features

home :: features

A New Paradigm for Respiratory Support and Treatment

Utilizing the United Hayek RTX ventilator and biphasic cuirass ventilation

By Carmen Brango RRT and Gary Mefford RRT

04.25.11

PRINT MAIL

Biphasic Cuirass Ventilation (BCV) is not new to the medical field. It has been used to treat patients with nearly all forms cardio-pulmonary illnesses requiring ventilator support and airway clearance treatment for some time. BCV is only relatively new to the way we practice respiratory therapy and provide ventilator support in the United States. BCV has been in Europe for more than ten years and Japan for nearly as long. It has been FDA approved for use in the U.S. for the last two and a half and is only recently beginning to see much clinical use here.

BCV is unique in that it is the only mode of ventilation that is non-invasive with an active expiratory phase. This makes Biphasic Cuirass Ventilation the mode of choice to deliver ventilator support in a more natural manner. The United Hayek RTX is the only device capable of providing BCV. It works using this unique technique and allows patients to be ventilated without the use of a mask, ET tube or trach. A light and flexible chest cuirass is sealed against the anterior chest wall. A negative pressure is generated within the cuirass to effect inspiration or continuous inspiratory assistance.

The device can then apply a positive pressure within the cuirass to induce and facilitate exhalation. This positive expiratory pressure means that expiration is an active phase in the respiratory cycle making the Hayek RTX particularly efficient at CO2 clearance. It's ability to provide a strong mean negative pressure makes it very effective at supporting lung recruitment and oxygenation. This highly physiologic means of support also provides improved cardiac function as well. BCV can be applied via 11 sizes of cuirass that fit patients from less than 1 kg up to 170 kg.

The pressure applied within the cuirass acts uniformly over the thorax. Subsequently, lung expansion is also uniform ventilating all areas of the lungs. In positive pressure ventilation (PPV) the gas pushed into the lungs inflates via the pulmonary path of least resistance creating a situation in which ventilation occurs most readily in highly compliant areas. Application of adequate pressures and volumes to aid ventilation of the less compliant areas of the lungs is well known to often be the source to barotrauma, volutrauma, and decreased cardiac output.

These complications, along with those of ventilator associated pneumonia, and the well-known side effects of placing and maintaining an artificial airway and many others do not occur with the use of BCV as a means of pulmonary support.

BCV can serve as a standalone means of noninvasive support in situations where BiPAP or CPAP might be used without the often poorly tolerated facial mask interfaces. BCV can frequently be used in place of PPV. This eliminates any potential of ventilator associated pneumonia (VAP) and other well documented side effects of PPV via artificial airway. BCV can be used in place of vest and cough assist type devices with better tolerance and clinical results.

BCV in conjunction with PPV is used as an aid to weaning, for lung protection, to improve oxygenation, improve lung compliance, increase right ventricular function, aid in expansion of atelectatic areas, and as a means of increasing ventilation when PPV setting limits have been reached.

BCV has been successfully used on patients with:

- Acute Respiratory Failure
- ARDS
- Chronic Obstructive Pulmonary Disease (COPD)
- Pulmonary Artery Hypertension
- Cardiogenic Pulmonary Edema
- Small airway diseases

- Neuromuscular (e.g. SMA, Duchennes, Ondines Curse etc)
- Head and Spinal Injuries
- Problems with Weaning from PPV
- Ventilation during anesthesia in Ear Nose and Throat (ENT) Procedures
- Cystic Fibrosis (CF), and those who require chest physiotherapy
- Aids Related Lung Disease
- Asthma
- Ventilation post cardiac surgery i.e. post-coronary bypass, Fontan, Fallot reapair

Modes

Continuous negative pressure (CNEP): Used in conditions with increased work of breathing, small airways disease, V/Q mismatching, for safe prolonged lung recruitment and patients who may tire easily post extubation. CNEP helps improve right ventricular function, especially when used in conjunction to PPV.

Control Mode: This mode provides full control over the patient's respiratory cycle.

