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Nosocomial pneumonia in mechanically ventilated patients, a prospective randomised evaluation of the Stericath closed suctioning system

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Abstract *Objective*: To compare the ventilator-associated pneumonia (VAP) incidence rates in mechanically ventilated patients according to the type of endotracheal suctioning (closed versus open). *Setting*: The Neurosurgery Intensive Care Unit of the Grenoble University Hospital, France. *Design*: A prospective randomised study performed after a 6-month period of nursing personnel training. *Patients*: One hundred four consecutive patients needing mechanical ventilation for more than 48 h were randomised into two groups. To be eligible, patients had to have no active infection or respiratory affection in their passes. In the Stericath group (S + , $n = 54$), patients were not disconnected from the ventilator during suctioning. The others were routinely managed (S–, $n = 50$). In both groups patterns of frequency and duration of suctioning were performed according to a standardised protocol. *Measurements*: The non-adjusted incidence rate of VAP was lower for S + than for S– (7.32 versus15.89 per 1000 patient-days, $p = 0.07$). Multivariate analysis performed using the Cox model showed an adjusted risk of VAP 3.5 times higher in S– (95% Cl: 11.00–12.33). The risk being 4.3 higher in patients receiving gastric acid secretion inhibitors (1.08–16.82). In non-censored cases ($n = 76$) length of ICU stay increased by an average of 16.8 days when VAP was present ($p = 0.0008$). No adverse effect due to Stericath use was noted and volume of tracheal aspirate was similar between groups ($p = 0.178$). *Conclusion*: The use of Stericath reduced the incidence rate of VAP without demonstrating any adverse effect.

Key words Nosocomial pneumopathy · Mechanical ventilation · Cox model · Closed suctioning device · ICU

Introduction

Pneumonia is the most frequently encountered severe nosocomial infection in intensive care units (ICU) [1, 2]. Currently, the incidence of ventilator-associated pneumonia (VAP) varies between 9 and 50% [3, 4, 5, 6, 7, 8, 9, 10]. The risk of pneumonia is 10 times higher in patients receiving mechanical ventilation [11] and is closely correlated with length of time on the ventilator. Fagon et al. [6] reported an increased incidence of VAP from 6.5% after 10 days of mechanical ventilation to 19 and 30% after 20 and 30 days, respectively. Mortality rates range from 30 to 70% [4, 6, 7, 9, 10, 12, 13]. Since VAP leads to prolonged hospitalisation [8], it plays a major role in rising health care costs [3, 4, 5, 6, 12, 13].

"Open" endotracheal suctioning has been blamed by some authors for facilitating pneumonia because of repeated insertion of the suctioning catheter [14, 15]. Closed circuit aspiration systems have therefore been

developed in order to limit this risk. Furthermore, if suctioning methods compromise the maintenance of positive expiratory pressure, the open one interrupts it [16], thus a safety level of PaO_2 and SVO_2 could be lowered [16, 17, 18, 19], which could result in decreased blood pressure [17, 20], cardiac arrhythmia [17] and increased intracranial pressure [21]. Closed aspiration systems have demonstrated their efficacy in preventing these complications, thereby improving the quality of care [17].

After an adequate training period, this prospective study was carried out with the objective of comparing the incidence rate of VAP between patients equipped with the closed suctioning system (Stericath)l and those receiving the usual care.

Methods

Over a 6-month period in 1995, the nursing personnel in the neurosurgical ICU at the Centre Hospitalier de Grenoble (France) were trained in the use of the Stericath. A randomised prospective study was then carried out over a 40-month period, after approval by the Medical Ethics Committee. One hundred four consecutive patients were included in the study, after informed consent had been provided by their families. Only patients free of any acute or chronic chest disease, hospitalised within the last 48 h and whose predicted time on the ventilator was greater than 48 h were eligible for the study. All were orally intubated, connected to a Cesar (CFPO, France) respirator equipped with an anti-bacterial filter (PAL). Patients had a naso-gastric tube, those with prior history of peptic ulcer disease and/or steroids administration received gastric acid secretion inhibitors (GASI) as preventive therapy.

