NICE advice

Shiley Endotracheal Tube with TaperGuard Cuff for intensive care patients at risk of ventilator-associated pneumonia

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Summary

The TaperGuard Evac oral tracheal tube is intended for airway management in critically ill patients needing mechanical ventilation. Two randomised controlled trials comparing the use of TaperGuard Evac with conventional tubes found no statistically significant differences between the groups in the incidence of ventilator-associated pneumonia, time to onset of ventilator-associated pneumonia, or length of intensive care unit stay. Using TaperGuard Evac costs £111.07 (for a box of 10 single-use tubes), plus a variety of accessories.

Product summary and likely place in therapy	Effectiveness and safety
• The TaperGuard Evac oral tracheal tube is intended for airway management by oral intubation of the trachea and for evacuation or drainage of the subglottic space in critically ill patients needing mechanical ventilation. • It can be used in settings such as intensive therapy units (ITUs) or intensive care units (ICUs). • It has features that are intended to help prevent microaspiration, including an inflatable taper-shaped cuff and subglottic secretion drainage. • It would be used in place of conventional oral tracheal tubes.	• Two randomised controlled trials compared the TaperGuard Evac oral tracheal tube with conventional tubes for patients in ICU needing mechanical ventilation. One trial with 96 patients was published in full, and the other with 289 patients was published as a conference abstract only. Where reported, both trials found no statistically significant differences between the groups in incidence of ventilator-associated pneumonia, time to ventilator-associated pneumonia onset or length of ICU stay. Neither of these studies used the Automatic Pressure Controller that is recommended by the manufacturer to be used with the TaperGuard Evac oral tube. • One prospective controlled cohort study compared 4 subglottic secretion management interventions in 656 patients needing mechanical ventilation in an ICU. The incidence of ventilator-associated respiratory infection was statistically significantly lower in the group treated with the TaperGuard Evac tube plus continuous control of cuff pressure, compared with groups treated with either the standard tube, or standard tube plus continuous control of cuff pressure. No other statistically significant change in the incidence of ventilator-associated pneumonia was seen between the treatment groups.

Technical factors	Cost and resource use
• The TaperGuard Evac oral tracheal tube is a single-use endotracheal tube with a taper-shaped cuff. The device has integrated subglottic secretion drainage through a separate evacuation lumen (termed 'Evac'). • The tube incorporates a Magill curve, a tapered cuff with a cuff inflation valve, a suction port above the cuff with an evacuation lumen, a hooded tip with a Murphy Eye, and a radiopaque line to assist in radiographic visualisation. The TaperGuard Evac is recommended to be used with an Automatic Pressure Controller.	• A box of 10 single-use TaperGuard Evac oral tracheal tubes costs £111.07. • A pressure cuff controller (£1000), suction pump (£700), disposable connecting tube (£20 for 10), non-reusable reservoir (£55 for 10) and non-reusable filter (£130 for 10) are recommended by the manufacturer for use with the TaperGuard Evac oral tracheal tube. • Alternative oral tracheal tubes range in price from £80.00 to £220.00 per box of 10 single-use tubes.

• The TaperGuard Evac oral tracheal tube is supplied in a variety of sizes and lengths. The tube is made of polyvinyl chloride, is latex free and comes in sterile packaging. It is intended for oral intubation only.	

Introduction

Ventilator-associated pneumonia (VAP), also known as postoperative pneumonia, is a hospital-acquired infection. There is no consensus definition, but it is often considered to be nosocomial pneumonia that occurs 48 hours or more after intubation with an endotracheal or tracheostomy tube, and was not present before intubation. Clinical signs and symptoms of VAP are similar to those of many common conditions in intensive care unit (ICU) patients, such as acute respiratory distress syndrome, sepsis and cardiac failure. There is no gold standard to diagnose VAP; a firm diagnosis is generally made on the basis of clinical signs and symptoms, chest X-ray and microbiological confirmation (American Thoracic Society, 2005).

The precise number of patients in the NHS having mechanical ventilation each year is unknown. However, the incidence of prolonged mechanical ventilation (defined as a period of 21 days or more) in critically ill patients in a health care region of the UK was reported as 4.4 per 100 ICU admissions and 6.3 per 100 ventilated ICU admissions. In addition, 1 in 16 ventilated patients needed prolonged mechanical ventilation (Lone and Walsh 2011; Nouraei et al. 2009).

The exact incidence of VAP is difficult to quantify because of a lack of standardised criteria for VAP diagnosis. There are no current data on the incidence of VAP in the UK, but in the USA VAP represents 31% of all ICU-acquired infections. According to a systematic review and meta-analysis of English language publications, VAP is associated with substantial morbidity, a 2-fold mortality rate, longer hospital stays and related additional hospital costs (Safdar et al. 2005). A more recent systematic review and meta-analysis,

based on English language publications only, also estimated that the overall attributable mortality rate of VAP is 13% (Melsen et al. 2013).

