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ORIGINAL PAPER

IMPACT OF A SUGGESTED NURSING PROTOCOL ON THE OCCURRENCE OF MEDICAL DEVICE-RELATED PRESSURE ULCERS IN CRITICALLY ILL PATIENTS

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Abstract

Aim: Medical Device-Related Pressure Ulcers are skin breakdowns related to certain medical devices that increase morbidity, lengthen hospital stays, and increase the cost of treatment. Approximately one third of reported pressure ulcers are associated with medical devices. The aim of this study is to examine the impact of a suggested nursing intervention protocol on the occurrence of medical device-related pressure ulcers in critically ill patients. *Design:* A prospective, quasi-experimental research design was used in this study. *Methods:* 100 patients participated in our study, divided into study and control groups. The researchers selected Endo-tracheal and Nasogastric tubes to examine their association with the development of pressure ulcers. The researchers observed the prevalence of pressure ulcers caused by the selected devices through daily clinical observation. Patients receiving routine care were used as a control group, while the suggested nursing intervention protocol was implemented to the study group of patients. The results of the given protocol on the study subjects were compared to the collected base line data for the control group. *Results:* The study revealed a highly statistically and clinically significant difference between the study and control groups in relation to incidence of endo-tracheal and nasogastric tube pressure ulcers. The results indicate that the incidence of endo-tracheal tube pressure ulcers decreased from 90% to 32.1% after implementation of the suggested nursing intervention protocol ($p = 0.031$), whereas the incidence of nasogastric tubes pressure ulcers fell from 77.8% to 13.1% ($p = 0.012$). *Conclusion:* the examined evidence based suggested nursing intervention protocol proved highly effective in reducing the occurrence of selected Medical Device-Related Pressure Ulcers in critically ill patients.

Keywords: critically ill, medical devices, nursing protocol, pressure ulcer.

Introduction

Pressure sores, pressure injuries, decubitus ulcers, and bedsores are synonyms for pressure ulcers, which are generally defined as localized injuries to the skin and/or underlying tissue as a result of continuous pressure for a prolonged period of time (Agrawal, Chauhan, 2012). Pressure ulcers have been described as the most frequent cause of iatrogenic and sorrorigenic wounds in intensive care units (ICUs) (34.9%) (Pokorná et al., 2016). According to (Apold, Rydrych, 2012; Fletcher, 2012), pressure ulcers are classified as either device-related pressure ulcers, or non-device-related pressure ulcers. Medical device related pressure ulcers (MDRPUs) are specifically defined as skin breakdown related to certain medical devices used for therapeutic of diagnostic reasons. Research suggests that nearly a third of reported pressure ulcers are associated with the use of medical devices [National Pressure Ulcer Advisory Panel (NPUAP), 2014]. Pressure ulcers related to the use of medical devices are areas of localized injury to the skin or underlying tissue as a result of the presence and/or fixation of certain devices. The soft tissue injury usually mimics the shape of the device, which is often rigid or secured with tight dressings. These Pressure ulcers can evolve into full-thickness pressure ulcers due to the lack of adipose tissue in many of the areas of ulceration (Black, Kalowes, 2016). If patients are given a medical device, they are 2.4 times more likely to develop a pressure ulcer of some kind (Black et al., 2010).

Critically ill patients may be particularly vulnerable to MDRPUs for a number of reasons, such as: malnutrition, hypotension, hypoalbuminemia,

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decreased mobility and inhibition of sensory perception as a result of sedative medications, neurological disease/injury, and severe neuropathy that prevent awareness of pressure and movement in response to tissue ischemia. Furthermore, decreased tissue perfusion and higher usage of supportive medical devices in the ICUs place these patients at higher risk of developing MDRPUs (Wolverton et al., 2004). The medical device itself creates pressure, humidity, and heat, changing the microclimate of the skin. Often these devices must be secured tightly to assure a proper seal, which, in turn, creates pressure in unusual areas rather than bony prominences. The materials used to secure the device e.g., tape or straps may make it difficult to inspect the underlying skin beneath them. All of these factors increase the risk of pressure ulcers (Reger, Ranganathan, Sahgal, 2007). General factors contributing to MDRPUs include edema and moisture. The presence of edema at the site of the device can lead to increased pressure and tension under the device; excess moisture from human fluids and bronchial secretion around the insertion site can weaken the skin through maceration, and alter the acid mantle of the skin; thus bronchial hygiene therapy is an important preventive precaution (Elhabashy, 2016). Friction from the constant rubbing of a tube or stabilizing device can also be a contributing factor (Apold, Rydrych, 2012). Loerakker et al. (2011) describes how tissue injuries caused by MDRPUs are exacerbated by compression, ischemia, deformation, and reperfusion of subcutaneous tissue.

