Lung Volume Recruitment: A Novel Method that Maximizes the Therapeutic Impact from MI-E Devices

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Abstract

Neuromuscular disease (NMD) refers to a group of diseases (motor neuron diseases, muscular dystrophies) that are collectively associated with progressive respiratory muscle weakness that ultimately result in a decline in vital capacity, a decrease in chest wall and lung compliance, atelectasis, an increase in work of breathing, and an impaired ability to cough. As a result, progressive neuromuscular diseases carry an increased risk of respiratory infection, respiratory failure, and mortality.[1] Non-invasive ventilation (NIV), mechanical insufflation-exsufflation (MI-E), and lung volume recruitment (LVR) have been repeatedly discussed in literature and clinical studies as critical elements of the respiratory support strategy for patients with NMD.[2,3]

This article will briefly summarize NIV's and MI-E's respective role in the respiratory support strategy for NMD and explore both the physiological evidence and clinical benefit for providing LVR. Additionally the article will discuss the primary application technique for LVR, namely breath-stacking, and analyze how this technique has been mistakenly applied to MI-E devices that operate using a pressure control (PC) mode of therapy. The article will explain why the "breath-stacking" technique does not work when attempted with a MI-E device using a PC mode. Finally the article will conclude with a comprehensive explanation of a novel approach for providing effective LVR that is based on the PC mode of operation and has sound physiologic backing.

The ultimate goal of this article is to promote use of MI-E devices in a way that facilitates the delivery of both mechanically-assisted coughing as well as effective LVR to a broad scope of patients thereby maximizing the therapeutic impact from a single home airway clearance (ACT) device.

Key Points

- Lung Volume Recruitment is used to enhance the clinical outcomes and quality of life for neuromuscular patients with respiratory insufficiency.
- A common practice is to deliver LVR using a "breath-stacking" approach with a resuscitation bag + one-way valve or a volume ventilator.
- "Breath-stacking" is unlikely to be effective when using a MI-E device with a PC mode, instead consider using the Long Slow Deep technique described in this paper.

Discussion

Ventilatory support has become a standard of care for both rapidly (ALS, SMA) and relatively rapidly (DMD) progressing neuromuscular disease as well as for chronic NMD conditions (e.g. other myopathies). For chronic NMD conditions, long term mechanical ventilation (LTMV) is the primary intervention to support respiratory muscle function extending survivability as well as improving health related quality of life.[1] NIV may provide clinical benefit by the reduction of nocturnal hypoventilation as well as the compounding effects of sleep disordered breathing (SDB) on NMD. Using NIV in addition to MI-E may delay mortality and is thought to have cardio-protective benefits in the Duchenne Muscular Dystrophy (DMD) patient population.[3] Mellies et al determined that NIV had a favorable long term effect on both nocturnal and diurnal gas exchange in patients with NMD. For non-DMD patients, NIV was associated with an improvement in vital capacity.[4]

NIV can be delivered in the form of simple bi-level therapy or using more sophisticated ventilators capable of features such as volume-targeted variable pressure support modes and mouthpiece ventilation (MPV); also termed sip and puff, for daytime ventilatory support. Volume targeted modes vary the pressure support to achieve an average tidal volume which is designed to adapt to the patient's changing ventilatory support needs over time.

For all patients, an effective cough maneuver (PCF 360-840 lpm)[5] is an essential protective mechanism against respiratory tract infections. MI-E is a mechanically-assisted therapeutic intervention designed to decrease the risk of respiratory infections that are exacerbated by progressively weakened respiratory muscles and decreased peak cough flow (PCF) values. Current clinical consensus is that PCFs <160 lpm are ineffective for cough clearance and that when peak cough flows (PCF) reach a threshold of 270 lpm in the NMD patient population, mechanical insufflation exsufflation is indicated.[6,7] MI-E therapy utilizes positive pressure to help a patient achieve a large lung volume; targeting maximum inspiratory capacity,

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followed by a rapid shift to negative pressure creating a large pressure gradient that raises expiratory flow rates to a level required to clear irritants, microbes, and secretions from the central airways.