1. Mandatory respiratory rate is set and delivered. This is a unique function of the Hayek RTX as it mimics physiological intrathoracic pressure swings of natural respiration.
2. Controls both inspiratory and expiratory phases and allows control of I:E ratio. Control Mode can provide significant elevation in alveolar minute ventilation without the negative effects on cardiac output and the risk of barotrauma from PPV. The pressure swings in Control Mode also provide an increase in cardiac output in low CO states, particularly those associated with anomalous cardiac flows and post op repairs. Patients that have a poor cardiac output response to PPV will generally not have problems with BCV.

Secretion Clearance: Indicated for atelectasis, or retained pulmonary secretions.

Vibration mode: This mode shakes, thins and advances secretions to the large airways at frequencies from 240-1200 cycles per minute with true high frequency chest wall oscillation. Vest type devices use chest wall percussion, which is not as well tolerated by many.

Cough mode: Provides a long deep inspiration followed by a sharp short exhalation mimicking a good cough. The patient can time huff and cough maneuvers with timing of machine for increased expiratory cough flows facilitating expectoration or RTX will provide strong pseudo cough for passive patients.

Cost effectiveness

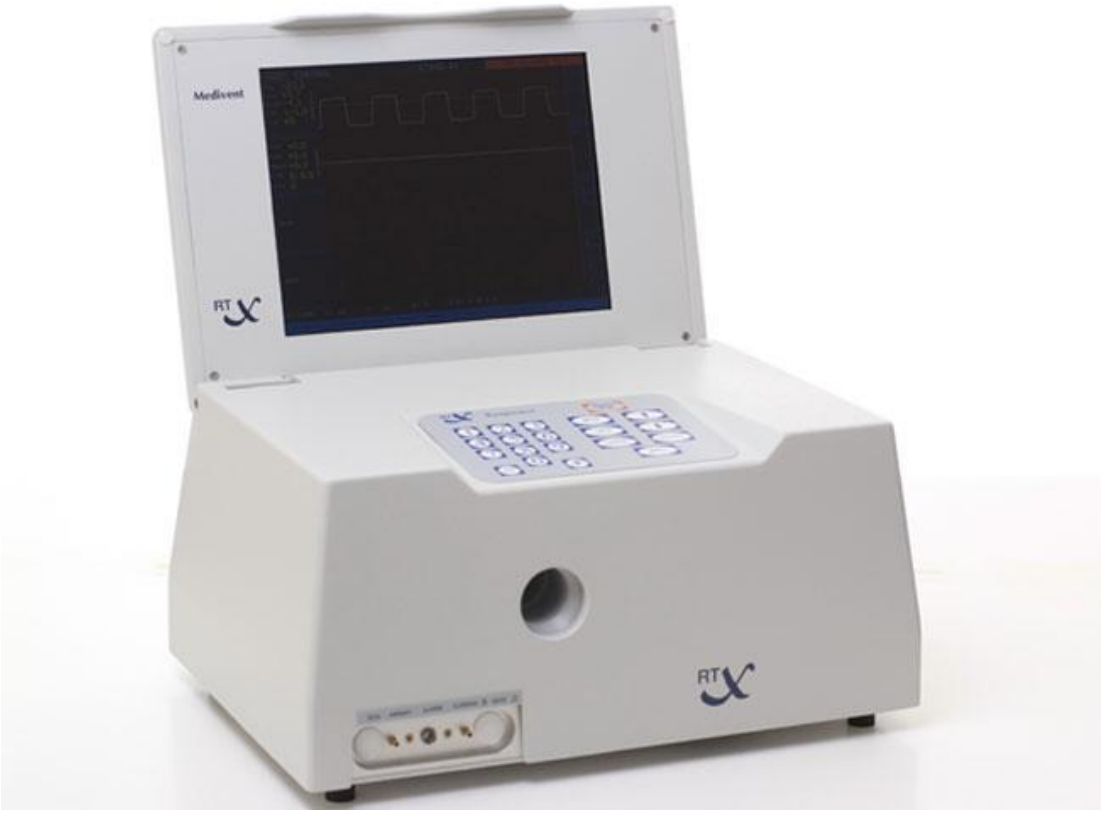
When doing a cost analysis for Biphasic Cuirass Ventilation as compared to other forms of invasive and non-invasive ventilation the most significant savings will be recognized when the comparison is done considering the areas and patients that produce the greatest costs. Hospitals receive the same DRG payment from Medicare for stays that vary in length and in services provided. This and the considerations of the new reimbursement paradigms of healthcare reform gives hospitals an incentive to avoid unnecessary costs in the delivery of care.

