Cuirass Therapy

A Clinical Summary | Metric Technologies Corporation | Talon Jones MD, Harvey Hawes MD

November 17, 2020

INTRODUCTION

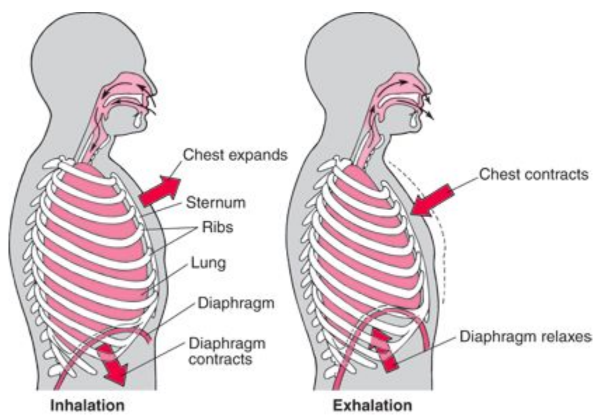
In the past fifty years, negative pressure ventilation (NPV) has become increasingly rare in the clinical setting with positive pressure (PPV) methodologies taking the lead in the management of respiratory failure(1). This is not necessarily from a history of literature proving it to be inadequate or inferior by comparison, but rather an aversion from therapy since the 1960s. Historically NPV units were large and cumbersome, and limited patients mobility and quality of life. No example exemplifies this quite as clearly as the iron lung utilized before the eradication of polio(2). NPV does come with certain limitations that PPV is able to manage, including the ability to provide extensive pulmonary hygiene, aspiration protection and oxygen supplementation for hypoxemic respiratory failure.

The Cuirass system is perhaps the most modern of the NPV systems. Its mobility, comfort and ease of use make it a particularly appealing option(2). However, the evidence for cuirass ventilation is limited at this time. Studies are small, with prospective designs being limited by the severity of respiratory failure, and the ethical limitations of randomization with life saving therapy. Regardless, the evidence that exists is promising, and shows an alternative therapy to PPV that is more cost efficient(3), easier to apply(4), carries hemodynamical physiological advantages(5), and carries a theoretical decreased risk of aerosolization. There could be developed protocols for this device to be used outside of formal clinical settings, potentially liberating valuable and limited clinical resources, allowing for greater access to respiratory support in a more equitable manner.

Furthermore, in light of the COVID-19 crisis, clinicians are rapidly seeking alternatives as infrastructure and resources become exceedingly expensive and scarce. Typically, in the critical care setting, PPV and endotracheal intubation requires a high level of skill that many clinicians do not routinely practice. As more and more physicians are asked to step outside of their specialty training area and into critical care in the face of COVID-19, safer alternatives for managing respiratory failure are needed. This is without even mentioning the user-independent risk of increased aerosolization of viral pathogens in COVID positive/suspected patients with PPV.

PHYSIOLOGICAL ADVANTAGE

Normal respirations exploit a negative transthoracic pressure gradient throughout inspiration. As the volume of the thorax is increased the intrathoracic pressure drops to subatmospheric. Air flow moves down the concentration gradient from the upper airways to the alveoli, facilitating gas exchange. This pressure gradient, in normal breathing, is created by the actions of the inspiratory respiratory muscles, the diaphragm and intercostals. As these muscles contract, the rib cage is expanded, and the abdomen compressed, increasing the volume of the thoracic cavity. The lungs, coupled to the chest wall, expand, and air is inspired through the glottis. Exhalation, the second phase of respiration, can be passive or active in nature. Initially, relaxation of the inspiratory muscles allows the system to return to its resting state, with expiratory muscle recruitment subsequently driving out air from the lungs as the thoracic volume drops below the resting state.