Medical devices commonly used in ICUs include endotracheal and nasogastric tubes, cervical collars, nasal cannulas, pulse oximetry probes, immobilizers, radial artery catheters, sequential compression devices, splints and braces, face masks for non-invasive positive pressure ventilation, and urinary catheters (Fletcher, 2012). The current study was concerned with endotracheal tubes (ETTs) and nasogastric tubes (NGTs) for many reasons; ETTs and NGTs are reported to be the most common cause of medical device-related ulcers. Coyer, Stotts, Blackman (2014) reports that 18.5% of all types of MDRPUs are caused by either ETTs or NGTs. In addition, pressure ulcers on patients' faces caused by endotracheal and nasogastric tubes affect their body image and psycho-social adaptation post ICU discharge (Coyer, Stotts, Blackman, 2014). Unfortunately, few studies have addressed particular devices (e.g., endotracheal tubes, or nasogastric tubes) and their impact on the development of pressure ulcers in ICUs. Watts et al. (1998) state that 10.5 % of developed pressure ulcers are caused by ETTs. Intubated patients are at risk of nontraditional pressure ulcers related to the tube itself and/or associated devices used to secure the tube.

Gastric intubation via the nasal passage (i.e., the nasogastric route) is a common procedure that provides access to the stomach for diagnostic and therapeutic purposes. Nasogastric tubes are commonly used on critically ill patients either for feeding or drainage (Ambutas, Staffileno, Fogg, 2014). Prolonged use of nasogastric tubes causes continuous pressure over the nares of the nose, leading to pressure ulcers. The prevalence of NGT related pressure ulcers is estimated to be 8% (Apold, Rydrych, 2012). Indeed, from clinical observation and experience we have found that prevalence of pressure ulcers associated with NGTs and ETTs is high.

Pressure ulcers are staged in different ways. Recently, the NPUAP has described the pressure ulcers staging system as follows: Stage I: intact skin with non-blanchable redness of a localized area; Stage II: partial thickness loss of dermis presenting as a shallow open ulcer; Stage III: full thickness tissue loss; and Stage IV: full thickness tissue loss with exposed bone, tendon or muscle, and, in addition, suspected deep tissue injury: purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear; Unstageable: full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, gray, green or brown) and/or eschar (tan, brown or black) in the wound bed.

A designed nursing intervention protocol means a series of nursing actions that may be implemented by nurses to manage a patient's clinical status, based on their needs. A designed nursing intervention protocol aims to solve actual or potential patient problems, making best use of resources, and optimizing patient care in accordance with current clinical guidelines or standards of practice of the Nevada State Board of Nursing (NSBN). The current study utilized nursing process as a theoretical framework (Potter, Perry, 2009). Risk assessment is the first step in planning pressure ulcer prevention strategies (Moore, Cowman, 2014; Alves et al., 2017). The purpose of assessment is to identify those at risk of pressure ulcer development by identifying key factors considered important, and then preventive interventions may be planned, implemented, and evaluated (Deeks, 2002; Alves et al., 2017). Braden score is a valid and useful tool for identifying patients who have increased risk of developing pressure ulcers. The Braden scoring system is categorized by six indicators: sensory perception, moisture, activity,

mobility, nutrition, and friction or shear (Fife et al., 2001).

