Assessment of Exhaled Aerosol Emissions using two Prevalent Nebuliser Technologies in Clinical Use Today.

Andrew O'Sullivan[1], James McGrath[2], Miriam Byrne[2], Patrick Power[1] and Ronan Mac Loughlin[1].

[1] Aerogen, IDA Business Park, Dangan, Galway, Ireland.

[2] Department of Physics National University of Ireland Galway, Ireland.

Summary

The design and operation features of two prevalent nebuliser technologies which are in clinical use today were assessed for their emission of exhaled aerosols. Vibrating mesh/jet nebuliser and facemask/mouthpiece are examples of aerosol generators and non-invasive ventilatory support. This study investigated the effect of these in terms of quantities of secondary aerosol mass concentrations emitted at varying distances (0.8 m & 2.2 m).

The characterisation of exhaled aerosol emissions for two combinations of commercially available aerosol generators and non-invasive ventilation interfaces was investigated. Mass & number concentrations, and size distribution of the airborne particles were continuously measured in real time at different distances relative to a simulated patient.

Results: The VMN/filtered mouthpiece was found to emit the lowest mass concentration over time (0.00441 mg/m^3 at 0.8 m & 0.00436 mg/m^3 at 2.2 m). The JN/open facemask emitted the highest mass concentrations (mg m-3) at both distances. For 0.8 m the JN/open facemask facilitated a near two fold higher emitted mass concentration (mg/m^3) compared with the VMN/valved facemask (0.048 vs 0.025 mg/m^3), near fivefold higher compared with the JN/filtered mouthpiece (0.048 vs 0.00980 mg/m^3) & tenfold higher compared with the VMN/filtered mouthpiece (0.048 vs 0.00441 mg/m^3).

This study successfully demonstrated the obvious escape of aerosol to the environment and further established the risk to caregivers and other bystanders during the course of a standard nebuliser treatment.

Introduction

The use of handheld nebulisers is widespread and facilitates non-invasive drug delivery to patients ranging from infant to adult. Whilst most hand held nebulisers are lightweight and easy to use, there is often the need for caregiver intervention [1], e.g. due to poor mobility or young age and the need for proper supervised drug dosing.

Nebuliser-generated medical aerosols are delivered to the lungs via a variety of patient interfaces, including facemasks & mouthpieces. The combinations vary in terms of the facemask or mouthpiece of choice but also in how the aerosols are generated. Venturi Jet Nebulisers (JN) require a driving gas flow for aerosol generation, meaning that there is the potential for aerosol to be driven out of the facemask & mouthpiece during both inhalation and exhalation [2]. Vibrating mesh nebulisers (VMN) generate low velocity aerosols.

Whilst the focus of drug delivery is on the patient, bystander caregivers are often exposed to aerosol as it escapes or is exhaled through the nebuliser system. The potential for inhalation of medications, not required by that person, is relatively high [3, 4], and has not been comprehensively described to date in the literature.

We set out to attempt to characterise the risk to caregivers and other bystanders during the course of a standard nebuliser treatment.

Methods

Exhaled aerosol emissions were evaluated by characterising the mass concentrations (mg/m^3) & mass medium diameters (MMD) (µm) emitted from a simulated patient. Inhaled dose (%) delivered was also recorded. All testing carried out n=3. This study incorporated two combinations of commercially available aerosol generators and non-invasive ventilation interfaces, see Figure 1; VMN/valved facemask/filtered mouthpiece (Aerogen Solo/Ultra, Aerogen, Ireland) vs JN/open facemask/filtered mouthpiece (Cirrus 2, Intersurgical, United Kingdom). A supplemental gas flow rate of 6 LPM was used with the VMN and a driving gas flow of 8 LPM for the JN, while a 2.5 mL dose of albuterol sulphate (1 mg/mL) was nebulised as a tracer aerosol.

Each aerosol generator/non-invasive ventilation interface combination was connected to a breathing simulator (ASL 5000, Ingmar Medical, PA, USA) *via* an absolute filter (RespirGard II 303, Baxter, Ireland). A simulated adult breath was used (BPM 15, V_t 500 mL, I:E 1:1). As shown in Figure 1, the primary aerosol instrument used in this study was the Aerodynamic Particle Sizer (APS) (APS, model 3321 TSI Inc., St. Paul, MN) measuring airborne particle size distributions from 0.5 to 20 µm. Throughout the experiments; mass and number concentrations, and size distribution of the airborne particles were continuously measured in real time using two APS's located at different distances (0.8 m & 2.2 m). A 5-minute baseline level of airborne particles was established in the room pre nebulisation. Nebulisation was then initiated with the APS's recording data for a total of 30 minutes. Facemask and mouthpiece tests were performed on separate days (and had different airflows as a result).