After randomisation, the Stericath group of patients (S + , $n = 54$) were not disconnected from the ventilator during suctioning. In the routinely managed group (S–, $n = 50$) patients were disconnected from the ventilator in order to be suctioned. Endotracheal suctioning was performed once every 2 h, at a pressure of less than –80 cmH_2O and was repeated only if needed. It did not exceed a period of 10 s, patients who were disconnected from the ventilator were pre-oxygenated for 30 s at an $FI0_2$ of l00%. This was in accordance with our hospital endotracheal suctioning protocol (Comité de Lutte contre les Infections Nosocomiales, CLIN-Grenoble, France, v2.0). This protocol requires hand washing before and after the care, sterile single-use catheter handled with sterile compresses and non-sterile single-use gloves. Nurses must worn overalls, glasses and face mask. When a second suction was needed in one suction period, the same material was used after having been cleaned with sterile solution. In a similar way, the closed system was cleaned after each suction.

The Stericath was changed every day at 8 a.m. A chest X-ray, complete blood count and arterial blood gas testing were carried out at least once a day. Rectal temperature was recorded every 4 h. Chest radiographs were read daily by a radiologist, ignoring the patients' allocation groups. The study was terminated for any patient who expired or was transferred to another service.

After 48 h of mechanical ventilation, the diagnosis of pneumonia was made when four criteria were present: a new and persistent infiltrate on chest X-ray, purulent endotracheal secretions with a positive sputum culture, peripheral leukocytosis of greater than 10,000/mm^3 or less than 4,000/mm^3 and a rectal temperature higher than 38 °C without other apparent cause of fever.

Statistical analysis was performed using the Stata program (Stata, College Station, Texas, USA). For numerical data, comparison of means between the groups was carried out using the Student *t*-test. The hypothesis of independence between qualitative variables was tested with Pearson's chi-squared test or with the unilateral Fisher's exact test. A p value of 0.05 or less was considered significant. The adjusted hazard ratio of developing VAP was estimated by the Cox semi-parametric model. The hypothesis of proportional hazards assumption was verified graphically by the –Ln[–Ln(S(t] method and tested according to the Grambsch and Therneau generalised method [22]. Sex, Stericath and GASI qualitative variables were coded as binary, value 1 was attributed to male, Stericath– and GASI(+) groups. The effect of pneumonia occurrence on length of ICU stay was assessed on non-censored data only, adjusted to treatment group and co-variates using ANOVA.

Two independent teams carried out data recording and statistical analysis.

Results

Closed head injuries (61.5%) and cerebro-vascular accidents (30.8%) were the principal causes of admission to the ICU. Table 1 shows the distribution of the main clinical parameters between the two groups. Univariate analysis failed to show any difference in the incidence rate of VAP between the two groups at the level of significance adopted, in spite of an incidence of 7.32 per 1000 patient-days for the S + group ($n = 4$) and of 15.89 for the S– group ($n = 9$) ($p = 0.07$). Microbial agent identification showed *Escherichia coli* ($n = 5$), *Staphylococcus aureus* (methicillin + , $n = 4$), *Streptococcus D* ($n = 1$), *Haemophilus influenza* ($n = 1$) and *Streptococcus pneumoniae* ($n = 1$).

Table 2 and Fig. 1 show the adjusted hazard ratio estimated by multivariate analysis according to the Cox model. The closed endotracheal suctioning group served as the reference. Adjusted co-variates were age, sex, Glasgow Coma Score (GCS) [23] on ICU admission and the use of gastric acid secretion inhibitors. Open endotracheal suctioning was accompanied by a 3.5 fold higher risk of VAP ($p = 0.05$). Prophylactic use of gastric acid secretion inhibitors increased this risk 4.3 times ($p = 0.04$).

In non-censored patients and in the absence of VAP, there was no statistical difference in adjusted length of ICU stay between the groups ($p = 0.26$). By contrast, length of ICU stay increased by an average of 16.8 days in the presence of VAP ($p = 0.008$).