VAP contributes to approximately half of all cases of hospital-acquired pneumonia (American Thoracic Society 2005; Vincent et al. 1995). Risk factors for developing VAP include a primary admitting diagnosis of burns, trauma, central nervous system disease, respiratory disease, cardiac disease, mechanical ventilation in the previous 24 hours, witnessed aspiration and paralytic agents (Cook et al. 1998). Non-modifiable risk factors for hospital-acquired pneumonia include old age, underlying chronic lung disease, immunosuppression and previous thoracoabdominal surgery (American Thoracic Society 2005; Tablan et al. 2004). A recent European study found that VAP did not occur more frequently in older people, but the associated mortality in these patients was higher (Blot et al. 2014).

Modifiable risk factors include reintubation, a depressed level of consciousness, malnutrition, oropharyngeal colonisation, enteral nutrition, supine positioning and stress bleeding prophylaxis (American Thoracic Society 2005; Tablan et al. 2004). Nonpharmacological preventive measures for VAP include, among others, an oral (non-nasal) route of intubation and continuous subglottic drainage (Kollef 1999; Dodek et al. 2004). For several years, designers have been developing endotracheal tubes with features intended to reduce VAP incidence, such as inflatable cuffs or subglottic suction ports.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

The TaperGuard Evac oral tracheal tube is a class IIa medical device for which the manufacturer, Covidien, received a CE mark in April 2009. The TaperGuard Evac oral tracheal tube had its CE mark renewed in June 2012.

Description

The TaperGuard Evac oral tracheal tube is intended to help prevent microaspiration of fluid into the lungs, which can cause VAP. It is a sterile, single-use endotracheal tube with a taper-shaped cuff and integrated subglottic drainage. The subglottic drainage is done through a separate evacuation lumen (the 'Evac'), which has a dorsal opening port above the cuff in addition to the main lumen. The lumen is accessed through a clear connecting tube with a capped Luer connector. The tapered cuff is designed to be better than a conventional cuff in reducing microaspiration of bacteria-laden secretions from the upper airway into the trachea. The TaperGuard Evac oral tracheal tube is made of polyvinyl chloride (PVC) and is latex free.

The tube is shaped in a Magill curve, which is widely recognised to be the optimum shape for most airways, and is made up of the following:

- Tapered cuff with a cuff inflation valve. The cuff is an inflatable area in the section of the endotracheal tube that sits inside the patient's trachea. The cuff forms a seal against the tracheal wall which prevents gases from leaking past the cuff, allowing positive pressure ventilation. The cuff also prevents matter such as regurgitated gastric contents going into the trachea. The cuff is made of PVC and is latex free.
- Suction port above the cuff with the Evac lumen.
- Hooded tip with a Murphy Eye. The Murphy Eye is an additional hole at the tip which allows gas to flow through the tube even if the main opening of the endotracheal tube is blocked, for example if it gets pressed against the tracheal wall. Without the Murphy Eye, the endotracheal tube could be completely obstructed.
- Tip-to-tip radiopaque line to give visibility in X-rays.

The TaperGuard Evac oral tracheal tube is sold in sterile packages, and is available in a range of sizes and lengths of (inner diameter [mm]/outer diameter [mm]/length [mm]): 6.0/9.8/354.0, 6.5/9.8/366.0, 7.0/10.4/375.0, 7.5/11.2/375.0, 8.0/11.8/376.0, 8.5/12.6/376.0 and 9.0/13.1/377.0. The tube is intended for oral intubation only.

The cuff pressure of the TaperGuard Evac oral tracheal tube is monitored by a cuff controller that automatically keeps the pressure constant. This compensates for small leaks in the system, and therefore reduces the risk of aspiration. The manufacturer states that use of the pressure cuff controller is essential to ensure optimal performance of the TaperGuard Evac oral tracheal tube. The cuff pressure can either be constant or

intermittent. The cuff controller is pre-set to a standard pressure of 25 cmH_2O, and the manufacturer recommends that the pressure should not exceed this. The cuff controller can also be used with other types of endotracheal tubes; some types of endotracheal tube cuffs can be used at pressures of up to 60 cmH_2O. Clinical staff determine the ideal cuff pressure for each patient according to the ventilation method and type of endotracheal tube used.

The aspiration system consists of a suction pump, disposable connecting PVC tube, disposable reservoir and disposable hydrophobic filter with PVC adapter. When connected to the TaperGuard Evac oral tracheal tube, the aspiration system removes secretions from the subglottic space by suction.

Intended use

The TaperGuard Evac oral tracheal tube is indicated for airway management by oral intubation of the trachea (that is, a tube inserted into a patient's trachea through the mouth to maintain an open airway) and for evacuation or drainage of the subglottic space.