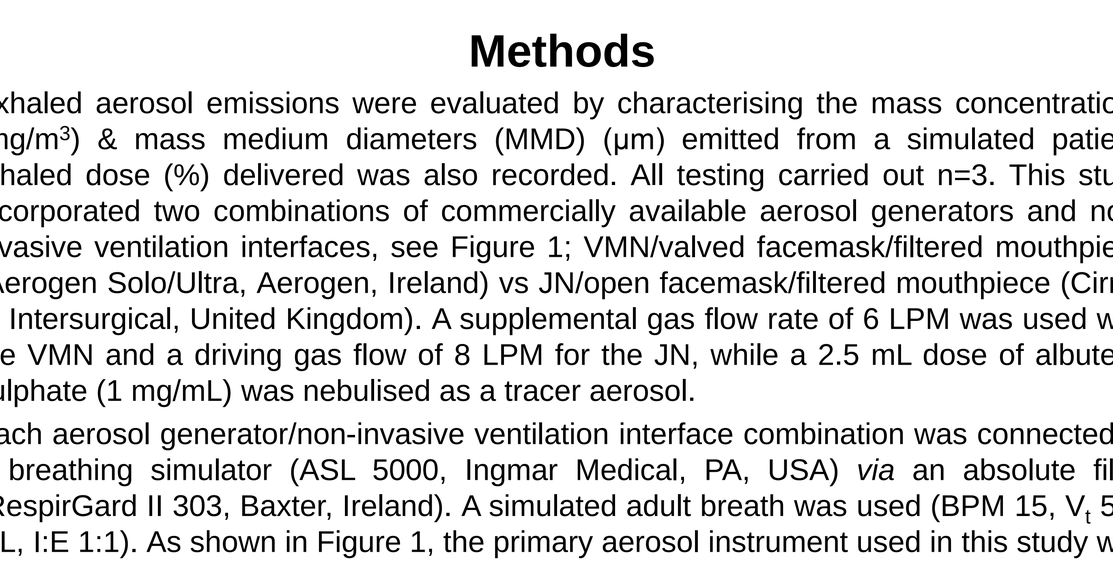

Figure 1: Aerodynamic Particle Sizer (APS) at varying distances relative to the simulated patient (ASL 5000) with VMN & JN facemask/mouthpiece iterations.

Results

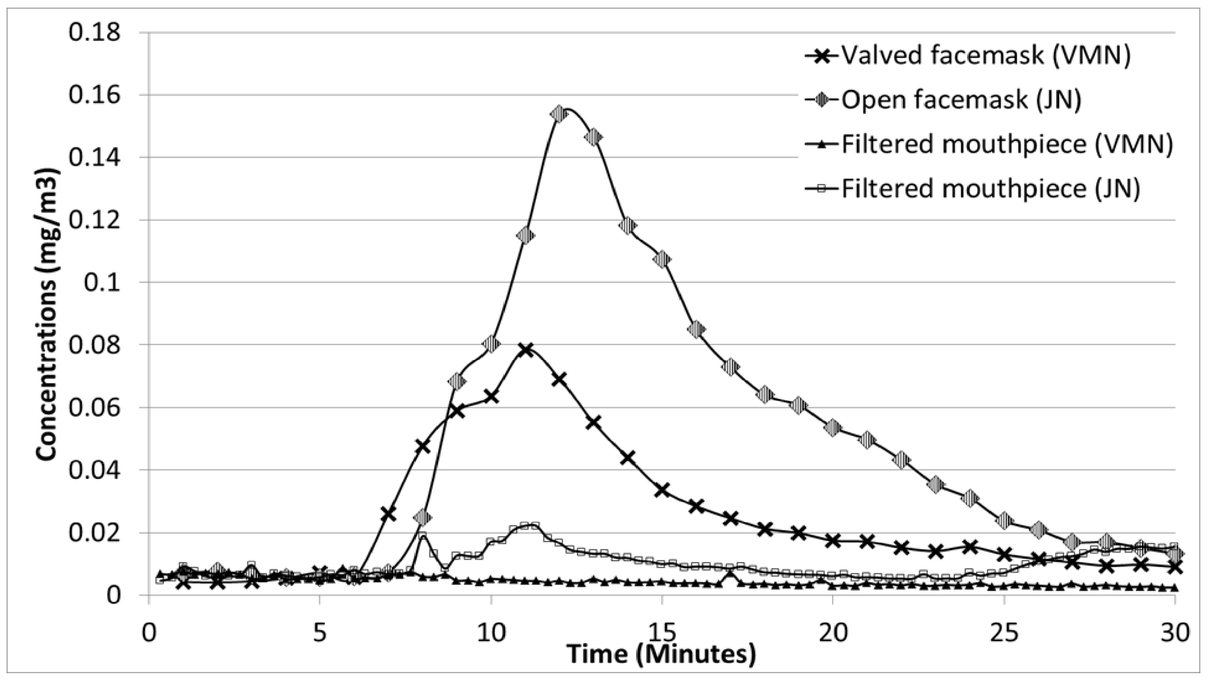

Figure 2: Illustration of total mass concentrations emitted by two aerosol generators and non-invasive ventilation interface combinations 0.8 m away from simulated patient.

