

A retrospective review of patients managed with the PneuX PY™ VAP prevention system **3C00, 1C02**

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Ventilator-associated pneumonia (VAP) is commonplace in intensive care and has implications for patients' morbidity and mortality in hospital. A range of interventions exists to prevent the development of VAP. We reviewed the impact of the PneuX PY™ VAP prevention system on the incidence of VAP and its effects on local practice. In total, 48 patients in a mixed medical and surgical intensive care unit received the PneuX PY VAP prevention system and its associated care package in 2010. The VAP rate for this cohort of patients was found to be 6.25% (n=3) in the local context of historical VAP rates above 26%. Notably, 17% of extubations were unplanned, of which almost two-thirds were self-extubations. The PneuX PY VAP prevention system facilitated lower VAP rates than those documented elsewhere and highlighted the incidence of unplanned extubations in local practice. Further evaluation of the implementation of the PneuX PY VAP prevention system in intensive care areas, in tandem with large-scale evaluation of its effectiveness, are still required.

Keywords: ventilator-associated pneumonia; intensive care; endotracheal intubation; innovation; unplanned extubation

Introduction

The presence of healthcare-associated infection (HCAI) is increasingly well recognised in current clinical practice, with ventilator-associated pneumonia (VAP) the most frequent infection occurring in patients after admission to the intensive care unit (ICU).¹⁻³ A number of non-UK studies have identified VAP rates between 9-27%.⁴⁻⁶ A small pilot study⁷ showed that 70% of pneumonias in a number of Scottish ICUs were primarily attributable to mechanical ventilation.

Consequently, there is ongoing effort to reduce the incidence and related sequelae of VAP. In the UK, the Department of Health 'Saving Lives' initiative,⁸ which focuses on 'High Impact Interventions' alongside the Patient Safety First 'Reducing Harm in Critical Care' campaign⁹ have attempted to create an environment for driving improvements and monitoring best practice, in an effort to reduce the harm from mechanical ventilation.

The aetiology of VAP is primarily attributed to the presence of an endotracheal tube. Oropharyngeal secretions that would normally be swallowed pool on top of the cuff of the endotracheal tube, and then pass around the cuff and into the lungs.¹⁰ Bench-top evidence¹¹ has demonstrated statistically significant increases in fluid volumes leaking past the cuffs of a number of different brands of conventional tracheal tubes, both in a validated 'model' trachea and excised human tracheas.

In order to prevent or delay the incidence of VAP, a range of interventions and prevention strategies have been employed with varying success.¹² These include simple techniques such as oral care,¹³ hand hygiene,¹⁴ aspiration of oropharyngeal

secretions,^{15,16} and combination strategies formulated into care bundles, such as the use of a semi-recumbent position, daily sedation hold and deep vein thrombosis prophylaxis.¹⁷ In addition, more advanced interventions are also employed, including kinetic bed therapy,¹⁸ use of modified tracheal tubes that incorporate subglottic secretion drainage,¹⁹ devices which maintain constant tracheal tube cuff pressure,²⁰ or tracheal tubes with specific coatings to prevent the formation of biofilms.²¹

Several tracheal tubes are marketed which facilitate subglottic secretion drainage, ie removal of the secretions that have pooled on top of the tracheal tube cuff. A number of studies have been undertaken to assess the impact of tracheal tubes with subglottic secretion drainage on the incidence of VAP; two meta-analyses^{19,22} have assessed the effectiveness of these tracheal tubes. One study demonstrated that the incidence of VAP was reduced by almost half (RR 0.51, 95% CI 0.37-0.71);²² the authors consequently recommended the use of tracheal tubes with subglottic secretion drainage in all patients expected to be ventilated for 72 hours or longer. More recently, a larger meta-analysis also found a similar reduction in relative risk for VAP in patients in the subglottic secretion drainage arm (RR 0.55, 95% CI 0.44-0.66)¹⁹ and again advocated that tracheal tubes with subglottic secretion drainage should be used for patients at increased risk of acquiring VAP.