The suggested nursing intervention protocol of the current study was designed in accordance with evidence based practice (Youssef et al., 2013). The protocol included many items such as the choice of correct size of ETT to fit the patient; the use of a lark head (also known as a cow hitch) to tie the ETT (AACN, 2014); the avoidance of ETT fixation by adhesive tabbing; the placing of a pad between skin and ETT cloth tape contacts that may rub together; the avoidance of tying the ETT fixation tape under the head; the repositioning of the ETT every two hours (right, middle, left); the avoidance of overtightening the knot on the tube; the fixing of the tape of the ETT away from the angle of the mouth; the provision of mouth care by normal saline solution; and the application of the ETT for no more than three weeks, by which time tracheostomy must be considered (Elhabashy, 2015). The implemented NGT preventive measures included: use of NGT with fine pores, especially for feeding; new taping methods for NGTs; checking that NGTs are not placed directly under an individual who is bedridden or immobile; the use of a water-soluble lubricant during insertion of NGTs; the avoidance of overheated NGT feeding; the provision of nasal care with warm distilled water; the wetting of the NGT adhesive tape with warm water before removal; and the changing of the polyvinyl chloride NGT every 2 weeks.

Unfortunately, most nursing activities and the suggested protocols of care are concerned mainly with preventing and treating pressure ulcers caused by continuous bony prominence pressure and pay no attention to the prevention of MDRPUs, which occur mostly in the first few days of admission at an ICU, when all caring activities are focused on patient survival. Moreover, MDRPUs cause further patient suffering and pain, in addition to financial burden, and increased length of stay (Pokorná et al., 2017).

The hypothesis of the current study was "H_1: Critically Ill Patients who receive the suggested nursing intervention protocol (μ_1) will have a lower incidence of medical device-related pressure ulcers than those who do not (μ_2), (H_1: $\mu_1 < \mu_2$)".

Aim

Taking into account the importance of applying evidence based practices to minimize the incidence of MDRPUs, and improve quality of care, this paper aimed to study the impact of a suggested nursing intervention protocol on the occurrence of medical device-related pressure ulcers in critically ill patients.

Methods

Design

A prospective, quasi-experimental research design was used in this study. The study concerned the impact of a nursing intervention protocol on critically ill patients. Randomization was not a feature of the study.

Sample

A convenience sample of 100 adult male and female critically ill patients who had been admitted to the selected ICU within the previous six months were recruited to the study to ensure a high level of homogeneity between the study and control groups. The estimated sample size was 98 patients by G Power analysis of independent *t* tests [One tail, Effect size = 0.55; $\alpha = 0.05$; Power (1-β) = 0.85]. The inclusion and selection process is mapped out in the Figure 1.

Data collection

Three tools were formulated to collect data pertinent to the study. The study tools were adapted except tool 1, which was constructed by the researcher. The tools were piloted on ten subjects to ensure their clarity, objectivity, relevance, and feasibility. Minor modifications were made accordingly. The subjects of the piloting were included among the study subjects. Moreover, The three formulated tools and the suggested nursing intervention protocol were presented to a panel of three experts consisting of three professors specialized in critical care and emergency Nursing, critical care medicine, and medical surgical nursing. Each expert was asked to check the adequacy of items that covered the domain under investigation, content, clarity, wording, length, format, and overall appearance. Minor changes in wording were made, based on the experts' recommendations. Cronbach's Alpha was used to assess the reliability of the tools, reflecting the degree of internal consistency among variables; the results of reliability test for all three tools were 0.769. The tools were:

1) Background and Medical Data and Health Determinants Sheet: consisting of eight items and including data such as: age; gender; smoking; diagnosis of admission; past medical history; date of admission and co-morbidity diseases such as diabetes and hypertension; date of insertion of oral ETT and/or NGT; and body mass index (BMI), estimated by Adolphe Quetelet formula (Weigley, 1989) i.e., bodyweight in kilograms divided by height in meters, squared. If height or weight could not be measured, the formula of Chumlea et al. (1988) was used.

