimise potential life-threatening adverse events.[44]

Interface related side effects are frequent, and about one-third of patients on oronasal masks experience pressure-related skin discomfort and injury.[44] Loosely fitting masks, in contrast, may cause leaks with subsequent patient-ventilator asynchrony and the potential for NIV treatment failure.[44] Newer interphase devices such as helmets have been proven to result in better tolerance and subsequent improved clearance of CO2.[45] Another minor adverse effect of

NIV which should be monitored is gastric distension, and active management of this complication by measures such as nasogastric tube insertion would help minimise the risk of aspiration.[44]

Barotrauma with resultant pneumothorax is a well-recognised side effect of NIV, with an incidence of about 5%.[28] The monitoring of patients who develop chest pain, and patients whose conditions worsen while on NIV should start with clinical evaluation and subsequent imaging techniques such as point-of-care lung ultrasound and chest x-ray, and subsequently the insertion of a chest drain if warranted.[28] Pneumonia is another complication of NIV, with an incidence of about 3–10% and this is associated with longer hospital stays and increased morbidity and mortality.[46] Lastly, it is important to keep in mind that mechanical ventilation increases intrathoracic pressure, which in turn can reduce preload with subsequent hypotension and haemodynamic instability.[44]

Summary of literature

With an improving healthcare system and standard of living in most societies around the world, life expectancy is increasing, leading to a higher proportion of the elderly population. This in turn leads to a greater number of people living long with chronic illnesses, many of whom are prone to acute exacerbations. Hence, there has been a surge in the number of patients presenting to EDs with ARF all over the world, mostly as a result of exacerbations of chronic cardiopulmonary illnesses.

Emergency Medicine as a specialty is relatively new and most of the guidelines used in the EDs have originally been extrapolated from other specialties, some of which did not take into consideration the uniqueness of emergency medicine. NIV is also a relatively new treatment modality which has taken its place in the management of ARF in the last two decades, and most available guidelines on its use come from the critical care environment. These two factors highlight the need for emergency medicine-driven protocols in order to cater for this unique environment.

This literature review highlights the fact that a lot of work has been done in the last decade or so to optimise the use of NIV, both in and out of the ICU environments. The review not only emphasises the effectiveness of NIV in the treatment of AECOPD and ACPE, but it also provides a window of opportunity for broadening of indications for NIV beyond the traditional indications already mentioned.

The literature review also emphasises the need for adequate monitoring of patients on NIV to achieve desired outcomes. It provides a good insight into the various monitoring options of patients on NIV, which include both clinical and gas exchange monitoring

parameters. It provides a detailed account of what initial monitoring options are essential, and which subsequent monitoring data is required based on the response to initial NIV settings. Lastly, monitoring for potential side effects is emphasised to minimise both minor and life-threatening adverse effects of NIV.

Gaps and needs for further research

While a lot of ground has been covered since the inception of NIV, there is an urgent need for high-quality research to broaden the indications of NIV beyond the traditional use in AECOPD and ACPE. Nevertheless, the majority of studies on NIV come from the critical care setting, and sometimes it may be challenging to adapt recommendations to the ED setting. This may be compounded by factors such as differences in clinician-patient ratios, availability of space, time spent with the patient, and availability of resources between the critical care and ED environments. Good departmental protocols on NIV may help bridge this gap to improve patient outcomes.

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PART B

ARTICLE FORMAT ACCORDING TO THE BRITISH MEDICAL JOURNALS (BMJ).

Evaluating the monitoring of physiological parameters of respiration in patients treated with non-invasive ventilation in the emergency department: A retrospective chart review at Sligo University Hospital in Ireland

ABSTRACT

Background: In the last two decades, acute respiratory failure presentations in the emergency department have more than doubled. Non-invasive ventilation has become the treatment modality of choice in selected patients, with a significant reduction in mortality seen in these cases. However, adequate monitoring of clinical and blood gas parameters is crucial to ensure treatment targets are met. This study aimed to evaluate the monitoring of physiological parameters of respiration in patients treated with non-invasive ventilation in the emergency department in Sligo University Hospital, Ireland.

Methods: This was a retrospective chart review of patients who presented to the emergency department in acute respiratory failure and were treated with non-invasive ventilation between September 2017 and March 2019. Patients' demographics, vital signs, and arterial blood gas were analysed using t-test, with $p < 0.05$ conferring statistical significance.

Results: A total of 50 charts were analysed. The average age of participants presenting with acute respiratory failure was 76.4 years (SD= 10.5) and 62% (n=31) of the patients were female. Results showed that initial and ongoing monitoring of vital signs remained guideline compliant throughout the entire duration of non-invasive ventilation in the emergency department. All but one patient had an initial blood gas analysis prior to initiation of non-invasive ventilation treatment, while repeat blood gas analyses were inconsistently performed; 38% (n=19) did not receive a repeat blood gas analysis.

Conclusion: The study highlights that clinicians use a non-standard approach in monitoring arterial blood gas during treatment of acute respiratory failure with non-invasive ventilation in the emergency department. A proforma may help bridge this gap to ensure standardised care is provided in order to improve treatment outcomes.

INTRODUCTION

Acute respiratory failure is a frequent presentation seen in the emergency department (ED). Long-term outcomes of these patients can be determined by early management decisions made in the ED.[1] The respiratory system aims to provide adequate oxygen in order to enable the body to carry out its many aerobic and metabolic functions, and in turn the respiratory system eliminates carbon dioxide, a by-product of metabolism, from the body.[2-4] Several criteria have been proposed to define acute respiratory failure, but regardless of the criteria used, all patients with acute respiratory failure will have either a primary ventilation and/or primary oxygenation disorder.

