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# The efficacy of a novel peristaltic feeding tube (PFT) in reducing reflux and aspiration of gastric contents in mechanically ventilated patients

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SUMMARY

Gastro-esophageal reflux (GER) is common in ventilated patients and is a cause of ventilator associated pneumonia (VAP). The novel persistaltic feeding tube (PFT) uses simulated peristalsis to seal the esophagus to fluid moving in a retrograde manner, whilst allowing normal drainage of fluid and secretions moving in an ante-grade manner. This study describes the first trial of the PFT in ventilated patients.

*Methods:* There were 10 subjects in the treatment (PFT) group and 10 patients in the control group, who had all undergone elective cardiac surgery and were ventilated in the intensive care unit (ICU) afterwards. The PFT was placed on admission to the ICU. In the control group a standard nasogastric tube (NGT) was inserted. Specimens were collected by suctioning from the oropharynx and from above the tracheal tube balloon every hour and from the trachea twice per 8 h shift. Samples were analyzed by ELISA for Pepsin A, as a marker for secretions of gastric origin. Esophageal pressure monitoring (as a measure of pleural pressure), which is an intrinsic ability of the PFT device, was also noted throughout the study – for future integration in mechanical ventilation strategies.

*Results:* The two groups were comparable with regard to demographics and duration of ventilation. There was a larger number

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of specimens positive for Pepsin A in the control group in the oropharynx ($p < 0.0001$) and above the ETT cuff ($p = 0.0001$), but not in the trachea ($p = 0.0603$), using the Wald Chi-squared test. However, when comparing mean concentrations of Pepsin at the three sites, there was a statistically higher concentration in the control group in the oropharynx, above the ETT and in the trachea, compared to the PFT group.

*Conclusion:* The PFT reduced the amount of GER in ventilated patients. A larger study is required to determine whether this translates to a reduction in VAP.

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## 1. Introduction

Gastro-esophageal reflux (GER) occurs when gastric contents regurgitate into the esophagus and from there, potentially, to the oropharynx and then into the tracheo-bronchial tree [1,2]. This is a common event in mechanically ventilated patients and contributes to the development of ventilator associated pneumonia (VAP). Several factors contribute to GER in these circumstances, such as functional impairment of the upper esophageal sphincter [2], impairment of esophageal motility by medications (e.g. sedatives, non-depolarizing muscle relaxants, adrenergic agonists) and nasogastric intubation that impairs function of the lower esophageal sphincter [3–5].

Bundles of care have recently been introduced to reduce GER and VAP [2]. These bundles include use of the semi-recumbent position to hinder GER and avoid subsequent oropharyngeal colonization and pulmonary aspiration of pathogens originating lower in the gastro-intestinal tract (GIT) [6–8].

Ventilator-associated pneumonia (VAP), defined as a hospital-acquired infection in patients receiving mechanical ventilation (MV) for at least 48 h [6], prolongs the time on MV and the length of stay in the intensive care unit (ICU) and in the hospital and worsens patient outcome [9–11]. In critically ill patients growth of pathogens in the stomach is encouraged by alkalinization of gastric contents by enteral nutrition and medications [12]. One possible cause of VAP is the fact that during GER fluid containing micro-organisms from the GIT may reach the oropharynx. These organisms may then be aspirated into the airways across the endotracheal tube (ETT) cuff (between the cuff and the tracheal wall) [13,14].

Given the role of GER in the causation of VAP, there is a strong need for a device that prevents or reduces GER during mechanical ventilation. We recently described the development of a unique device called the peristaltic feeding tube (PFT) which is designed to reduce the amount of GER and by extension reduce the rate of VAP in mechanically ventilated patients [15]. The PFT works as a conventional nasogastric feeding tube, but adds the feature of simulated peristalsis within the lumen of the distal esophagus. This peristalsis seals the esophagus to fluid moving in a retrograde fashion (like GER), whilst allowing normal drainage of fluid and secretions moving in an ante-grade fashion. The peristaltic motion is derived from synchronized cyclical inflation and deflation of three balloons at the distal end of the PFT, governed by an external control unit.

This paper describes the first trial of the PFT in mechanically ventilated patients, to reduce the rate of GER.

## 2. Materials and methods

This study was a prospective, single-center, randomized, open label, controlled clinical study to determine the safety and initial efficacy of the PFT device for the reduction of GER in mechanically

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