“I can’t catch my breath’...The use of Noninvasive Ventilation as Adjunct Therapy to Reduce the Need for Intubation.

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Abstract

Noninvasive ventilation (NIV) is currently used as an adjunct therapy for treatment of respiratory failure with or without hypoxia. NIV is used to support patients with severe acute respiratory failure associated with Coronavirus-19, exacerbations of chronic obstructive pulmonary disease, acute cardiopulmonary edema and hypercapnia as well as to avoid reintubation of patients who were recently extubated. Published evidence that supports the use of noninvasive ventilation was collected from a comprehensive search of MEDLINE, EMBASE, PubMed, Cumulative Index Nursing and Allied Health Literature (CINAHL) and Cochrane databases. The purpose of the quality improvement (QI) project was to implement the early use of NIV support to reduce the incidence of endotracheal intubation. The outcomes of this QI project documented the need for NIV based on vital signs, arterial blood gases (ABG) values, and the arterial oxygen level (pO2) divided by the level of the amount of the patient’s oxygen requirement or FiO2 (i.e., the P/F ratio). The QI project revealed that the implementation of NIV was associated with an 86% reduction in the need for intubation in a cohort of 14 patients. These results reveal the value of implementing NIV during patient care as this type of ventilation support has shown help relieve the need for invasive respiratory support.
Problem Description

Patients frequently present to an acute care hospital setting with a complex set of signs and symptoms. One of the most common symptoms acute presented by patients in my is shortness of breath (SOB) which typically varies from mild dyspnea to severe acute respiratory failure. Acute respiratory failure (ARF) is a life-threatening derangement of arterial blood gas exchange and acid-base status that develops over hours to days (Liu et al., 2016). SOB leads to an inadequate oxygenation of tissues throughout the body coupled with a high demand for oxygen that can lead to severe clinical consequences.

Numerous disease processes and physiologic processes can lead to ARF the medical management of this condition may differ depending on the underlying cause. Among these conditions, ARF may result from chronic obstructive pulmonary disease (COPD), acute cardiogenic pulmonary edema (ACPE), pneumonia (viral, bacterial or fungal) and acute lung injury (Liu et al., 2016). Severe ARF can progress to acute respiratory distress syndrome (ARDS) in which the lungs sustain an acute inflammatory injury that may result in permanent damage. The acute inflammatory state associated with ARDS leads to increased pulmonary vascular permeability and increased lung weight as well as loss of aerated lung tissue (Bellani et al., 2016).

Therefore, all patients who present with worsening dyspnea must be evaluated carefully as this condition can progress and, if not treated promptly, emergency interventions might ultimately be required. For example, Liu et al. (2016) reported that many patients whose signs and symptoms undergo progressive deterioration ultimately develop acute respiratory distress and require immediate invasive interventions, including endotracheal intubation and mechanical ventilator assistance.
Available Knowledge

Noninvasive ventilation (NIV) is a form of ventilatory support that delivers positive pressure ventilation through a noninvasive mask. Nasal masks and facemasks, among others, can be used to provide NIV. Administration of NIV reduces pulmonary workload, improves cardiac output, and enhances lung compliance (Berbenetz et al., 2019). In addition, positive pressure ventilation can prevent alveolar collapse and enhance alveolar expansion via improvements of inspiration, airway compliance, and thus improved oxygenation. NIV includes two distinct modes of ventilation. Continuous positive airway pressure (CPAP) delivers constant positive airway pressure throughout the respiratory cycle, while bi-level noninvasive positive-pressure ventilation (NIPPV) provides intermittent inspiratory positive airway pressure and positive end-expiratory pressure (Berbenetz et al., 2019).

Invasive mechanical ventilation (IMV) is a mode of ventilation that relies on invasive techniques to deliver oxygen and provide ventilatory support. IMV requires the use of an endotracheal tube that passes through the cavity and the throat and into the trachea; this device is then connected to a respirator. While IMV is typically effective at improving hypoxemia, providing respiratory support, relieving respiratory distress, and providing relief for the increased work of breathing, its use requires patient sedation and in some cases, paralysis via a neuromuscular blocking agent (Slutsky, 1994). IMV can be used to improve pulmonary gas exchange, alveolar ventilation, oxygenation, and lung inflation, as well as to provide support for the respiratory muscles (Slutsky, 1994). However, IMV has been associated with numerous adverse consequences.
Advantages of NIV over invasive ventilation include noninvasive delivery method such as facemask, can be applied for short, intermittent periods, there is no sedation involved and lack of sedation which allows patients to be fully awake and active in their medical care (Osadnik et al., 2017). Liu et al. (2016) published the results of a meta-analysis that assessed the efficacy of NIV compared to either conventional IMV and/or no ventilation therapy in patients in ARF regardless of the underlying decreased rates of intubation and mortality while in the Intensive Care Unit (ICU). However, this intervention had no impact on total in-hospital mortality or the length of ICU or hospital stay.