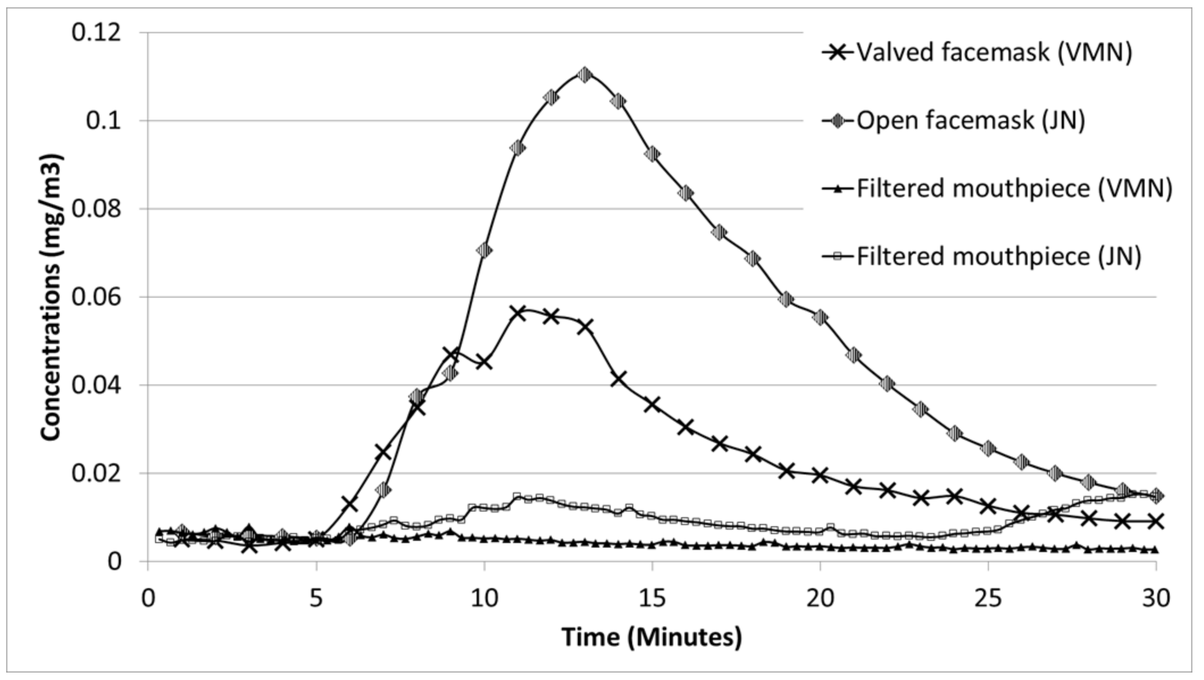

Figure 3: Illustration of total mass concentrations emitted by two aerosol generators and non-invasive ventilation interface combinations 2.2 m away from simulated patient.

Based on the myriad of aerosol generators & non-invasive ventilation interface combinations tested, the JN/open facemask emitted the highest mass concentrations (mg/m^3). At 0.8 m the JN/open facemask facilitated a near two fold higher emitted mass concentration compared with the VMN/valved facemask (0.048 vs 0.025 mg/m^3), near fivefold higher compared with the JN/filtered mouthpiece (0.048 vs 0.00980 mg/m^3) & tenfold higher compared with the VMN/filtered mouthpiece (0.048 vs 0.00441 mg/m^3).

A similar trend continued for the APS at a distance of 2.2 m away from simulated patient, with the JN/open facemask having again emitted the highest mass concentration over the 30 minute run time. The VMN/filtered mouthpiece was found to have emitted the lowest mass concentration over time (0.00441 mg/m^3 at 0.8 m & 0.00436 mg/m^3 at 2.2 m) while emitted particles had a larger MMD. Finally, the VMN/filtered mouthpiece combination allowed for the highest inhaled dose (50.32 ± 1.9%) compared with the VMN/valved facemask (46.69 ± 3.1%), JN/open facemask (21.95 ± 0.7%), and JN/filtered mouthpiece (35.94 ± 1.8%).

Conclusions

The initial findings described herein successfully demonstrated the obvious escape of aerosol to the environment and further established the risk to caregivers and other bystanders during the course of a standard nebuliser treatment. Considering the results above it is evident that of the two patient interfaces (facemask and mouthpiece) and aerosol generators (VMN and JN) tested, the mouthpiece combinations released lower fractions of exhaled mass concentrations across both distances (0.8 m & 2.2 m). Additionally the VMN/mouthpiece combination delivered the highest inhaled dose to the patient.

References

(1) American Thoracic Society. Skills of the health team involved in out-of-hospital care for patients with COPD. Am Rev Respir Dis 1986;133:948–949.

(2) Somogyi R, Vesely AE, Azami T, Preiss D, Fisher J, Correia J, Fowler RA. Dispersal of respiratory droplets with open vs closed oxygen delivery masks: implications for the transmission of severe acute respiratory syndrome. Chest 2004;125(3):1155–1157.

(3) Chughtai, A.A., Seale, H. and MacIntyre, C.R., 2013. Availability, consistency and evidence-base of policies and guidelines on the use of mask and respirator to protect hospital health care workers: a global analysis. BMC research notes, 6(1), p.216.

(4) Ari A, Fink JB, Pilbeam S. Secondhand aerosol exposure during mechanical ventilation with and without expiratory filters: An in-vitro study. Ind J Resp Care 2016; 5(1): 677-82.