The area's most identified when it comes to hospital costs are pretty standard throughout the U.S. in acute care facilities. They include pharmacy, infection control, disposables, and length of stay. The intensity of services required by the majority of patients receiving PPV often places them within these high cost groups. By facilitating reduction of monies spent on these four areas, strong case results for adoption of Biphasic Cuirass Ventilation as a primary method of providing pulmonary support. This shift in strategy will have the effect of reducing costs and very significantly enhancing the facility's bottom line.

To compare the Hayek RTX to other ventilators would not be an accurate comparison due to the fact that the Hayek RTX is the only device capable of delivering Biphasic Cuirass Ventilation. It is reported that the number of Americans who die each year as a result of medical errors that occur in hospitals may be as high as 98,000. Total national costs of these errors due to lost productivity, disability, and health care costs were estimated at $17 to $29 billion. In 2000, the CDC estimated that hospital-acquired infections added nearly $5 billion to U.S. health care

costs every year. The RTX offers a lower potential for error and no potential of infection compared to other means of ventilation.

Once a patient is committed to intubation and invasive ventilation a threshold is crossed into much higher cost accrual. Multiple risks are associated with the process of intubation itself including airway damage and malplacement of the ET tube. Infection risk and the additional medications and LOS associated elevates exponentially. Anesthesiologists are often required to secure an artificial airway safely. Anti-anxiety, and pain medication use increases during the intubation period. Patients then must be transferred to the ICU to be monitored.



ICU costs are highest during the first two days of admission, stabilizing at a lower level thereafter. Intubated patients are often monitored with more frequent radiological and lab studies than non-intubated patients. A ventilation strategy that offers a high potential of avoiding the need for intubation altogether will decrease the amount these very high cost patients.

When patient ventilator days are decreased pharmacy costs decrease, the risk of hospital-acquired infections is reduced and there is significant reduction in the risk associated with patient care. The potential of accidental extubation and sequeli along with many other potentials associated with endotracheal intubaton included the dreaded "Never Event" VAP are non-existent. Utilization of the pulmonary treatment and support intervention of Biphasic Cuirass Ventilation is proven to reduce these patients' ICU and overall length of stay and/or duration of invasive mechanical ventilation if required and will lead to substantial reductions in total inpatient costs.

Hospital-acquired infections occur in up to 12 percent of pediatric intensive care unit (PICU) patients. Pneumonia is the second most common hospital- acquired infection and accounts for 22.7 percent of such infections in the PICU. The primary factor for development of a hospital-associated bacterial pneumonia in all patients is invasive mechanical ventilation, which increases the likelihood of infection 6 to 21 fold. Ventilator-associated pneumonia (VAP) occurs in about 5 percent of mechanically ventilated children, and of those children who acquire VAP, almost 20 percent die.

In the adult setting when a patient arrives in the ER and presents with COPD exacerbation, CHF, and/or respiratory insufficiency non-invasive ventilation is typically the first line of defense to stabilize the patient's respiratory demands. The interface is the crucial factor in determining if non-invasive ventilation (NIV) will prevent the patient from becoming intubated. If the patient isn't comfortable with the therapy, they will not be cooperative and the therapy will inevitably fail usually resulting in intubation and invasive PPV. In a recent set of clinical trials carried out in a California hospital system, every patient that was tried on Biphasic Cuirass Ventilation said they would much rather have the cuirass instead of a mask or ET tube.

The patient group selected all had previous admissions and had been placed on other forms of NIV such as BiPAP. BCV as the first line of ventilatory support in the Emergency Room setting offers significant cost advantages over traditional ventilation via ET intubation. It also offers equally significant benefits to patients in the form of improved satisfaction of care, decreased length of stay (LOS) and reduction of sedation use that is directly associated with intubation. A decrease in morbidity and mortality rates is to be expected also. Patients who are extubated and subsequently require reintubation are known to have a marked increase in mortality and VAP rates.