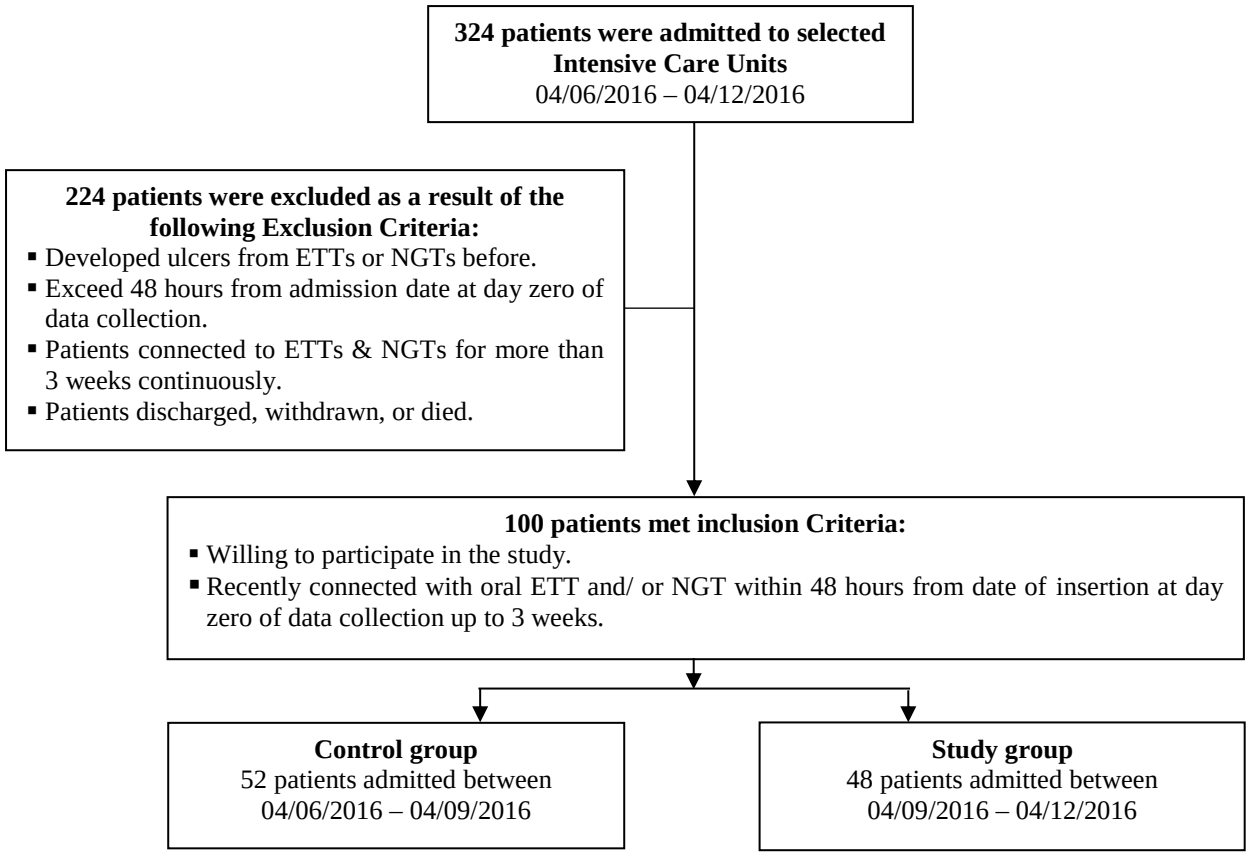

Figure 1 Flow chart of inclusion and selection of study subjects

2) Glasgow Coma Scale (GCS) developed by Teasdale, Knill-Jones, van der Sande (1978), and used to measure the level of consciousness of patients. A maximum score of 15 is divided between three main variables: Eye opening response (4), Verbal response (5), and Motor response (6). The researcher checked the response of the subjects pertinent to the three variables of the GCS. Then, the level of consciousness was determined by the sum of the given score for each variable and classified as follows; a score of 15 = fully-conscious, 14–8 = semiconscious, and 7–3 = coma.