The PneuX PY™ VAP prevention system

One innovation designed to prevent VAP is the PneuX PY™ VAP prevention system (Venner Medical, Singapore), (Figure 1). This system includes subglottic secretion drainage, an

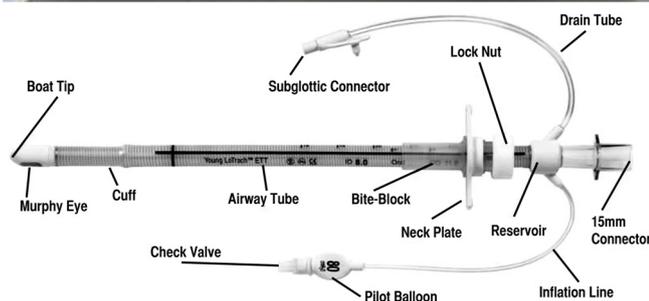


Figure 1 The Venner PneuX™ PY VAP prevention system (reproduced with permission from Venner Medical, Singapore).

internal lining inside the tracheal tube to prevent the formation of biofilms, the facility for retrograde upper airway irrigation, the provision of an effective airway seal with a low volume/low pressure cuff, and a constant pressure inflation device to maintain optimal cuff pressure. The manufacturer claims that, while individually each one of these features helps provide protection from VAP, in combination, the system affords added protection.

Evidence already exists to suggest that the PneuX system can prevent pulmonary aspiration in laboratory investigations.¹¹ One study showed that it prevents pulmonary aspiration in clinical practice,²³ while a retrospective observational study showed a 1.8% incidence of VAP in a cohort of 53 patients intubated with the PneuX system.²⁴ The latter study also demonstrated that elective tracheal tube exchanges were safe and had no impact on VAP rates. However, published data documenting the PneuX system's clinical effectiveness and the actual incidence of VAP in patients using the system is limited, with ongoing studies yet to be published; this current evaluation attempts to add to this growing evidence base.

Methods

Approval to undertake this review was obtained from the Clinical Governance department within Hull and East Yorkshire Hospitals NHS Trust. Through this process it was deemed that this analysis was a service evaluation and not research.

The evaluation aimed to highlight two issues in the use of the PneuX system in the intensive care environment: whether the PneuX system provided patients with protection from VAP; and whether local practice was affected during the period of the PneuX system use.

Male gender		56%
Mean (SD) age (years)		57.5(18.7)
Type of patient	Medical	32
	Surgical	7
	Neurosurgical	9
Median (IQR) duration of PneuX system <i>in situ</i> (mins)		3,559 (2,470-6,054)
Mean (range) duration to tracheal tube exchange (mins)		821 (75-2,280)

Table 1 Patient demographics.

We collected data on all patients intubated with the PneuX system in our intensive care department during 2010 using both paper and electronic hospital records.

Given the lack of a universal 'gold standard' diagnostic criterion for VAP, we chose to define the diagnosis according to the recommendations of the American Thoracic Society and the Infectious Diseases Society of America.²⁵ Clinical diagnosis of VAP was made if new radiographic infiltrates were present on chest X-ray at 48 hours after initial intubation, in combination with at least two of the following: fever, leukocytosis, or purulent tracheo-bronchial secretions. Additionally, *post hoc* calculation of the Clinical Pulmonary Infection Score (CPIS)²⁶ was performed in those patients who remained intubated with the PneuX system, and had the requisite data to complete CPIS scoring at 48 hours post intubation.

The intensive care department had not previously used tracheal tubes with the facility to perform subglottic secretion drainage. Therefore, usage criteria were agreed by clinicians in order to standardise use and maximise potential benefit. The system was used initially for patients expected to be ventilated for 72 hours or more. Part way through the year, the time frame was reduced to include any patients expected to be intubated for greater than 24 hours. This was primarily because clinicians felt unable to predict periods of intubation accurately and because they wanted to maximise the potential benefits of using the system. The decision to use the PneuX system was at the discretion of the consultant intensivist on call. Those patients who had already been intubated with a conventional tracheal tube could have their endotracheal tube exchanged if this was deemed appropriate. It was preferential that these tube exchanges occurred within 24 hours of first intubation, in line with the manufacturer's recommendations.

The nursing and on-going management of the PneuX system was guided by a standardised nursing care plan provided by the supplier, who also provided ongoing telephone and on-site support as required. In addition, a selection of in-house senior intensive care nursing staff were able to give immediate and ongoing support.

During the review period, the VAP prevention strategy in place comprised a care bundle consisting of elevation of the head of the bed, deep vein thrombosis prophylaxis, gastric ulcer prophylaxis, and daily sedation holds. Compliance and monitoring of this care bundle was undertaken as per the

'Saving Lives' initiative for all patients intubated during admission to the department, including those with the PneuX system in place.

Results

Over the review period the PneuX system was used on 48 patients (Table 1) for a cumulative total of 3,982 hours (166 days) throughout the year, with a median (range) duration of the system being in place of 59.3 hours (range 3.6-344).

Seventy-one percent of patients had a conventional tracheal tube exchanged to the PneuX system, with a mean time to exchange of 13 hours and 41 minutes after initial intubation.