MI-E therapy can be associated with a raise in peak cough flows of more than four times that of an unassisted cough[8] and has been shown to decrease recurrent respiratory infections.[2] In addition, MI-E therapy has been shown to prevent the need for tracheostomy.[9] Several studies have shown MI-E to decrease hospitalizations,[9,10] as well to increase survivability.[2,11,12,13] MI-E is better tolerated/preferred over suctioning and patients find MI-E therapy less irritating, less painful, less tiring and more comfortable as compared to invasive suctioning.[14]

Background on Lung Volume Recruitment

Clinical Evidence

LVR is an important therapeutic intervention. When properly administrated, LVR is associated with the mitigation and or reversal of alveolar atelectasis, improvement in lung and chest wall compliance, and aids in the assisted cough effort aimed at avoiding respiratory infections. Excerpts from clinical studies regarding LVR are summarized below:

- Implementation of LVR twice daily in a cohort of DMD patients helped maintain respiratory system compliance despite a loss in vital capacity (VC) associated with a progression of their disease.
- LVR implementation sharply attenuated the rate of VC decline from 4.5% decline per year to 0.5% decline per year and assisted PCF stability was maintained within a therapeutic range.[15]
- In the cited study, the attenuated decline in VC was observed up to 10 years while the stability in PCF was maintained for up to 8 years.
- Bach and colleagues have described a decrease in daytime ventilator use when the cohort of patients regularly used LVR (air stacking) as part of their respiratory support strategy.[16]
- Bach and associates concluded that "Noninvasive respiratory management including NIV and mechanically assisted cough (MAC) can be used to avoid respiratory failure, hospitalizations, and tracheotomy for patients with NMDs and spinal cord injury (SCI) who have functioning bulbar musculature and can be used to extubate and decannulate patients."[17]

Physiology of LVR

Animal and human studies have provided complimentary and consistent information about the physiologic mechanisms behind alveolar recruitment. Albert and colleagues performed compelling research on alveolar recruitment by creating an animal model with anesthetized and ventilated rats.[18] Both gross alveolar recruitment and microscopic alveolar recruitment were evaluated at three recruitment pressure settings: 20 cmH_2O, 30 cmH_2O, and 40cmH_2O respectively. The impact of time on alveolar recruitment was then evaluated at each recruitment pressure beginning at the baseline collapsed level at 0 seconds and extending exposure to the inflating pressure up to a maximum of 40 seconds. The majority of recruitment occurred at the recruitment pressure of 40 cmH_2O (78% gross, 85% microscopic) within the first 2 seconds of pressure delivery. Significantly less recruitment was achieved at the lower pressures of 30 cmH_2O (56% gross, 78% microscopic) and the least amount of recruitment occurred at a pressure of 20 cmH_2O (36% gross, 52% microscopic).

Breath Stacking Examples

Breath-Stacking with a Resuscitation Bag. Our resuscitation bag has a total volume capacity of 2 liters with a one-handed squeeze technique yielding an average of approximately 800 mL. Subtracting the average leak around the interface or mouthpiece during inhalation leaves us with an estimated volume delivery per bag squeeze at 500 mL. Assuming the patient can synchronize glottis opening and closing with each breath, the first breath would yield a lung volume of approximately 500 mL, while the second breath would conceptually add to the initial breath yielding a cumulative lung volume of approximately 1000 mL assuming there is no additional leak. The cumulative volume is larger than the volume of the first breath dependent upon the total amount of volume the patient could accept with the second breath ≤2 L.

Breath-Stacking with MI-E in PC Mode. By comparison, a PC mode is only set to deliver and maintain a target inhale pressure. Opening and closing the glottis in between each manual pressure delivery does not result in the set pressure being increased in each subsequent manual pressure delivery rather it will simply add or "stack" inhalation time. Increasing the amount of time spent at a target inhale pressure during the inhale phase may increase the net lung volume achieved, however a "time stacked" technique is both inefficient and limiting in its application. By requiring the patient to open and close their glottis, the technique would be limited to patients who have intact glottis control and exclude patients with bulbar weakness. Secondly regarding efficiency of the technique: multiple, manually delivered, "time-stacked" breaths are not necessary to achieve alveolar recruitment. This technique may be potentially tiring for the patients given the active inhale effort that is required, and may lead to less than optimal results when time spent at set/optimal pressure is carefully scrutinized (see Figure 1).

In 1993 Rothen et al[19] studied alveolar recruitment on anesthetized humans with healthy lungs. The study procedure started by ventilating the anesthetized patient using 40 cmH_2O, alveolar atelectasis was then established by introducing -15 cmH_2O. CT scans were used to quantify baseline atelectasis as well as alveolar recruitment following a stepwise recruitment pressure application (10, 20, 30, 40 cmH_2O) with a breath hold time of 15 seconds. 10 cmH_2O was determined to be equivalent to the subjects tidal volume, a sigh breath (VT x 2) or 20 cmH_2O sustained for 15 seconds did not significantly reduce atelectasis on CT scans. In both groups, inflation to Vital Capacity; at an inflation pressure of 40 cmH_2O, virtually eliminated any residual atelectasis; lower pressure settings did not alleviate the atelectasis.