3) Pressure Ulcer Staging System Checklist (PUSS): this checklist was developed by the NPUAP. The tool was utilized to assess skin condition and detect if any ETT and/or NGT related pressure ulcers had occurred in any participants, and, if so, to what degree (study and control groups). It consists of six items. Each item was checked for presence: yes (1) or no (0). The scale ranged from 0–6; Those with a score of zero are considered free from pressure ulcers; a score of one indicates stage one: non-blanchable erythema of intact skin; a score of two indicates stage two: partial-thickness skin loss with exposed dermis; a scores of three indicates stage three: full-thickness skin loss; a score of four indicates stage four: full-thickness skin and tissue loss; a score of five indicates unstageable pressure ulcer: obscured full-thickness skin and tissue loss; a score of six indicates deep tissue pressure ulcer: persistent non-blanchable deep red, maroon or purple discoloration.

Once official permission and ethical approval were granted to carry out the current study, the researchers checked the occurrence and staging of pressure ulcers caused by oral ETTs and/or NGTs on a daily basis guided by tool three. The observation began when the ETT and/or NGT was inserted (day zero) and continued until 21 days of continuous insertion (the maximum allowed length of insertion). If patients were disconnected during the 21 days for more than 24 hours, as a result of extubation, discharge, withdrawal, or death of the subject, they were excluded from the study. The researchers selected ten highly qualified registered nurses, covering the three shifts. They helped in assessment of skin condition and implementation of the nursing protocol to ensure continuity of care. The results from data collection during the first three months were regarded as a control set, providing baseline data crucial for the next part of data collection which encompassed the implementation of the Suggested Nursing Intervention Protocol for other newly admitted

patients in the same unit. The implementation with the study group of subjects lasted another three months. Throughout this period skin assessment was performed using tool three. Finally, the researchers compared the results (the outcome of the given protocol) to the collected baseline data (for the control group).

A potential for bias existed in relation to sampling and selection, as some subjects may have been less likely to be included than others. In addition, some differences relating to age, nutritional status, and diagnoses in subjects may have been contributing factors to the occurrence of MDRPUs.

Data analysis

Data for analysis were obtained from the study tools that were categorized, tabulated, and analyzed. Data entry was performed using the SPSS software (statistical package for social sciences version 21). Descriptive statistics were applied: e.g., mean, standard deviation, frequency, and percentage. Tests of significance were performed to test the study hypotheses, i.e., paired and unpaired t-test, chi square test, and ANOVA test. Pearson's correlation coefficient was applied to quantitative variables. A significant value was considered $p < 0.05$.

Results

100 patients participated in this research: 48 in the study group, and 52 in the control group. The mean age of the sample was 47.42 ± 10.44 years, with 46 participants between 41–50 years. 55 were men. 25 were diagnosed as cardiac patients, while 38 had no co-morbidity diseases. The total Body Mass Index (BMI) of patients was 24.52 ± 5.58, and 29 of them were categorized as over weight. 58 of the included subjects were semiconscious. 52 were nonsmokers. 17 subjects were connected only to ETTs, 42 were connected only to NGTs, and 41 were connected to both NGTs and ETTs, of which 23 were from the control group and 18 from the study group (Table 1). 43 of the subjects were connected to oral ETTs for six to ten days, and 49 were connected to NGTs for the same duration. The subjects in the two groups provided similar demographic and medical information, with no significant differences.

Table 1 Frequency distribution of connected medical device (oral ETT or/and NGT) in the studied subjects, control and study groups (n = 100)

	ETT only	NGT only	ETT & NGT	Total
Study group	10	20	18	48
Control group	7	22	23	52
Total	17	42	41	100

EET – Endotracheal tube; NGT – Nasogastric tube

27/30 subjects developed oral ETT pressure ulcers in the control group – an incidence of 90%. The breakdown of frequency of occurrence in the control group was as follows; three (10%) experienced one occurrence, 13 (43.5%) experienced two occurrences, and 11 (36.5%) occurred experienced three occurrences. Meanwhile, 9/28 of the study group developed oral ETT pressure ulcers with significant p-value (0.031) (Table 2).