The aim of managing acute respiratory failure in the ED is to improve hypoxia and/or hypercapnia in blood analysis.[5] This in turn should lead to clinical improvement as evidenced by the reduced work of breathing, and improved level of alertness. It is important to note that the critical care management of acute respiratory failure in the ED also aims to identify patients who need invasive mechanical ventilation, and those in whom any lifesaving treatment would be futile.[6]

In Ireland the annual incidence of acute respiratory failure in the ED is 150 per 100,000 population.[7] While the incidence of patients presenting with acute respiratory failure has more than doubled in the last 15 to 20 years as a result of more people living longer with chronic illnesses such as chronic obstructive pulmonary disease (COPD) or congestive heart failure, studies have shown that there has not been any increase in mortality in these cases that would otherwise be expected.[8] Better understanding of the disease and treatment options available have led to a reduction in mortality rates in these patients. Factors such as the recent introduction of non-invasive ventilation (NIV), long-term home oxygen therapy, and improved treatment strategies for chronic cardiac failure patients have been given credit for the improved mortality rates.[8]

Continuous and robust monitoring of patients in acute respiratory failure who are being treated with non-invasive ventilation in the ED can lead to early detection of improvement or worsening of the clinical condition.[9] Early initiation of NIV in the ED in those patients who fail standard medical therapy has been shown to improve outcomes, and as a result averting the need for invasive mechanical ventilation and subsequently sparing intensive care unit beds and resources.[9] This study aimed to evaluate the proportion of patients for whom vital signs monitoring and repeat ABG were obtained at specified time intervals after starting NIV in the emergency department in Sligo University Hospital in Ireland.

METHODS

This retrospective chart review (audit) was conducted in the Emergency Department of Sligo University Hospital, a 359-bed acute general hospital located in the northwest region of the Republic of Ireland. The ED catchment area covers Sligo County, as well as either whole or parts of five other counties. The department serves patients of all age groups, with those above the age of 65 years forming a majority of presenters to the ED. An estimated 40,000 patients are seen in the ED on an annual basis.

A convenience sampling method was used; all hand-written clinical charts of patients 18 years of age and older who were initiated on NIV between September 2017 and March 2019 were retrieved. This time period was selected as it covered two consecutive winter months when NIV is used more frequently. It also covered two change-over periods when over 15 doctors transition through the department and are replaced thus minimising bias to individual practice. In this study, non-invasive ventilation strictly included those patients who were initiated on either continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BPAP), while those who received standard oxygen therapy via nasal prongs or face masks were excluded. Type 1 acute respiratory failure was defined as hypoxemia (partial pressure of oxygen [pO2] <8 kPa) with normal or low partial pressure of carbon dioxide (pCO2) level, while type 2 was defined by hypercapnia (pCO2 >6 kPa) acute respiratory failure (ARF) with acidosis (pH <7.3) regardless of the partial pressure of oxygen (pO2). For the purpose of this study, PO2 was used to evaluate the severity of type 1 ARF while pH was used for type 2 ARF.

Patients' notes in the EDs are hand-written by both doctors and nurses, then scanned and stored in a password protected computer. While the initial vital signs are entered manually into the observations chart by triage and/or resuscitation room nurses, subsequent vital signs in the resus area are recorded at least every 15 minutes automatically by machine, except for Glasgow Coma Scale (GCS) which is recorded manually at least every 30 minutes by nurses. All included cases had their vital signs printed out from the machine and attached to the patients' charts. In this hospital, doctors are responsible for conducting arterial puncture for arterial blood gas analysis.

In our ED, patients' length of stay (LOS) in the resuscitation area is 3 hours on average. On rare circumstances would patients be admitted to the hospital within an hour of arrival to the ED, and this would be in mechanically ventilated, critically ill patients who would be admitted to the intensive care unit.

A standardised data collection sheet was used to record the following variables: age, sex, type of ARF, respiratory rate, oxygen saturation (SpO2), GCS, NIV mode, and lastly pH and pO2 from the arterial blood gas (ABG). Initial ABG was used to diagnose ARF and to initiate NIV, while 2nd ABG and continuous monitoring of vitals were used to modify treatment. Data were later captured into a Microsoft Excel spreadsheet and basic analyses were used to describe the data. Student's t-test was used to determine difference between independent variables, with a p-value <0.05 conferring statistical significance.

Study approval was granted by the Emergency Department of Sligo University Hospital, the Audit Department in Sligo University Hospital, and the University of Cape Town Human Research Ethics Committee (HREC ref: 116/2020).

RESULTS

Eighty-four patients' cases of ARF were identified from the ED resus register. Of these, 34 cases were excluded due to missing ED doctor's notes, missing ED nursing notes, misplaced blood gas results, grossly ineligible notes, and inability to locate charts of patients who have since demised. The remaining 50 cases met the inclusion criteria and were analysed.

Demographics

Notably, from the study sample there was a large percentage (n=31, 62%) of female patients presenting with ARF which necessitated NIV (Table 1). The median age for all participants presenting with ARF was 76 years with an age range of 52 years (42 years to 95 years).

Table 1 shows a higher occurrence of type 1 ARF in those above the age of 80 years, and in contrast, type 2 ARF is observed in higher proportions in those younger than 80 years old. The mean age for type 1 ARF was 82.5 years (SD=7.9), while the mean age for type 2 ARF was 72.3 years (SD=10.1); the difference in average age was statistically significant (p<0.001).

Table 1. Type of acute respiratory failure in relation to patients' demographics, vitals, arterial blood gas, and mode of non-invasive ventilation

			Type 1 ARF N (%) 20 (40)	**Type 2 ARF N (%) 30 (60)**
Age	<60		0 (0)	2 (7)
	60–69		1 (5)	7 (23)
	70–79		6 (30)	14 (47)
	80–89		9 (45)	6 (20)
	90–100		4 (20)	1 (3)
Sex	male		6 (30)	13 (43)
	female		14 (70)	17 (57)
Initial Respiratory Rate	<12		0 (0)	1 (3)
	12–20		0 (0)	1 (3)
	21–30		8(40)	18 (60)
	>30		12 (60)	10 (34)
Initial SpO2	≥94%		3 (15)	2 (7)
	88–93%		5 (25)	10 (33)
	80–87%		7 (35)	10 (33)
	<80%		5 (25)	8 (27)
Initial Glasgow Coma Scale	15		13 (65)	16 (53)
	12–14		7 (35)	8 (27)
	9–11		0 (0)	3 (10)
	≤8		0 (0)	3(10)
Initial Blood Gas	**pH**	<7	N/A	2 (7)
		7–7.2	N/A	10 (34)
		7.21–7.3	N/A	13 (43)
		>7.3	N/A	4 (13)
	pO_2 (kPa)	<8	13 (65)	N/A
		8–10.5	7 (35)	N/A
		>10.5	0 (0)	N/A
NIV treatment mode	CPAP		16 (80)	3 (10)
	BPAP		4 (20)	27 (90)