The VAP rate for the combined cohort of patients was calculated at 6.25% (95% CI, 1.3-17%), with similar incidence regardless of whether the PneuX system was used on primary intubation or after tracheal tube exchange (Table 2). Based on the cumulative total of PneuX system use and the occurrence of VAP, we calculated an incidence of 17.9 VAPs/1,000 bed days.

CPIS data was available for 24 patients for *post hoc* analysis, which identified five patients with potential VAP, ie a CPIS score of ≥ 6 at 48 hours. Two cases were excluded due to the presence of pre-existing pneumonia; CPIS scoring corroborated the ATS/IDSA criteria in two of the three patients identified with VAP.

In the three patients who had VAP as diagnosed by the ATS/IDSA guidelines, the onset of VAP was identified on days 3, 7 and 9 after initial intubation (Figure 2).

The majority (66%) of extubations were planned. However, of the remaining unplanned extubations, two were deemed to be accidental, where the patient was not responsible for tracheal tube removal, and five were classed as self-extubation. In a single case the tracheal tube was removed for clinical reasons.

Discussion

In this assessment of the efficacy of the PneuX system, it is apparent that the crude incidence of VAP is low in this particular group of patients. It is likely that this is largely due to the small sample size. In our evaluation, 29% of patients were initially intubated using the PneuX system; in a pilot study by Doyle and colleagues,²⁴ 17% of patients underwent initial tracheal intubation using the PneuX system. Both studies highlight the difficulties in identifying patients who are likely to be intubated for prolonged periods. These low figures also reflect the difficulty of having expensive intensive care specific equipment in locations like emergency departments and general wards. Doyle et al²⁴ found no VAP in their patients during PneuX system use; this contrasts with the current rate of 6.25% despite patients having a shorter period of intubation. This is contrary to expectation, given evidence suggesting that the incidence of VAP rises with longer duration of intubation.²⁷ However, previous clinical studies using the PneuX system^{23,24} were conducted in ICUs well practised in its use, which may indicate the significant contribution that experience with the PneuX system may have in obtaining consistent and positive clinical outcomes.

In terms of the safety of the system, the majority of extubations were planned in advance but 17% were classified as unplanned, with a majority (62%) of these being self-

	No of patients	VAP incidences	%
Primary intubation with PneuX system	14	1	7.14
Tube exchange	34	2	5.88
Total	48	3	6.25

Table 2 Data showing number of patients and VAP incidence according to whether they underwent primary intubation of tracheal tube exchange with the PneuX VAP prevention system.

VAP incidences

37-year-old female

- Pneumonia - no organism identified
- Primary PneuX system intubation
- Intubated for 11 days
- VAP criteria met day 9 post intubation

85-year-old male

- Emergency abdominal aortic aneurysm repair
- ETT exchanged to PneuX system after 15 hours 20 minutes post initial intubation
- Intubated for 11 days 14 hours
- VAP criteria fulfilled at day 7 post initial intubation
- Has been transferred across hospital sites

37-year-old female

- Self poisoning
- ETT exchanged to PneuX system after 12 hours 20 minutes post initial intubation
- Intubated for a total of 39 hours 40 minutes
- Self extubated
- VAP criteria met day 3 post initial intubation post reintubation with standard ETT

Figure 2 Characteristics of three patients diagnosed with VAP.

extubations. Reported unplanned extubation rates vary widely from 2% to 22%²⁸⁻³² and an approximate rate of between 0.1 and 3.6 per 100 intubation days.³³ Reported self-extubation rates appear to be less variable (4% to 11%),³⁴⁻³⁶ though case mixes differed in these studies. Certain variables are associated with increased self-extubation; these include age, diagnosis, the method of securing the tracheal tube, and levels of consciousness and sedation.^{33,35,36} The overall percentage of patients who self-extubated in our cohort was 13%. This variation emphasises the need for local evaluation of unplanned extubation rates and suggests that system design contributes to this rate.