Rationale

Noninvasive ventilatory support can be used in all hospital settings including the ICU and Telemetry units. Several recent observational studies have documented that NIV can be useful to stabilize mid-to-moderate ARF in patients with viral pneumonia caused by Coronavirus disease-2019 (COVID-19). A recent systemic review and meta-analysis by Camarota et al. (2021) discussed the overall benefits of NIV and the increased demand for its use. Among their findings, they reported rates of intubation ranging from 12-13% in a cohort of 19 patients who were diagnosed with hypoxemic ARF.

NIV is also useful as an adjunct therapy in patient that were maintained on IMV and were recently extubated. Several studies reported the use of NIV reduces the reintubation rate (risk ratio [RR] = 0.42; 95% confidence interval [CI], 0.16-0.78) after planned extubation in patients at high-risk for failure compared to patients managed with conventional oxygen therapy (Bajaj et al., 2014).
Specific aims

The use of NIV at an early stage of potential respiratory reduces the need for endotracheal intubation, a procedure that associated with poor patient outcomes, prolonged length of hospital stays, and increased mortality rates (Camarota et al., 2021). The goal of the QI project was to implement the early use of NIV support in patients receiving conventional medical treatment and to determine whether this intervention reduces the incidence of endotracheal intubation.

Methods

Context

The QI project was implemented in El Paso Texas (population of 679,813 people). The study was carried out in a hospital that integrates private medical practice with a large academic center affiliated with the Texas Tech University System. Texas Tech Physicians of El Paso, an affiliate of Texas Tech University Health Sciences El Paso, is the region’s largest multispecialty medical group practice in this region, with five locations and over 250 specialist and subspecialist health care providers and practitioners who provide care for those living in El Paso. This QI project was implemented in an urban hospital with a capacity of 122 beds that provides services for all patients ages (i.e., 0 to more than 100 years). The hospital is organized into five departments including the emergency department (ED), a medical/surgical unit ICU, two telemetry units, a medical/surgical unit, labor & delivery and neonatal ICU.

The QI project included patients who were treated in the ED, the medical/surgical ICU, and the telemetry unit, each of which has a capacity of 16, 12, and 30 beds, respectively. The QI project was implemented during the night shift when 50 staff members are routinely on duty. The leadership structure includes the house supervisor in the role of Administrator On Duty. Each department has a nurse who is in charge of the unit. The number of bedside and medical/surgical/telemetry nurses varies on each shift. In addition to nursing and auxiliary staff,
patient care is provided by the 16 respiratory therapists (RTs) in the respiratory therapy department. Four to six respiratory therapist are typically on duty during the night shift (based on hospital census) including the charge RT.

**Interventions**

Multiple interventions were implemented in the QI project including a 10-day reflective study that tracked patient encounters as part of the care of a hospitalist and intensivist nurse practitioner (NP). During the 10-day reflective period, one-hundred and four patient encounters were performed. These included both initial encounters and follow-ups. These patients were admitted from the ED to the ICU and telemetry units. A review of the patient log revealed that 17 patients presented with the main complaint of shortness of breath. The most common diagnosis was ARF due to various causes, most frequently viral or bacterial pneumonia.

Upon completion of the reflective practice log all patient cases were reviewed. This review discovered that the patient population that most encountered during these 10 days included both males and females who were between 20–65 years of age. Three possible practice problems were identified. The problems identified in these patients involved the diagnosis of ARF with or without hypoxia.

A careful analysis of the practice setting, together with a rigorous review of the literature suggested that NIV was used only rarely as an adjunct to other medical interventions. In addition to the findings revealed by the 10-day reflective practice log, the use of ventilatory support during the past two years was evaluated. This is of particular importance given that El Paso was identified as the epicenter of the COVID-19 global pandemic in 2020. As noted by Camarota et al. (2021), hospitals worldwide were stressed by the massive influx of patients admitted for ARF due to COVID-19. The COVID-19 pandemic, which led to a sudden and substantial increase in
the numbers of patients in need of respiratory support, played a key role in my decision to change my current practice.