BCV is a highly effective therapy for post extubation respiratory insufficiency. Hospital mortality of ventilated patients who develop VAP is 46 percent compared to 32 percent for ventilated patients who do not develop VAP. According to the centers for Medicare and Medicaid Services, the average cost of a VAP infection runs about $135,795 per hospital stay with an estimated 30,867 reported cases of VAP in the U.S. each year.

New technology to prevent VAP such as VAP bundles, the use of subglottic-suctioning endotracheal tubes and silver coated endotracheal tubes are available. However, despite numerous studies of various such interventions, there is insufficient evidence upon which to base strong recommendations, and important safety concerns remain regarding the use of some of these devices.

Most importantly, cost-effectiveness data are lacking for these device-associated VAP-preventive measures; however simply put "avoid intubation, avoid VAP". Another factor that affects VAP rates is duration of invasive PPV. BCV offers a powerful means to reduce time on PPV, ICU and overall LOS when used as an adjunct for lung protection and weaning for patients in which intubation is unavoidable. BCV is a highly proven cost reducer for these patients.

When a patient presents to the ER in severe respiratory distress the initial means of pulmonary support of choice in recent years is usually mask applied NIV or BiPAP Although great strides have been made in mask interfaces for NIV all models are ultimately found to be very uncomfortable for the patient. Patient cooperation is essential for mask NIV therapy to be successful. With the higher BiPAP pressures these patients require the mask is applied more tightly, more irritating leaks occur and patients frequently resist treatment due to their high level of discomfort.

Also the mask inflicts inability to communicate adding to anxiety and discomfort. Pressures on the bridge of the nose and elsewhere at pressure points under the mask become irritated resulting in pain and a desire to pull the system off. The result is poor compliance with the therapy. The higher treatment pressures required to treat respiratory failure and COPD successfully forced through the mask may result in stomach distention adding to patient's discomfort. The drying effect of the gas flow through the mouth and the challenges of mouth care while providing support often result in oral airway obstruction.

When using Biphasic Cuirass Ventilation, ventilation occurs more naturally with pressures coming from outside the rib cage exactly as we breathe normally, eliminating these adverse effects and increasing patient compliance with the therapy. The use of the cuirass is much more tolerable and allows the patient to communicate freely. When Biphasic Cuirass Ventilation was applied to the patients in one trial group every patient started on BCV had positive outcomes. In each of the cases BCV was substituted for BiPAP and/or re-intubation with PPV.

Prolonged mechanical ventilation (PMV) cases are often a source of high cost outlier patients for hospitals. These types of cases can frequently be avoided altogether with early use of BCV. Once a patient is committed to invasive PPV and intubation, failure to wean will eliminate any potential of full recovery of costs for that case. BCV can be used to expedite the weaning process in difficult to wean patients decreasing the risk of high costs associated with PMV. Patients requiring PMV usually require tracheostomy. These patients also have limited and more costly discharge options as their intensity of service increase. BCV does not require tracheostomy, and is easily transferred

to home or long term facility resulting is significant increase in patient options at time of discharge.

A comprehensive ventilation strategy utilizing BCV also provides the safest and most comfortable care available to your patients needing pulmonary support. Your patients will have a much more pleasant experience while going through some of the toughest times in their lives.

BCV Trails Case Studies

Near miraculous results can occur when ventilation is provided in a more natural manor. BCV is not for every patient, but most with indications will benefit. These case studies present a sampling of results that occurred primarily in one care unit in one facility over only a few days.

The most dramatic results can be expected when BCV is adopted as a comprehensive ventilation strategy and implemented long term in entire facilities. The supportive literature on BCV is replete with similar positive results for patients of a much greater multitude of conditions.

Patient 1

A 61-year-old male s/p fall with multiple traumatic injuries primarily mid-thoracic spinal fractures which had been fused and stabilized at the time of the trials, but which had resulted in significant pulmonary muscle weakness. Negative Inspiratory Force measured at -6 on first day of trial. Patient had very recently failed attempts to wean from ventilation subsequently developed a new pneumonia and had to be supported on Bi-level positive pressure ventilation via trach at 31/10. Physician requested BCV with RTX with goals of clearing retained secretions, and advancing spontaneous breathing trials.

