

Oral Care Bundle versus Chlorhexidine in the Prevention of Ventilator Associated Pneumonia

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Abstract

Background: VAP is a nosocomial infection that occurs at least 48 hours after intubation in mechanically ventilated patients, with an incidence of 15%-60%.

Aim of Study: To compare the outcomes of a new oral care bundle versus the classic chlorhexidine as a control in terms of VAP prevention.

Patients and Methods: This was a prospective randomized open-label controlled trial conducted on 100 patients at Ain Shams University General Surgery ICU from December 2022 to June 2023. Patients were divided into two groups.

Results: There was statistically significant lower OHAT score and lower MV duration, lower CPIS score and lower incidence of VAP in oral care bundle than chlorhexidine group ($p < 0.05$). While there was no statistically significant difference between oral care bundle and chlorhexidine group as regard the APACHE II score ($p > 0.05$).

Conclusion: The implementation of new oral care bundle resulted in significant reduction in the incidence of ventilator associated pneumonia. Also we founded that the new oral care bundle was associated with significant reduction in mechanical ventilation duration and improvement in oral health compared to the classic oral care with chlorhexidine among mechanically ventilated critically ill patients.

Key Words: Oral care bundle – Chlorhexidine – Ventilator associated pneumonia.

Introduction

MECHANICAL ventilation, an important mean of life support, can provide oxygen supply for patients with respiratory failure, maintain smooth airways of patients, relieve respiratory failure and may be a

crucial treatment modality for critically ill patients with certain conditions [1]. VAP is a nosocomial infection that occurs at least 48 hours after intubation in mechanically ventilated patients, with an incidence of 15%-60%. The occurrence of VAP increases the risk of death of patients on mechanical ventilation by eight times and is an important cause of death in patients in intensive care [2].

Chlorhexidine as a commonly used broad-spectrum antimicrobial has been widely regarded. Oral care with chlorhexidine can reduce oral bacterial colonization and the migration and colonization of microorganisms in the lung [3]. In addition, 0.12% chlorhexidine solution was found to be beneficial to oral tissue healing and regeneration. Also, the dissociation of chlorhexidine generates a sterilization effect [4].

Inclusion of chlorhexidine oral rinse in VAP bundles was based on meta-analyses reporting a 30-40% decrease in VAP rates and the belief that VAP was associated with excess intensive care unit (ICU) mortality [5]. However, data have prompted reevaluation of daily oral care with chlorhexidine. Two independent meta-analyses suggest chlorhexidine may fail to prevent VAP and increase mortality in medical and surgical ICU patients [6,7].

The aim of this study was to compare the outcomes of a new oral care bundle versus the classic chlorhexidine as a control in terms of VAP prevention.

Patients and Methods

This was a prospective randomized open-label controlled trial conducted on 100 patients at Ain Shams University General Surgery ICU from December 2022 to June 2023.

Inclusion criteria: All mechanically ventilated patients for 48hr.

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Exclusion criteria: Patients who were admitted with any other type of pneumonia and patients who didn't receive routine oral care for any reason such as developing local infection or undergoing oral surgery.

Sampling method & Sample Size: Sample size was calculated using Power Analysis and Sample Size Software (PASS 11, Version 11.0.08). To achieve power 80%, at alpha error 5% and assuming that the incidence of VAP is higher in chlorhexidine group than new oral care bundle group with medium effect size difference ($h=0.5$), the minimum required sample was 100 patients (50 in each).

Ethical consideration: After ethical approval by the Faculty of Medicine, Ain Shams University, informed written consents was taken from patient's legal guardian in a private room. All possible risks and right to withdraw were explained at this step.

Methods: All patients were subjected to the following: Full history taking including: Demographic data, medical history, Cause of ICU admission, Physical examination, full clinical assessment, and examination of vital signs, APACHE II score, routine laboratory investigations and Radiological investigations: Chest X-ray and chest computed tomography.

Selective investigations: Clinical Pulmonary Infection Score (CPIS): Patients were grouped as VAP (+) and VAP (-) in accordance with the obtained data. Score ≥ 7 indicate higher likelihood of VAP [8]. Oral health dysfunction assessment using the Oral Health Assessment Tool (OHAT): [9,10] OHAT consists of eight categories ('lips', 'tongue', 'gums and tissues', 'saliva', 'natural teeth', 'dentures', 'oral cleanliness', and 'dental pain') with three possible scores (0: Healthy, 1: Some changes present and 2: unhealthy condition).

