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Research article

Under (less) pressure – Facial pressure ulcer development in ventilated ICU patients: A prospective comparative study comparing two types of endotracheal tube fixations

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ABSTRACT

Introduction: The development of medical device-related pressure ulcers (MDR PUs) as a result of an endotracheal tube fixator (ETTF) use affects patients particularly in the intensive care unit (ICU).

Study design and data collection: Prospective comparative study followed two similar groups of ventilated ICU patients: Group A treated with cloth tape ETTF (CT-ETTF) and Group B treated with Anchorfast Hollister-ETTF (AH-ETTF). Data were collected regarding PU development, location, grade, time from intubation and hospitalisation.

Results: Significant differences in PU development ($p < 0.01$), hospital LOS until PU development ($p < 0.01$), and ventilation days until PU development ($p < 0.01$) were found between the two groups all in favour of Group B.

Linear regression conducted to identify the primary reason for these findings, revealed that the key factor responsible for more than 40% of the difference in ventilation days until ETT MDR PU formation between the groups was the usage of AH-ETTF ($R^2 = 0.436$, $p = 0.000$).

Conclusions: There was a significant advantage to AH-ETTF over CT-ETTF in pressure ulcer development. This should be taken into consideration when deciding which ETTF type to use.

Implications for clinical practice

- Pressure ulcers related to endotracheal tube fixators are common and important issue.
- Incidence of Pressure ulcers related to Endotracheal Tube Fixators may be as high as 58% when using standard cloth tape Endotracheal Tube Fixators.
- Incidence of the pressure ulcers may vary related to Endotracheal Tube Fixators type.
- Using appropriate Endotracheal Tube Fixators may reduce development of pressure ulcers.

Background

Among hospitalised patients, intensive care unit (ICU) patients, in particular intubated and mechanically ventilated ICU patients, have a higher risk of developing facial pressure ulcers (PU) (VanGilder et al., 2009). One of the risk factors predisposing this population to medical device-related pressure ulcers (MDR PUs) is the use of various external devices and fixators. The use of these devices among patients can range from optional to mandatory and even lifesaving (e.g.: endotracheal tube fixator [ETTF] in mechanically ventilated patient). Research regarding medical device-related pressure ulcers (MDR PUs) is limited. However, it is known that the rate of MDR PUs related to ICU patients is relatively high, ranging from 34.5% (Black et al., 2010) to 40% (Hanonu and

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Karadag, 2016). Hanonu and Karadag (2016) found that almost half of the MDR PUs in their research were directly related to ETTFs (45%). Development of PUs and MDR PUs in particular, is not limited to the actual time physically spent in the ICU but can affect the patients' quality of life and recovery many months after discharge (Savelkoul et al., 2017).

Facial PU development due to endotracheal tube (ETT) placement is an important healthcare issue, especially among critically ill patients in the ICU. On one hand, the ETT must be properly fixed to prevent unexpected extubation, which is a life-threating emergency event. On the other hand, patients are often ventilated for a period spanning days and even weeks, thus are at risk of pressure ulcer development related to ETTF. Currently, there are a number of ETT fixation (ETTF) methods used, which include strings/cloth tapes, adhesive tapes and endotracheal tubes attachment devices, such as the Anchorfast Hollister ETTF. The latter devices are marketed as designed to lower the risk of MDR-PU development (Hollister, 2019) but data supporting this claim is uncertain.

Objectives

The aim of this prospective comparative study was to determine the incidence of MDR PUs among patients using the different ETTFs (CT-ETTF and AF-ETTF)

Study location and ethical consideration

The study was conducted in an 18-bed general ICU in large general hospital in central part of Israel. No changes in admission policy or bed occupancy occurred during the 3.5-year research period (2014–2017). Approval for the research was obtained from the local Institutional Review Board (IRB) (approval 106/16 and 216/13).

Research design

Our study was a prospective comparative study that followed two similar groups of ICU ventilated patients for the development of MDR PUs. Group A was treated with cloth tape ETTF (CT-ETTF), while Group B was treated with the Anchorfast Hollister ETTF (AH-ETTF). Both groups were based on a convenience sample and had the same inclusion criteria that included: first mechanical ventilation event during current hospitalisation, no existing facial wounds or pressure ulcers at time of admission to the ICU and intubation performed in the ICU or within two hours prior to ICU arrival. The patients were assessed daily for facial pressure ulcer development. In case of pressure ulcer development, the following data was recorded: site of PU development, PU grade, time from intubation and hospitalisation in ICU. Sample size in both groups was based on 0.8 power, alpha = 0.05, and a medium population effect size demanding 64 patients in each group (Cohen, 1992). Due to lost for follow up patients, we increased the population in both groups by 25% to 80.

Data collection

Group A was treated with CT-ETTF, as per facility policy. This included a mandatory daily cloth tape replacement performed by two critical care registered nurses (CCRNs) or less commonly, by a CCRN and an ICU physician. In our unit, gauze pads on pressure sites (ears, lips, cheeks) were used as a method of routine protection from MDR PU development. The time required for the CCRNs to compete the procedure was estimated based on researcher observation; the observed CCRNs were unaware that they were being observed.

