Original Research Article

An observational prospective study on incidence of Ventilator Associated Pneumonia (VAP) in patients with continuous endotracheal-tube cuff-pressure control system

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Abstract

Background: Ventilator Associated Pneumonia (VAP) is one of the most important nosocomial infections in the Intensive Care Unit (ICU), causing significant morbidity and mortality. Apart from other measures, prevention of the leakage of oro-pharyngeal secretions in the lungs, using Endotracheal Tube Cuff Pressure Control System (ETCPCS) is an important upcoming strategy. **Aims:** In order to evaluate the significance of continuous cuff pressure monitoring in intubated patients. **Methods**: A total of fifty patients, of either gender with age >18 years who were mechanically ventilated for more than 48 hours, after intubation maintaining standard aseptic techniques and adhering strictly to VAP prevention bundle,were observed. Pressure in the cuff was maintained around 20 to 30 cms H_20. Patients' vitals, general and systemic examination, ventilator parameters and other investigations like leucocyte count, arterial blood gas measurements, chest X-Ray, and tracheal tube culture were recorded. **Results:** The incidence and the incidence density of VAP were found to be 24% and 26.37 respectively. Out of the 12 (24%) confirmed VAP patients, 4 (33%) were early onset whereas 8(66%) were categorized as late onset VAP. **Conclusion**: Continuous cuff pressure measurement may be associated with the incidence of VAP in the lower range whereas the significance of other factors like the adequacy of nursing staff in the ICU cannot be ruled out.

Keywords: Ventilator Associated Pneumonia, Intensive Care Unit, mechanical ventilation, Continuous cuff pressure.

Introduction

Ventilator Associated pneumonia (VAP) is defined as pneumonia occurring more than 48 hours after the onset of mechanical ventilation [1]. Early-onset pneumonia occurs within the first 4 days of intubation, whereas late-onset VAP develops 5 days or more after intubation. It is one of the most important nosocomial infections in ICU causing significant morbidity and mortality[2].The incidence of VAP is 1–4/1000 ventilator days, but it can be high as 10/1000 ventilator days. The incidence of morbidity varies from 9% to 68% andthat of mortality from 33% to 71%. VAP may also increase the length of Intensive Care Unit (ICU) stay by 28 %[3].It is commonly believed, that VAP primarily occurs because the endotracheal or tracheostomy tube allows free passage of bacteria into the lower segments of the lung in a person who often has underlying respiratory or immune problems[4-6].A combination of bacterial damage and consequences of the immune response lead to disruption of gas exchange with resulting symptoms. Diagnosis of ventilator-associated pneumonia is difficult and is not standardized[7].The criteria used for diagnosis of VAP vary by institution, but tend to be a combination of several of the following radiographic features, clinical signs, and laboratory evidence[8].There are various criteria for diagnosing VAP in the ICU with a special emphasis on the value of clinical diagnosis, microbiological culture techniques, and biomarkers of host response. Most commonly used criteria are Johanson criteria although Clinical Pulmonary Infection Score (CPIS) and Centers for Disease Control and Prevention (CDC) are also commonly used[9].There are invasive and noninvasive strategies for obtaining the culture sample.American and Canadian guidelines strongly recommend the use of Supraglottic Secretion Drainage (SSD). Special tracheal tubes with an incorporated suction lumen as the EVAC tracheal tube form Covidien / Mallinckrodt can be used. New cuff technology based on polyurethane material in combination with subglottic drainage (Seal Guard Evac tracheal tube from Covidien /Mallinckrodt) claim significant delay in early and late onset of VAP[9,10].In view of the need to evaluate the significance of continuous cuff pressure monitoring in intubated patients this study was undertaken at our hospital. The objective of this research was to evaluate the incidence of VAP in a sample of patients intubated and mechanically ventilated in ICU receiving continuous endotracheal-tube cuff-pressure control system which in our case

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was IntelliCuff® Integrated cuff pressure controller by Hamilton Medical.