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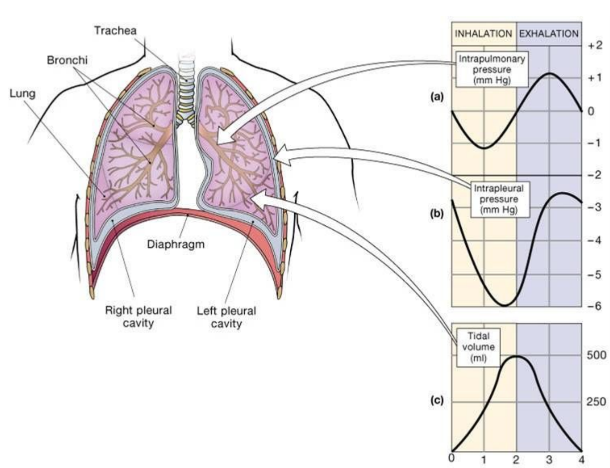

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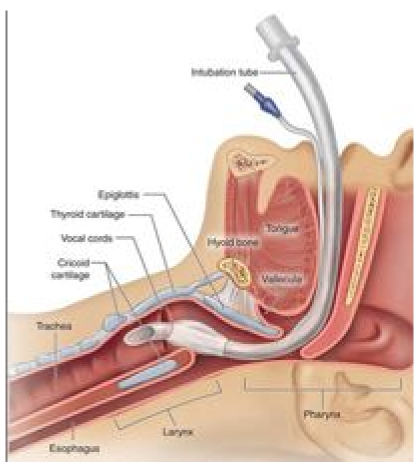
Positive inspiratory pressure, that is, air forced through the glottis via a ventilator, is not a physiological process and the body reacts as such. Barotrauma and oxygen toxicity from persistently high FiO2 values, are just two of the variables that can lead to ventilator associated morbidity and eventual ARDS (6). As patients become more alert and sedation is reduced, positive pressure becomes uncomfortable and patients begin to resist the ventilator - a process called ventilator dyssynchrony. Further, with disuse the diaphragm is susceptible to atrophy similar to other muscle groups (7). There are other cardiovascular physiologic consequences of positive pressure ventilation such as a decrease in venous return to the heart, thereby decreasing possible cardiac output. Cuirass ventilators reduce intrathoracic pressure and therefore right atrial pressure, creating a gradient to increase venous return.(5) Shekerdemian et al. proved that in pediatric patients post-cardiac surgery, conversion of PPV to NPV increased pulmonary blood flow and stroke volume, augmenting cardiac output (5,8).

Intubation and extubation, the insertion and removal of breathing tubes through the glottis, carry high risk complications including loss of airway control and death, and exposure events to pathogens such as bacteria, fungus and viruses - both for patient and healthcare staff. With respect to Covid-19, endotracheal intubation and extubation are considered the greatest risk of transmission of disease from patient to healthcare staff. Endotracheal tubes are directly irritating to the upper airway and larynx stimulating a cough reflex on extubation.



https://www.jems.com/2008/01/01/intubation-101-what-do-what-ca/

This extends further to non-invasive positive pressure ventilation. CPAP and BiPAP are becoming increasingly more available and early adjuncts. However, forced air generated by these machines can aerosolize respiratory secretions and increases the risk of pathogen inspiration by care-givers. Fortunately, no endotracheal device is required for the initiation of therapy with NPV, minimizing the direct exposure of clinicians to airborne pathogen particles.

It should be noted that there are potential complications from NPV as well, with common complaints being musculoskeletal pain, and a theoretical risk of aspiration mediated by effects on the lower esophageal sphincter.

CLINICAL APPLICATIONS

It is important to remember that NPV is not a substitute for PPV, however there are disease processes that could benefit from NPV as an alternative to PPV. There is likely a role for NPV to be included in a holistic ventilatory strategy for patients with acute and chronic respiratory failure, especially in children. Finally, there are also probably disease processes, and potentially performance enhancing strategies unique to NPV, though literature support is currently lacking.

Thus cuirass therapy could be indicated for:

(i) Primary Respiratory Disease/COPD

Physiologically, COPD patients are at a disadvantage from a pulmonary mechanics perspective. As an obstructive airway disease that predominantly impacts the expiratory phase of ventilation, these patients trap air leading to significant auto-peeping, hypoventilation and subsequent acidosis(9). In the COPD population, cuirass ventilation has been shown to aid respiratory muscle weakness, improve both short term and long term acidosis (9), and assist secretion clearance (1). These cases/studies predominantly used intermittent NPV for short durations using a cuirass ventilation system. Overall residual volumes decreased, airway pressures improved, and intercostal/diaphragmatic contraction was more efficient leading to less muscle fatigue (9,10).

