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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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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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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 via a product specific algorithm. We evaluated two adaptive servo-ventilation devices, the Respironics BiPAP® auto SV™ and ResMed VPAP™ Adapt 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 (Respironics Comfort Gel ™Full and Mirage Quattro). The masks were fitted to a Laerdal SimMan® version 2 mannequin and demonstrated minimal leak levels. The SimMan® was connected to a Hans Rudolph Electronic Breathing Simulator (HR 1101) 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 simulation and compliance 40, amplitude 0 and resistance of 50 during central apnea simulation.

Results: During simulated obstructive apnea the VPAP™ Adapt SV delivered an average pressure of 7.53 cmH2O and an average Vt of 299.7 ml. Max/Min pressures were 11.148 cmH2O and 5.104 cmH2O. The BiPAP® auto SV™ delivered an average pressure of 6.41 cmH2O with an average delivered Vt of 257.2 ml. Max/min pressures were 11.8 cmH2O and 3.18 cmH2O. During simulated central apnea the VPAP™ Adapt SV delivered an average pressure of 8.95 cmH2O and an average Vt of 354.4 ml. Max/min pressures were 14.5 cmH2O and 5.08 cmH2O . The BiPAP® auto SV™ delivered an average pressure of 7.04 cmH2O and average Vt of 280.06 ml. Max/Min pressures were 11.81 cmH2O and 3.22 cmH2O.

Conclusion: Each system responded adequately to both types of apnea however, some differences were recognized. The VPAP™ Adapt 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 ten seconds per apneic episode. [1]Individuals will experience loss of flow and typically employ paradoxical type 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 hypotonia of airway musculature. [2] Less common than obstructive apnea is central sleep apnea. Central sleep apnea typically presents as an intermittent lack of neurological 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 and BiPAP therapy becomes problematic in patients who exhibit complex sleep apnea syndrome (complex SAS), a condition which includes both obstructive and central type components, as well as in patients with cheyne-stokes or other irregular 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. ResMed's website states: "The VPAP™ Adapt SV is an adaptive servo-ventilator designed specifically to treat central sleep apnea in all forms, including complex and mixed sleep apnea. The adaptive servo algorithm: adapts to the patient's ventilatory needs on a breath by breath basis, automatically calculates a target ventilation (90% of the patient's recent average ventilation) and adjusts the pressure support to achieve it." (http://www.resmed.com/us/products/vpap_sv/vpap-adapt-sv.html?nc=patients) 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 "is clinically proven to treat obstructive, central and complex apneas and hypopneas, along with periodic breathing." (http://bipapautosv.respironics.com/).

The ResMed VPAP™ Adapt 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 it's 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 electronic breathing simulator. [3]