Intervention: Patients were randomly allocated to be control or intervention with an allocation ratio of 1:1. In the control group: All patients received standard VAP bundle including stress ulcer prophylaxis, venous thromboembolism prophylaxis, daily sedation holiday, bed head elevation between 30-45 degrees, and oral care using twice daily commercial 0.125% chlorhexidine mouth wash. In the intervention group: Similar VAP bundle was applied, and the new comprehensive oral care bundle was used instead of chlorhexidine oral care [11]. Comprehensive care (twice daily): It contains oral assessment (inspection of the oral space, teeth, and gums), tooth brushing, oral/lip moisturization, and suctioning oropharyngeal secretions above the cuff. Maintenance care: It involved (every 4 hours and as needed) contains only oral/lip moisturization and suctioning oropharyngeal secretions above the cuff.

Follow-up and treatment: All enrolled patients were followed-up during their ICU stay and receive their standard treatment. Patients were assessed for

the presence of VAP during their duration of mechanical ventilation until extubating them, tracheotomy, discharge, or mortality.

Statistical methods:

Data were analyzed using IBM SPSS software package version 24.0. Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results were judged at the 5% level. The used tests were Chi-square, Fisher's Exact or Monte Carlo correction, Student *t*-test and Mann Whitney test.

Results

There was no statistically significant difference between oral care bundle and chlorhexidine group as regard age, sex, BMI ($p>0.05$) (Table 1).

Table (1): Comparison of demographic data among the study groups.

	Oral care bundle (N=50)	Chlorhexidine (N=50)	Test of sig.	
			t/x^2	<i>p</i> -value
Age, years:				
Mean \pm SD	55.40 \pm 10.05	56.84 \pm 6.72	0.842	0.402
Range	30-73	43-73		
BMI:				
Mean \pm SD	32.15 \pm 6.77	29.86 \pm 4.87	1.942	0.055
Range	18.6-45.5	19-45		
Sex (N, %):				
Male	37 (74%)	40 (80%)	0.508	0.476
Female	13 (26%)	10 (20%)		

SD: Standard deviation.

t : Independent student *t*-test.

p-value >0.05 : Non significant.

p-value <0.05 : Significant.

p-value <0.001 : Highly significant.

There was no statistically significant difference between oral care bundle and chlorhexidine group as regard the indication for ICU admission ($p>0.05$) (Table 2).

There was no statistically significant difference between oral care bundle and chlorhexidine group as regard the vital data ($p>0.05$) (Table 3).

There was no statistically significant difference between oral care bundle and chlorhexidine group as regard the laboratory data ($p>0.05$) (Table 4).

There was statistically significant lower OHAT score and lower MV duration and lower CPIS score in oral care bundle than chlorhexidine group ($p<0.05$). While there was no statistically significant difference between oral care bundle and chlorhexidine group as regard the APACHE II score ($p>0.05$) (Table 5).

Table (2): Comparison of cause of admission to ICU among the studied groups .

Cause of admission	Oral care bundle		Chlorhexidine		Test of sig.	
	(N=50)		(N=50)		X ²	p-value
	N	%	N	%		
HF	6	12	8	16	8.710	0.728
MI	5	10	5	10		
AF	10	20	8	16		
DKA	5	10	3	6		
Renal impairment	9	18	8	16		
Stroke	5	10	3	6		
ICH	4	8	3	6		
COPD	2	4	1	2		
Septicemia	2	4	1	2		
Hemoptysis	1	2	2	4		
LCF	1	2	3	6		
Pyelonephritis	0	0	3	6		
Hypertensive encephalopathy	0	0	2	4		

SD: Standard deviation.

X²: Chi square test.

HF: Heart failure.

AF: Atrial flutter.

DKA : Diabetic ketoacidosis.

ICH : Intracranial hemorrhage.

COPD: Chronic obstructive pulmonary disease.

LCF : Liver cell failure.

p-value >0.05: Non significant.

p-value <0.05: Significant.

p-value <0.001: Highly significant.