(ii) Adjunct to PPV

PPV does not come without its own inherent risks and complications, some of which can be mitigated by NPV. Long-term PPV leads to significant ventilator dependence, oxygen toxicity, barotrauma, diaphragmatic atrophy and aerosolization exposure through trach/tube changes and pulmonary hygiene (6,7). The goal is always to wean from ventilation as quickly as clinically appropriate, however dependence can sometimes be a significant burden (7). Cuirass NPV's non-invasive nature mitigates much of the morbidity associated with PPV weaning, by allowing the respiratory muscles to gradually improve their strength while still providing adequate ventilation. Positive pressure can be weaned more aggressively, as the biphasic nature of Cuirass ventilation aids cardiac output and oxygenation without the need for high levels of PEEP (6). Further studies have shown that patients with NPV bridge to extubation faster, more comfortably, and are able to mobilize earlier, thereby mitigating patient and caregiver anxiety, all while hastening physiological recovery.

Endotracheal tube (ET) intubation requires appropriate planning and an advanced skill set prior to procedural attempt. Multiple failed attempts to intubate leads to airway trauma and resulting edema that can further exacerbate intubation difficulties. This is particularly evident with intubation in the field with the emergently decompensating airway. Studies have shown that cuirass systems can be applied more quickly by physicians regardless of comfort and expertise, and with fewer complications(4). Further, cuirass systems have shown promise as a bridge therapy when a team is planning endotracheal intubation, but more advanced planning and additional time are needed to ensure safety of ET tube placement. In the trauma literature, where inertia and time are two of the leading barriers to survival, a safe, effective and rapid means of ventilation could be the difference between rapid and hindered transport.

(iii) Acute/Chronic Neurological Respiratory Muscle Weakness

Neurological respiratory disease poses a uniquely different set of issues than primary respiratory failure. Multiple sclerosis, polymyositis, muscular dystrophy, and central alveolar hypoventilation syndrome patients cannot generate enough diaphragmatic contraction to circumvent atelectasis or clear secretions. With the pathologies being primarily neurological, lung compliance is typically unaffected, and upper airway protective mechanisms are intact (1).

In the acute respiratory failure setting it is likely these patients will still require intubation and PPV. As these patients are weaned from PPV, they are typically too weak to generate a strong enough cough to clear secretions and adequate tidal volumes independently. With biphasic external Cuirass devices this can be circumvented, and assist with weaning earlier and more comfortably (1).

In the more chronic setting, evidence shows that patients maintained on NPV intermittently at home typically do better longitudinally with decreased episodes of acute respiratory decompensation if they are initiated on intermittent nocturnal NPV earlier in their disease course (1,3). Less time in hospital translates to decreased expense on the health care system. Further, cardiac/thoracic surgery patients with injured phrenic nerves typically require ventilation support at home as they rehab from injury (11). Certain evidence has shown that cuirass biphasic devices can assist with ventilation during these months. Finally, patients with Bilateral Idiopathic Diaphragmatic paralysis on intermittent ventilation have shown to improve forced vital capacity (FVC) and functional residual capacity (FRC) in as little as two weeks, in addition to subjective improvements in functional symptoms such as dyspnea, orthopnea and ability to perform daily activities (12).

(iv) Pediatric Respiratory Failure

Respiratory failure is the most common reason for intensive care admission in the pediatric world especially within the first two years of life. Typically respiratory failure in infants and toddlers is secondary to infectious causes. Cuirass based negative pressure ventilation has appeared to be a relatively safe and effective alternative to positive pressure therapy (6). In 2017, Hassinger *et al.* showed that up to 70% of children ventilated via negative pressure did not require more advanced airways measures, with a relatively low complication rate of 3%. Those patients that failed NPV therapy typically failed early in their clinical course with more severe respiratory distress similar to their adult counterparts (13). In 2020, Nunez *et al.* validated these findings further with similar NPV success (69%) and complications (<2%)(13,14).