In determining the efficacy of the PneuX system, the key difficulty was how to define VAP. A number of scoring tools were considered to aid diagnosis, such as the CPIS.²⁶ However, it was felt that the ATS/IDSA²⁵ criteria would provide both corroboration of clinical judgment and a simple tool to aid the identification of VAP. Due to its broad criteria it was felt that it may result in an increase in false positive VAP diagnoses, but this was deemed preferable to the consequences of underestimating the incidence. In order to further strengthen

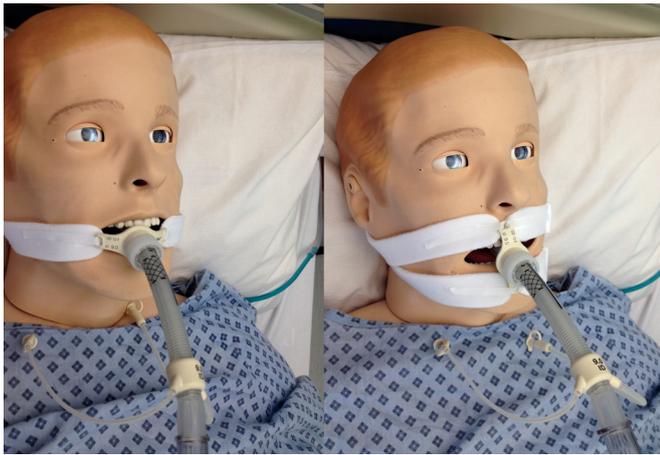


Figure 3 Techniques in securing PneuX endotracheal tube.

the diagnosis, CPIS scoring was added. However, the value of CPIS scoring is still debated. Some studies have shown high levels of correlation with microbiologically diagnosed VAP,²⁶ while others found it not superior to conventional clinical criteria³⁷ and unsuitable for all patient subgroups.³⁸ More specifically in this context, the inability to complete datasets to enable CPIS scoring for all patients reduced the confidence in the VAP diagnosis made using the ATS/IDSA recommendations.

There were no discernible similarities between the cases of VAP identified. In one instance a patient with the PneuX system *in situ* acquired VAP after inter-hospital transfer to another intensive care unit with no experience in using the PneuX system.

The data obtained incorporated the period of the introduction of the PneuX system into local clinical practice. A number of teaching sessions were held which discussed the functionality of the system and tracheal tube management. These were led by representatives from the manufacturer and, subsequently, by the intensive care nurse educators. It became apparent that intensive care staff only felt proficient with the use of this system after a sustained period of use. Issues were raised about difficulty in securing the tracheal tube, which has implications for the risk of unplanned extubation. There is currently no reference data on self-extubation rates using the PneuX VAP system but the method employed to secure the system's tracheal tube (**Figure 3**) may have played a role in both this perception of difficulty in securing the tube and in the number of unplanned extubations. Evidence from quality improvement studies^{39,40} has shown that use of standardised procedures, such as in securing tracheal tubes, improves the rate of self-extubation.

A number of observations were raised by staff over the period of the PneuX system's use, though there was no formal assessment or documentation. Of note, physiotherapists commented that the tracheal tube felt 'too long,' which prevented suction catheters entering the trachea sufficiently to provide adequate suction. Some staff felt that the bite block and lock nut (**Figure 1**) acted as the perfect grip for patients and although it secured the tube in the right position, it aided patients in self-extubation.

Staff commented positively on the process of aspirating subglottic secretions depending upon the quantity and

characteristics of the secretions obtained; however some were hesitant to perform retrograde airway irrigation once per shift; the reasons for this reluctance should be explored.

For ongoing management, a predefined daily care plan for the PneuX system was provided. However, no attempt was made to assess compliance to this plan and its potential effect on VAP incidence. Compliance with locally established ventilator care bundles was also not retrospectively monitored and it is possible that these variables may have affected the VAP rate. Any future prospective analysis on the effectiveness of the PneuX system would need to monitor compliance to these bundles and protocols.

We have no data for patients intubated with standard tracheal tubes during the study period; however, the data from our patients in whom the PneuX system was used suggest a lower VAP rate than in published historical controls. Subsequent data from our unit has shown a decreased VAP incidence from 31% in 2009 to 26% in 2011 in both retrospective and prospective reviews.^{41,42}

The lack of a control group in this study makes it difficult to assess the safety of the PneuX system; however, there appeared to be a higher rate of unplanned extubations than in other published studies. We found the majority of unplanned extubations to be self-extubations, which does raise a concern about patient safety.

Despite the limitations, our data provides a baseline against which future local initiatives and interventions can be measured. Our study suggests that a prospective, randomised controlled trial comparing the PneuX system with other interventions to reduce the incidence of VAP should be undertaken to determine the value of the system in clinical practice.

Following this study, and considering the cost, the department has not continued to use the PneuX VAP prevention system. However, as a result of this study and our desire to decrease the incidence of VAP, our department has adopted an alternative subglottic suctioning tracheal tube device and uses ongoing monitoring of VAP, with root cause analysis when it occurs.

Declaration

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Conflicts of interest

None, other than the funding issue.

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