Table (3): Comparison of vital data among the studied groups.

Vital data	Oral care bundle		Chlorhexidine		Test of sig.	
	(N=50)		(N=50)		t	p-value
	Mean	SD	Mean	SD		
HR	85.72	9.73	85.34	9.80	0.195	0.846
RR	31.74	5.69	32.38	3.46	-0.68	0.498
Temp-erature	37.06	0.19	37.04	0.14	0.598	0.551
SBP	129.66	20.87	127.68	20.64	0.477	0.634
DBP	84.20	13.08	84.34	9.80	-0.061	0.952

SD : Standard deviation.

t : Independent student t-test.

HR : Heart rate.

RR : Respiratory rate.

SBP : Systolic blood pressure.

DBP: Diastolic blood pressure.

p-value >0.05: Non significant.

p-value <0.05: Significant.

p-value <0.001: Highly significant.

Table (4): Comparison of laboratory data among the studied groups.

CBC	Oral care bundle		Chlorhexidine		Test of sig.	
	(N=50)		(N=50)		t	p-value
	Mean	SD	Mean	SD		
WBCs	10.79	4.33	10.30	4.45	0.556	0.579
RBCs	4.06	0.78	3.87	0.52	1.436	0.154
HB	13.98	2.68	13.48	1.35	1.167	0.246
HCT	39.46	8.09	41.01	2.51	-1.293	0.199
Platelets	255.48	50.62	270.56	51.15	-1.482	0.124
CRP	8.27	1.03	8.54	1.68	-0.998	0.321

SD : Standard deviation.

p-value >0.05: Non significant.

t : Independent student t-test.

p-value <0.05: Significant.

WBCs : White blood cells.

p-value <0.001: Highly

RBCs : Red blood cells.

significant.

HB : Hemoglobin.

HCT : Hematocrit value.

CRP : C-reactive protein.

Table (5): Comparison of APACHE II, CPIS score, OHAT score and MV duration among the studied groups.

	Oral care bundle		Chlorhexidine		Test of sig.	
	(N=50)		(N=50)		t	p-value
	Mean	SD	Mean	SD		
APACHE II score	28.80	5.46	29.28	5.38	-0.443	0.659
CPIS score	2.30	1.74	3.10	1.99	-2.138	0.035*
OHAT score	4.68	2.65	7.22	3.30	-4.239	0.0001*
MV duration	5.62	2.72	7.54	3.46	-3.085	0.003*

SD : Standard deviation.

p-value >0.05: Non significant.

t : Independent student t-test.

p-value <0.05: Significant.

p-value <0.001: Highly significant.

There was statistically significant lower incidence of VAP in oral care bundle than chlorhexidine group (p<0.05) (Table 6).

Table (6): Comparison of the incidence of VAP among the studied groups.

VAP	Oral care bundle		Chlorhexidine		Test of sig.	
	(N=50)		(N=50)		X ²	P-value
	N	%	N	%		
Yes	6	12	19	38	9.013	0.003*
No	44	88	31	62		

SD: Standard deviation.

p-value >0.05: Non significant.

X²: Chi square test.

p-value <0.05: Significant.

p-value <0.001: Highly significant.

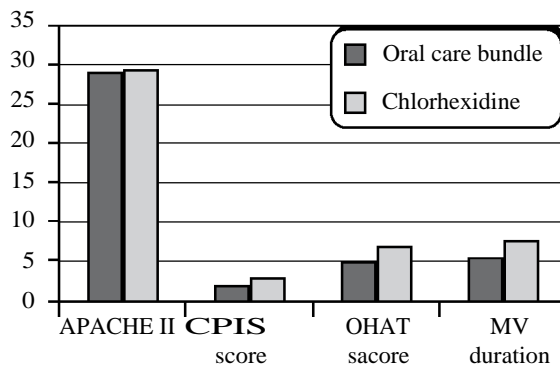


Fig. (1): APACHE II, CPIS score, OHAT score and MV duration among the studied groups.

