A Novel Active Airway Humidification Technology (RespirAq®) for Invasively Ventilated Patients: A Feasibility Study

M. Moylan[1], R. Martynoga[2], D. McCormack[2], H. Cunningham[1], S. Grau-Bartual[1];
[1]Auckland University of Technology, Auckland, NZ, [2]Waikato District Health Board, Hamilton, NZ.

Introduction

Additional humidification is necessary to prevent hypothermia, disruption of the airway epithelium, bronchospasm, atelectasis, and airway obstruction when patients are ventilated.

The RespirAq humidifier is an active heated humidifier that humidifies without the need for additional water (Figure 1). Within 100 milliseconds, the humidifier can switch between a super-hydrophilic state to capture moisture during expiration, and a super-hydrophobic state which returns the moisture during inspiration. The device has been designed to deliver 37°C fully humidified (95% relative humidity) respiratory gases for invasively mechanically ventilated patients.

Aims

This study aims to provide feasibility data for a subsequent pivotal trial examining the impact of RespirAq active humidifier on scheduled cardiothoracic surgical patients during invasive mechanical ventilation (IMV). We have recently demonstrated the device meets the EN ISO 80601-2-74:2020 during bench testing and in healthy volunteers using non-invasive ventilation.

Our primary endpoint is that the device meets the EN ISO 80601-2-74:2020 standards in IMV patients. Following outcomes of this study will inform the appropriate device design for subsequent pivotal trials to investigate the safety and efficacy of the RespirAq active humidifier in all non-contraindicated patient populations on IMV.

Methodology

Scheduled coronary artery bypass surgery (CABG) patients requiring invasive mechanical ventilation post-surgery at the Waikato District Health Board in Hamilton, New Zealand were recruited into the study. Safety was assessed by evidence of serious adverse and adverse events during the study period.

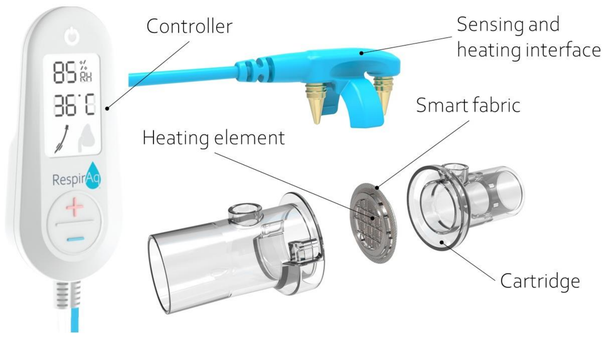
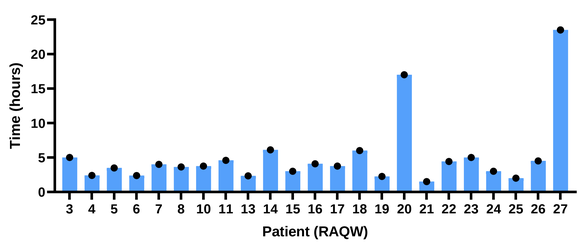


Figure 1: RespirAq controller and active humidifier.

Results

Twenty-three patients (mean age 61.65 ± 11.36, 91.3% male), were recruited. There were no device or procedure related serious adverse or adverse events. Time on the RespirAq active humidifier ranged between 1.5 and 23.5 hours (mean 5.12 ± 5.03 hrs) (Graph 1).



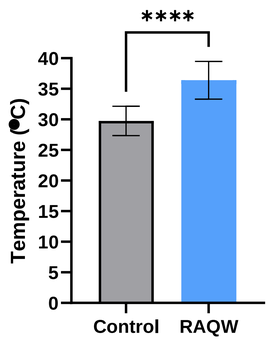
Graph 1: Patient's time on the RespirAq active humidifier.

Results cont.

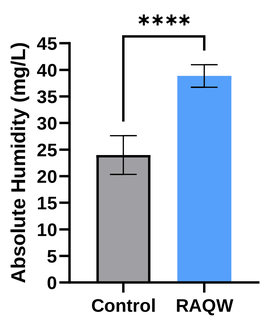
The airflow temperature significantly increased from 29.75 ± 2.408˚C (without RespirAq humidification), to 36.40 ± 3.078 ˚C (mean ± SD, n=23, p<0.0001) with the active humidifier (Graph 2).

Absolute humidity significantly increased from 23.99 ± 3.636 mg/L to 38.86 ± 2.124 mg/L (mean ± SD, n=23, p<0.0001) (Graph 3).

No rain-out condensation was observed in any patient during the study period.



Graph 2: Airflow temperature (˚C) without humidification (control) and with RespirAq active humidifier (RAQW) (mean ± SD, n=23, p<0.0001).



Graph 3: Airflow absolute humidity (mg/L) without humidification (control) and with RespirAq active humidifier (RAQW) (mean ± SD, n=23, p<0.0001).

Conclusion

Results show that the device meets the 33 mg/L absolute humidity established by the EN ISO 80601-2-74:2020 standards in IMV patients (p<0.0001) and suggest that the RespirAq active humidifier may deliver the performance of a heated humidifier at the size, reliability, and ease-of-use of a heat and moisture exchanger.

A prospective randomized clinical trial is warranted to confirm these findings.

Acknowledgements

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