The TaperGuard Evac oral tracheal tube can be used in all patients in an intensive therapy unit (ITU) or ICU who need airway management by oral intubation of the trachea and drainage of the subglottic space.

The TaperGuard Evac oral tracheal tube should not be used for people having procedures using lasers or electrosurgical active electrodes close to the device. Contact with the laser beam or electrode, in the presence of oxygen or nitrous oxide-enriched mixtures, could result in rapid combustion of the tracheal tube, potentially causing burns and releasing harmful chemicals.

Setting and intended user

The TaperGuard Evac oral tracheal tube can be used in ITU and ICU settings by appropriately trained personnel such as nurses or anaesthetists. Placement of endotracheal tubes by inadequately or inappropriately trained personnel could result in serious injury to the patient.

Current NHS options

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to

the TaperGuard Evac oral tracheal tube:

- Microcuff endotracheal tube (Kimberly-Clark)
- Mallinckrodt Evac oral tracheal tube Seal Guard, Murphy Eye (Covidien)
- Mallinckrodt Seal Guard (Covidien)
- LoTrach (Venner)
- UnoFlex reinforced endotracheal tube (ConvaTec).

Costs and use of the technology

The TaperGuard Evac oral tracheal tubes and additional accessories have the following costs:

- box of 10 single-use TaperGuard Evac oral tracheal tubes (any size): £111.07
- reusable automatic cuff controller (illustrative price based on Shiley model): £1000
- reusable suction pump: £700
- 10 non-reusable reservoirs: £55
- 10 non-reusable hydrophobic filters: £130
- 10 non-reusable suction tubes: £20.

The manufacturer states that intracuff pressure management is a key factor in the performance of the TaperGuard Evac tube and any cuffed endotracheal tube. It recommends that the TaperGuard Evac tube should be used with the Shiley Pressure Control (reusable automatic cuff controller). The manufacturer states that using the TaperGuard Evac oral tracheal tube without the cuff controller may result in reduced effectiveness, depending on the type of cuff pressure management chosen.

Secretions can be suctioned for removal using other generic automatic or manual devices but the manufacturer does not recommend this.

The remaining accessories in the list above are recommended by the manufacturer for use with the TaperGuard Evac oral tracheal tube. The CE marking for the TaperGuard Evac oral

tracheal tubes does not dictate the use of any particular accessories.

The number and variety of available endotracheal tubes makes a direct cost comparison difficult. However, alternatives to the TaperGuard Evac cost between £80 and £220 per box of 10 tubes.

Likely place in therapy

The TaperGuard Evac oral tracheal tube is intended to replace endotracheal tubes which have no subglottic access or those with a cylindrical or barrel-shaped cuff.

Specialist commentator comments

One specialist commentator noted that the amounts of subglottic secretions from different patients vary, ranging from no secretions at all to 20 ml per day.

This commentator remarked that no safety issues in their critical care unit had occurred with the use of the TaperGuard Evac oral tracheal tube. They noted that this device is also being used in non-critical care areas such as the emergency department and operating theatre, where patients are ventilated, and again no safety problems had been observed in these settings.

Another commentator pointed out that the published data suggest that subglottic suctioning is effective in preventing VAP, and also noted that several brands of tracheal tubes that have subglottic suction are available but that there is no clear evidence to show which of these is better. The commentator stated that subglottic suctioning is already included in the 2011 high impact intervention care bundle to reduce ventilation-associated pneumonia (Department of Health, 2011), but estimated that about 75% of UK ICUs have not adopted this aspect. The main reason for this is the higher price of these tracheal tubes, although the commentator considered this to be an insignificant cost compared with the costs of treating VAP. One commentator stated that VAP is a major problem in the UK, with a significant financial burden for treatment which they estimated to be typically about £10,000 per case, in addition to serious health consequences and potential death of the patient (VAP has an attributable mortality of 13%). This commentator reflected that some simple evidence-based interventions to prevent VAP do exist and are highly likely to be effective, but felt that these are underused in the NHS.

One specialist commentator had found the TaperGuard Evac oral tracheal tube with the continuous cuff monitoring easy to use. They noted that training is straightforward and education time is relatively short.

One commentator pointed out that different brands of tracheal tubes are used in the NHS. Another commentator clarified that the manufacturer supplies the TaperGuard Evac oral tracheal tube in pre-selected lengths, and it is only intended for oral intubation.

Equality considerations

NICE is committed to promoting equality and eliminating unlawful discrimination. We aim to comply fully with all legal obligations to:

- promote race and disability equality and equality of opportunity between men and women
- eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief, in the way we produce our guidance (these are protected characteristics under the Equality Act 2010).

Risk factors for VAP include age (incidence increases with advancing age) and chronic illnesses (underlying chronic lung disease). Age and chronic conditions are protected characteristics under the Equality Act (2010).