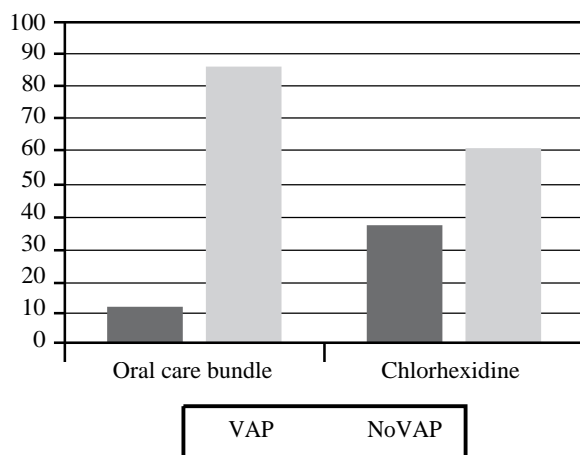


Fig. (2): Incidence of VAP among the studied groups.

Discussion

The main results of our study were as following:

To eliminate the effect of any confounding factor that may affect the final outcome the current study enrolled two well-matched groups in baseline data, as there was no statistically significant difference between the studied groups as regard demographic data, clinical data, cause of admission to ICU, vital signs, and laboratory data.

The current study showed that there was statistically significant lower OHAT score and lower MV duration and lower CPIS score in oral care bundle than chlorhexidine group ($p < 0.05$). While there was no statistically significant difference between oral care bundle and chlorhexidine group as regard the APACHE II score ($p > 0.05$).

In line with our study Dale et al. [10] enrolled 3260 patients; 1560 control group (received usual oral care with Chlorhexidine), 1700 intervention (received oral care bundle). The studied groups were non-significantly differed in baseline data including demographics, comorbidities, APACHE-II score and reason for intubation. The study showed

that the use of oral care bundle resulted in significant reduction in Beck Oral Assessment Scale (BOAS) score, but in contrast to the current study there was no significant difference between control and study groups in duration of mechanical ventilation ($p = 0.79$).

Results from our study were also in the line with Singh et al. [12] who compared the incidence of VAP in critical care patients receiving.

Oral care with and without toothbrushing and the application of moisturizers to the mouth. Care for the study group ($n = 110$) consisted of chlorhexidine wash, tooth brushing, and moisturizing gel over gums, buccal mucosa, and lips. The control group ($n = 110$) was treated with chlorhexidine wash only. The studied groups were well-matched in baseline data. The study showed that the duration of mechanical ventilation and ICU stay was significantly reduced in study group compared to these measurements in control group (p -value = 0.003).

Our study was supported by Singh et al. [12] which showed that Abnormal chest X-rays, positive auscultatory findings, fevers, and positive culture reports were significantly reduced in study group (who received chlorhexidine wash, tooth brushing, and moisturizing gel over gums, buccal mucosa, and lips) compared to these measurements in control group (treated with chlorhexidine wash only). The incidences of VAP and mortality were also significantly lower in study group compared with the incidences in control group ($p = 0.006$ and $p = 0.022$; respectively).

As well, Dale et al. [10] showed that ICU mortality for the intervention (oral care bundle) and control groups (oral care with chlorhexidine) were 399 (23.5%) and 330 (21.2%), respectively ($p = 0.46$). Time to infection-related ventilator-associated complications ($p = 0.90$) and oral procedural pain ($p = 0.10$) were similar between control and intervention groups.

In contrast to our study the current study de Lacerda Vidal et al. [13] showed that the use of toothbrushing plus 0.12% chlorhexidine gel demonstrated a lower incidence of VAP during the follow up period (28/108 VAP cases – control group X 17/105 VAP cases – intervention group), but the difference was not statistically significant ($p = 0.084$). This disagreement may be due to variation of sample characteristics.

Also, in contrast to our study Chacko et al. [14] performed a comparison between the intervention group consisted of 104 patients who were given oral care in the form of suctioning of the oropharyngeal secretions, a mouth swab containing CHX 0.2% and an oral cavity cleaning with manual toothbrush. A

control group of 102 patients were given the standard oral care of a mouth swab cleaning with CHX 0.2%. Inclusion criteria in this study is mechanical ventilation of at least 4–6h. The authors did not find significant statistical differences between the groups (p -value=0.82), suggesting that toothbrushing and suctioning of the oropharyngeal secretions did not have any more effect to standard oral care. This disagreement may be due to the deference in the duration of mechanical ventilation.