In 1999 Rothen and associates[20] revisited the vital capacity maneuver (inflation to 40 cmH_2O) in a subsequent clinical study to evaluate the efficacy of recruitment levels and pulmonary shunting using a reduced time at recruitment pressure. In this updated study, the authors concluded that similar results could be obtained, that is virtual abolishment of atelectasis, using a pressure delivery time of only 7-8 seconds. The reduction in pressure delivery time was aimed at reducing the risk of adverse cardiovascular effects while applying the VC maneuver. This new study confirms key facts regarding LVR with the following two points: 1) 40 cmH_2O was the target inhale pressure used for the VC inflation maneuver; applying a lesser pressure for a prolonged time does not necessarily result in re-opening of more lung units, and 2) CT scans indicated nearly complete resolution of atelectasis after only 3.5 seconds.

Bach and associates[21] have described passive LVR techniques using pressure ventilators and MI-E devices, however the target inhale pressure was 50 cmH_2O or greater. It is worth considering that 40 cmH_2O represents a minimal target inhale pressure and that based on Dr Bach's work, higher target inhale pressures may be indicated in the NMD patient population.

LVR Application Techniques

LVR can be separated into two primary application techniques. The more commonly known technique is often termed "breath-stacking" associated with volume delivery whereas the second technique utilizes a pressure control mode. Breath-stacking may be delivered in its most simple construct utilizing a resuscitation bag combined with an integrated one-way valve, however breath-stacking may also be achieved using a mechanical ventilator.

1. **Breath-Stacking Techniques**

   In the resuscitation bag technique, the integration of a one way valve prevents the patient from exhaling while facilitating stacking of successive inhalation breaths; one on top of the other, thereby increasing the net lung volume achieved. The equipment is inexpensive, and the technique is relatively simple as the one way valve does not require the patient to have glottis control in order to prevent exhalation during the procedure. This technique does require that the patient is able to create a lip seal and have upper or lower limb mobility to squeeze the bag if performed autonomously, otherwise caregiver assistance and training on an effective technique would be indicated.

   An alternate method used to facilitate breath stacking is the use of a volume ventilator set to provide on demand inspiratory support while configured to avoid nuisance alarms. Breath-stacking with a volume ventilator in the home setting would require the patient to have glottis control and the ability to create a lip seal. Several home ventilators (LTV, Trilogy) are compatible with mouthpiece ventilation (MPV) where a user can be trained to breath-stack in a volume mode. Toussaint and associates[22] concluded that "air-stacking" via resuscitation bag was as effective as the same technique performed with a home mechanical ventilator.

   Regardless of the equipment used, it should be noted that the "breath-stacking" LVR technique is dependent upon the ability to deliver a fixed volume with each breath that the patient receives. In addition to glottis control, the ability to control leak, limb mobility, caregiver assistance and training are all considerations when evaluating the appropriateness of selecting breath-stacking as the choice in LVR technique.

2. **Alternative LVR Delivery Technique: Pressure Control**

   The second and possibly less commonly known method for delivering effective LVR utilizes a pressure control mode of therapy with a uniquely different technique. A pressure control (PC) mode of therapy can be found in both mechanical ventilators as well as certain MI-E devices.

   The concept of utilizing a MI-E device; such as the Philips CoughAssist 70-series, may not be completely novel to some clinicians, however the technique when using the PC mode often is. Clinicians, recognizing the value of LVR, have attempted to use a MI-E device to perform LVR by simulating the "breath-stacking" technique. In this scenario the clinician will set the MI-E device to a manual mode, set a target inhale pressure setting, and then use the toggle/foot pedal to manually deliver sequential, time variable, positive only pressures (usually three), during the inhale phase. This technique is often combined with the patient being instructed (if able) to close their glottis at the end of each manually delivered positive pressure period, then subsequently open their glottis with the start of the next manually delivered inhale phase. Unfortunately, breath-stacking in a pressure control mode is simply impossible based on the mode's mechanism of operation. While it is true that an individual with glottis control may feel as if they have achieved a large lung volume at the end of multiple, manually delivered, positive pressure phases, they simply are not stacking breaths as they would with a volume ventilator or resuscitation bag with an integrated one-way valve. In reality since the device is being used in a pressure control mode the set target inspiratory pressure does not change, and thus prevents true breath stacking.