ARF, acute respiratory failure; SpO2, oxygen saturation; pO2, partial pressure of oxygen; NIV, non-invasive treatment; CPAP, continuous positive airway pressure; BPAP, bilevel positive airway pressure

Initial vital signs of interest

At presentation, a higher mean respiratory rate (RR) was recorded for type 1 ARF (mean=35.9, SD= 7.1) while a lower mean RR was recorded for type 2 ARF (mean =29.4, SD= 6.3), a difference that was statistically significant (p=0.0013). The study also revealed means for initial SpO2 at presentation, with 84.9% (SD=8.6) for type 1 ARF and 82.7% (10.9) in type 2 ARF. The difference was not statistically significant (p=0.4544). Lastly, the mean GCS scores for each group were 14.4 (SD=1.0) and 13.3 (SD= 2.7) for type 1 and type 2 ARF, respectively. This difference was not statistically significant (p=0.1001)

Acute respiratory failure severity and mortality

All but one patient had their ABG measured prior to initiation of NIV in the ED, representing 98.0% (n=49) of patients. Seventy-nine percent (n=24) of type 2 ARF patients presented with mild to moderate acidosis, 7% (n=2) with severe acidosis, and 14% (n=4) with no acidosis. Thirty-five percent of patients (n=7) with type 1 respiratory failure presented with severe hypoxaemia on ABG, while 65% (n=13) of these patients presented with mild to moderate hypoxaemia. Two study subjects died while being treated for type 2 ARF with NIV.

Aetiology of respiratory failure

Of the 30 patients who presented in type 2 ARF, 25 (83%) of them had a known diagnosis of COPD. Five patients had no known previous diagnosis of COPD, but they were classified as newly diagnosed COPD with exacerbation based on history and clinical findings. Amongst the 20 patients with type 1 ARF, 17 (85%) were diagnosed with ACPE and the remaining 3 were diagnosed with atypical pneumonia, aspiration pneumonitis, and bilateral pneumonia respectively.

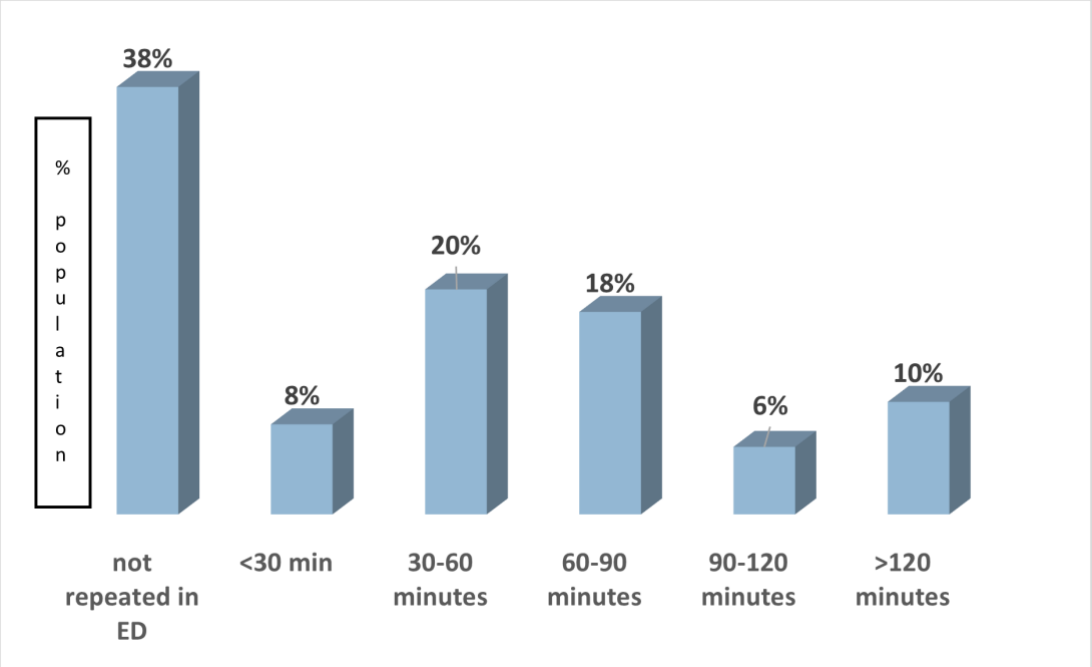
Table 2. Aetiology of acute respiratory failure

	Diagnosis	**n (%)**
Type 1 ARF	ACPE	17 (85)
	Aspiration Pneumonitis	1 (5)
	Bilateral Lobar Pneumonia	1 (5)
	Atypical pneumonia	1 (5)
Type 2 ARF	AECOPD	25 (83)
	Newly diagnosed COPD	5 (17)

ARF, acute respiratory failure; ACPE, acute cardiogenic pulmonary oedema; AECOPD, acute exacerbation of chronic obstructive pulmonary disease; COPD, chronic obstructive pulmonary disease

Repeat Blood Gas

Repeat blood gas shows that the highest proportion 38% (n=19) of participants had no blood gas repeat in ED. After 2 hours of follow-up (greater than 120 minutes) only 10% of participants had blood gas repeat after initiation of NIV. Less than 30 minutes, 30-60 minutes and 90-120 minutes had 8% (n=4), 20% (n=10), 18% (n=9) and 6% (n=3) participants respectively.



ED, emergency department

Figure 1. Overview of duration of time until blood gas was repeated from initiation of non-invasive ventilation in the emergency department (n=50)

Discussion

The study participants' demographics indicate a higher prevalence of ARF in the elderly population, the majority of which were female. The most common indications for ED NIV, which include AECOPD and ACPE, occur predominantly in those 65 years and above.