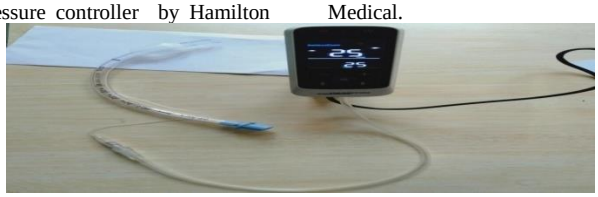

Fig 1: Continuous endotracheal tube cuff pressure control system with cuff pressure of 25 mbar

Methods

The study was conducted over a period of 15 months, extending from July 2018 to December 2019, in an intensive care unit (ICU) of a tertiary care center. A total of 50 patients who were kept on mechanical ventilator were randomly selected. An informed written consent was taken from close concerned relatives of all the patients, of either gender aged 18 years and more referred from the emergency room, clinical or surgical wards, whom were intubated for more than 48 hrs at the participating ICU. A thorough physical examination, routine investigations and any special investigation if required was done for the study. The patients excluded were those with chronic tracheostomy, intubated and referred from other centers, known immune deficiency diseases, malignancies or immunosuppressant drugs, suspected aspiration before tracheal intubation, extremes of age and those who were admitted with pneumonia at the time of admission and patients of Acute Respiratory Distress Syndrome (ARDS).After inflating the endotracheal tube cuff, the pilot balloon was connected to the endotracheal cuff pressure control system (Intelli Cuff® in our case). Pressure in the cuff was maintained around 20 to 30 cmH_2O. Other measures of VAP prevention bundle like proper hand washing, sterile technique for invasive procedures, raising the head of the bed to at least 30 degrees, discontinuing mechanical ventilation as soon as possible, supra glottic suction were also carried out. Indication for mechanical ventilation was noted. In each patient, ventilator mode and settings were recorded and any change in setting was recorded daily. Patients' vitals, general and physical examination, temperature, oxygen saturation and position of the patients were monitored regularly. During the early stages of ventilation, patients were adequately sedated. All necessary measures were taken for prevention of hospital-acquired infections. A battery of routine investigations was performed and special investigations, like culture of the tracheal tube, blood and urine, were performed. Sputum from the patients was collected from the tip of the suction catheter and transported to the laboratory in a sterile tube. Patients were monitored from the date of inclusion in the study to the final outcome in the ICU. VAP was diagnosed on clinical grounds based on Johanson criteria [Table 1] fever, oxygenation status, quantity and purulence of tracheal secretions, leukocyte count, type of radiographic abnormality and the VAP group was classified into two groups, early-onset type (within 48–96 h) and late-onset type (>96 h). Once the clinical suspicion was established, empirical antibiotic therapy was initiated based on local guidelines prescribed. Patients were routinely screened by arterial blood gas (ABG) analysis every 12 hourly and appropriate steps were taken to correct any change.

Data collected from the included patients was assessed daily in terms of VAP occurrence and compliance with the measures of the VAP prevention bundle and recorded at the standardized follow-up form. Patients were followed up until hospital discharge or death.

Statistical analysis

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to the data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Statistical software SPSS (version 20.0) and Microsoft Excel were used to carry out the statistical analysis of data.

Results

In our observational study the number of patients was not fixed and we observed the patients who received the above mentioned intervention (continuous endotracheal cuff pressure control system) over a period of fifteen months. A total of 61 patients were included in this study out of which 11 patients were excluded on the basis of the study design and the exclusion criteria referred from the emergency room, clinical or surgical wards. Patients who were intubated for more than 48 h at the participating ICU were recruited for the study. A total sample size of 50 patients with total of 284 ventilator days was available for study. The age distribution of confirmed VAP cases was studied and it was found that, the incidence of VAP was highest in patients of age between 31-60 years. Reason could be that the majority of admitted patients were in this age group.The number of people between 31 – 60 years accounts for 58% of the total number of patients in our study (table 1). Out of the 12 VAP patients in the study n-8 (66.66%) were males and 4(32.33%) were females. Patients developing VAP were predominately males in our study. The reason could be that more of the patients admitted in ICU were males and RTA was among the leading cause of ICU admission which again affecting the males predominately (table 1).

