4-12-2010

Evaluation of the Respironics Bipap® Auto SV and Resmed VPAP Adapt SV to Lung Simulator Generated Central and Obstructive Sleep Apneic Episodes.

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This research was also published in the December 2009 issue of the Respiratory Care Journal.
ABSTRACT

Background: Recent developments in non-invasive positive pressure ventilation have led to the production of adaptive servo-ventilation devices that examine an individual’s breathing characteristics and adjust pressure levels based on a product specific algorithm. Evaluation of two adaptive servo-ventilation devices, the Respironics BIPAP auto SV™ and ResMed VPAP™ Auto SV to lung simulator generated central and obstructive sleep apneic episodes.

Methods: Each system was adjusted to the following settings: EPAP minimum 5 cmH2O, IPAP maximum 15 cmH2O, adaptive modes, 15 breaths per minute. Each system was tested using its own brand of ventilation circuit and face mask (Respiratory Comfort Gel “Full” and Mirage Quattro). The masks were applied to a Laerdal SimMan® vented mannequin demonstrating minimal leak levels. The SimMan® was connected to a Hans Rudolph Electronic Breathing Simulator (HR1101) which generated 15 normal breaths followed by central and obstructive apneic episodes. The lung simulator scripts were constructed with the following parameters: compliance 40 cmH2O, amplitude 20 cmH2O, resistance ramped from 5 to 200 ml/sec during obstructive apnea episode and compliance 40, amplitude 0 and resistance of 0 during central apnea simulation.

Results: During simulated obstructive apnea the VPAP™ Auto SV delivered an average pressure of 7.03 cmH2O and an average VI of 200.7 ml. MaxMin pressures were 11.14 cmH2O and 5.08 cmH2O. The BIPAP™ auto SV™ delivered an average pressure of 6.41 cmH2O with an average delivered VI of 202.3 ml. MaxMin pressures were 11.38 cmH2O and 3.18 cmH2O. During simulated central apnea the VPAP™ Auto SV demonstrated an average pressure of 8.95 cmH2O and an average VI of 354.4 ml. MaxMin pressures were 14.5 cmH2O and 5.08 cmH2O. The BIPAP™ auto SV™ delivered an average pressure of 7.04 cmH2O and average VI of 206.0 ml. MaxMin pressures were 11.81 cmH2O and 3.22 cmH2O.

Conclusion: Each system responded adequately to both types of apneas however, some differences were recognized. The VPAP™ Auto SV has more clinician definable parameters and our observations were that it performed better in tests simulating central apneic episodes. We observed that the BIPAP™ auto SV™ performed better during obstructive apneic episodes. Initially the BIPAP™ auto SV™ demonstrated a long rise time and delivered smaller volumes when respiratory rate was set on “auto”, using a set rate of 15 alleviated this discrepancy.

INTRODUCTION:

Sleep disordered breathing (SDB) exists within varying patient populations and may occur secondary to a number of pathologies. The most common type of sleep disordered breathing is obstructive sleep apnea. Individuals with obstructive sleep apnea experience nocturnal upper airway closure for a minimum of two seconds per apneic episode. Individuals will experience loss of flow and typically employ paradoxical respiratory effort in an attempt to compensate. Obstructive type disordered breathing carries a number of etiologies including maxillofacial malformation, increase in adipose tissue distribution in neck and genioglossus muscle. Less common is the cause of the sleep apnea is central sleep apnea. Central sleep apnea typically presents as an intermittent lack of neurologic drive to breath.

The standard therapeutic modality for each type of apneic event is continuous positive airway pressure (CPAP) or bi-level positive pressure (BIPAP) ventilation. The nocturnal application of positive pressure to the airways acts to splint open collapsed airways. Positive pressure levels are set as a result of polysomnographic testing and are patient specific. Application of traditional CPAP or BIPAP may become less effective in more complex sleep apneas (complex SAS), a condition which includes both obstructive and central type components, as well as individuals with sleep-related hypoventilation breathing patterns. Adaptive servo-ventilation has been developed to treat these patient types.

ResMed and Respironics have each developed units which feature adaptive servo-ventilation. Each system utilizes a proprietary algorithm to provide this mode of ventilation. RespMed’s website states: “The VPAP™ AutoSV is an adaptive servo-ventilator designed specifically to treat central sleep apnea in all forms, including complex and mixed apneas. The adaptive servo-ventilation algorithm adapts to the patient’s ventilatory needs on a breath by breath basis, automatically calculates a target tidal volume (20% of the patient’s pre-sleep ventilation) and adjusts the pressure support to achieve it” (http://www.respironics.com/support/datasheets/BIPAP-autoSV.pdf).