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency (MHRA) website revealed no manufacturer Field Safety Notices or Medical Device Alerts for the TaperGuard Evac oral tracheal tube. Two events with a TaperGuard device were identified from searches of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE). These reports related to endotracheal tubes but

the brand of the device was not stated, so it is not clear whether these refer to the TaperGuard Evac oral tracheal tube. In 1 of the events (April 2014), when a nurse changed the tube, she found that the inflation line had been cut and was on the bed, near the patient's neck. The tube needed to be replaced but no additional harm to the patient was reported. In another event (September 2013), during mechanical ventilation an alarm related to leakage alerted the healthcare provider. The user reported that pretesting of the cuff had been performed, but that the balloon on the endotracheal tube appeared to be porous. A decision was made to extubate the patient and re-intubate with a replacement tube.

Clinical evidence

A literature search identified 1 fully published randomised controlled trial (Mahmoodpoor et al. 2013) and 1 randomised controlled trial published in the form of a conference abstract only (Saito et al. 2013). Both compared the TaperGuard Evac oral tracheal tube (with subglottic secretion drainage) with conventional endotracheal tubes for mechanical ventilation in ICU patients.

One prospective controlled cohort study (Lorente et al. 2014) was also identified. This study compared 4 subglottic secretion management interventions in patients needing mechanical ventilation in an ICU. The 4 interventions included: standard tracheal tubes (Mallinckrodt Hi-Lo tracheal tube, which has a cylindrical polyvinyl chloride (PVC) cuff but no subglottic drainage), with either continuous or intermittent control of cuff pressure; and the TaperGuard Evac oral tracheal tubes with subglottic drainage, with either continuous or intermittent control of cuff pressure. Two publications reporting the same case series study were identified (Suys et al. 2013; Spapen et al. 2013). The authors of this study investigated whether the use of the TaperGuard Evac oral tracheal tube for intermittent aspiration of subglottic secretions could cause tracheal damage.

A historical controlled study evaluated the use of an intervention bundle (that included the TaperGuard Evac oral tracheal tube) to prevent VAP compared with standard care without the intervention bundle (Pérez-Granda et al. 2014).

None of these studies was conducted in the UK.

The Mahmoodpoor et al. (2013) trial (presented in tables 1 and 2) compared the impact of 3 different tracheal tubes on the prevention of VAP in critically ill patients. The types of tube were: the TaperGuard Evac oral tracheal tubes, which had a taper-shaped cuff and

subglottic secretion; the SealGuard tubes, which had a cylindrical/barrel-shaped polyurethane (PU) cuff and a subglottic secretion suction port; and the Hi-Lo tubes, which were standard tubes with a barrel shaped PVC cuff. It was not clear whether the Hi-Lo tubes studied had subglottic secretion drainage. In the trial, 96 patients in the surgical ICU who were expected to need mechanical ventilation for more than 96 hours were assigned to have intubation using either the TaperGuard Evac (n=32), the SealGuard (n=32), or the Hi-Lo tube (n=32). The ICU admission categories provided by the authors were 'surgery' for most patients or 'medical' for other patients. Further details regarding the admission category were not reported. During the 3-day study period, no statistically significant differences were seen between the 3 groups of patients for mean cuff pressure, incidence of VAP, length of ICU stay, ICU mortality, use of prokinetic drugs or neuromuscular blocking drugs, and Richmond Agitation Sedation Scale.

The Saito et al. (2013) study (presented in table 3) was reported as a conference abstract only and therefore provided limited information. This was a randomised controlled trial comparing the TaperGuard Evac oral tracheal tube with the Hi-Lo Evac tube in 289 adults who were expected to need mechanical ventilation for at least 48 hours. Both types of tube had subglottic suction drainage. The primary outcome was incidence of VAP. The incidence rate of microbiologically confirmed VAP was 21.7% (23/106) in the TaperGuard Evac group and 21.7% (23/106) in the Hi-Lo Evac group (p=1.00). No statistically significant differences between groups were observed for time to VAP onset, duration of mechanical ventilation, length of ICU stay, and the rate of achieving appropriate cuff pressure. There was no statistically significant difference in the incidence of reintubation because of laryngeal oedema between the TaperGuard Evac group and the Hi-Lo Evac group.