Patient was placed on CNEP of -15 for continuous therapy and Secretion Clearance mode during routine bronchodilator neb therapy was utilized intermittently over 2 days. On initial secretion clearance treatment patient was suctioned for large volumes of creamy tan sputum, which was reported by the respiratory therapist to be the largest amount produced at any previous treatment.

Following Secretion Clearance and Cough Assist therapy patient was maintained on CNEP -15 and positive pressure vent was adjusted to spontaneous breathing mode of CPAP with pressure support 18-20. Patient was able to maintain good stability with normal vital signs and O2 saturations in the mid 90s on 35-40 percent O2. Subsequent secretion clearance and cough assist therapy after 4 hours of CNEP on day 1 had very similar results for sputum production. Day 1 trial ended after 6 hours of BCV use. Patient returned to BiLevel settings for nocturnal rest per physician direction.

Day 2: CNEP again initiated at -15. Secretion clearance and cough assist treatment applied in morning and afternoon with large volumes of sputum retrieved with each. Patient advanced to CPAP mode during first treatment. CPAP with positive pressure support was titrated to patient respiratory rate. Pressure Support averaged 15 cm through out the day with periods of only 10 cm while maintaining good VS. Radiologic interpretation for chest X-ray obtained early morning on day 2 indicated improved aeration of bilateral lung fields.

Trial was considered a success by physician as patient advanced further into spontaneous breathing trials that would not have been considered possible without BCV. Large volume of secretions cleared and radiologic improvements added to improved clinical picture that allowed patient to be moved off of Medical ICU to step down unit in preparation for long-term placement at end of day 2 trials. Day 2 trials ended after 8 hours due to goals met and patient discharging from unit.

Patient 2

A 70-year-old male patient with advanced end stage COPD who had complained about BiPAP mask as means of support.

BCV initiated with goal of providing relief of severe dyspnea without face mask interface. Upon removal from BiPAP patient was demonstrating single word dyspnea and was barely conversant sue to severe SOB. Patient had

been wearing nasal cannula under full mask BiPAP at 5 l/m with O2 saturations 90-92 percent. O2 was left at 5l/m per nasal cannula with CNEP initiated at -12.

BCV was continued for 4 hours during which time patient improved to be able to converse with greater than 5-6 words per breath, holding good conversation with multiple visitors with minimal signs of fatigue. O2 saturations improved to 95-97 percent over trial. After 4 hrs patient maintained improvement after removed from BCV trial ended with goals met.

Patient 3

An 84-year-old male patient with laryngeal cancer and right apical mass with nearly complete right lung atelectasis with mediastinal shift on AM chest X-ray. BCV initiated with goal of increasing aeration of R lung and improving atelectasis. BCV started with CNEP of -30 for 30 minutes to initiate lung recruitment. Secretion clearance treatment executed for 35 minutes with results of production of copious amounts of dark beige sputum.

CNEP resumed after secretion clearance at -20 for 1.5 hrs at which time secretion clearance and cough assist was repeated. Sputum production: large volumes of cream colored suctioned. Patient was maintained on CNEP of -28 pending follow up chest X-ray. Chest X-ray post 3.5 hours of BCV demonstrated marked improvement with complete re-inflation of R lung field. BCV trial ended. Goals met.

Patient 4

A 68-year-old male male with history of bronchitic COPD with O2 dependence and chronic ETOH abuse. S/P MVC with multiple peripheral contusions and abrasions. C-collar in place due to suspected cervical trauma, but no observable neru-muscular dissociative symptoms. Ongoing and increasing sedation required due to symptoms of significant agitation secondary to ETOH withdrawal.
Patient was extubated following good weaning indicators at 1600. At 1610 patient was showing obvious signs of impending failure and intubation equipment was being gathered to re-intubate per standard protocol.

BCV trial requested in attempt to avoid reintubation. BCV initiated shortly after 1610. Secretion clearance treatment resulted in production of large amount of tan sputum that required naso-tracheal suctioning to clear as patient would not initiate adequate cough. Sedation level required to control agitation resulted in patient being barely arousable and with very weak cough effort. At start of BCV patient O2 saturation was 92 percent on 35 percent venti mask. Following secretion clearance and cough assist O2 saturation increased to 96 percent.

