

In Vivo Validation of a Triggering System to Deliver Abdominal Neuromuscular Stimulation During Exhalation

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Rationale: VentFree™ is an investigational muscle stimulator (Liberate Medical) that applies transcutaneous neuromuscular electrical stimulation (NMES) to the abdominal wall muscles during exhalation (Te). The long-term goal of the device is to promote extubation in difficult to wean patients (McCaughey. Critical Care 2019;23:261). The trigger in the prototype (Trigger from Inhalation) fixes duration of stimulation to 70% of the duration of each preceding inhalation (Ti). In patients with a small Ti:Te ratio and during bradypnea, we observed long delays between end of stimulation and end of exhalation. To overcome this limitation, we developed a Trigger from Exhalation that starts the stimulator 100 ms into exhalation, and turns it off when exhalation flow decreases to 20% of its peak value. We hypothesize that Trigger from Exhalation ensures abdominal wall muscle stimulation for a longer portion of exhalation time than the Trigger from Inhalation. **Methods:** The two triggers were tested in 7 healthy subjects and in 7 patients with COPD during unsupported breathing, and during pressure support of 8 cmH₂O, with and without PEEP of 5 cmH₂O. Time between end of stimulation and end of expiratory flow, sensitivity (correctly triggered stimulations over total breaths), and error rate (stimulations delivered at the wrong time (during inhalation) over total breaths) were calculated. **Results:** During all testing conditions, time between end of stimulation and end of expiratory flow was shorter with the Trigger for Exhalation (0.57 ± 0.046 (SD) s) than with the Trigger for Inhalation (1.56 ± 0.069 s; $p < 0.001$) in both subject groups. Mean trigger sensitivity was greater with Trigger for Exhalation ($99.2 \pm 0.7\%$) than with Trigger for Inhalation ($97.1 \pm 2.2\%$; $p < 0.01$) in both subject groups during all testing conditions. The error rate with Trigger for Exhalation ($0.0 \pm 0.1\%$) and Trigger for Inhalation ($0.1 \pm 0.1\%$), were similar ($p = 0.29$). **Conclusion:** The Trigger from Exhalation ensures abdominal wall muscle stimulation for a longer portion of exhalation time and for a greater percentage of exhalations than does the Trigger from Inhalation. Future work should determine whether this increased stimulation duration with the Trigger from Exhalation augments the supportive effect of VentFree on ventilation outcomes. **Support:** Veterans Administration Research Service, Liberate Medical LLC, National Science Foundation

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