The Lorente et al. (2014) study (presented in tables 4 and 5) was a prospective controlled cohort study. It examined whether the joint use of VAP-preventive interventions to avoid ventilator-associated respiratory infection could reduce healthcare costs. The interventions investigated were the TaperGuard Evac oral tracheal tube with or without continuous control of endotracheal tube cuff pressure (CCCP), compared with the Hi-Lo tracheal tube without subglottic drainage with or without CCCP. A total of 656 patients who needed mechanical ventilation during the 1-year study period were included. Of these, 84 patients were treated with the TaperGuard Evac oral tracheal tube, 71 patients with the TaperGuard Evac oral tracheal tube with CCCP, 241 patients with the Hi-Lo tracheal tube, and 260 patients with the Hi-Lo tracheal tube with CCCP. There was statistically significant heterogeneity in the characteristics of patients treated in the 4 groups, including diagnostic group (for example cardiac surgery, cardiology, respiratory),

type of ICU admission (for example postoperative, medical, and traumatic), cuff diameter, the Acute Physiology and Chronic Health Evaluation (APACHE)-II score, duration of mechanical ventilation, and presence of respiratory infection before intubation. The incidence of ventilator-associated respiratory infection was statistically significantly lower with the TaperGuard Evac plus CCCP than either with the Hi-Lo without CCCP (3.77 compared with 20.62 per 1000 days of mechanical ventilation, $p<0.001$) or the Hi-Lo plus CCCP methods (3.77 compared with 15.64 per 1000 days of mechanical ventilation, $p=0.006$). No statistically significant differences were found in the incidence of ventilator-associated respiratory infection between the following comparisons: the TaperGuard Evac with CCCP compared with the TaperGuard Evac without CCCP; the TaperGuard Evac without CCCP compared with Hi-Lo without CCCP; the TaperGuard Evac without CCCP compared with Hi-Lo plus CCCP; and Hi-Lo plus CCCP compared with Hi-Lo without CCCP.

The Suys et al. (2013) study (presented in table 6) was a prospective case series investigating tracheal injury caused by intermittent subglottic secretion drainage using an automated cycle device in 6 consecutive patients who were intubated with the TaperGuard Evac endotracheal tube. After 24 hours of intubation, a CT scan of the neck showed entrapment of the posterior tracheal mucosa into the suction port orifice of the endotracheal tube in all patients. Bronchoscopy showed a diversity of tracheal mucosal lesions (maceration, erythema, linear erosion and ulceration) in the area next to the suction part of the endotracheal tube. Three patients had bedside percutaneous tracheostomy at 14, 16 and 17 days of ICU stay respectively. The same results were presented in a duplicate publication (Spapen et al. 2013).

A historical controlled study was identified (Pérez-Granda et al. 2014) that evaluated the impact of an intervention bundle for the prevention of VAP over a 35-month period in a major heart surgery ICU in Spain. The intervention bundle consisted of 4 measures including:

- a specific training programme
- aspiration of subglottic secretions using a TaperGuard Evac endotracheal tube over a 13-month period
- introduction of an inclinometer to improve the semi-reclining position
- reinforcement of oral care with chlorhexidine.

The primary end point was the reduction in the incidence rate of VAP from the

4 sequentially implemented measures. Data from 401 patients before implementing the bundle and from 1534 patients during the intervention bundle were collected. After implementing the intervention bundle, there was a statistically significant reduction in incidence rate of VAP (23.9 compared with 13.5 episodes per 1000 days of ventilation, p=0.005) and the mean number of days of mechanical ventilation/1000 days of stay (507 versus 375, p=0.001). The sequential application of preventive measures in time achieved a relative rate reduction of VAP of 41% (incidence rate ratio 0.41; 95% confidence interval [CI] 0.28 to 0.62). The mortality rates before and during the intervention were 13.0% and 10.2% respectively. VAP rate was reduced most significantly by training and using the inclinometer.

Table 1 Overview of the Mahmoodpoor et al. (2013) trial

Study component	Description
Objectives/ hypotheses	To compare the effect of different cuff materials (polyurethane) and shapes (cylindrical, conical) of tracheal tubes for mechanical ventilation on prevention of VAP in critically ill patients. The tubes being compared were the Hi-Lo tubes (PVC, barrel), the Sealguard tubes (PU, cylindrical/ barrel) and the TaperGuard tubes (PVC, cone/tapered).[a]
Study design	Randomised controlled trial.
Setting	A 12-bed surgical ICU in Tabriz, Iran. Follow-up duration was 3 days.
Inclusion/ exclusion criteria	All patients who were admitted to the ICU and expected to be under mechanical ventilation for more than 96 hours. Exclusion criteria were previous history of immunosuppression or pneumonia and intubation before admission to the ICU.
Primary outcomes	Cuff pressure manually monitored every 3 hours by a manometer and maintained between 20–30 mmHg by a nurse to reduce the risks of aspiration and tracheal mucous damage. Pressure more than 30 mmHg was considered as over-inflation of the cuff and under 20 mmHg as under-inflation.