**Study of Interventions**

A comprehensive review of the literature resulted in the identification of 11 high-quality publications, including systematic reviews, meta-analyses, prospective studies, observational studies, and randomized control trials that included a total of 14,943 patients. The literature was extracted from PubMed, Science Direct, Cumulative Index Nursing and Allied Health Literature (CINAHL) and Cochrane Library databases. The search was performed using the following terms: Noninvasive Ventilation, NIV, Invasive Mechanical Ventilation, IMV, Intubation, Reduce Intubation, BIPAP, AVAPS, Noninvasive Respiratory Support (NIRS), Extubation Trial Failure, Mechanical Ventilation, Intubation Rates, Success and Prevention, Acute Respiratory Failure, Hypercapnic Respiratory Failure, Hypoxemic Non-hypercapnic Respiratory Failure, COPD, Cardiopulmonary Edema, Pulmonary Edema, COVID, Coronavirus-19, and Hypoxia (Berbenetz et al., 2019; Camarota et al., 2021; Faqihi et al., 2021; Liu et al., 2016; Ornico et al., 2013; Osadnik et al., 2017).

**Measures**

The ACE Star Model of Knowledge Transformation (Figure 1) was used to translate the research findings into practice. This framework promotes evidence-based practice by stressing the need to identify knowledge to be translated, integration of research reviews to translation, and limitations of the discussion to information supported by research (White & Dudley-Brown, 2021).
The five key points presented by the ACE Star Framework include:

1. Discovering knowledge
2. Summarizing the evidence
3. Translation of evidence into practice
4. Integration of evidence into practice
5. Determination of the outcomes and effects of implementing evidence.

*The ACE Star framework*

![ACE Star Framework Diagram]

Figure 1.

The design, implementation, and evaluation of this QI intervention were completed using the Plan-Do-Study-Act (PDSA) approach (Harris et al., 2018). The nursing staff and RTs are frequently the first to identify critical symptoms in patients presenting with SOB and ARF. Bedside nurses and RTs are among the stakeholders that influence the decision to make changes, as these providers are tasked with monitoring patients for an extended period of time. Collaboration between bedside nurses and RTs was a vital component of the decision to implement the use of NIV to improve patient outcomes. This QI project included both men and women between 20–65 years of age who presented to the hospital with symptoms that included
SOB and were diagnosed with ARF. Once the etiology of ARF was determined, NIV was implemented if deemed necessary for appropriate patient care.

Analysis

Patients diagnosed with acute respiratory illness were included in this QI project. The etiology of the illness was determined, together with information related to inclusion criteria and the use of NIV. The findings were collected and recorded in an Excel document that included initial signs and symptoms, respiratory rate, heart rate, blood pressure, and arterial blood gas (ABG) values together with the ratio of pO\textsubscript{2} to FiO\textsubscript{2} (P/F ratio) measured before the application of NIV (Ornico et al., 2013; Osadnik et al., 2017).

Patient vital signs, laboratory values, and demographics were also recorded, together with activities, responses, and outcomes to interventions as shown in Figure 2.

Figure 2.

The NIV was implemented only in patients that met the inclusion criteria for its use that were based on age, underlying etiology, baseline vital signs, and ABG values. The specific inclusion criteria were as follows:
(1) Patients presenting with ARF with pO$_2$/FiO$_2$ (P/F) ratio <200 (Liu et al., 2016)

(2) Patients post-extubation with a respiratory rate greater than 30/min with labored breathing, PaO$_2$ <80 mmHg but >60 mmHg, pCO$_2$ >45 mmHg, tachycardia, hypertension

(3) Patients diagnosed with ACPE with current heart failure, tachypnea with a respiratory rate of 25/min or greater, and hypoxia with an oxygen saturation of <90% (Berbenetz et al., 2019).

(4) Patients diagnosed with COVID-19 with a P/F ratio of <150 and an O$_2$ sat. < 92% (Camarota et al., 2021).

(5) Patients with hypercapnic ARF without COPD and ABG pCO$_2$ >45 mmHg (Faqihi et al., 2021).

(6) Patients diagnosed with a COPD exacerbation and hypercapnia (pCO$_2$ >45 mmHg and a pH <7.35–7.45 (Osadnik et al., 2017).

Once NIV was initiated, the ongoing need for this treatment was reassessed based on follow-up measurements of vital signs, ABGs including pO$_2$ and FiO$_2$, and the P/F ratio, as well as the patient’s general condition (i.e., degree of arousal and compliance). If patient's clinical condition or any of the aforementioned values deteriorated within the previous 4–48 hours, endotracheal intubation and IMV was initiated (Bellani et al., 2017; Berbenetz et al., 2019; Cabrini et al., 2019; Camarota et al., 2021; Faqihi et al., 2021; Frat et al., 2018; Liu et al., 2016; Ornico et al., 2013; Osadnik et al., 2017).

