ORIGINAL ARTICLE

The Incidence of Oral Pressure Ulcers Related to Endotracheal Tubes: A Prospective Cohort Study

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ABSTRACT

Objective: To examine the incidence and implications of oral pressure ulcers (OPUs) associated with prolonged intubation and mechanical ventilation, particularly in patients in Intensive Care Units (ICUs). The purpose of the study was to determine the incidence of OPUs in ICU patients with endotracheal tube (ETT) placement.

Study Design: A prospective cohort study was conducted over six months, from 2 February 2024 to 25 July 2024.

Place and Duration of Study: Dr Ramelan Naval Hospital Surabaya Indonesia, during six months 2/02/2024-25/07/2024

Materials and Methods: A total of 372 ICU patients at Dr Ramelan Naval Hospital were included in this study. The participants were limited to ICU patients with ETT placement who presented with OPUs, without any age restriction. The exclusion criteria were patients without ETT and OPU, as well as patients who died before the observation period ended.

Results: The overall incidence of OPUs related to ETT placement was 16.13%, peaking 3–5 days after installation. Males exhibited a higher rate (55%) than females, with the age group 61–75 years and those with underlying pneumonia being the most affected. Mortality among patients was 55.38%, with 1.94% of these cases involving OPUs, while 44.62% survived, of which 33.73% developed OPUs. The higher incidence of OPUs resulted from prolonged pressure exerted by ETT placement, with a peak occurrence between 4–6 days post-ETT installation.

Conclusion: The incidence of OPUs related to ETT placement is relatively low at 16.13%. However, it is associated with a high mortality rate of 55.38%, underscoring the significant clinical impact of this complication. OPUs predominantly develop between 3–6 days post-ETT placement, highlighting the critical need for early identification and preventive measures during this period to improve patient outcomes.

Key Words: *Critical Ill, Endotracheal Tube, Intensive Care Unit, Oral Health, Oral Pressure Ulcer.*

Introduction

Intensive Care Units (ICUs) are the centres of care for critically ill patients who require life support. These patients often experience organ dysfunction, particularly of the cardiovascular and respiratory systems, and a significant portion frequently experiences unconsciousness and airway failure.[1,2] This often necessitates intubation to maintain airway patency and ensure adequate ventilation. The use of mechanical ventilation exerts sustained pressure on the oral cavity, resulting in an open-mouth posture. This posture induces the evaporation of oral moisture, contributing to dry mouth, increased friction and shear forces between the oral mucosa and devices made of rigid, hard materials, thereby increasing the risk of oral pressure ulcers (OPUs).[3]

OPUs represent a distinctive subset of pressure ulcers associated with medical devices,[4] characterised by prolonged compression of oral tissues. Medical device-related pressure ulcers show variable prevalence rates, ranging from 7% to as high as 45% based on Amrani et al, 2020[5] and 11.5% to 75%, according to epidemiological studies from Kim et al,2021.[6] Devices causing such pressure ulcers

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include urinary catheters, nasogastric tubes, oxygen masks, pulse oximeters, cervical collars, electrodes and wiring, orthopaedic fixations and, notably, the endotracheal tube (ETT), which is the most frequently documented cause of medical device-related pressure ulcers.[7]

The prevention and management of OPUs in unconscious patients are imperative to mitigate the intense pain and discomfort that can reduce health-related quality of life.[8] The purpose of this study was to determine the incidence of OPUs in ICU patients with ETT placement. The findings of this study may contribute to the formulation of effective prevention strategies, emphasising professional oral hygiene practices to reduce the occurrence of OPUs.

Materials and Methods

This investigation is a prospective cohort quantitative study employing a descriptive methodology. The study protocol received approval from the Institutional Review Board of Dr Ramelan Naval Hospital under protocol number 29/EC/KEP/2023. This approval was granted based on the study's adherence to the ethical principles outlined in the World Medical Association's Declaration of Helsinki.

Data collection was conducted over a six-month period, from February to July 2023. The total sample size during this period consisted of 372 patients. The sample size for this study was determined using the following formula to calculate the incidence.[9]

$$n = \frac{Z^2.P.(1-P)}{E^2}$$

Where:

Estimated prevalence (P): 50% (0.5)

Margin of error (E): 5% (0.05)

Confidence level: 95%, with Z=1.96Z=1.96

Using this formula, the calculated sample size (n) was 246. Due to the limited population size, the sample size was adjusted using the finite population correction formula:

$$n\,(adjusted) = \frac{n}{1+\frac{n+1}{N}}$$

Here:

Initial sample size (n): 246

Population size (N): 372

The adjusted sample size required for this study was 148 patients (rounded from 147.83). The study sample included all ICU patients with ETT placement, without any age restrictions. The medical records of the patients, including age and underlying conditions such as diabetes mellitus, hypertension, pneumonia, kidney failure, epilepsy and tuberculosis, were recorded. The exclusion criteria were patients without ETT placement and patients who died before the observation period ended.