Statistical methods	Data were analysed using SPSS. Variables were shown as mean ± standard deviation. Independent t-test, Mann Whitney U-test and chi-square test were used for statistical analysis. A p value of less than 0.05 was considered significant.
Participants	Surgical ICU patients expected to need mechanical ventilation for more than 96 hours (n=96).
Results	There was no significant difference in mean cuff pressure between the 3 groups during 72 hours. Pneumonia was seen in 11 patients (34%) in the PVC group, 8 (25%) in the SealGuard group and 7 (21%) in the TaperGuard group. Changes in mean cuff pressure between SealGuard and PVC tubes and between the TaperGuard and PVC tubes did not show any significant difference. There was no significant difference in over-inflation between the 3 groups.
Conclusions	The authors stated that the use of PU endotracheal tubes resulted in reducing VAP compared with endotracheal tubes with a PVC cuff. In PU tubes the TaperGuard had less incidence of VAP compared with the SealGuard tubes.
Abbreviations: ICU, intensive care unit; PU, polyurethane; PVC, polyvinyl chloride; VAP, ventilator-associated pneumonia. [a] The authors recognised the material of the TaperGuard tube cuffs as PU; however, according to the manufacturer the TaperGuard tube cuffs are made of PVC rather than PU.	

Table 2 Summary of the Mahmoodpoor et al. (2013) trial

	TaperGuard	SealGuard	Hi-Lo	Analysis
Randomised	n=32	n=32	n=32	
Efficacy	n=32	n=32	n=32	
Outcomes				
Mean cuff pressure (mmHg), mean±SD	24.10±0.49	24.07±0.48	24.20±0.47	NS
Incidence of VAP[a], % (n)	21% (7/32)	25% (8/32)	34% (11/32)	NS

Length of ICU stay[b]	17 (13–31)	18 (12–33)	12 (8–22)	NS
ICU mortality[c]	5	5	6	NS
Prokinetic drugs[c]	2	2	3	NS
Neuromuscular blocking drugs[c]	1	2	1	NS
Richmond Agitation Sedation Scale[d], mean±SD	−0.7±0.3	−0.65±0.4	−1.0±0.5	NS

Abbreviations: n, number of patients; NS, not statistically significant; SD, standard deviation; VAP, ventilator-associated pneumonia.

[a] Pneumonia was defined based on clinical, radiological and laboratory findings based on clinical pulmonary infection score.

[b] Unit was not reported. Presumably it was in hours. It was unclear whether the data reported were medians and those in the brackets were ranges.

[c] Units of this measurement were not report.

[d] No further details were reported about the scale.

Table 3 Summary of the Saito et al. (2013) trial (based on abstract only)

Study component	Description
Objectives/ hypotheses	To determine whether an endotracheal tube with tapered-type cuff (the TaperGuard Evac) can reduce the incidence of VAP compared with the spindle type Hi-Lo Evac tubes.
Study design	Single-centre, randomised controlled trial.
Setting	Data not available from the abstract.
Inclusion/ exclusion criteria	Data not available from the abstract.

Primary outcomes	VAP incidence (microbiologically confirmed, based on semiquantitative bronchoalveolar lavage fluid culture of 3+ or phagocytosis on Gram staining).
Statistical methods	Data not available from the abstract.
Participants	Adult patients (≥18 years) expected to need mechanical ventilation for at least 48 hours.
Results	The rate of microbiologically confirmed VAP was 21.7% (23/106) in the TaperGuard Evac group and 21.7% (23/106) in the Hi-Lo Evac group (p=1.00). No significant differences between groups were observed for time to VAP onset, duration of mechanical ventilation, and ICU stay. The rate of achieving appropriate cuff pressure was 83.2% (332/1974)[a] for the TaperGuard Evac tubes and 82.4% (328/1867)[a] for the Hi-Lo Evac tubes (p=0.549). There was no significant difference in the incidence of reintubation because of laryngeal oedema between the TaperGuard Evac group and the Hi-Lo Evac group (11.5% [6/52] versus 2.0% [1/49]; p=0.113).
Conclusions	The authors concluded that differences in cuff type and shape under identical conditions of cuff pressure control have no influence on the incidence of VAP.
Abbreviations: ICU, intensive care unit; n, number of patients; VAP, ventilator-associated pneumonia. [a] There is a discrepancy between the reported rate and the reported percentage.	

Table 4 Overview of the Lorente et al. (2014) study

Study component	**Description**
Objectives/ hypotheses	To determine whether the joint use of VAP preventive measures (the TaperGuard Evac oral tracheal tube with or without CCCP; the Hi-Lo tracheal tube without subglottic drainage, with or without CCCP) to avoid VARI could reduce health care costs.
Study design	Prospective controlled cohort study.