The study also reveals that there were more patients with ARF above the age of 65 treated with NIV, with 6 (12%) patients below 65 years of age and 42 (88%) patients aged 65 or older. The prevalence of COPD in patients 65 years and older has been found to be at least five-times higher compared to those aged 40 years old or younger. 10] Similarly, the prevalence of congestive cardiac failure (CCF) has been found to be higher in people aged more than 60 years at 36% of the population while the prevalence in those aged less than 60 years was 4%

of the population as per the EPICA (Epidemiology of Heart Failure and Learning) study.[11] This high prevalence of COPD and CCF, which are the main indications for NIV in ARF, are in keeping with the findings of our study.

While data on the benefit of NIV in ARF secondary to CCF and COPD exacerbations are unequivocal, there is new evidence to advocate for the use of NIV in ARF caused by conditions such as community acquired pneumonia, severe/life-threatening asthma, ARF in immunosuppressed patients, and for palliative purposes.[12] We see in our study that the two terminally-ill patients who died were put on palliative NIV for comfort, and invasive mechanical ventilation was not considered for futility of care.

All patients' GCS and vitals were monitored at least every 30 and 15 minutes, respectively. This is in keeping with recommendations by the British Thoracic Society and the European Respiratory Society/American Thoracic Society guidelines which recommend continuous monitoring of respiratory rate and SpO2 while patients receive NIV.[13,14]

Our departmental NIV guideline, which have been adopted from the British Thoracic Society (BTS) 2016, recommend the following monitoring of ABG: at initiation; 1 hour, 4 hours, and 8 hours post initiation while patients are still in the ED.[13] The BTS guideline further mentions that NIV is more appropriate for mild to moderate hypercapnic ARF.[13] Thirty-eight percent of patients in this study did not have a blood gas repeated while on NIV in the ED, and this was independent of the LOS in the ED which averages 3 hours. This shows a lack of compliance with the recommended ABG repeat of approximately 60 minutes post NIV initiation. Seventy-nine percent of patients with hypercapnic ARF in our study had mild to moderate acidosis, in keeping with BTS NIV indications.

Only two patients died in the ED while on NIV. Both patients had hypercapnic ARF with moderate acidosis prior to NIV initiation. They both deteriorated clinically while on NIV, with a decision made to not escalate their care to invasive mechanical ventilation as both cases were not for resuscitation due poor functional baseline. These cases are in keeping with the European Respiratory Society/American Thoracic Society guideline recommendation for the use of NIV for palliation of terminally-ill patients with ARF as it improves dyspnoea, and reduces morphine requirements. [14]

The BTS 2019 NIV audit recommends careful prognostication prior to NIV initiation, so as to pre-empt deterioration by utilising monitoring data to escalate care timeously.[13] Many departments in UK hospitals, where NIV is administered, have developed an NIV prescription

pro-forma sheet to record all relevant information during NIV treatment.[15] This information helps clinicians choose appropriate patients for NIV, helps with planning care prior to NIV initiation, helps to interpret monitoring data, and helps clinicians to modify or escalate treatment appropriately.[15] Our study highlights the fact that our clinicians utilise a non-standard approach to monitoring physiological parameters of respiration in the ED, which could be related to doctors using a higher judgement when deciding on how to monitor patients initiated on NIV. This could be mitigated by introducing an NIV pro-forma sheet, which is standard practice in the UK, to ensure appropriate action is taken in response to monitoring data.

The study sample is representative of the NIV population seen in the Sligo ED and in EDs in Ireland at large. This is evidenced by the indications for NIV in our ED, which closely correlate with indications for other EDs in Ireland. The other important similarity is the demographics of our study participants, which closely resemble those elsewhere in Ireland.

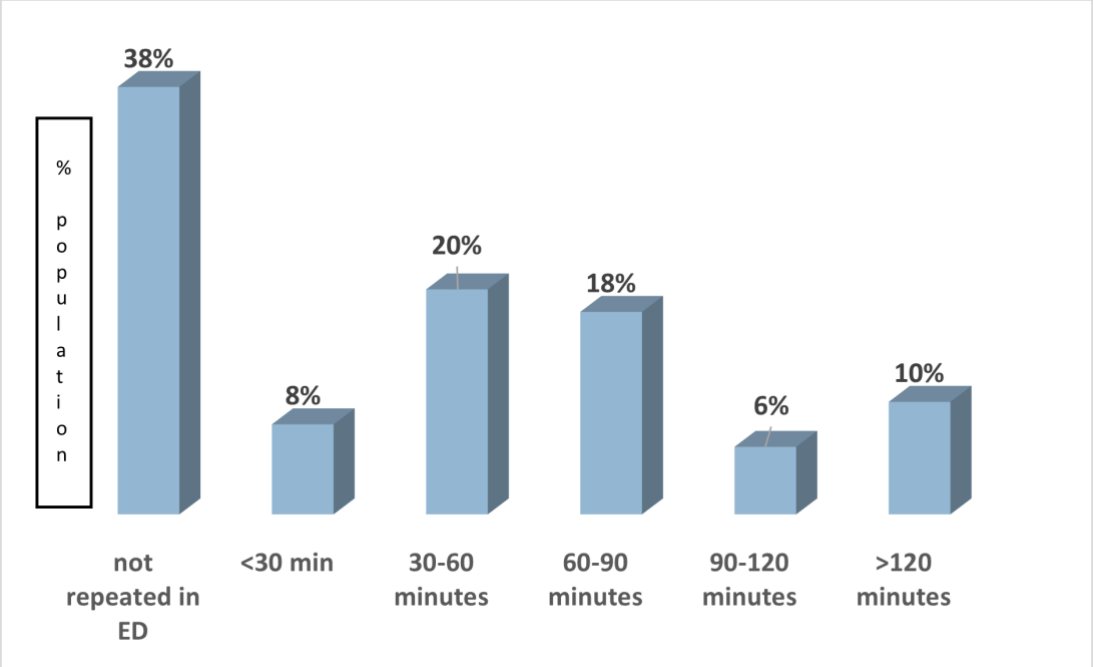
Missing data was the main limitation factor in this retrospective chart review. The data was missing at random (MAR) and multiple imputation is the best way to handle this problem. In this study we applied complete case analysis which has unbiased estimation if data is missing completely at random (MCAR) because imputation is beyond the scope of this descriptive study. Retrospective search of cases of choice was compounded by incomplete ED resus registers, which sometimes omit important information such as whether patients were initiated on NIV or not. In order to mitigate the effects of incomplete data, all clinical records of patients with grossly missing data were excluded from analysis.