To illustrate, we will use the resuscitation bag and one-way valve to examine first the breath-stacking technique, next we will compare that to the same technique applied to the CoughAssist MI-E device (*see Box on **Page 17 Breath Stacking** examples*), and finally we will explore a novel method for performing LVR with the CoughAssist MI-E device.

A New Proposal: The Long Slow Deep (LSD) Technique

A novel technique for LVR with a MI-E device has been developed by taking into consideration both the physiologic requirements for effective alveolar recruitment as well as the mechanism of operation when using a pressure control mode of therapy. We propose the term long, slow, deep (LSD) to describe this passive inhalation recruitment technique.

True "breath-stacking" requires a device with a preset volume delivery, glottis control or the integration of a one-way valve to prevent exhalation during the multiple inhale efforts. The LSD technique by contrast is a single, completely passive breath that is delivered using a target inhale pressure set greater or equal to critical alveolar opening pressure (40 cmH_2O)[18,19,20] and for an extended pressure delivery inhalation time period of 3-3.5 seconds[18,20] for the average adult. The LSD technique may offer several advantages for a patient that already has a MI-E device prescribed for cough therapy namely:

- No additional equipment or devices are required
- No active patient effort is required, the LSD technique is completely passive making it comfortable and not tiring for most patients
- No glottis control is required making the LSD technique an option for a broad spectrum of patients including bulbar ALS patients
- Little coordination or technique training is necessary. When combined with a triggering feature a patient simply has to be coached to completely relax (relinquishing control of the inhale phase to the MI-E device) so that target pressure may be achieved for the inhale time required for optimal LVR therapy
- At the end of the breath patients may be coached to passively

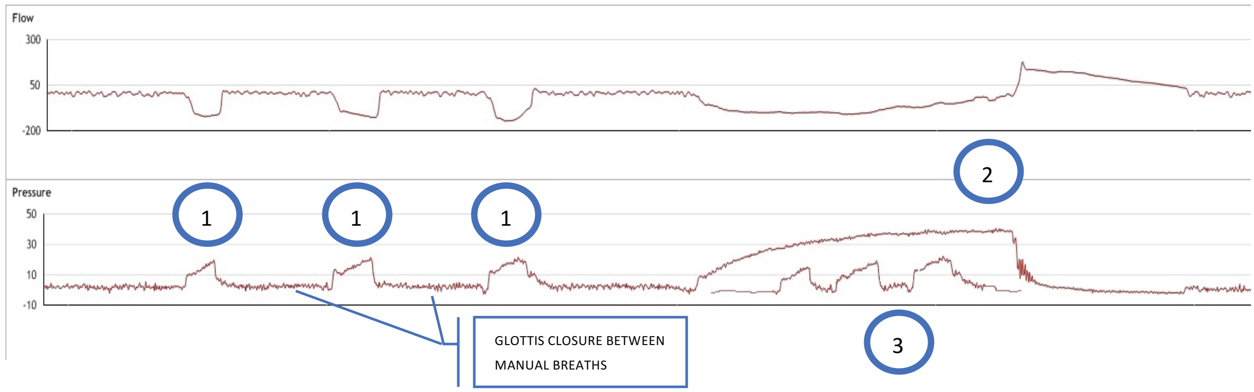

Figure 1. The pressure and flow waveforms for this model were obtained via SD card download from a CoughAssist 70-series device. The composite graphic demonstrates use of both the manual time-stacked technique (1) and followed by the single, passive inhale effort, LSD technique (2). Both techniques used a target inhale pressure setting of 40 cmH_2O and a low flow setting. Technique 1 was associated with manually delivered, variable inhale times (T_I) with each of the 3 delivered breaths, whereas technique 2 utilized a single breath with a 3.5 second T_I. Close examination of the pressure trace with technique 1 reveals failure for the manual breaths to reach target pressure — in part because each manual breath is associated with a rise time to reach the target inhale pressure setting. Technique 2 reached and maintained the target inhale pressure as illustrated by 3 where the manually assisted breaths are superimposed within the single passive breath.