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. following standard mask fitting practice and demonstrated minimal leak. The Laerdal SimMan ® was then 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 cmH_2O, amplitude 20 cmH_2O, resistance ramped from 5 to 20, to 50, to 200 ml/sec and then an apnea period. Central apnea = Compliance of 40, amplitude 20, 25, 0, resistance 20, 30, 50, and then an apnea period.
Each machine was set as follows: The ResMed VPAP™ Adapt SV was at set: Mode ASV, EEP: 5 cmH_2O, Mask: Full face, Learn Circuit, Smart Stop: off, Leak alert: off, Low pressure support alarm: on, Minimum pressure support 3 (default value), Max Pressure support 15 (default value). The Respironics BIPAP® Auto SV™ was set at: Breath per minute 15, I time: 2 seconds, Rise time: 5, Ramp setting: 0 minutes, IPAP max 15 cmH_2O ,IPAP Min 4 cmH_2O, EPAP: 5 cmH_2O, Apnea Setting 0 seconds.
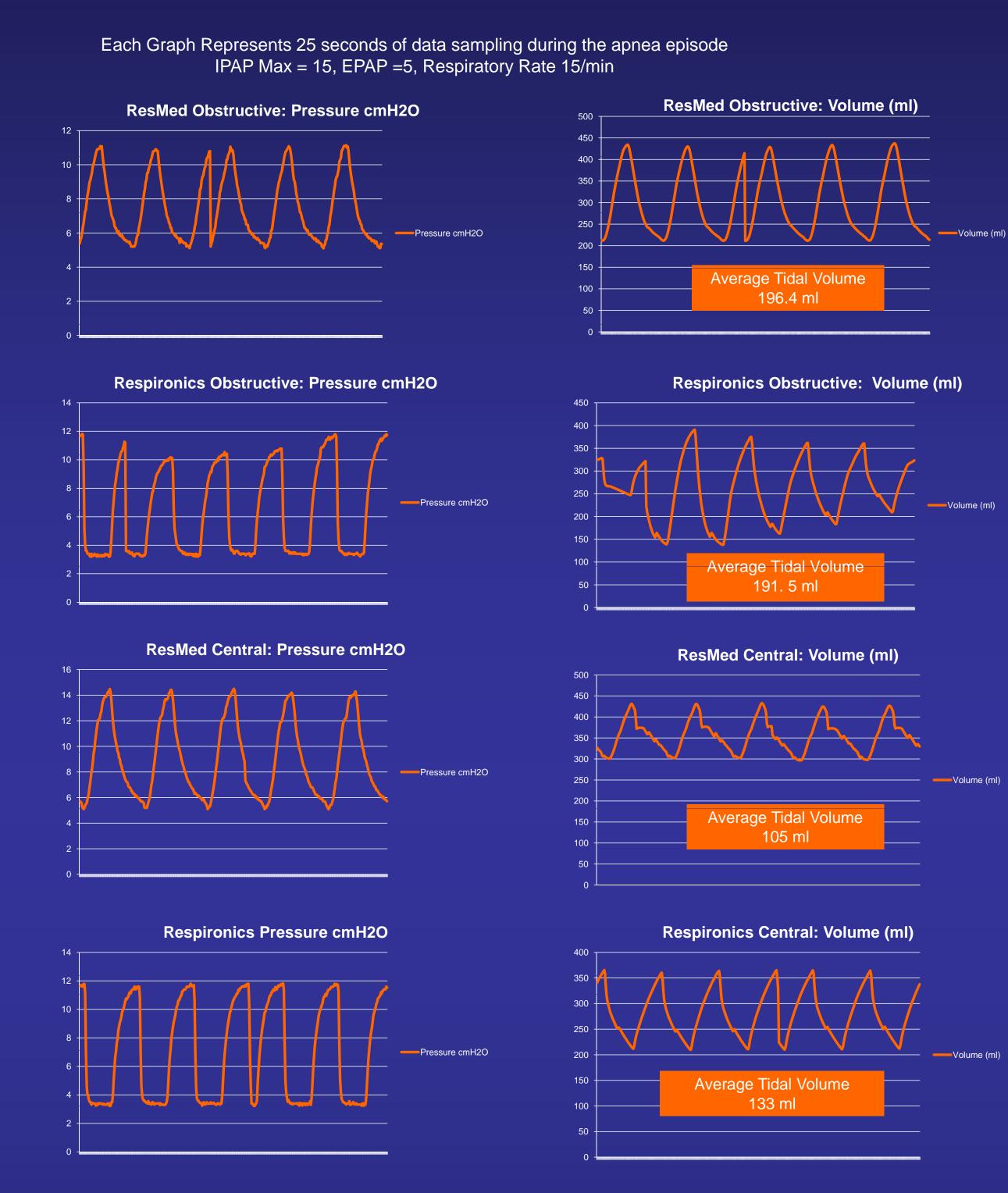
Note: Initially the BiPAP® auto SV™ demonstrated a long rise time and delivered smaller volumes when respiratory rate was set on "auto"; using a set rate of 15 alleviated this discrepancy.

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 process prior to trials. Data sample size was 50 milliseconds. Data points were analyzed via a Microsoft Excel spreadsheet.

RESULTS:

Baseline values during the 14 test breaths leading up to the apnea episodes
Lung Simulator: Resistance 5, Compliance 40, Amplitude 20:
ResMed = Tidal Volume 740 ml, IPAP 14.8 cmH2O, EEP 5 cmH2O
Respironics = Tidal Volume 750 ml, IPAP 10, EPAP 5

Each Graph Represents 25 seconds of data sampling during the apnea episode
IPAP Max = 15, EPAP =5, Respiratory Rate 15/min

ResMed Obstructive: Pressure cmH2O

ResMed Obstructive: Volume (ml)
Average Tidal Volume 196.4 ml

Respironics Obstructive: Pressure cmH2O

Respironics Obstructive: Volume (ml)
Average Tidal Volume 191. 5 ml

ResMed Central: Pressure cmH2O

ResMed Central: Volume (ml)
Average Tidal Volume 105 ml

Respironics Pressure cmH2O

Respironics Central: Volume (ml)
Average Tidal Volume 133 ml

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 central 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 ResMed VPAP™ Adapt SV system demonstrated a greater ease of use to the clinician with a more intuitive user interface. The VPAP™ Adapt 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 set rate of15 breaths per minute, alleviated this problem. This may be of clinical importance.