

Can the Flutter Valve improve respiratory mechanics and sputum production in mechanically ventilated patients? A randomized crossover trial

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ABSTRACT

OBJECTIVE: The Flutter Valve (Varioraw SARL, Scandipharm Inc, Birmingham, AL) has proven efficacy in hypersecretive spontaneously ventilated patients. This study was designed to evaluate whether an airway clearance protocol using the Flutter Valve can affect the therapeutic and physiologic outcomes in mechanically ventilated patients with pulmonary infection.

METHODS: In a randomized crossover study, sputum production, respiratory mechanics, hemodynamics, and gas exchange were evaluated from 20 mechanically ventilated patients submitted to 2 interventions. FLUTTER intervention consisted of connecting the Flutter Valve to the exhalation port of the mechanical ventilator. Control intervention (CTRL) was normal ventilation in pressure controlled mode.

RESULTS: Compared with CTRL, FLUTTER improved sputum production ($P < .001$), respiratory system static compliance ($P = .02$), peak expiratory flow ($P = .048$), expiratory flow at 75% of tidal volume ($P = .005$), and arterial PO_2 -to-inspired oxygen concentration ratio ($P < .001$). Respiratory resistance, heart rate, and mean arterial pressure remained unaltered during the interventions ($P > .05$).

CONCLUSION: The Flutter Valve improves lung secretion removal, mucus production, respiratory mechanics, and arterial oxygenation in mechanically ventilated patients with respiratory infection, without causing clinically relevant hemodynamic repercussions.

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Mechanically ventilated patients present increased mucus production¹ and impairment of mucociliary clearance owing to the mechanical effect of artificial airways, high fractions of inspired oxygen, lesions caused by tracheal suctioning, inadequate humidification, and drugs, including paralyzing agents.^{2–4} As a result, the retention of pulmonary secretions and atelectasis are more prone to take place, impairing respiratory mechanics (progressive reduction in pulmonary compliance and increased resistance) and causing hypoxemia and pneumonia.⁵ All these complications lead to a longer length of stay and increased mortality and costs.⁶

Physiotherapeutic approaches for intubated patients include tracheal suctioning, positioning, mobilization, postural drainage, percussion, manual or mechanical vibration, assisted cough, ventilation with positive end-expiratory pressure (PEEP), and manual or ventilator-driven hyperinflation.⁶ These techniques are commonly used in intensive care settings, aiming to reduce the retention of pulmonary secretions and to prevent pulmonary complications, thus optimizing oxygenation and reexpanding atelectatic airspaces.⁷

In spontaneously breathing patients, the more efficient secretion removal by the Flutter Valve (Varioraw SARL, Scandipharm Inc, Birmingham, AL) is commonly reported.^{8–10} The Flutter Valve is shaped like a pipe with a hardened plastic mouthpiece at one end, a plastic protective, perforated cover at the other end, and a high-density stainless steel ball resting on a plastic circular cone under the perforated cover. When the patient exhales through the flutter, the steel sphere moves up and down inside the pipe, generating oscillations in expiratory pressure and airflow that vibrate the airway walls, probably diminishing the mucus adhesiveness and decreasing the collapsibility of the airways and accelerating airflow.⁸ This device was initially designed to assist the removal of bronchial secretions in patients with cystic fibrosis.¹¹ Because of the low cost and ease of implementation of the Flutter Valve, it has been largely used in respiratory therapy outpatient services to treat a range of pulmonary hypersecretive conditions.¹² Because the evidence about the use of oscillatory devices is limited to spontaneously breathing patients, the purpose of the study is to evaluate the effects of the Flutter Valve on respiratory mechanics, gas exchange, and hemodynamic variables in mechanically ventilated patients with pulmonary infection.

MATERIALS AND METHODS

We carried out a randomized crossover study to test the hypothesis that the Flutter Valve can improve respiratory mechanics and sputum production in mechanically ventilated patients. The study took place at the adult intensive care service of a tertiary referral hospital between February 2008 and August 2009. The protocol

was approved by the university ethics committee in clinical research, and informed consent was obtained from each patient's next of kin in all instances (in addition to the relatives' consent, 7 patients provided their own informed consent).

Subjects

Sample size was estimated for the primary outcome variables by means of SigmaStat 3.1 software (SYSTAT Software Inc, Point Richmond, CA), using the preliminary results from 8 patients, with 5% significance level and 80% power given by paired *t* test. According to these input data, 10 subjects were required for the study to detect a 72% difference and a 52% standard deviation in the secretion production. Considering the static compliance of the respiratory system, 20 subjects were required for the study to detect a 15% difference and a 25% standard deviation.

Mechanically ventilated patients (>18 years) were included, provided they had clinical and radiologic diagnosis of pulmonary infection (new or progressive infiltrates on portable chest radiographs, fever, abnormal white blood cell count, purulent sputum, and microbiological analysis of specimens collected using non-bronchoscopic bronchioalveolar lavage)¹³ and hypersecretion (defined as the need for tracheal suctioning in < 2 hours). Exclusion criteria were absence of cough reflex, hemodynamic instability (mean arterial pressure [MAP] < 60 mm Hg), pneumothorax or nontreated pleural effusion, atelectasis (diagnosed by x-ray), intracranial hypertension (> 20 mm Hg), acute respiratory distress syndrome, and acute bronchospasm or discomfort during the experimental protocol (defined as ineffective inspiratory efforts followed by an increased use of accessory muscles or active expiration).

Interventions

All patients were submitted to control (CTRL) and FLUTTER interventions (see below) on the same day, with a washout period of 6 hours between them. The intervention order was defined according to block randomization (2 blocks of 10 patients) by a statistician who was unaware of the study, and its result was kept in numbered sealed identical envelopes. The researcher responsible for protocol implementation became aware of the intervention order at the onset of data acquisition. He was not in charge of data analysis.

Before the interventions were carried out, all patients underwent a preparation protocol that consisted of adopting the semi-recumbent position (45 degrees), cuff pressure adjusted to 60 cmH₂O, change of the bacteriological filter, checking for circuit leaks, high-pressure alarm adjusted to 42 cmH₂O, and tracheal suctioning. Pre- and post-intervention measurements were preceded by a lung homogenization maneuver^{14,15} that consisted of 3 consecutive inflations up to total lung capacity, with pressure limited to 35 cmH₂O in pressure-controlled ventilation.

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