Discussion

In this study the overall incidence of VAP was 12.29 per 1000 patient-days. These rates are similar to those previously reported in the literature under the same clinical and diagnostic conditions. Indeed, Verwaest et al. [24],

Table 1 Patient's main hospitalisation characteristics according to endotracheal aspiration randomised allocation. Open group: Stericath–; closed group: Stericath + ; mean (SD) (*GCS* Glasgow Coma Scale [23], *ICU* intensive care unit, *SAPS I* Simplified Acute Physiology Score [39], *MV* mechanical ventilation, *GASI* gastric acid secretion inhibitor therapy, *GOS* Glasgow Outcome Scale [40])

	Stericath +	Stericath–	*p*
	n = 50	*n* = 54	
Age (years)	43 (20.7)	43.8 (17.8)	0.841
Male (*n*)	37	36	0.667
Cause of admission			
Closed head injuries (%)	64	59	0.620
Cerebro-vascular accidents (%)	30	33	0.715
GCS on ICU admission	8.1 (4.9)	7.6 (4.4)	0.567
SAPS I on ICU admission	7.88 (3.2)	6.91 (2.44)	0.500
Intubation duration (days)	12.8 (11.3)	14.1 (11)	0.590
MV duration (days)	11.3 (12.2)	14.9 (15.4)	0.254
Length of ICU stay (days)	15.6 (13.4)	19.9 (16.7)	0.134
Coma duration from ICU admission (days)	2 (3.8)	3.1 (4.8)	0.260
GASI therapy	7	12	0.278
Tracheal sputum volume*	2 (1.2)	2.3 (0.8)	0.178
Delay in pneumonia occurrence (days)	(*n* = 4)	(*n* = 9)	
Median	5	5	0.938
Range	3–10	2–23	
GOS	2.9 (1.5)	3 (1.5)	0.624
Mortality rate (%)	26	27.8	0.838

* Mean of 2-h nursing notes ranging from 1–4: 1 = trace, 2 = moderate, 3 = lightly abundant, 4 = heavily abundant

Table 2 Adjusted hazard ratio (HR) estimation of nosocomial pneumopathy occurrence (with its 95% confidence interval) according to the semi-parametric Cox model ($n = 104$; chi^2 (6) = 13.41; $p = 0.0369$) (*GCS* Glasgow Coma Scale [23], *GASI* gastric acid secretion inhibitor therapy, *ICU* intensive care unit, *LL* HR 95%CI lower limit, *UL* HR 95%CI upper limit, *p(ph)* chi^2 test of proportional hazards assumption)

	HR	*p*	95%CI		
			LL	UL	p(ph)
*Stericath(–)	3.49	0.05	1	12.33	0.333
Age (years)	0.96	0.069	0.92	1.01	0.189
*male	4.35	0.225	0.53	35.6	0.754
GCS on ICU admission	0.96	0.057	0.84	1.11	0.199
*GASI code	4.26	0.609	1.08	16.82	0.734

* coded as 1

Joshi et al. [25], Craven et al. [10] and Deppe et al. [14] report rates of 16.1, 12.8, 21 and 27%, respectively.

The sensitivity and specificity of bacteriological diagnosis by endotracheal sputum sampling in these studies are lower than by fiberoptic bronchoscopic (FOB) sampling using a protected specimen brush or broncho-alveolar lavage [26]. On the other hand, the use of FOB sampling techniques in neurosurgical ICU patients should remain exceptional given their undesirable effects on gas exchange [27, 28] and on cerebral haemodynamic parameters [29]. Finally, FOB sampling has no effect on either the mortality rate or on the length of hospital stay when compared with simple endotracheal suctioning [30] and is much more expensive [31]. In addition, according to Nierdermann et al. [32], its use as an exclusive means of diagnosing pneumonia selects a particular patient sub-population and under-estimates the total number of patients with VAP [32].

In this study, after adjusting for well known predictive factors, the Stericath has been shown to be useful in the prevention of VAP (Table 2) compared with conventional endotracheal suctioning techniques. In a similar study, Deppe [14] did not show a statistically significant protective effect of the closed system on the incidence of pneumonia (26% versus 29%) and observed an increase in the incidence of endotracheal colonisation related to the closed device (67% versus 39%, $p < 0.02$). However, in Deppe's study the frequency of suctioning had not been established by the protocol and patient survival rates with the closed system were significantly higher [14].