Group B was treated with AF-ETTF as per facility policy and manufacturer recommendations. Application of the AF-ETTF was also performed by two CCRNs or, less commonly, by a CCRN and an ICU physician. Unlike CT-ETTF, AF-ETTF does not require daily changing. The time required for the CCRNs to compete the procedure was estimated based on researcher observation; once again the CCRNs were unaware that they were being observed. Data was first collected from Group A (N = 78) prior to the introduction of AF-ETTF into the department (2014–2015). Data collection from Group B (N = 77) began six months after the introduction of the AH-ETTF to the department in 2015 and after data collection for Group A was completed. Data collection from Group B was performed during 2016–2017.

Data analysis

All statistical analyses were conducted using SPSS version 25 (descriptive statistics, chi square, independent *t*-test and linear regression). Descriptive statistics was performed for demographic data; categorical variables were described as frequency and percentage and continuous variables as mean (M) and standard deviation (±). The independent *t*-test was performed for all continuous variables (age, albumin on admission, hospital LOS until PU development, ventilation days until PU development) and the chi square test (χ^2) for categorical variables (gender, Diabetes Mellitus [DM] as chronic condition admission diagnosis based on admission letter) to identify group differences.

Linear regression (R^2) was performed to identify the primary reason for differences in ETT MDR PU formation. The dependent variable was defined as ventilation days until ETT MDR PU formation. The independent variables were: group (A or B), age, gender, albumin, DM on admission.

Results

The most common diagnoses for ICU admission among both groups were (in order of frequency of occurrence): respiratory or pulmonary emergencies, sepsis or septic shock, and emergency neurological or neurosurgical conditions (Table 1). Other reasons for admission accounting for less than 20% of the research population included: trauma, post-surgical recovery, cardiac conditions, haematologic conditions, and post-CPR. The independent *t*-test for age (t = −0.113, p = 0.91), albumin on admission (t = −0.616, p = 0.54) and chi square test for gender (χ^2 = 0.171, p = 0.68), diagnosis of Diabetes Mellitus (DM) as a chronic condition upon admission (χ^2 = 0.01, p = 0.92), showed no significant demographic differences between the two groups (Table 2). The independent *t*-test did show clinical differences between the groups for PU

Table 1
Main diagnosis on admission to ICU.

Diagnosis upon admission	Total N (%)	Group A, n (%)	Group B, n (%)
Pulmonary or respiratory emergency	84 (54%)	39 (50%)	45 (58%)
Septic shock/sepsis	29 (19%)	14 (18%)	15 (19%)
Emergency neurological or neurosurgical conditions (stroke/neurosurgery)	20 (13%)	9 (12%)	11 (14%)
Trauma	7 (5%)	6 (8%)	1 (1%)
Post-surgical recovery	8 (5%)	5 (6%)	3 (4%)
Emergency cardiac conditions (MI)	1 (1%)	1 (1%)	0
Haematological conditions	4 (3%)	4 (5%)	0
Post-CPR	2 (1%)	0	2 (3%)
Total	155	78 (100%)	77 (100%)

Table 2
Demographic data.

	Group A (N = 78)	Group B (N = 77)	Statistical test value, p value
Age M(±)	70.76 (±15.26)	71.04 (±15.73)*	t = −0.113; 0.91
Gender (male) – n (%)	42 (53.8%)	44 (57%)	χ^2 = 0.171, p = 0.68
Albumin upon admission M(±)	29.18 (±6.84) g/L	29.87 (±7.12) g/L	t = −0.62; 0.54
DM diagnosis	31 (39.7%)	30 (39.0%)	χ^2 = 0.01, p = 0.92

* Unknown age in one case.

development that were highly significant: rate of ETT MDR PU formation difference between groups (t = 7.45; p < 0.01), hospital LOS until ETT MDR PU formation (t = −3.45, p < 0.01), and ventilation days until ETT MDR PU formation (t = −3.74, p < 0.01), all revealing a significant advantage to Group B (Table 3).

Linear regression conducted to identify the primary reason for these findings revealed that the key factor responsible for more than 40% of the difference in ventilation days until ETT MDR PU formation between the groups was the usage of AH-ETTF (R^2 = 0.436, p = <0.001). ETT MDR PU location and grade at discovery varied between the different types of ETTF (Tables 4 and 5).

Average application time for CT-ETTF and AF-ETTF was almost identical: average 4:04 minutes and 4:05 minutes respectfully, (eight minutes of nurse time per procedure, since two nurses are necessary for the procedure as per facility policy). However, the CT-ETTF required that same amount of time (eight minutes) daily for the cloth tape change while AF-ETTF did not. Moreover, we disregarded the time spent for allocating the accompanying CCRN for the procedure, focusing on application time only.

Table 3
Clinical data.