Patient maintained well with good vitals with CNEP of -15 and q4 secretion clearance therapy until 0400 at which time he decompensated and required reintubation to support better suctioning and positive pressure ventilation. Goal of preventing intubation was met for 12 hours, but high levels of sedation required to control severe agitation resulted in loss of ability to maintain airway, and very weak cough which, combined with chronic obstructive process, ultimately required re-intubation.

Patient 5

A 56-year-old male with a history of morbid obesity and chronic ETOH abuse admitted with altered mental status, severe liver disease and peritonitis with possible illeus. Chest X-ray severe right lung atelectasis/infiltrates/effusions.

Patient was on positive pressure ventilation with Assist Control rate of 25, VT 500ml, PEEP 15 and O2 100 percent. O2 saturation was 80-82 percent. BCV was requested with goal of improving oxygenation. BCV was set with largest size chest shell at CNEP of -30. CNEP had to be decreased as patient's abdomen filled most of shell and obstructed connection openings at that pressure. CNEP of -20 found to work. Started at 2200.

After 14 hrs of BCV O2 was weaned to 50 percent with O2 saturation of 98 percent. Serial ABGs obtained show patient progressing throughout this time. Initial ABG at 21:26 drawn on 100 percent O2. Final ABG in sequence is drawn the next day at 10:56 on 60 percent. PaO2 initially 64.3 mmHg on 100 percent improved to 105.7 mmHg on 60 percent. Alveolar to arterial O2 difference index improved from 596.9 to 277.3 over trial period. ABG sequence follows.

Time	FiO2	pH	pCO2	pO2	HCO3	SaO2	AADO2	Time on BCV
2126	1.0	7.28	38.4	54.3	17.6	87.4	596.9	pre
0046	1.0	7.314	30.9	129.0	15.3	96.1	541.9	2hr 46 mins
0424	1.0	7.337	31.8	148.0	16.6	96.9	518.7	6 hrs 24 mins
1056	.6	7.334	34.2	105.7	17.8	95.6	277.3	12hrs 56 mins

BCV trial ended after 14 hrs with goals met.

In Conclusion

The cost benefits described although very significant pale compared to the satisfaction benefit for patients. Those who have had the previously standard methods of care are very pleased when they experience BCV as a means of non-invasive non-mask support. When patients experience resolution of their respiratory compromise more quickly and safely everyone is pleased.

For parents and other loved ones who do not have to experience the grief of having their children loose their precious little voice there is no comparison. Loss of the basic abilities of having a drink, taking nourishment and speaking can be a devastating blow to a patient and should be avoided if at all possible. BCV can provide full support of ventilation without the patient needing to suffer those losses.

BCV is a powerful noninvasive tool that can prevent intubation or tracheostomy if used early, and potentially prevent ICU admission. For patients in ICU it can decrease time on PPV and ICU LOS. BCV can be applied post ICU discharge to prevent costly readmission to ICU. If patients have chronic support or airway clearance needs the RTX can be set up in the home to keep patients healthy and out of the system post discharge. The RTX is a device that truly offers a high potential for rapid return on investment when used aggressively.

All modes are provided with a single interface of a light flexible cuirass with a soft foam seal that is totally comfortable for the patient and allows the patient to eat, drink and talk while being fully supported. When you make Biphasic Cuirass Ventilation available to your patients you will see that there is really no downside to this mode of treatment. Patients are happier about their stay and the facility will save money. Biphasic Cuirass Ventilation is a win-win situation.

— Carmen Brango RRT and Gary Mefford RRT are clinical specialists for Hayek Medical Devices. HMD is the distributor in the US and Canada for United Hayek's RTX and other medical devices. Carmen is based in Philadelphia and can be reached via Carmen.Brango@hayekmedical.com while Gary is based in Fort Worth, TX and can be reached via Gary.Mefford@hayekmedical.com.

To obtain more information on the RTX and BCV visit the website UnitedHayek.com. To obtain purchase or rental information or set up a site visit and demonstration of the RTX call 1-855 2 GET BCV.

Click here for citations for this article.