With regard to NGT related pressure ulcers, 35/45 subjects of the control group developed NGT pressure ulcers – an incidence of 77.8%. The breakdown of frequency of occurrence in the control group was as follows: 30 experienced one occurrence, and five experienced two occurrences. In contrast, only five of the 38 subjects developed NGT pressure ulcers, all of whom developed pressure ulcers with significant p-value (0.012) once (Table 2).

Table 2 Frequency of occurrence of oral ETT pressure ulcers among the study and control groups (n = 100)

		Did not occur	Occurred once	Occurred twice	Occurred three times	Number of patients who developed pressure ulcers	Total number of detected pressure ulcers.	p-value
EET	Study group	19 (67.9%)	8	1	0	9 (32.1%)	10	0.031
	Control group	3 (10.0%)	3	13	11	27 (90.0%)	62	
NGT	Study group	33 (86.9%)	5	0	0	5 (13.1%)	5	0.012
	Control group	10 (22.2%)	30	5	0	35 (77.8%)	40	

EET – Endotracheal tube; NGT – Nasogastric tube;

The results indicate that the mean of frequency of occurrence of ETT & NGT pressure ulcers in the study group decreased significantly after intervention when compared with the control group (p = 0.004; p = 0.002) (Table 3).

The current study found that 27/72 of the detected ETT related pressure ulcers in the included subjects were located in the angle of the mouth, while 4/72 were located in the loop of the ear (Table 4). Table 5 shows that 25/45 of the NGT related Pressure Ulcers were located in the naris of the nose, while 2/45 were located in others sites.

Table 3 The mean and standard deviation of developed ETT & NGT pressure ulcers in study and control groups

	Study group mean ± SD	Control group mean ± SD	Independent t-tests p-value
ETT pressure ulcer	0.20 ± 0.45	1.19 ±0.81	0.004
NGT pressure ulcer	0.10 ± 0.30	0.76 ±0.61	0.002

EET – Endotracheal tube; NGT – Nasogastric tube

Table 4 Frequency distribution of the detected ETT pressure ulcers in relation to location in the study and control groups

	Occipital	Cheek	Lips	Angle of the mouth	Loop of ear	Helix	Total
Study group	1	1	3	5	0	0	10
Control group	5	10	15	22	4	6	62

Table 5 Frequency distribution of the detected NGT pressure ulcers in relation to their locations in the study and control groups

	Nair	Tip of nose	Cheek	Others	Total
Study group	3	2	0	0	5
Control group	22	13	3	2	40

In addition, the current study illustrated that 42 subjects of the control group developed first stage oral ETT pressure ulcers, while five subjects developed third stage oral ETT pressure ulcers. In comparison, six subjects of the study group developed first stage oral ETT pressure ulcers, while no subjects developed either third or fourth stage pressure ulcers (p = 0.022). Moreover, 31 subjects of the control group developed first stage NGT pressure ulcers, while one subject developed a third stage NGT pressure ulcer. In comparison, three subjects of the study group developed first stage NGT pressure ulcers. No third or fourth stage pressure ulcers were detected in the study group (p = 0.018) (Table 6).

Table 6 Frequency distribution of the detected pressure ulcers stages caused by ETTs & NGTs in the study and control groups

Stages	ETT pressure ulcers		p-value	NGT pressure ulcers		p-value
	Study group	Control group		Study group	Control group	
1st stage	6	42	0.022	3	31	0.018
2nd stage	4	15		2	8	
3rd stage	0	5		0	1	
4th stage	0	0		0	0	
Total	10	62		5	40	

EET – Endotracheal tube; NGT – Nasogastric tube

Discussion

The results of the current study illustrate that the suggested nursing intervention protocol significantly minimized the occurrence and the frequency of ETT and NGT pressure ulcers. Therefore the stated hypothesis of the current study was confirmed. The study demonstrated the high vulnerability of critically ill patients to the development of MDRPUs, as indicated by the control group of 52 subjects. With regard to ETT related pressure ulcers, the incidence

in the control group was 90%. Incidence of NGT pressure ulcers in the control group was 77.8%. Despite this high vulnerability, evidence based nursing practices can significantly minimize the occurrence of MDRPUs, as evidenced by the study group of 48 subjects, in which the incidence of ETT pressure ulcers was minimized at 32.1%. The incidence of NGT pressure ulcers in the study group connected to NGTs was kept at 13.1%. Patients who received the suggested protocol were six times less likely to develop ETT pressure ulcers than those who did not receive it (1.19 : 0.2), and the possibility of developing NGT pressure ulcers was 7.6 times (0.76 : 0.1) less likely as a result of the implementation of the suggested nursing protocol.