Table 1:Demographic profile of the study patients

Age	percentage
0-30	33.3%
31-60	58.3%
>60	8.3%
Sex Male/Female	66.6%/32.3%

Table 2: Calculation of VAP rate (Incidence and incidence density)

Month	No of Patients on Mechanical Ventilation.	Duration of mechanical ventilation (In days)	No. of VAP cases Diagnosed.	VAP rate per 1000 Ventilator days.	Incidence of VAP
July 2018 to Sep. 2019	50	455	12	26.37	24%

In this study, the VAP incidence and incidence density was 24% and 26.37 per 1000 ventilator days respectively. The ventilator associated pneumonia density rate was calculated as:

$$\frac{\text{Total number of VAPs in ICU}}{\text{Total number of ventilator days in ICU}} \times 1000$$

The ventilator associated pneumonia incidence was calculated as:

$$\frac{\text{Total number of VAPs in ICU}}{\text{Total number of study patients in ICU}} \times 100$$

Patients developing early and late onset VAP : Out of 12 confirmed VAP patients, 4 (33%) were categorized as early onset & 8 (66%) were categorized under late onset VAP (Fig 2).

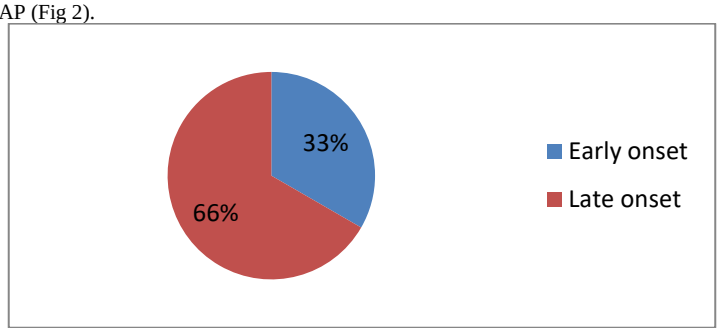

Fig 2: Patients developing early and late onset VAP

The most common group of patients was trauma and elective general surgical patients.

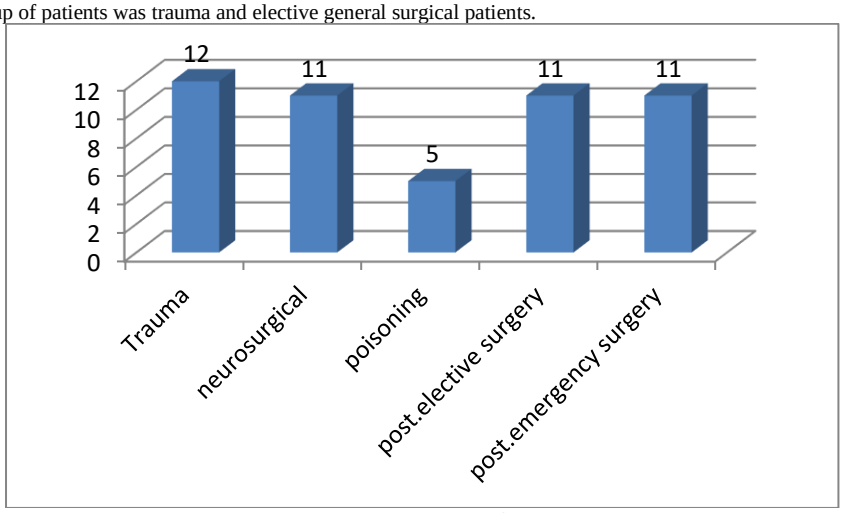

Fig 3: Clinical spectrum of patients

In majority of our cases, the CXR infiltrate was in the Right lung (68.2%) whereas 13.6% of patients had in the left lung with 18.2% having bilaterally.