The meta-analysis reported that there was a reduction in the number of VAP episodes was observed among those receiving ventilator care bundles, compared with the non-care bundle group (OR=0.42, 95% CI: 0.33, 0.54). Additionally, the implementation of care bundles decreased the duration of MV (MD=-0.59, 95% CI: -1.03, -0.15) and hospital length of stay (MD=-1.24, 95% CI: -2.30, -0.18). The study concluded that the implementation of ventilator care bundles reduced the number of VAP episodes and the duration of MV in adult ICUS.

However, another systematic review and meta-analysis by Silva et al., [15] compared the effectiveness of 0.12% chlorhexidine alone and 0.12% chlorhexidine in combination with toothbrushing to prevent ventilator-associated pneumonia (VAP) in mechanically ventilated patients. The meta-analysis revealed that the risk of VAP was 24% lower in patients receiving chlorhexidine combined with toothbrushing than in those receiving chlorhexidine alone (RR: 0.76; 95% confidence interval: 0.55-1.06), with moderate certainty of evidence and without statistical significance. This disagreement can be explained by that the difference in sample size.

Also, de Camargo et al., [16] in their systematic review assessed whether toothbrushing-based oral health measure (OHM), performed in intensive care units, can reduce the risk of ventilator associated pneumonia (VAP). This review included 12 randomized clinical trials and concluded that toothbrushing does not seem to promote a reduction of VAP-outcomes compared to swab/gauze cleaning, when topic CHX is applied for oral hygiene of patients submitted to mechanical ventilation.

Limitations:

This study was limited by small sample size, being a single center study and relatively short follow up period. Further comparative studies with larger sample size and longer follow-up are needed to confirm our results and to identify risk factors of adverse events.

Conclusion:

The implementation of new oral care bundle resulted in significant reduction in the incidence of

ventilator associated pneumonia. Also we founded that the new oral care bundle was associated with significant reduction in mechanical ventilation duration and improvement in oral health compared to the classic oral care with chlorhexidine among mechanically ventilated critically ill patients.

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حزمة العناية بالفم مقابل الكلورهيكسيدين فى الوقاية من الالتهاب الرئوى المرتبط بجهاز التنفس الصناعى

الخلفية: VAP هو عدوى مستشفى تحدث بعد ٤٨ ساعة على الأقل من التنبيب فى المرضى الموضوعين على التهوية الميكانيكية، مع نسبة حدوث تتراوح بين ١٥٪ إلى ٦٠٪.

الهدف من الدراسة: مقارنة نتائج حزمة العناية بالفم الجديدة مقابل الكلورهيكسيدين الكلاسيكى كعلاج. السيطرة من حيث الوقاية من VAP.

المرضى والطرق: كانت هذه تجربة عشوائية محتملة مفتوحة التسمية أجريت على ١٠٠ مريض فى وحدة العناية المركزة للجراحة العامة بجامعة عين شمس فى الفترة من ديسمبر ٢٠٢٢ إلى يونيو ٢٠٢٣. تم تقسيم المرضى إلى مجموعتين.

النتائج: كان هناك انخفاض ملحوظ إحصائياً فى درجة OHAT ومدة MV أقل، وانخفاض درجة CPIS وانخفاض معدل الإصابة بـ VAP فى حزمة العناية بالفم مقارنة بمجموعة الكلورهيكسيدين ($p < 0.05$). فى حين لم يكن هناك فروق ذات دلالة إحصائية بين مجموعة العناية بالفم ومجموعة الكلورهيكسيدين فيما يتعلق بدرجة ($p < 0.05$ APACHE II).

الاستنتاج: أدى تنفيذ حزمة العناية بالفم الجديدة إلى انخفاض كبير فى حدوث الالتهاب الرئوى المرتبط بجهاز التنفس الصناعى. كما توصلنا إلى أن حزمة العناية بالفم الجديدة ارتبطت بانخفاض كبير فى مدة التهوية الميكانيكية وتحسين صحة الفم مقارنة بالعناية بالفم الكلاسيكية باستخدام الكلورهيكسيدين بين المرضى المصابين بأمراض خطيرة والذين يخضعون للتهوية الميكانيكية.