OPUs were observed in all oral mucosa by a single oral medicine specialist once a day for 15 days. The OPUs were classified based on clinical appearance. Ulcerated lesions with erythema were classified as stage 1, while ulcerated lesions covered by a white or yellow pseudo-membrane, which may be accompanied by bleeding, were classified as stage 2.[6]

Informed consent procedures involved a detailed explanation by the researcher to the family members. Key aspects covered during the informed consent process included an explanation of the study's objectives, the voluntary nature of participation, assurance of confidentiality regarding gathered information and a comprehensive overview of the procedures employed throughout the study. Consent was obtained after ensuring that the legal representatives had a clear understanding of these elements.

The obtained data were compiled, and frequency distribution was analysed with cross-tabulations using Statistical Package for Social Sciences (SPSS) software version 23 (SPSS Inc., Chicago, IL, USA).

Results

The overall incidence rate of OPUs was 16.13% (60 out of 372 cases) (Table I). The peak of OPU-related ETT occurrences was observed on days 3–5 post-ETT installation, with 55% (33/60) of cases occurring during this period. The majority of OPUs were classified as stage 1 75% (45/60), while 15% (15/60) were classified as stage 2 (Table II).

Within this cohort, males exhibited a higher incidence rate (55%) compared to females (45%). The predominant age group affected was 61–75 years, constituting 38.3% (23/60) of cases. The most prevalent underlying conditions were pneumonia (32%), diabetes mellitus (30%), septic shock (16%) and kidney failure (16%) (Table II).

Table I: The incidence of OPU related to ETT installation in ICU

Characteristic	Number (%)
OPU	60 (16.13%)
Non-OPU	312 (83.87%)

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Table II. Incidence and Mortality rates associated with OPUs in the ICU

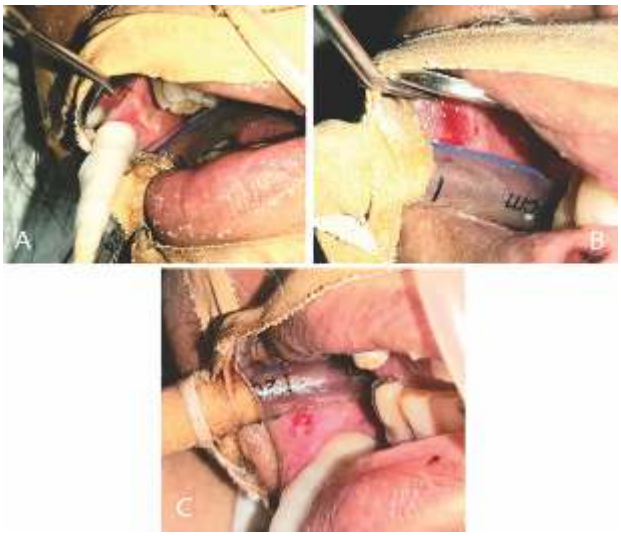
Characteristics	Number (%)
Mortality	206(55.38%)
OPU	4 (1.94%)
Stage 1	4 (1.94%)
Stage 2	0
Non-OPU	202 (98.06%)
Survive	166 (44.62%)
OPU	56 (33.73%)
Stage 1	41 (24.69%)
Stage 2	15 (9.03%)
Non-OPU	110 (66.26%)

Table III: Characteristics of Subjects with OPU in this study

Characteristic	Number (n=60; %)
Sex	
Female	27(45.00%)
Male	33 (55.00%)
Ages (years); Mean ± SD	
0–40; 20.24 ± 14.84	15 (25.00%)
41–60; 51.57 ± 5.19	15 (25.00%)
61–75; 67.11 ± 4.29	23 (38.30%)
76–87; 80.93 ± 4.27	7 (11.70%)
OPU onset (days)	
3–5; 4.09 ± 0.84	33 (55.00%)
6–10; 6.65 ± 2.39	21 (35.00%)
11–14; 12.71 ± 0.76	6 (10.00%)
Type of OPU	
Stage 1	45 (75%)
Stage 2	15 (15%)
Underlying Disease	
Pneumonia	19 (32.00%)
Diabetes Mellitus	18 (30.00%)
Septic Shock	16 (27.00%)
Kidney Failure	16 (27.00%)
Hypertension	6 (10.00%)
Epilepsy	4 (6.00%)
Tuberculosis	4 (6.00%)

Discussion

The incidence of OPUs in this study was recorded at 16.13%, with a predilection for manifestation between days four and six following intubation. This rate is comparatively lower than the 31.3% and 22.6% reported in prior studies after five days of ETT installation.[6,7] The appearance of OPUs may be influenced by several factors, including age, disease severity and underlying conditions.[10] Age appears to be a significant factor in the occurrence of OPUs, as the highest incidence was observed in older patients