The study results show a higher proportion of adults above the age of 65 presenting with ARF, with the vast majority having either CCF or COPD exacerbations, the two main indications for NIV. The study also illustrates that monitoring of vitals and initial ABG is compliant with protocols, while subsequent monitoring is varied and not guideline compliant. Perhaps the reason lies behind the fact that vital signs are recorded by nurses and usually this is an automated process in the resus setting, while ABG monitoring is a function executed by doctors who may use higher judgement and may not necessarily comply with this protocol. Moving forward, a mandatory NIV prescription pro-forma for all patients initiated on NIV may help bridge this gap as this will reduce practice variability amongst clinicians. Improved awareness of the role of NIV in ARF for clinicians, and better visibility of the departmental guidelines on NIV may improve the monitoring of these patients.

Conflicts of interest

The authors declare no conflicts of interest.

Figures and Figure legends



ED, emergency department

Figure 1. Overview of duration of time until blood gas was repeated from initiation of non-invasive ventilation in the emergency department (n=50)

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Part C: Addenda

BMJ

Improving your paper's chances of a favourable first review

While there will be papers that will not be accepted because they are not relevant to our readership, do not add to the literature, or contain fatal methodological flaws, many papers that might be eligible for publication are either rejected, or undergo multiple revisions, due to inadequately described methods and results, failure to convey the importance of the paper to the readership, or overstating the conclusions. Please consider the following suggestions when drafting your article:

Importance

The importance of the research question should be addressed in the introduction. Where relevant consider: the magnitude of the problem, gaps in prior studies, how the research question will help provide better care to patients. Keep your introduction short and to the point!

Methods

Use a research reporting guideline. There are over 280 guidelines (see http://www.equator-network.org) so one will surely fit your study. In completing the guideline, avoid using N/A (not applicable) as in most cases the information suggested *is* applicable. Be sure to include the setting, population, time frame, inclusion and exclusion criteria. State your primary and secondary outcomes. Describe how you determined your sample size; this may be a sample size calculation based on your outcome, necessitated by time frame of the study or the size of a particular population.

If the study involves medical record review, explain who the abstractors were, whether a data extraction form was used, how the accuracy of the extraction was checked (e.g. did a second reviewer review some or all of the charts). Provide an analysis for the agreement of the reviewers and how discrepancies were handled.

Results

For most studies include a "Table 1" – a description of the study population with regard to age, gender, other demographics and relevant presenting characteristics. In some cases, a table could have multiple columns to distinguish groups receiving different treatments, or those that were and weren't included in the study/intervention. For several types of studies, a flowchart showing patient recruitment is highly advised (see http://www.equator-network.org). The primary outcome should also be represented in a table or figure. Use tables and figures to provide most of the raw summary data, and text to summarise the most important points.

When hypothesis testing, report the size of the comparative statistic (e.g. the difference between the means or the odds ratio) and a 95% confidence interval. P values should

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When hypothesis testing, report the size of the comparative statistic (e.g. the difference between the means or the odds ratio) and a 95% confidence interval. P values should

also be reported but are supplemental to the confidence intervals. In studies of diagnostic tests, report sensitivity, specificity, NPV, PPV and LRs.

Discussion

Begin the discussion with a summary of your findings. Discuss how your findings fit into prior literature, and, if different, why you think you got the results you did. Explain the implications of your findings. Avoid going beyond the constraints of your data in drawing conclusions or making recommendations.

Include a limitations section in your discussion.

https://emj.bmj.com/pages/wp-content/uploads/sites/19/2017/02/EMJ_improving_your_paper.pdf

Non-Invasive Ventilation data abstraction form

Patient's ID:	Age:	Sex	Hospital:

Diagnosis: Type 1 ARF ☐ Type 2 ARF ☐	NIV Mode: CPAP ☐ BPAP ☐

Initial vital signs of interest:

RR: SPO2: GCS:

Initial ABG:

pH: PCO2: PO2:

Vital signs monitoring: ☐ ≤ 15 minutes ☐ > 15 minutes intervals

Repeat blood gas: ☐ < 30 min ☐ 30-60 min ☐ 60-90 min ☐ 90-120 min ☐ > 90 min

pH: PCO2: PO2:

Change to NIV: ☐ no change ☐ pressure increased ☐ pressure decreased

☐ Weaned ☐ Intubated ☐ CPAP switched to BPAP or vice versa ☐ deceased

Reason for change of NIV	Tick one
No change	
Improved hypoxia/acidosis	
Worsening or no significant improvement in hypoxia/acidosis	
Improving vitals (no ABG repeat)	
Worsening or no significant change in vitals (no ABG repeat)	

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Evaluating the monitoring of physiological parameters of respiration in patients treated with non-invasive ventilation in the emergency department: A retrospective chart review at Sligo University Hospital in Ireland

By

Dr Retselisitsoe Vincent Matalasi

Division of Emergency Medicine, Department of Surgery,

University of Cape Town

MTLRET006

This study is in partial fulfilment of the requirements for the degree Masters of Philosophy in the Faculty of Health Sciences at the University of Cape Town

Supervisor(s):

A/Prof. Peter Hodkinson

Dr Michael Sweeney

Month and year of Graduation: June 2021

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Dear Vincent,

The Ethics Review Committee has examined your application for Ethical Approval of "An evaluation of physiological function monitoring in patients newly initiated on non-invasive ventilation in the emergency department in Sligo University Hospital."

The committee regards this proposal as an audit and as such does not fall under the committee's remit but suggest you submit this proposal to the Audit Department of SUH.

We wish you good wishes with your project.

Regards,

Sally Browne

Saolta
Grépa Ollscoile Cúram Sláinte
University Health Care Group

Emergency Department
Sligo University Hospital

Consultants: Dr Kieran Cunningham
Mr Fergal Hickey
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Dear Dr Matalasi

I am more than happy for you to progress with the audit "Evaluation of monitoring of respiratory physiological parameters in patients treated with non-invasive ventilation in the Emergency Department in Sligo University hospital".

I look forward to seeing the results. If you need any assistance, please let me know.