According to Respironics’ website, “The BIPAP® auto SV™ sleep therapy system is specifically designed to be the best choice for managing complicated sleep-disordered breathing patients. It combines a number of technologies to recognize and react to changing pressure needs and it’s clinically proven to treat obstructive, central and complex apneas and hypopneas, along with periodic breathing.” (http://www.respironics.com/support/datasheets/BIPAP-autoSV.pdf)

The Respironics VPAP™ Auto SV and BIPAP® auto SV™ Respironics BIPAP auto SV™ were examined for efficacy in response to both obstructive and central apnea. Each system was evaluated on its ability to provide clinically therapeutic pressure levels, levels which may decrease airway collapse in a majority of patients. An average clinically effective pressure is 8 cmH2O for obstructive sleep apnea. Response to Central apnea was considered to be effective if an exhaled tidal volume of 500 ml or more was measured via slow-flow, breathing simulations.

METHODOLOGY:

The Respironics unit was connected to a Respironics Comfort Gel™ Full and the Resmed was connected to a Mirage Quattro. Both masks were fitted to a Laerdal SimMan® version 2 mannequin. The SimMan® was interfaced with a Hans Rudolph Electronic Breathing Simulator (HR1101) to simulate a sleep disordered breathing patient.

We programmed the HR1101 to generate both obstructive and central apneic episodes. Scripts were written for the HR 1101 with the following parameters: Obstructive apnea = Compliance of 40 cmH2O, amplitude 20, 25, 30, resistance ramped from 5 to 20, 30, 50, 200 ml/sec and then an apnea period. Central apnea = Compliance of 40, amplitude 20, 25, 30, resistance 20, 30, 50 and Rise time 0 seconds.

Each machine was set as follows: The Respironics VPAP™ Auto SV was set at: Mode ASV, EEP: 5 cmH2O, Mask: Full face, Learn Circuit, Smart Stop: off, Leak alert: off, Low pressure support alarm: off, Ramp setting: 0 minutes, IPAP max 15 cmH2O (IPAP Min 4 cmH2O), EPAP: 5 cmH2O, Pressure CGH: 0 cmH2O.

The Respironics BIPAP® Auto SV™ was set at: Mode ASV, EEP: 5 cmH2O, Mask: Full face, Learn Circuit, Smart Stop: off, Leak alert: off, Low pressure support alarm: off, Ramp setting: 0 minutes, Pressure CGH: 0 cmH2O, IPAP Max 15 cmH2O, IPAP Min 4 cmH2O, EPAP: 5 cmH2O, Apnea Setting 0 seconds.

Note: Initially the BIPAP® auto SV™ demonstrated a long rise time and delivered smaller volumes when respiratory rate was set on “auto”; using a set rate of 15 alleviated this discrepancy.

DATA COLLECTION:

The volumes and pressures that were generated by each machine were measured by the Hans Rudolph Electronic Breathing Simulator (HR1101). The Hans Rudolph 1101 lung simulator was calibrated per manufacturer’s standard calibration protocol prior to trials. Data sample size was 50 millisecond. Data points were analyzed via a Microsoft Excel spreadsheet.

RESULTS:

Baseline values during the 14 test breaths leading up to the apneic episodes

Lung Simulator Respironics Respironics
Respironics = Tidal Volume 740 ml, IPAP 14.8 cmH2O, EEP 5 cmH2O
Respironics = Tidal Volume 750 ml, IPAP 10, EPAP 5

CONCLUSION:

Conclusion: Each system delivered tidal volume breaths of at least 190 ml or larger during simulated obstructive apnea and of 100 ml or larger during simulated central apnea. In our abstract we reported averaged tidal volumes larger than actual delivered tidal volumes— we had not corrected for the elevated baseline for volume. If the comparison of performance is based on actual delivered tidal volumes then both units are comparable. When responding to simulated obstructive apnea. When responding to simulated obstructive apnea the Respironics BIPAP® auto SV™ delivered an average of 21% more volume. However, if one uses a therapeutic target for tidal volume of 200 ml both units fell below this target.

It is the opinion of the researchers that the RespMed VPAP™ Auto SV system demonstrated a greater ease of use to the clinician with a more intuitive user interface. The VPAP™ Auto SV also has more clinician definable parameters.

Initially when the BIPAP® auto SV™ was set to Auto it had excessively long rise times and delivered smaller volumes; setting the system to a rate of 15 breaths per minute, alleviated this problem. This may be of clinical importance.