Figures: (Figure 1A) Stage 2 OPU Characterised by a Single Ulceration, Coloured by a White or Yellow Pseudo-membrane with Irregular Margins. Surrounding tissue is Erythematous, and in Some Cases, Bleeding may Occur (Figures 1B and 1C).

with an average age of 67.11±4.29 years, a figure that is not markedly different from reported in the study conducted by Noie et al, 2024.[11] However, younger patients with average ages of 20.24±14.84 and 51.57±5.19 years also experienced OPU occurrences. This can be explained by the increased fragility of capillaries, decreased collagen and elastin and reduced perfusion in the elderly.[5]

Critically ill patients with chronic underlying diseases exhibit a high mortality rate (55.38%). The occurrence of OPUs 4–6 days after ETT installation in this study underscores the complexity and multifactorial nature of their development. Proposed etiological mechanisms linking tissue compression to OPU development include ischemia, reperfusion injury, impaired lymphatic drainage and sustained cellular deformation.[12] With the installation of an ETT in the oral cavity, the device creates persistent and consistent pressure on the oral mucosa.[13] This pressure can lead to tissue ischemia, reducing the oxygen supply to the cellular and tissue levels. Consequently, this condition can induce tissue destruction, clinically manifesting as OPUs.[7]

The factors contributing to the incidence of OPUs are multifactorial; however, these ulcers ultimately share a common pathway leading to ischemia and necrosis.[14] When soft tissues are compressed for

prolonged periods between bony prominences and external surfaces, microvascular occlusion, tissue ischemia and hypoxia occur.[15] Pressure exceeding normal capillary pressure (ranging from 12–32 mmHg) results in reduced oxygenation and compromises the microcirculation of the affected tissue. If compression is not relieved, a pressure ulcer can develop.[15] This significant pressure can result from compression by the firm tube of an ETT.[16] OPUs were classified into early lesions and advanced lesions.[17] Early lesions, or stage 1, appear as erythematous areas, which in this study were observed in 75% of cases. Advanced lesions, or stage 2, were observed in 25% of cases. These results differ from the study by Kim CH et al[4]., where stage 2 lesions (31.9%) were more prevalent than stage 1 lesions (14%)[4]. The variation in the stages of OPUs can be attributed to several factors, including the duration of ETT intubation, the method of securing the intubation (e.g. non-commercial ETT holding with or without a bite block using adhesive tape, or a commercial ETT holder) and the patients' conditions.[2,13] All study subjects had chronic underlying diseases such as pneumonia, diabetes mellitus, septic shock and kidney failure, which cause dysregulation in the circulation of nutrients and oxygen in the vasculature, thereby exacerbating ischemia and contributing to the development of OPUs[10,14]

The incidence of mortality in this study was high, but the mortality rate among patients with OPUs was lower (1.94%). This may be due to the systemic conditions of most study subjects, which had poor prognoses. The development of pressure ulcers is not limited to the oral mucosa. In critically ill patients, the potential for pressure ulcer development at any site is present. Pressure ulcers in the skin are caused by static patient positioning, leading to tissue ischemia.[18]

OPUs result in prolonged pain and a decreased quality of life.[8] The areas of mucosa affected by OPUs are easily colonised by bacteria, increasing the risk of infection. Inadequate care, leading to secondary infections, can subsequently increase the risk of sepsis and contribute to morbidity in the patient's systemic condition.[19]

A preventive approach to OPU development in ICU patients can include repositioning the ETT every 24 to 48 hours, regularly disinfecting both the device and maintaining oral cavity hygiene.[13] If OPUs do occur, it is crucial to reposition the device and provide regular topical asepsis and anti-inflammatory therapy at the site of OPU formation.[14] This underscores the pivotal role of professional oral health care in managing and preventing OPUs.[6,20] Collaboration among oral medicine specialists, dental hygiene professionals, anaesthesiologists and intensive care nurses in the management of daily oral health care for intubated patients further contributes to mitigating the occurrence of OPUs.

The incidence of OPUs, which was only 16.38%, with the mortality incidence at 1.94%. However, the incidence and mortality related to OPUs in this study are still reliable. The incidence of OPUs depends on the general condition of the patient, systemic diseases, oral health status and factors related to the ETT. Additionally, the results reflect the effects of regular healthcare practices, such as topical asepsis of the entire mouth and the intraoral surface of the ETT tube, performed by an oral medicine specialist and regularly replacement of endotracheal tube position. The limitation of this study is the relatively small sample size and the short duration of the research, to answered in multicentre studies are needed to determine the global incidence of OPUs and their relationship with other factors.

Conclusion

The incidence of OPUs related to ETT installation is relatively low at 16.13%. However, it is associated with a high mortality rate of 55.38%, highlighting the significant clinical impact of this complication. OPUs predominantly develop between three and six days post-ETT installation, emphasising the critical need for early identification and preventive measures during this period to improve patient outcomes and quality of life.

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CONFLICT OF INTEREST

Authors declared no conflicts of Interest.

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DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon request.