Regards

Yours Sincerely,

Dr Michael Sweeney FRCSI FCEM
Consultant in Emergency Medicine
Medical Council Number 18361

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room G50- Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6492
Email: hrec-enquiries@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

03 March 2020

HREC REF: 116/2020

A/Prof P Hodkinson
c/o Ms Vathiswa Mzamo
Division of Emergency Medicine
F51, OMB

Dear A/Prof Hodkinson

PROJECT TITLE: AN EVALUATION OF MONITORING OF RESPIRATORY PHYSIOLOGICAL PARAMETERS IN PATIENTS TREATED WITH NON-INVASIVE VENTILATION IN THE EMERGENCY DEPARTMENT IN SLIGO UNIVERSITY HOSPITAL-MASTERS CANDIDATE-DR R MATALASI

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study, subject to approval from the REC in Ireland.

Approval is granted for one year until the 30 March 2021.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

The HREC acknowledge that the student: Dr Retselisitsoe Matalasi will also be involved in this study.

Please quote the HREC REF in all your correspondence.

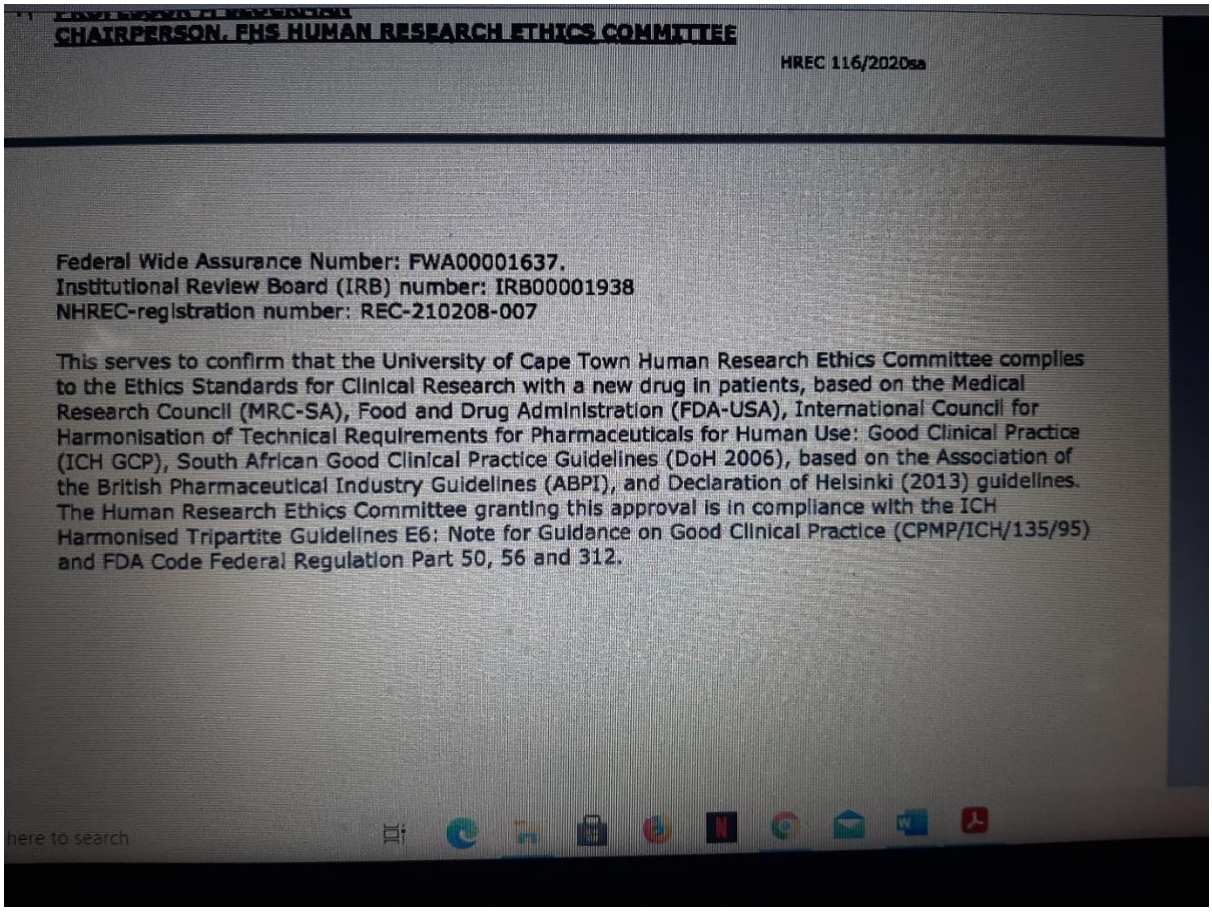
Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

pp **PROFESSOR M BLOCKMAN**
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC 116/2020ss



CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

HREC 116/2020sa

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

here to search

Research Protocol

An evaluation of monitoring of respiratory physiological parameters in patients treated with non-invasive ventilation in the emergency department in Sligo University Hospital.

Student: Retselisitsoe Vincent Matalasi

Division of Emergency Medicine, Department of Surgery,

University of Cape Town

MTLRET006

Supervisor: Dr Dineo Moiloa

Division of Emergency Medicine, Department of Surgery,

University of Cape Town

Co-supervisors:

Dr Michael Sweeney

Consultant Emergency Physician

Sligo University Hospital

Ireland

This study is in partial fulfilment of the requirements for a Master of Philosophy:

Clinical Emergency Care

October 2019 Retselisitsoe Vincent Matalasi

Declaration

I, Retselisitsoe Vincent Matalasi, hereby declare that the work on which this dissertation is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

I authorize the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Plagiarism Declaration

1. I know that plagiarism is a serious form of academic dishonesty.

2. I have read the document about avoiding plagiarism, am familiar with its contents and have avoided all forms of plagiarism mentioned there.
3. Where I have used the words of others, I have indicated this by the use of quotation marks.
4. I have referenced all quotations and properly acknowledged other ideas borrowed from others.
5. I have not and shall not allow others to plagiarise my work.