All diagnostic methods taken into account, the incidence of VAP ranges from 9 to 50% in different studies [3, 4, 5, 6, 7, 8, 9, 10]. The incidence reported in this study is lower than that observed in the beginning of the decade, due to the better preventive measures cur-

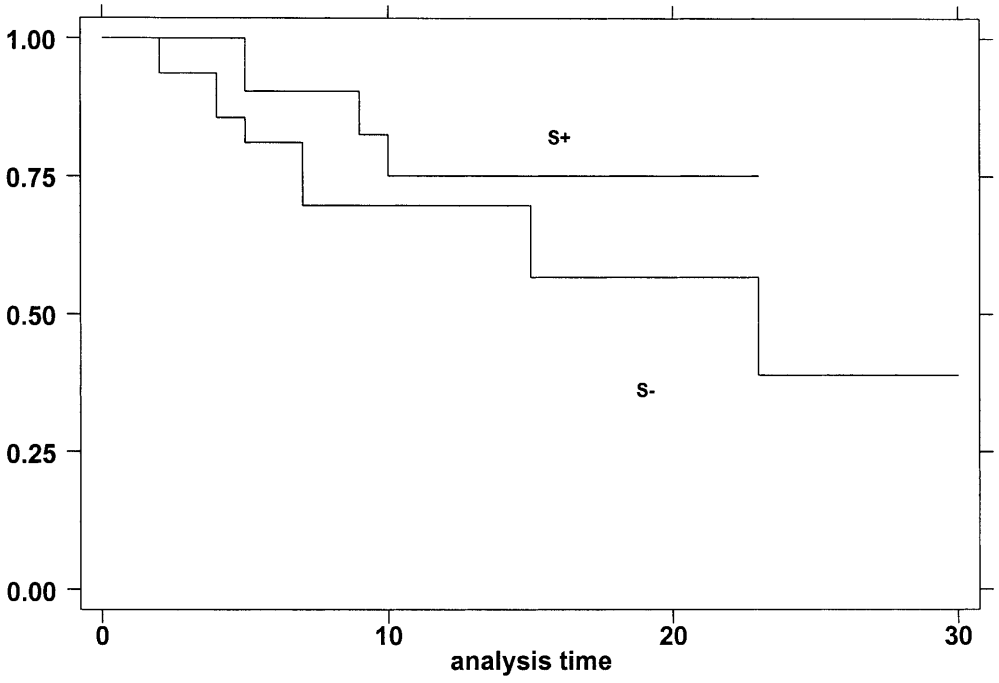

Fig. 1 Estimated proportional hazard survivorship function for ventilator-associated pneumonia (VAP) according to type of suctioning device (closed: S + versus open: S–), adjusted for age, sex, Glasgow Coma Scale at ICU admission and gastric secretion inhibitor preventive therapy (*x axis* admission time to VAP (days), *y axis* cumulative survival) Cox model: the lines represent the probability of remaining free of VAP during the ICU stay

rently being employed, such as the use of disposable single-use material, sterilisation of invasive equipment, routine use of anti-bacterial filters [33] and shorter hospital stays [14]. Among other known risk factors, the use of antacid gastro-protective agents has significantly increased the incidence of pneumonia [10, 34]. Age did not appear to be a risk factor, contrary to data in the literature [6, 35]. This result is probably linked, as in the study by Hsieh et al. [3], to the large number of closed head injuries recruited in this study. Elderly patients died earlier in this sub-population, thereby diminishing their risk of developing pneumonia. Due to homogeneity, the GCS variable did not distinguish itself as a risk factor in this study.

Ventilator-associated pneumonia increased the length of stay by 16.8 days (95 % CI 7.5–26) in non-censored patients. The length of stay decreased with increasing GCS [3, 4, 5, 36], as with age because the oldest patients had the highest GCS ($r = 0.33$, $p = 0.0033$).

By its effect on the length of stay, VAP significantly increased the cost of health care. To illustrate, Fagon estimated in the early 1990s that for every 20-day prolongation in length of stay in the ICU, hospitalisation costs increased by about FF 180,000 [13]. This difference, as well as the exogenous contamination prevention, could be a justification for the use of an additional device such Stericath. Although this has not been studied, it could protect non-infected patients from those who are infected. Over the last few years research has been more focused on improving methods for detecting pneumonia and must be followed by new prospectively evaluated methods of prevention of nosocomial infections [37, 38]. Other studies are needed to confirm the apparent safety of closed systems and to improve our knowledge on their condition of use.

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