Evaluation of the efficacy of a newly developed endotrachel tube

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29558

Source
NTR

Brief title
N/A

Health condition

endotracheal tube, tracheal sealing, double cuff, ventilator-associated pneumonia, prevention

Sponsors and support

Primary sponsor: University Hospital Brussels
Source(s) of monetary or material Support: A demand for local funding at the University Hospital Brussels (Wetenschappelijk Fonds Gepts) is pending.

Intervention

Outcome measures

Primary outcome

If on any occasion a blue spot is observed on the trachel mucosa caudal to the tube’s tip, leakage will be confirmed and the experiment ended.

Secondary outcome

Throughout the experiment, following items are carefully and continuously evaluated: tube localization in the trachea (standard chest X-ray, fibroscopy), interaction with ventilation and humidification (monitoring of in- and expiratory tidal volume and airway pressures), effect of common manipulations (tracheal aspiration, transport, airway care, disconnection of ventilator, eventual weaning,...)

Study description

Background summary

Ventilator-associated pneumonia (VAP) is a type of hospital-acquired pneumonia in the critically ill that develops more than 48h after endotracheal intubation. The occurrence of a single episode of VAP increases duration of ventilation , ICU and hospital stay. VAP is associated with a high attributable mortality and adds an estimated cost of up to $ 40,000 to a typical ICU admission. VAP will also lead to more and specific antibiotic use, increasing the risk of development of multidrug resistant bacteria. A compelling argument can be made that the presence of the endotracheal tube (ETT) increases susceptibility to VAP because of leakage and microaspiration of bacteriologically contaminated secretions around the inflated ETT cuff and biofilm formation and bacterial colonization inside the ETT. Leakage of secretions into the distal airways occurs alongside voids created by cuff folds. In addition, patient disconnection from the ventilator, either accidentally or preparing extubation, or cuff deflation from any origin may cause inflow of secretions. Suggested solutions to avoid leakage/aspiration include the use of specific cuff materials (e.g. polyurethane) or shapes (e.g. conical), double-cuffed ETTs, continuous automatic regulation of cuff pressure and ETTs equipped with a suction lumen for aspiration of subglottic secretions. In an effort to limit bacterial colonization and biofilm formation in the lumen of the ETT, a silver-coated ETT has been developed. Comparative trials assessing these specifically designed ETTs have shown a decreased incidence of VAP. However, none of these ETTs has shown an effect on meaningful outcome parameters such as duration of mechanical ventilation, ICU stay, or hospital stay. Moreover, important safety and feasibility concerns remain regarding subglottic suctioning (pharyngeal and laryngeal injury), silver-coated ETTs (trend toward higher mortality) and polyurethane-cuffed ETTs (condensation in the cuff causing false manometric cuff pressure readings). We have developed an improved ETT that prevents secretion inflow based upon a physiological concept of "pressurized tracheal sealing" (see detailed description). The efficacy of the improved ETT is not based on any existing technique or material. Superiority of this ETT in preventing leakage of secretions was demonstrated in vitro in the “standard” vertical syringe model but also in an artificial trachea. This novel ETT obtained a European and US patent. We now intend to study its tracheal "sealing" function in vivo.

Study objective

Ventilation-associated pneumonia (VAP) is an important complication in intubated mechanically ventilated patients. VAP is associated with a substantial increase in morbidity, mortality, and cost. One of the most relevant causes of VAP is passage of oropharyngeal

secretions that are contaminated with bacteria alongside the cuff of an endotracheal tube (ETT). This cuff is an air-filled balloon that allows positioning and fixation of the ETT in the trachea and also serves as first "barrier" against inflow of oropharyngeal secretions. Unfortunately, the commonly used polyvinylchloride cuffs are very permeable and do not offer sufficient protection against leakage. Every actually proposed and clinically used method to solve the leakage problem (different cuff models of regarding material, width and shape, subglottic aspiration, continuous cuff pressure control,...) has been shown to somewhat but not entirely diminish the degree of leakage. Within the Intensive Care Unit of the University Hospital Brussels, we have developed a novel principle that allows to annihilate completely the inflow of secretions into the lower airways and thus decrease the incidence of VAP. Essentially, we use an existing double-cuffed ETT. Between both inflated cuffs , a supplemental canal is inserted through which a continuous positive pressure of 5 cm H2O is provided. This pressure is created and continuously regulated by an external source (e.g. manometer, CPAP device,...). In vitro experiments using this novel type of ETT showed that continuous application of positive pressure between the two cuffs resulted in an upward movement of secretion s towards the oropharynx and oral cavity wher they were easily aspirated. Even in long-term use and in contrast to all other types of tested conventially used ETTs, leakage of secretions was never observed. Moreover, the system did not interfere with controlled or assisted volume or pressure steered ventilation.
We now want to evaluate the sealing effect of this novel ETT i vivo conditions

Study design

Start of study = time of dye instillation

Fiberoptic examination of trachea : 1 and 6 h after intubation and then every 12 h (maximum 6 times)

Study ends when 10 patients are fully evaluated

Intervention

Patients are intubated lege arte by an experienced intensivist/anesthesiologist. Appropriate sedoanalgesia (midazolam, propofol and remifentanil) and muscle paralysis (atracurium), if required, is administered during the entire study period .
Patients remain mechanically ventilated in volume-or pressure control mode.
Tracheal tube size is chosen according to the Higenbottam-Payne equation, and both cuffs are inflated with air to a pressure of 25 cm H2O, as verified with an aneroid manometer.
Following thorough aspiration of upper and lower airway secretions, one milliliter of methylene blue diluted in 1 mL of saline solution (NaCl 0.9%) is carefully placed on the top of the proximal cuff.
Fiberoptic visualization of the trachea is performed 1 and 6 h after intubation and then every 12 h (maximum 6 times) to detect the possible presence of blue dye in the trachea.

Contacts

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Eligibility criteria

Inclusion criteria

mechanically ventilated patients > 18 years, electively intubated with the novel ETT

Exclusion criteria

- patients ventilated for < 24h
- refusing informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2014
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4284
NTR-old	NTR4428
Other	METC : 2014/109

Study results

Summary results

1.SUYS E, NIEBOER K, STIERS W, DE REGT J, HUYGHENS L, SPAPEN H. Intermittent subglottic secretion drainage may cause tracheal damage in patients with few oropharyngeal secretions. Intensive Crit Care Nurs 2013, 29; 317-320.

2.SPAPEN H, SUYS E, NIEBOER K, STIERS W, DE REGT J. Automated intermittent aspiration of subglottic secretions and tracheal mucosa damage. Minerva Anesthesiol 2012; 79:316-7.

3.SPAPEN H, MOEYERSONS W, STIERS W, DESMET G, SUYS E. Condensation of humidified air in the inflation line of a polyurethane-cuffed endotracheal tube during mechanical ventilation causes false continuous cuff pressure readings. J Anesthesiology (submitted)