6. I declare that this is my own work.

7. I am attaching the summary of the Turnitin match overview (when required to do so).

Signature ……

Date: 23rd October 2019

Background

“Non-invasive ventilation refers to the administration of mechanical ventilation without using an invasive artificial airway (endotracheal tube or tracheostomy tube)”. (1) The use of non-invasive ventilation to treat both acute and chronic respiratory failure has expanded significantly in the recent past, and so has the spectrum of cardio-respiratory emergencies which can be treated and the location of its application. (1)

Acute respiratory failure correlates to an arterial PO2 of <60 mm Hg, an arterial PCO2 tension of >45 mm Hg, or both. It is important to correlate these blood gas ranges with history and clinical assessment of the patient. (2) The aim of non-invasive ventilation is to achieve the same physiological parameters as invasive ventilation, without the risks associated with invasive ventilation. (3) Identifying the right patients and recognising its limitations is essential to achieve desired outcomes while treating patients with non-invasive ventilation. (3)

Emergency clinicians are presented with patients suffering from either acute hypoxaemic, and/or hypercapnic respiratory problems around the clock. (4) A step-wise approach in the management of these patients in the emergency makes sense, and this encompasses delivery of oxygen with nasal cannulae, masks, and both non-invasive and invasive mechanical ventilation. (5) Reversible causes of respiratory failure, such as acute exacerbation of chronic obstructive pulmonary disease and acute cardiogenic pulmonary oedema, are essential for the success of non-invasive ventilation in the emergency department. (4)

Two modes of delivery of non-invasive ventilation exist, and these are continuous positive airway pressure (CPAP), and bilevel positive airway pressure (BPAP). (6) CPAP applies single pressure during inspiration and expiration, while BPAP delivers varying inspiratory and expiratory pressures. Non-invasive ventilation reduces the work of breathing by counteracting with intrinsic PEEP, and by so doing recruiting extra alveoli and decreasing shunting. (6, 7) Features such as patient’s cooperation with the provider, clinical

characteristics, less air leaking, etc are some of the factors which determine success of non-invasive ventilation. (8)

Non-invasive ventilation should be performed in a clinical environment with adequate nurse to patient ratios and monitoring. (4) Irrespective of the clinical condition, monitoring should be adjusted to the patient's status and severity of respiratory insufficiency. (4) Patients with acute respiratory failure are fragile and critically ill with a high probability of morbidity and mortality, for this reason appropriate monitoring of real-time physiological parameters will identify patients who are unresponsive to non-invasive ventilation who may require treatment adjustment or endotracheal intubation. (2)

Periodic monitoring of patient's mentation, gaseous exchange and cardiovascular function is crucial for success of this treatment modality and avoiding related complications such as treatment failure, patient discomfort with the mask, decreased venous return with subsequent hypotension, gastric distension with possibility of aspiration, and rarely pneumothorax. (9) While there is abundance of data regarding the relationship between monitoring and outcomes of non-invasive ventilation patients in the intensive care unit, there is scarcity of data regarding the relationship between monitoring and outcomes of these patients in the emergency department. (10)

Purpose of the study

This study aims to evaluate how respiratory physiological parameters (oxygen saturation, arterial blood gas, and end-tidal CO2) are monitored in acute respiratory failure patients treated with non-invasive ventilation in the emergency department in Sligo University Hospital in Ireland. It is a well-known fact that lives are not saved by non-invasive ventilation alone, but proper monitoring of physiological parameters in response to treatment and actions taken thereafter. With this retrospective descriptive study of chart reviews, we hope to get more insight into the monitoring patterns of patients treated with non-invasive ventilation by nurses and doctors in our abovementioned emergency department.

Research question:

Amongst patients presenting to the emergency department in Sligo University Hospital with acute respiratory failure who have been initiated on non-invasive ventilation, what is the pattern of monitoring of respiratory physiological parameters?

Study aim and objective:

The aim of this study is to determine the pattern of monitoring of respiratory physiological parameters in patients treated with non-invasive ventilation in the emergency department in Sligo University Hospital.

In order to achieve this aim, the following objectives will be analysed:

- The types of respiratory function monitoring done at the start of treatment with non-invasive ventilation.

Study design and methods:

Study design: This is a single centre, descriptive and retrospective study using patients' charts review.

Study setting and population:

The proposed study will take place in the emergency department in Sligo University Hospital which is situated in the northeast region of the Republic of Ireland. The study will evaluate monitoring of patients presenting with acute respiratory failure who were treated with a non-invasive ventilation over a period of eighteen months from September 2017 until March 2019. This study period covers two consecutive winters months, and this is advantageous as exacerbations of chronic cardiorespiratory conditions are common during the cold months in Ireland and this is likely to increase our sample size.

About 100 patients are seen monthly in the 'Resus' area of our emergency department and based on the demographically similar western populations where acute respiratory failure accounts for 11% of all emergency department visits, (2) we estimate our cases to range between 120 – 180 subjects. After elimination of those cases which do not meet the inclusion criteria, our final population size is estimated to be around 100 cases. Hopefully this will be a large enough sample to help reduce sampling error. This will be a convenience sample whereby all available cases which meet the inclusion criteria will be analysed, and for that reason sample size calculation has not been done. Since non-invasive ventilation is mostly initiated in the resus area of the emergency department, all consecutive charts of patients who were managed in resus during the above time period will be analysed.

Inclusion criteria:

- Age 18 years and above.
- Charts of patients who were newly initiated on non-invasive ventilation in our emergency department during the period September 2017 to March 2019.

Exclusion criteria:

- Minors (< 18years of age)
- Charts with grossly incomplete and/or ineligible data.

Hypotheses:

I. Monitoring of respiratory physiological parameters is adequate at the start of treatment with non-invasive ventilation in the emergency department.

II. Subsequent monitoring of these parameters by emergency department clinicians is variable during the course of treatment with non-invasive ventilation and may be inadequate.

The study will aim to investigate the above-mentioned hypotheses.

Research procedure and data collection:

- Data will be collected and analysed over a period of two to three months.
- Resus room register will be used to identify names of patients and their patient numbers during the aforementioned study period.
- Emergency department charts of interest will be retrieved by the departmental clerks.
- Patients' demographic data will be anonymised by removing all identifiers including names, chart number, sex, date of birth, race, religion, address, place of residence, etc. This will be performed by hiding all above identifiers on the photocopied emergency department charts.
- Doctors' and nurses' names and other identifiers will as well be expunged.