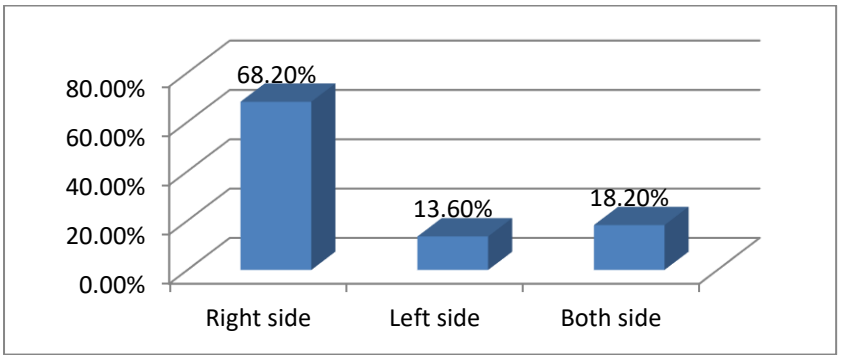

Fig 4: CXR findings

Most of patients were ventilated on Synchronised Intermittent Mandatory Ventilation (SIMV) mode (48%), 26% on Controlled Mandatory Ventilation (CMV) and 26% on Pressure Controlled Ventilation (PCV).

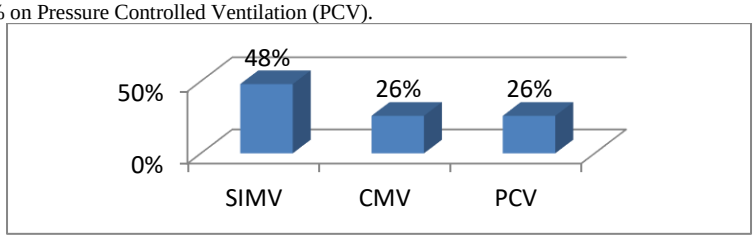

Fig 5: Mode of ventilation

Out of 50 study patients only one received open suction, rest of them received closed suction. One patient which did not receive open suction did not develop VAP.

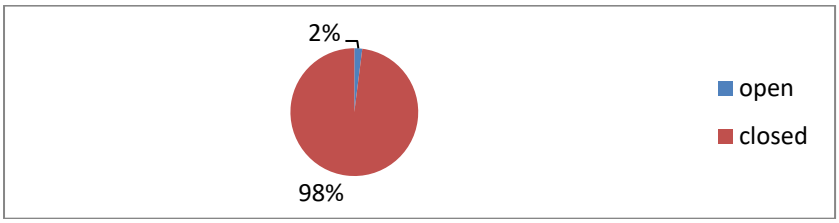

Fig 6: Type of Endotracheal suction used in study patients

Discussion

The use of mechanical ventilation has increased many folds since its first usage in polio epidemics in 1950s. Mechanical ventilators improve gas exchange, reduce work of breathing and improve hemodynamics. However mechanical ventilators are also associated with various complications. Complications may include those of intubation (upper airway trauma, intubation of the esophagus, intubation of the right mainstem bronchus etc.), machine failure, Ventilator induced lung injury (Volutrauma/ Barotrauma) and Ventilator associated pneumonia (VAP). From systematic review and meta-analysis, it has been found that the global incidence of Ventilator Associated pneumonia (VAP) is 1–4/1000 ventilator days, but it can be high as 10/1000 ventilator days[3].Ventilator Associated pneumonia (VAP) incidence rates as high as 40 to 50/1000 ventilator days has been reported from Asian and North Indian ICUs. The 48-hours time frame was set to differentiate any new infection from processes already going at the moment of intubation. VAP is categorized into an early and late onset VAP, due to the difference in epidemiological features and treatment options available for the two forms[11].Various studies have reported the frequency of VAP ranging from 18% to 57.14 % as shown below.