	Group A (N = 78)	Group B (N = 77)	Statistical test value, p value
Hospital days until PU formation	6.07	15.29	t = −3.45; p < 0.01**
Ventilation Days Until PU formation	5.04	13.86	t = −3.74; p < 0.01**
PU formation	45	7	t = 7.45; p < 0.01**

** Indicates statistical significance.

Table 4
ETT-MDR PU Location.

	Group A (n = 78), n (%)	Group B (n = 77), n (%)	Total (N = 155)
No PU	*33 (42%)*	*70 (91%)*	*103*
Right Ear	9 (11.5%)	0	9
Both Ears	9 (11.5%)	0	9
Right Ear and Lip	2 (2.5%)	0	2
Left Ear	18 (23%)	1 (1.3%)	19
Left Ear and Lip	1 (1%)	0	1
Lip	6 (8%)	4 (5%)	10
Right cheek	0	1 (1.3%)	1
Right & Left cheek	0	1 (1.3%)	1
Total ETTF MDR PU	45 (58%)	7 (9%)	52 (33.5%)

Table 5
ETT-MDR PU grade at time of discovery.

PU grade	Group A (n = 78), n (%)	Group B (n = 77), n (%)	Total (n = 155)
1	20 (25.6%)	0	20
2	23 (29.5%)	7 (9%)	30
3	2 (2.6%)	0	2
Total	45 (58%)	7 (9%)	52

Discussion

Patients in the ICU are prone to developing PUs, particularly MDR-PUs. The current study demonstrates significant differences in MDR-PU rates among the different ETTF types used in the ICU. Recently, two distinct studies have been published on this topic, but with different conclusions on the issue (Hampson et al., 2018; Landsperger et al., 2019).

Hampson et al (2018) conducted a retrospective study in single medical center 15 bed medical-surgical ICU in Australia, with a relatively small sample (n = 42). Results show the rate of PU development was higher when AF-ETTF is used. However, it is important to remember that retrospective studies are prone to various biases. Moreover, the research did not account for the learning curve necessary for the introduction of new technologies (Greenhalgh et al., 2005; Harvey et al., 2018). The study initiated data collection for MDR-PU immediately following the introduction of the device to the participating departments, thereby including the staff's learning curve in the collected data. Another potential bias is staff resistance to change (introduction of AF-ETTF), which could manifest in over-reporting PU events by the staff (Mareš, 2018).

More recently, Landsperger et al. (2019) published results of a randomised control study (RCT). Patients were randomised either to AF-ETTF or to adhesive tape ETTF (without blinding). No information regarding the introduction of the AF-ETTF is available. However, the authors stated both options were in use prior to the beginning of the study. Therefore, one may assume AF-ETTF use was not new to the staff. With a sample twice as large and a patient average age over 10 years younger as our study population, the researchers nevertheless came to a conclusion similar to the current study: usage of AF-ETTF results in a lower rate of MDR-PU development.

Our research makes an additional distinction among ETTF type in relation to MDR PU. We found a lower MDR PU development rate on patients' lips in favour of AF-ETTF. This is consistent with recent RCT research findings (Landsperger et al., 2019).

Another interesting finding is the side (left/right) of MDR PU development within group A. Our study found that MDR PU is almost twice as likely to develop on the left side (in particular the left ear) compared to the right side. We believe that this difference is due to the location of the ventilator and ventilation tubes, which is on the left side of the patient in this ICU, resulting in less accessibility to the left side for assessment and prevention.

Finally, we found the AF-ETTF saves precious nursing time. At least eight minutes of nursing time (four minutes x two CCRN) can be spared each day (excluding the first ventilation/intubation day) when AF-ETTF is used, as there is no need for routine cloth tape changes.

Limitations

The study is a single centre research with a relatively small sample size; no randomisation or blind patient assignment was performed. Patient severity of illness scores, such as: Acute Physiology and Chronic Health Evaluation (APACHE), Simplified Acute Physiology Score (SAPS) or Sequential Organ Failure Assessment (SOFA) was not applicable during the research period and was not performed retroactively due to IRB limitations.

Conclusions

The differences we found in MDR PU rate between the different ETTF types are significant and should be taken into consideration when deciding the type of ETTF to employ. Our study is limited by the relatively small population sample and lack of randomisation. Moreover, we compare standard cloth tape fixation to AH-ETTF while there are a variety of other ETTF types available on the market that can be evaluated. Further research is needed to find the optimal options for ventilated patients ETTF in regards to lowering the risk of MDR PU development. Based on the findings of the study, an economical research should be conducted to compare the cost differences between standard ETTF and AF-ETTF as well as staff time required for each type of ETTF implementation.

Meanwhile, in order to reduce the risk of ETTF MDR-PU, we recommend that healthcare providers consider the use of AH-ETTF fixator over CT-ETTF where possible and applicable.

Ethical issues

The IRB approval for the research was obtained (number 216/13 and 106/16).

Care was taken to anonymize any clinical data so patient identity remains undisclosed.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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