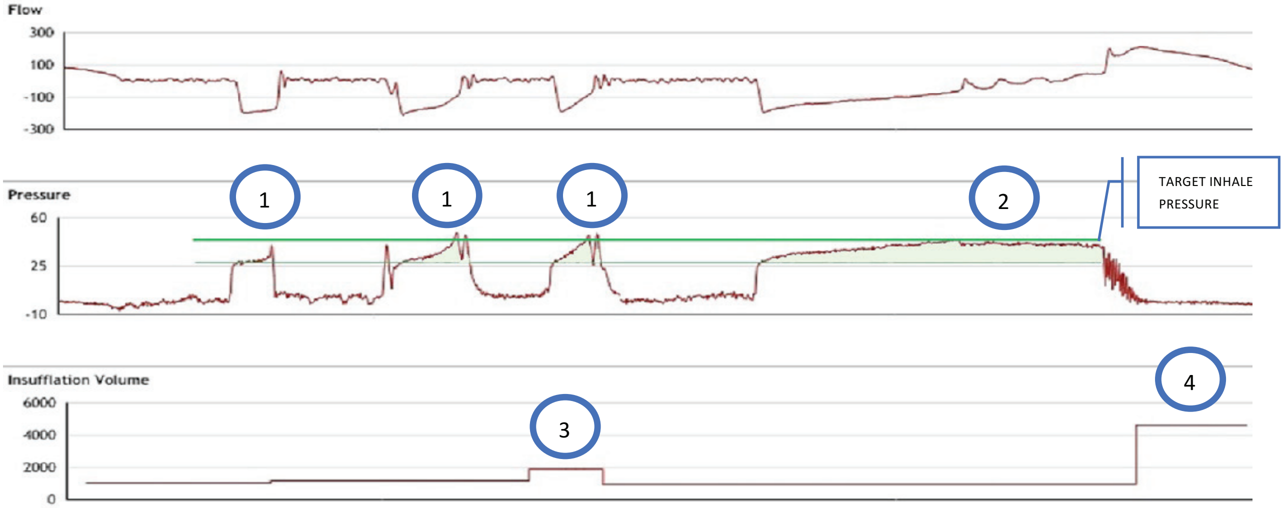

Figure 2. As with Figure 1, the pressure and flow waveforms for this model were obtained via SD card download from a CoughAssist 70-series device. The composite graphic demonstrates use of both the manual time-stacked technique (1) and followed by the single, passive inhale effort, LSD technique (2). Both techniques used a target inhale pressure setting of 40 cmH_2O, however given that the manual technique in Figure 1 failed to achieve target inhale pressure, the flow setting was changed to High. As with Figure 1, technique 1 was associated with manually delivered, variable inhale times (T_I) with each of the 3 delivered breaths, whereas technique 2 utilized a single breath with a 3.5 second T_I. In this model the manually delivered breaths did achieve the target inhale pressure setting of 40 cmH_2O. When compared to the single, passive, LSD breath (2) considerably less time was spent at critical alveolar opening pressure with the manual technique as indicated by the green lines and light green shaded area (1), (2). In addition, when comparing the device-reported VT_I trend the VT_I for the manual technique (3) was 2 L compared to 4.3L for the LSD technique (4) which equals less than half of the trended insufflation volume achieved with the single, passive LSD technique.

exhale and take a short rest period prior to performing subsequent LVR efforts (up to five) ideally repeated 2-3 times per day.

Two models were set up to graphically illustrate the differences in the two LVR techniques that utilize an MI-E device (PC mode) and underscore the advantages associated with the passive LSD technique. (See Figures 1 and 2.)

Conclusion

In this article we have briefly discussed some of the clinical benefits associated with LVR in the NMD patient population and described two different techniques for achieving LVR. The first technique involves true breath stacking with a resuscitation bag or a mechanical ventilator. This technique while useful, may require glottis control (volume ventilator) on the part of the patient and frequently requires a caregiver to squeeze the bag or manage the ventilator. The second technique relies on the use of a Pressure Control mode where both a target inspiratory pressure and an inspiratory time are set. This can be implemented using a mechanical ventilator, but very importantly can be also be initiated using a MI-E device with a pressure control mode.

The two key physiologic factors to consider when implementing LVR using the pressure control mode are:

1. target inhale pressure set at or **above** alveolar critical opening pressure of 40 cmH_2O (Bach et al ≥50 cmH_2O in NMD

subjects)
2. inhale time set in the range of 3.5 seconds (adult)

This later technique involves a single, extended, passive inflation that we have described as long, slow, deep (LSD) and should be considered by the healthcare team when a patient already has access to a MI-E device to maximize the therapeutic impact from a single home ACT device. The distinctive advantage of this technique is that the maneuver is passive and does not require patient effort other than to trigger the breath and requires minimal caregiver assistance other than to help maintain mask seal. The passive LSD technique should also be considered due to the broad patient population that may benefit from this technique including bulbar ALS patients with loss of glottis control as well as other NMD patients with intact glottis control but progressive muscle weakness.

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