ACCESS

Globally, access to critical ventilatory support is limited. Constraints in education, infrastructure, cost, technological and human resources all significantly burden the ability to deliver intensive respiratory care. Positive pressure ventilators require high amounts of compressed oxygen, critical care/anesthesia trained clinicians, respiratory therapists, cardiac monitoring, in addition to consumable products. In a survey of over 800 hospitals operating in low resource settings conducted through the World Health Organization, only 59% of those surveyed had reliable continuous electricity (15), nevermind the aforementioned more advanced resources. In 2017, The World Federation of Societies of Anesthesiologists Reported that 43 countries were found to have less than one anesthesiologist per 100,000 people (16).

Focusing attention to Western Africa, critical care is expanding with particular emphasis on large urban areas, however rural communities are still vastly under-resourced. Comparing crude mortality rates against North America, the difference in resources, training, and infrastructure is clear with an estimated 9.3% mortality rate in North America versus 32.9% and 50.4% in Nigeria and Ethiopia respectively (17–19). In 2018, Lalani *et al.* reviewed mortality rates at two National Referral Hospitals in Wstern Kenya. Their retrospective cohort showed that ICU mortality was 53.6%, with stroke (aOR 8.14), vasopressor therapy (aOR 7.98), and acute respiratory failure/mechanical ventilation (aOR 6.37) showing the highest adjusted odds of mortality (20). Expanding to the pediatric world, RSV lower respiratory tract infections are a common problem in Kenya. A problem that patients are not always presenting to hospitals for, whether it be cost, access or cultural reasons (21). Regardless, there is already a large referral burden that stresses hospital resources. In Kifili, Kenya, the rate of presentation to hospitals for RSV was nearly double if the patient's family lived close to the hospital (21 vs 11 per 100 cases) (22). As access, education and socioeconomic development improves it is likely that patients are even more likely to access health services further stressing resources. With limited financial and clinical resources low cost respiratory support devices will be needed to help mitigate the infrastructural burden.

These global concerns are felt within North America as well. Vulnerable, remote, and marginalized populations suffer from socioeconomic disadvantages that have historically created inequities in care. Remote regions are limited by both material and human resources, restricting the level of medical intervention that some of our most marginalized populations can receive in both acute and chronic settings. These populations are some of our most susceptible especially in the context of COVID-19, with a high rate of confounding medical issues (hypertension, obesity, older age, smoking). Positive pressure ventilators carry a heavy expense both financially and in terms of resources/training, a cost that many rural communities cannot afford economically or in terms of human resources.

With so many hurdles to overcome and the constant threat of the COVID-19, low resource environments require sustainability within achievable means using simple, low cost, energy efficient, user-friendly devices that can be introduced and maintained in these limited conditions, without sacrificing safety. A cuirass device would help mitigate issues with access, cost, lack of critical care physicians/RT's, human resources, and extent of clinical knowledge. They require less monitoring, and given their relative ease of use, clinicians and nurses of a wide variety of backgrounds could develop clinical comfort quickly. Cuirass devices provide a low cost alternative that has the potential to alleviate the historical inequity of respiratory care both globally and to our most remote settings within North America.

CONCLUSION

As COVID-19 cases continue to rise globally, clinicians must turn to alternatives that save cost, preserve resources, avoid hospitalizations, and minimize risk to health care professionals. With its wide potential respiratory application, shallow learning curve, mobility and non-invasive nature, Cuirass ventilation poses a low risk-high reward alternative therapy that has the potential to avoid life-threatening respiratory failure, and ease the burden of global disease.

APPENDIX

A cuirass is considered an FDA Class II Device, though may only need to prove it is substantially similar to a previous device. Might even be easier as most NPV devices could pre-date the 1970's exemption, though expert consultation is needed.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=868.5935

https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k#se

In Canada, a cuirass is considered a Class 3 Device.

https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-industry-keyword-assist-manufacturers-class-medical-devices.html

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