Setting	A 24-bed medical-surgical ICU of the University Hospital of the Canary Islands and a 650-bed tertiary hospital in Tenerife, Spain over a 1-year period. Follow-up duration was presumably until discharge from the unit.
Inclusion/ exclusion criteria	Patients in ICU needing mechanical ventilation.
Primary outcomes	Main outcomes included incidence of respiratory infection (including pneumonia or tracheobronchitis, diagnosed by an expert panel blinded to the type of endotracheal tube and cuff pressure system using predefined criteria), daily healthcare costs, and cost of antimicrobial agents.
Statistical methods	Qualitative variables were reported as frequencies and percentages, and were compared using the chi-square test or Fisher's exact test as appropriate. Quantitative variables are reported as mean±SD and were compared using ANOVA. Poisson regression analysis for unconditional maximum likelihood inference with exact p values was used to compare respiratory infections per 1000 days of mechanical ventilation and daily healthcare costs between pairs of groups. Bonferroni correction was applied to correct for multiple testing. The probability of remaining free of VARI was plotted using the Kaplan–Meier method, and comparisons between groups were done using the log-rank test. A p value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS and StatXact.
Participants	Patients in ICU needing mechanical ventilation (n=656), including: • 84 on the TaperGuard Evac oral tube • 71 on the TaperGuard Evac oral tube with CCCP • 241 on Hi-Lo tracheal tube • 260 on Hi-Lo tracheal tube with CCCP.

Results	The incidence of VARI was lower in the TaperGuard Evac oral tracheal tube with CCCP group, compared with the Hi-Lo tube group (p<0.001), the Hi-Lo tube with CCCP group (p=0.006), and the TaperGuard Evac oral tracheal tube group (p=0.008). Daily healthcare costs were also lower in the TaperGuard tube with CCCP group compared with the Hi-Lo tube group (p<0.001), the Hi-Lo tube with CCCP group (p<0.001), and the TaperGuard group (p<0.001).
Conclusions	The authors concluded that the combined use of the TaperGuard and CCCP reduced the incidence of VARI and saved healthcare costs.
Abbreviations: ANOVA, analysis of variance; CCCP, continuous control of endotracheal tube cuff pressure; ICU, intensive care unit; n, number of patients; SD, standard deviation; VAP, ventilator-associated pneumonia; VARI, ventilator-associated respiratory infection.	

Table 5 Summary of the Lorente et al. (2014) study

	TaperGuard + CCCP	**TaperGuard**	**Hi-Lo + CCCP**	**Hi-Lo**	**Analysis**
n	n=71	n=84	n=260	n=241	
Selected outcome					
VARI per 1000 days of MV	3.77	14.93	15.64	20.62	The TaperGuard + CCCP vs Hi-Lo: p<0.001
					The TaperGuard + CCCP vs Hi-Lo + CCCP: p=0.006
					The TaperGuard + CCCP vs TaperGuard: p=0.008[a]
					The TaperGuard vs Hi-Lo: p=0.36
					The TaperGuard vs Hi-Lo + CCCP: p=0.99

					Hi-Lo + CCCP vs Hi-Lo: p=0.44

Abbreviations: CCCP, continuous control of endotracheal tube cuff pressure; MV, mechanic ventilation; n, number of patients; SSD: subglottic secretion drainage; VAP, ventilator-associated pneumonia. VARI, ventilator-associated respiratory infection; vs, versus.

[a] According to Bonferroni correction, all p values <0.008 were considered statistically significant.

Table 6 Summary of the Suys et al. (2013) study

Study	Study characteristics	
Suys et al. (2013); Spapen et al. (2013)	Study design	A prospective case series
	Objective	To investigate whether intermittent subglottic secretion drainage, using an automated cycle device, could cause tracheal injury.
	Setting	Intensive care unit in the University Hospital, Vrije Universiteit Brussel, Belgium.
	Population	6 consecutive patients, intubated with the TaperGuard Evac endotracheal tube.
	Intervention	Intubation with the TaperGuard Evac endotracheal tube. Before the CT scan was performed, patients were curarised and intermittent subglottic secretion drainage was applied.
	Outcome measures	A high-resolution CT scan of the neck after 24 hours to measure tracheal injury.
	Findings	CT imaging showed entrapment of the posterior tracheal mucosa into the suction port orifice of the endotracheal tube in all patients. Bronchoscopy revealed a diversity of tracheal mucosal lesions (maceration, erythema, linear erosion, and ulceration) in the area adjacent to the suction part of the endotracheal tube. Three patients had bedside percutaneous tracheostomy at 14, 16 and 17 days of ICU stay respectively.

Abbreviations: CT, computerised tomography; n, number of patients; ICU, intensive care unit; VAP, ventilator-associated pneumonia.

Recent and ongoing studies

One randomised controlled trial (reported to have completed in June 2014) comparing the TaperGuard tracheal tube with the Hi-Contour Brandt endotracheal tube for postoperative pneumonia in patients after aortic surgery was identified in the preparation of this briefing (ClinicalTrials.gov identifier: NCT01457248). It was not clear whether the TaperGuard tubes studied were the TaperGuard Evac tubes. Results of this trial had not been published at the time of preparing this briefing.