- All charts of patients with acute respiratory failure who were initiated on non-invasive ventilation will be isolated.
- Charts will be thoroughly analysed by the principal investigator, and with the help of co-supervisor where uncertainty arises. All charts which meet the above-mentioned inclusion criteria will be included in the study, while those meeting the exclusion criteria will be returned.

To minimise the risk of observer bias, I will undergo a thorough revision of this topic from the training I have already had in clinical research methods in my first and second years of MPhil in Emergency Medicine, so I become cognisant with the required standard. I will couple this revision with the most up to date online resources. Variables of interest will be transcribed from the patients' emergency department charts to the standardised data abstraction forms. Utilisation of data abstraction forms will ensure the abstractor does not deviate from what is required, and this will also help minimise observer bias. The emergency department in Sligo University Hospital is a busy department, and it would be difficult to get staff members or students to play the role of abstractors. For this reason, blinding will not be possible for the purpose of this study. Utilisation of rigorous research methodology will help mitigate the internal validity of this study. A review of variables; namely pulse oximetry, capnography, and arterial blood gas in our case will be conducted to sensitise the abstractor to the data of interest. Continuous evaluation of data abstraction will be conducted to ensure accuracy of data and any discrepancies will be reviewed to clarify issues.

Data abstraction forms will be used to ensure consistency and accuracy of data from the abstractor. These data abstraction forms will be in the electronic format. This will help for centralisation of data storage, and hopefully reduce input and transcription error. Providing exact numbers of character spaces for the coder to input the response will help reduce error in coding. A small pilot test of 5 cases will be conducted to ensure that all coded elements of the abstraction form can be populated.

Patients' charts with missing or incomplete data will be analysed and based on how much data is missing and its significance in the overall picture, a decision will be made whether or not to include those charts in the study. A few missing variables will be treated as a minor nuisance, while charts with a large proportion of missing observations will be excluded as their inclusion may affect the study's integrity. Variables which have many missing values will also be omitted.

Particular interest will be paid to how these patients were monitored based on data derived from the doctors' notes and nursing notes. As alluded to in the background, physiological parameters monitoring via measurement of vital signs is essential in assessing response to

treatment. Documentation of adequacy of gaseous exchange via the use of pulse oximetry, capnography, and arterial blood gas analysis will be evaluated.

We will also evaluate the frequency of monitoring of each of the above variables, and we will as well evaluate whether monitoring was done routinely or whether monitoring was done only in response to clinical deterioration.

Data analysis and interpretation:

Descriptive statistics will be utilised to summarise the sample and the observations that have been made. The data which will be collated and analysed by the researcher and supervisors include initial execution and recordings of respiratory vital parameters at the start of non-invasive ventilation treatment, and subsequent execution and recording of these parameters during the course of treatment in the emergency department until the patient has been formally handed over to another speciality for continuation of care. Figures and tables will be used to illustrate significant findings from the study. The data will be extracted onto EXCEL spreadsheet and the STATA 12 statistical package will be utilised for analysis.

Ethical considerations:

Ethical approval will be sought from the Human Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town. Facility approval will be sought from the department of emergency medicine, Sligo University Hospital in Ireland. No consent will be sought from patients and emergency department doctors and nurses as their identifying information will be expunged. This is provided for in the latest issue of the General Data Protection Regulation guidelines in Ireland, and the hospital where the audit will be performed is fully adherent to these guidelines.

Potential risks and benefits:

There are no direct risks or benefits to individuals recruited in this audit as there will be no direct contact with the patient due to the retrospective nature of the study. Also, no intervention will be carried as this will be a purely retrospective descriptive study. The patients' and clinicians' identities will not be identifiable in dissemination of the information related to this audit. Potential risk may arise where information regarding patients' or clinicians' identity is compromised, but reasonable measures will be instituted to mitigate this from happening while the data is used during the study.

Privacy and confidentiality:

Privacy and confidentiality of patients and clinicians' data will be maintained by anonymising their identifiers prior to data extraction.

Data will be stored in the investigator's personal password protected laptop computer.

Reimbursement:

There will be no reimbursement for data clerks helping to retrieve patients' charts as this is an integral part of their job in a teaching university hospital.

Study strengths and limitations:

The retrospective nature of the study may create problems in terms of verifying certain information which may not be clear while retrieving and analysing data from chart reviews as this may result in incorrect data being analysed or correct data being dismissed as unclear/incomplete. Illegible handwritings may as well create problems while retrieving these data. The study will be conducted at a single centre and this will affect generalizability of its findings. Data will be abstracted by the lead investigator, and this has a potential of introducing bias to the study. It is important that the investigator only focuses on what has been done, and how it has been done while abstracting the data, this may help mitigate the potential of bias. Using standardized data abstraction forms will help with uniformity of data collected and help minimize bias.

The advantages of this type of study is that it is relatively cheaper to conduct compared to other studies which are intended to establish cause-and-effect relationships. This study will also be faster to conduct as it is less resource intensive. Despite the numerous above-mentioned limitations, the findings of this study can be used as a platform for more comprehensive studies which would ultimately lead to the department implementing more sound guidelines on monitoring of patients managed with non-invasive ventilation.

Expected outputs related to the study:

I. The results of the study will be communicated to the departmental clinical management, and thereafter with their permission a feedback presentation will be given to the clinicians (doctors and nurses) during weekly teaching days on our monitoring patterns of patients managed with non-invasive ventilation.

II. Follow up informal and formal trainings will be instituted with the help of clinical management to update NIV monitoring knowledge to bring about the desired outcomes.

Projected time frame:

	June 2019	July 2019	Aug 2019	Sept 2019	Oct 2019	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020	April 2020
1	X	X									
2					X	X					
3				X							
4							X	X			
5								X	X		
6							X				
7								X	X	X	
8											X

1. EM-DRC 2. Ethics 3. Facility approval 4. Data collection 5. Data analysis 6. Writing report 7. Continuous literature review 8. Submit final report

Budget:

Item	**Quantity**	**Cost in South African Rands**
Internet		own
Stationery, Exercise books	Quantity yet to be determined	100.00
Dissertation compilation and publication		500.00
Contingency		500.00
Grand Total		1600.00

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