Table 1:Frequency of VAP (comparison with other studies)

STUDY	YEAR	VAP Rates percentage (%)
Agrawal et al[12]	2006	23
Joseph et al[13]	2009	18
Mukhopadhyay et al[14]	2010	42
Reena et al[15]	2011	27.22
Ranjan et al[16]	2014	57.14
Our study	2019	24%

This figure is at the lower end of the range of 15-58% as reported by other investigators but not comparable to other studies in the developed countries[11,17].The differences in the incidences is can be attributable to various factors such as differences in the study Population, differences in the definition of VAP e.g. clinical Vs microbiological criteria and may be to the use of preventive strategies . The higher incidence of VAP in our study as compared to the other ICUs in the developed world can be because of the lack of adequate nursing staff which may have adverse effects on patient care. The incidence of VAP in our study is lower as compared to that of other Indian ICUs where continuous endotracheal cuff pressure controller was not used. Overall incidence of VAP in our study was 24%. The incidence density was 26.37/1000 ventilator days which is comparable to the ICUs in other developing Countries. Out of the 12 patients who developed VAP in this study 66% were males and 32% were females which is similar to a study conducted by Eleni Apostolopoulou et al[2]wherein 71% were male and 29% were females. Also a study conducted in India by Joseph et al[13] reported that 66.7 % were male and 33.3 % were female. Out of the 12 cases of VAP, 33.3% were categorized as early-onset and 66.6%were late-onset VAP . Similar results were obtained by Mukhopadhyay et al with 38% being early-onset VAP and 62% late onset VAP. The categorization of VAP is important for starting initial empiric antibiotic therapy .We sent endotracheal aspirates for cultures in patients who are intubated for 2 or more days with excess secretions[14] This practice helps us choosing the right antibiotic later if patient develops symptoms and signs of VAP. Role of previous endotracheal aspirate in guiding the initial treatment of ventilator associated pneumonia has been shown by Jung B et al[17]. Out of 25 positive samples, Acinetobacter was most commonly isolated organism in our study followed by Klebsiella and Pseudomonas aeuroginosa.All of these patients did not develop VAP. Only 12 patients out of the 25 had developed VAP. In this study, we found a significant reduction in the incidence of VAP with the use of a continuous endotracheal tube cuff pressure control system as compared to other studies in the Indian ICUs where continuous endotracheal tube cuff pressure control system was not used but other conditions were same like nursing staff, long duty shift schedules etc. Previously, two RCTs of small sample size analyzed the use of a continuous or an intermittent cuffpressure control system. In the study by Valencia et al., which included 142 mechanically ventilated patients, the authors found no significant differences in VAP rate between the groups(continuous versus intermittent cuff- pressure control system) (29% versus 22%; P = 0.44)[9]. The RCT by Nseir et al., including 122 patients expected to receive mechanical ventilation for at least 48 hours, found that the group of patients receiving the continuous compared to the intermittent cuff-pressure control system showed a lower rate of VAP (9.8 versus 26.2%; P = 0.03)[19].The benefit of the continuous cuff-pressure control system to reduce the risk of VAP could be due to a lower risk of deflated cuff pressure (determined by a lower percentage of cuff pressure lower than 20 cm H_20). Thus, more constant maintenance of cuff pressure above 20 cm H_20 with a continuous system could lead to a lower risk of the progression of subglottic secretions into the lower respiratory tract and finally of VAP. Our study has certain limitations. First the study was carried out in a single ICU, and the results may therefore not be applicable to other ICUs. The study was not comparative where we could have obtained VAP incidence in non-interventional group under same ICU setting to draw more reliable conclusions. The results of our study suggest that continuous control of Pcuff is associated with reduced micro aspiration of gastric contents, reduced tracheobronchial bacterial concentration, and reduced incidence of VAP. The results of our study are somehow expected, given that the under inflation of the tracheal cuff is a recognized risk factor for micro aspiration and that continuous control of Pcuff allowed significant reduction of underinflation of the tracheal cuff. This is also a fact that under inflation of the tracheal cuff is not the only risk factor for micro-aspiration. In addition, total suppression of micro-aspiration is probably impossible, especially during thesuctioningof tracheal secretions and tracheal tube

