

A bench study to investigate the safety and performance of Simeox® for secretion clearance

INTRODUCTION

- Conditions with chronic mucus hypersecretion can result in retained secretions, which are a significant contributor to morbidity and mortality.
- Management includes airway clearance techniques (ACT).
- Simeox® (PhysioAssist) is a novel device that generates intermittent short pulses of negative pressure during exhalation to mobilise secretions from distal to central airways.
- The desired outcome is augmentation of secretion clearance.



AIM

A bench study to investigate the performance of Simeox® in test lung conditions.

METHODS

- A test lung (ASL 5000, IngMar Medical) was connected to Simeox with an upper airway dummy.
- A pneumotachograph and pressure transducer were inserted into the circuit to measure airway flow and pressure.
- Outcomes assessed were safety and performance.
 - Safety was assessed by change in end-expiratory lung volume (Δ EELV) and maximum expiratory bronchial resistance (MEBR).
 - Performance was assessed by peak expiratory (PEF) and inspiratory (PIF) flow.
- The procedure was repeated at 25%, 50%, 75% and 100% device power.
- Simeox was compared with mechanical insufflation-exsufflation (MI-E) set to generate equivalent expiratory pressure.
- Data were compared using a paired Wilcoxon matched-pairs signed rank test

RESULTS

Safety

- Simeox produced a smaller Δ EELV compared with MI-E (Fig. 1).
- Simeox produced less MEBR than MI-E (Fig. 2).

Efficacy

- Simeox produced a larger PEF/PIF than MI-E (Fig. 3).
- At each Simeox power level, PEF/PIF was greater than 1.1.

	Simeox	MI-E	P-value
Δ EELV (L)	0.89 [0.62,1.05]	2.06 [1.31,2.58]	<0.0001
MEBR (cmH ₂ O.s/L)	100.2 [87.9,136.1]	160.5 [100.6,269.4]	<0.0001
PEF/PIF	(2.98 [2.35,3.7]	1.75 [1.56,2.02],	<0.0001

Table 1. Results from a bench study comparing Simeox with mechanical insufflation-exsufflation (MI-E). Δ EELV = change in end-expiratory lung volume; MEBR = maximum expiratory bronchial resistance ; PEF/PIF = the ratio between peak expiratory flow and peak inspiratory flow. Data are presented as median [IQR]. P-values are the results of a Wilcoxon matched-pairs signed rank test.

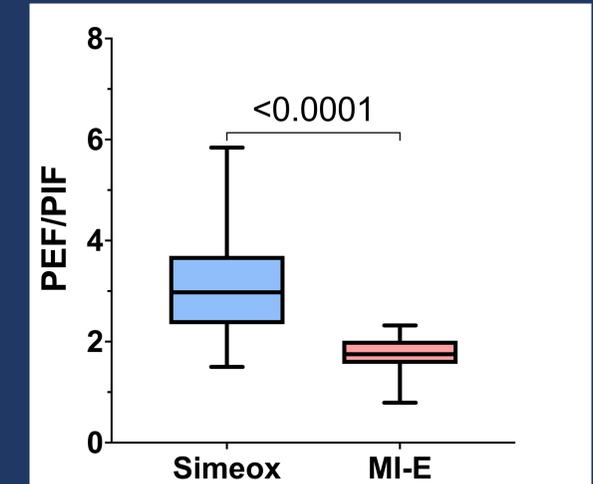


Figure 2. The ratio between peak expiratory flow (PEF) and peak inspiratory flow (PIF) during airway clearance technique, comparing Simeox and MI-E. Data were compared using a Wilcoxon matched-pairs signed rank test.

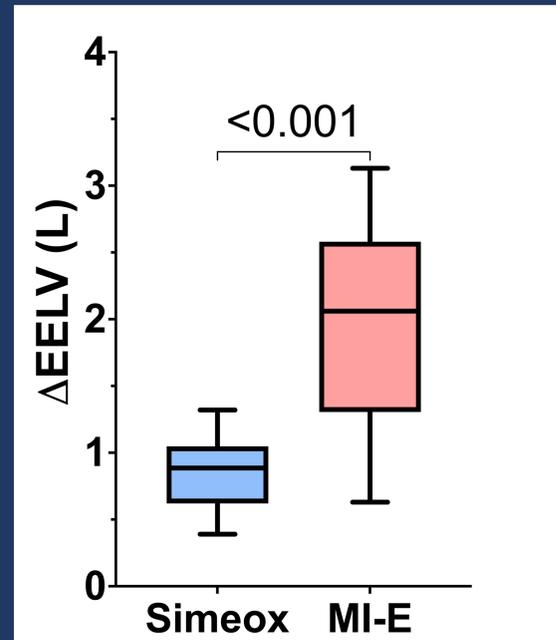


Figure 1. Change in end-expiratory lung volume (Δ EELV) following airway clearance technique, comparing Simeox and MI-E. Data were compared using a Wilcoxon matched-pairs signed rank test.

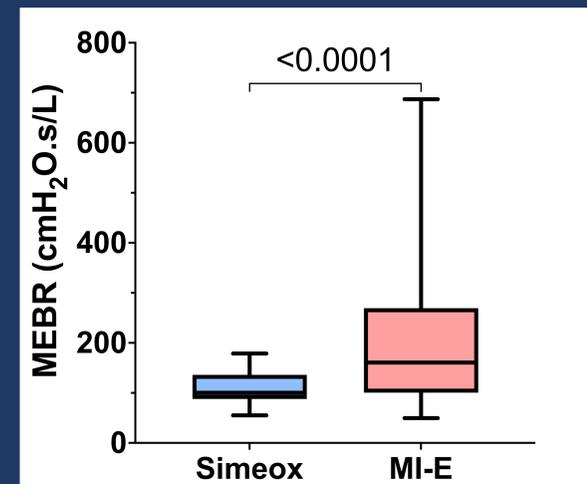


Figure 2. Maximum expiratory bronchial resistance (MEBR) during airway clearance technique, comparing Simeox and MI-E. Data were compared using a Wilcoxon matched-pairs signed rank test.



CONCLUSION

- In a lung model, Simeox did not display any deleterious effect on EELV and airway patency when compared with MI-E.
- Simeox generated PEF with adequate flow bias to move secretions proximally. This flow bias was larger than that generated by MI-E.
- These data support efficacy trials of Simeox in patients, and subsequent randomised studies comparing its efficacy with commonly used ACTs.