**Ethical Considerations**

This QI project addressed ethical considerations by seeking approval from the University of Texas at El Paso Institutional Review Board (IRB). The required training for conducting human subjects research, intervention, or interaction was completed. A QI project application
was submitted to the IRB committee for review and approval. Among the ethical considerations were the inclusion criteria. Our study included patients who presented with ARF with or without hypoxia, including patients diagnosed with COVID 19, COPD with exacerbation and hypercapnia, hypercapnic respiratory failure, and ACPE as well as those patients who were extubated after being on mechanical ventilation support.

The IRB also performed a risk assessment and evaluated our risk management procedures and risk/benefit ratio. The IRB concluded that patients involved in the study [1809424-2] were not at risk as NIV is currently used as a treatment for respiratory compromise. There was no possibility of coercion or undue influence associated with this project. There was also no possibility that the patient data could be compromised as the findings were collected in real-time and became part of the permanent documentation in the patient’s electronic health record. Identifiable data were available to others involved in this QI project including the work supervisor.

**Results**

The QI project enrolled 14 patients who met the criteria for inclusion, including both females and males between 45–65 years of age. All patients presented with the chief complaint of SOB and were diagnosed with ARF. Each patient was evaluated for inclusion based on the aforementioned criteria and baseline measurements were documented. NIV was initiated immediately for all qualified patients. Among the results, two of the 14 patients that were included in this QI project were eventually intubated due to clinical deterioration. One patient who was placed on NIV after extubation was re-intubated 24 hours later due to ARF. Another patient was intubated due to a deterioration in clinical status from values collected at baseline. The other 12 patients tolerated NIV and were eventually transitioned to a less intensive mode of
oxygenation. Overall, our data reveal that only two (14%) of the 14 patients in our cohort ultimately required intubation for ARF. By contrast, 12 (86%) of the 14 patients who would have required intubation in the absence of NIV required no additional ventilatory support.

**Discussion**

**Summary**

The quality improvement project identified an increasing need for NIV versus IMV in a cohort of patients who presented to the hospital with a chief complaint of SOB. The most current evidence focused on the use of NIV was collected as part of a meticulous literature review. Methods used to document the efficacy of this intervention included monitoring of patient’s vital signs as well as frequent evaluation of ABGs and the calculated P/F ratio (Liu et al., 2016; Berbenetz et al., 2019; Bellani et al., 2017; Cabrini et al., 2019; Camarota et al., 2021; Faqih et al., 2021; Frat et al., 2018; Ornico et al., 2013; Osadnik et al., 2017).

**Interpretation**

Results of the mentioned QI project revealed that the appropriate use of NIV can eliminate the need for intubation in 86% of the patients enrolled in our study. While ARF may result from several different etiologies, the results indicate that, when initiated early, the use of NIV can eliminate the need for intubation in most cases. The design and implementation of this QI project did not permit me to evaluate other patient outcomes such as length of hospital stay or overall mortality.

**Limitations**

Various limitations were identified during the implementation of this QI project. One limitation was that the number of stakeholders involved in this study was very limited due to staffing and/or time constraints. Furthermore, the two nurses involved in implementing this
project noted that this option was not cost-effective for the patients because we were required to collect blood and process numerous laboratory studies. These tests were performed based on recommendations in the relevant literature, although they may not have been fully necessary given our ultimate decision parameters, which was initial or continued use of NIV or intubation and initiation of IMV. In real-life practice, the success or failure of NIV frequently required rapid decision-making and responses (i.e., one to two hours).

In some cases, it was not possible to collect arterial blood for ABG measurements due to variations in the patient’s anatomy and the skill-set of the individuals asked to perform the blood draw. Other issues included the upper age limit which was set at 65 years. During the timeframe of the QI project, many of the patients who presented to the hospital with SOB who were diagnosed with ARF and treated with NIV were older than 65 years of age and thus not included in our patient cohort.

**Conclusion**

ARF can lead to severe illness, including ARDS and death in the absence of timely and appropriate treatment. My findings support the use of NIV as an important and versatile option for the treatment of ARF, including that associated with COVID-19. NIV is an effective strategy that can be used in an acute care setting to treat ARF in patients presenting with COPD exacerbation or cardiogenic edema. Current literature demonstrates the efficacy of using NIV including better patient outcomes, decreased hospital stay and decreased mortality rate (Baja et al, 2014)
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