movements. An observational cohort study performed in 81 critically ill patients identified under inflation of the tracheal cuff as an independent risk factor for VAP in the subgroup of patients who did not receive antimicrobials. However, a recent randomized controlled study examined the effects of automatic control of Pcuff on the incidence of VAP. Patients were randomized to receive continuous regulation of Pcuff with an automatic device (n = 73) or routine care of Pcuff (control group, n = 69). No significant difference was found in VAP rate between the two groups. Although VAP was the primary outcome in the study by Valencia and colleagues[20-22] In addition, the use of different devices to control Pcuff and the different incidence of VAP might explain the different results obtained in our study. In our study continuous control of Pcuff with automatic devices might have given patients somebenefit,as the understaffing of our ICU can result in significant under inflation time durations with manual inflations. A recent study demonstrated that automated Pcuff controllers with rapid pressure correction interfere with the self-sealing mechanism of highvolume low-pressure PVC-cuffed tracheal tubes and reduce their sealing characteristics which is not the case with our device as it provides slow pressure correction[22]. Microaspiration is the first step in pathophysiology of VAP. Although our results suggest an important role of microaspiration of gastric contents, previous studies suggested a minor role for this mechanism in the pathogenesis of VAP[23].A study byNseir S1.innov. 2011 in RCT Continuous control of tracheal cuff pressure and microaspiration of gastric contents in critically ill patients found that the percentage of microaspiration , bacterial concentration in tracheal aspirates and VAP rate were significantly lower in the intervention group compared with the control group. However, no significant difference was found in tracheal ischemia score between the two groups. So it was concluded that Continuous control of P (cuff) is associated with significantly decreased micro aspiration of gastric contents in critically ill patients·Our study has some limitations. First, we performed this study in a single center. Therefore, our results may not be extrapolated to all ICU patients, especially in ICUs with lower incidence of VAP . Finally, we did not evaluate the effects of continuous control of Pcuff on micro aspiration of oropharyngeal secretions or on the microbiology of these secretions. However, to our knowledge, there is no reason that continuous control of Pcuff could be efficient in reducing microaspiration of gastric contents without reducing micro aspiration of oropharyngeal secretions. Furthermore, the microbiological assessment of oropharyngeal secretions was beyond the objectives of this study. Furthermore since our study is not comparative so we cannot clearly conclude that Pcuff use could lead to decreased incidence of VAP as ideally comparison with non-interventional group under the same ICU circumstances could have been more rational. Current guidelines on the prevention of VAP do not contain recommendations for the use of a continuous or an intermittent endotracheal -tube cuff-pressure control system[10,20,13]. Thus, despite the limitations of our study, our findings could help in decision making on VAP prevention measures. They support the use of a continuous endotracheal-tube cuff-pressure control system. Furthermore in our hospital with inadequate manpower automatic cuff pressure control device could prove as a better option than manual devices as it does not need frequent attention from already overburdened nursing staff.

Conclusion

VAP continues to be a commonly encountered challenge amongst critically ill patients and carries significant burdens of morbidity, antibiotic utilization and cost. Studies on prevention strategies directed towards the pathophysiologic mechanisms of VAP have shown variable success. However, certain measures as described in this study have been shown to improve patient outcomes and, therefore, we recommend care providers consider a multidisciplinary strategy incorporating Continues endotracheal tube cuff pressure control system and other VAP prevention bundle components like NIPPV when possible; sedation and weaning protocols for those patients who do require mechanical ventilation; mechanical ventilation protocols including head of bed elevation and oral care, and removal of subglottic secretions. Future research that considers clinical outcomes as primary endpoints will hopefully result in more detailed prevention strategies.

Recommendations

We recommend that continuous endotracheal cuff pressure control system may be incorporated in our ICU set up and related comparative studies be done to elucidate the effectiveness of continuous endotracheal cuff pressure system.

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