Costs and resource consequences

The study by Pérez-Granda et al. (2014) included an assessment of the financial impact of a bundle of measures to reduce VAP, including the use of the TaperGuard Evac oral tracheal tube. The authors reported that implementing this care bundle reduced the cost of antimicrobial therapy from €70,612 to €52,775/1000 days of stay, p=0.10, which is equivalent to a reduction from £55,996 to £41,851 (exchange rate at December 2014).

Strengths and limitations of the evidence

Two randomised controlled trials were available, 1 fully published (Mahmoodpoor et al., 2013) and the other as a conference abstract only (Saito et al. 2013). Both studies, particularly the Saito et al. abstract, reported limited information on the methods used on which to estimate the quality of these studies. For example, there was no information on the randomisation methods, sample size calculation and the methods of detecting VAP used in the studies. The authors of the Mahmodpoor et al. trial recognised the small sample size as a limitation of the study. Also, the follow-up duration in the Mahmodpoor trial was 3 days; thus, any VAP incidence occurring due to prolonged mechanical ventilation beyond 3 days would not be observed.

In the prospective controlled cohort study (Lorente et al., 2014) comparison groups were defined by the types of endotracheal tubes that the patients had for mechanical ventilation, and there was statistically significant heterogeneity in many aspects of the patient characteristics between the comparison groups, including APACHE-II score, duration of mechanical ventilation and respiratory infection. This may affect the

comparability between the groups and introduce bias in the results.

Another available study was a case series of only 6 patients (Suys et al., 2013), which added no evidence on the efficacy but only information on the safety of the TaperGuard Evac oral tracheal tube.

None of the studies identified using the TaperGuard Evac oral tracheal tube were conducted in the UK and so the generalisability of these results to the NHS is unclear.

Overall, the evidence identified was sparse and of limited quality that does not allow firm conclusions to be drawn on the potential of the TaperGuard Evac oral tracheal tube to reduce the incidence of VAP or other respiratory infections.

Relevance to NICE guidance programmes

NICE has issued the following related guidance:

- Acutely ill patients in hospital (2007) NICE guideline CG50. Date for review: TBC.
- Prevention and control of healthcare-associated infections (2011) NICE guideline PH36 Date for review: November 2014.

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Search strategy and evidence selection

Search strategy

Search strategy

1. Databases were searched from inception to November 2014. The keyword "TaperGuard" was used for the searches. The number of citations found is in brackets after each database:

Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) (14); Embase (via OVID) (39); Cochrane Library (1); CAB Abstracts (1); Web of Science Science Citation Index (7).

These citations were sifted through to find any relevant material, using the inclusion criteria in the 'Evidence selection' section below.

2. The internet was searched using the keywords 'TaperGuard'.

3. ClinicalTrials.gov, WHO ICTRP, and Current Controlled Trials were also searched for ongoing trials.

4. Information provided by the manufacturer in supporting this briefing was checked to identify any further information.

5. The manufacturer's website was thoroughly investigated.

6. Information provided by the manufacturer was thoroughly checked for relevant studies.

Evidence selection

The inclusion criteria were as follows:

- **Patients:** mechanically ventilated patients who may be at risk of ventilator-associated pneumonia (VAP), in an intensive care unit (ICU) or an intensive therapy unit (ITU).
- **Intervention:** the TaperGuard Evac oral tracheal tube.
- **Comparator:** conventional endotracheal tube.
- **Outcomes:** any clinical efficacy and safety outcomes, including but not limited to:
  - incidence of VAP
  - length of ICU/ITU stay
  - length of hospital stay
  - incidence of secondary infection
  - incidence of aspiration
  - duration of mechanical ventilation
  - antibiotic usage
  - mortality
  - adverse events.

- **Study design:** for effectiveness any controlled study will be included. For the safety aspect of the device, any controlled study, non-controlled study and case report will be included. Any relevant systematic reviews and meta-analysis will also be included. Proof-of-concept, basic science, and non-English language studies will be excluded.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers, and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by the Birmingham and Brunel Consortium. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality assured and approved for publication.

Project team

Birmingham and Brunel Consortium

Medical Technologies Evaluation Programme, NICE

Authors

- Zulian Liu, Research Fellow, Birmingham and Brunel Consortium, University of Birmingham
- Rui Duarte, Research Fellow, Birmingham and Brunel Consortium, University of Birmingham

Peer reviewers and contributors

- Catherine Meads, Deputy Director, Birmingham and Brunel Consortium, Brunel University
- Laura Norburn, Public Involvement Adviser, Public Involvement Programme, National Institute for Health and Care Excellence

Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- John Moore, Consultant in Anaesthetics and Intensive Care Medicine, Central Manchester University Hospitals NHS Foundation Trust
- Sandeep Dhir, Consultant in Intensive Care Medicine and Anaesthesia, Sherwood Forest Hospitals NHS Foundation Trust
- Duncan Wyncoll, Intensive Care Unit Consultant, Guy's and St Thomas' NHS Trust

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