Apold and Rydrych (2012) conducted a study concerned with implementation of standardized best practices to prevent risks related to medical devices, and indicated that implementation of evidence based practices reduced MDRPUs by 60%. In addition, the NPUAP strongly recommends applying evidence based nursing practices for effective prevention and management of MDRPUs, as supported by different experimental and evidenced studies. The dramatic decrease in the frequency of occurrence of MDRPUs may be explained as follows: the MDRPUs are a preventable nursing problem, do not require advanced or expensive equipment, and if nurses receive adequate education and training, they can easily provide preventive care as part of routine daily care. While MDRPUs are difficult to cure, they are easy to prevent.

The results show that the frequency of occurrence of ETT pressure ulcers was one third more than that of NGT pressure ulcers, a finding which supports those of Black and Kalowes (2016) and Cox and Rasmussen, 2014, in a study of enteral nutrition in the prevention and treatment of pressure ulcers in adult critical care patients. However, Black et al. (2010) tested MDRPUs in hospitalized patients, finding that the frequency of occurrence of NGT pressure ulcers was one third greater than that of ETT pressure ulcers. The results of the current study may be due to increased manipulation of the ETT e.g., by suction, oxygen administration, and the weight of the mechanical ventilator tubing system which requires strong fixation. In addition, the ETT is bigger in diameter and can be more easily moved, and may be loosened by encrusted salivation.

them or to their families. In addition, participants were made aware of the possibility of withdrawing from the study at any time. Confidentiality and anonymity of the information were assured through

The current study indicated that more than two thirds of the included subjects developed oral ETT and NGT pressure ulcers (stage one), while less than 10% of the subjects developed severe pressure ulcers (stages three-four). VanGilder et al. (2009) in a study entitled International Pressure Ulcer Prevalence Survey, a specific analysis conducted over three years in acute care units, found that half of ETT and NGT pressure ulcers were stage one and 15% stage two, whereas further stages rarely occurred. Black et al. (2010) state that MDRPUs are commonly stage one or two; however, MDRPUs can easily worsen to further stages if not found and treated. The mild stages of oral ETT and NGT pressure ulcers observed in the current study may be due to the location of the pressure ulcers on the face of the subjects, therefore making them easier to detect and treat. Neglected pressure ulcers leading to further stages of development occur fastest in subcutaneous tissues in areas vulnerable to oral ETT and NGT pressure ulcers.

Conclusion

Pressure ulcers caused by ETT/NGT medical devices are a common and continuing clinical problem, and cause significant morbidity in patients of all diagnoses. Since the prevention of MDRPUs is more effective than their treatment, the current study applied an evidence based suggested nursing intervention protocol to prevent the occurrence of ETT/NGT pressure ulcers. The data showed that the incidence, frequency of occurrence, and stages of oral ETT and NGT pressure ulcers decreased significantly after implementation of the suggested nursing intervention protocol. Therefore, based on the findings of the current study, the stated hypothesis has been confirmed (H_1: $\mu_1 < \mu_2$).

Ethical aspects and conflict of interest

Before data collection, primary approval of the scientific research ethical committee to carry out the study was obtained (IRPNO.FWA00019867). In addition, official permission to conduct the study was obtained from the medical director of the selected institution. Verbal consents were obtained from head nurses of these units. Participation in the study was voluntary and informed consent was obtained and signed by the participants after the purpose and nature of the study had been explained to coding of the data. No conflict of interest was encountered.

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Authors' contribution

Concept and design (SE, KM), data collection (SE, MS, AY), analysis and interpretation of data (SE, MS), drafting of the manuscript (SE), critical revision of the manuscript (AY, MS), final completion of the article (SE, MS).

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