The Official Title of the study

The effect of implementing nursing interventions on prevention medical device related pressure injury in critically ill patients.

NCT number (if available) : Not applicable

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This study aims to assess the effect of implementing nursing interventions on preventing medical device-related pressure injuries in critically ill patients.

Operational definition: The selected nursing interventions refer to the skin care Bundle, which includes eight key components.

Design and methods:

Research design: A parallel randomized control trial research design will be conducted.

Setting: The current study was conducted in intensive care units (ICUs) at Main Alexandria University Hospital in Egypt. Those units received patients with critical illness and immobility who were independent on nursing care to meet their basic needs.

Subjects:

This study will include a convenience sample of 120 critically ill patients who require ventilatory support. Adult patients (age ≥18 years) in the ICU who were more than 24 hours after admission were eligible for inclusion. The exclusion criteria for the patients were as follows: (i) patients who had skin diseases such as systemic lupus erythematosus and burns that may have influenced the judgment of medical device related pressure injury; (ii) patients who were not in the ICU for treatment or examination during the investigation; and (iii) patients with medical device related pressure injury before they were admitted to the ICU

Tools of the study:

Three parts make up Tool one, which evaluates general patient data.

Part one: Patients' characteristics such as age, sex, admission cause, history, length of stay, APACHE II score, body mass index, no of invasive devices used and mechanical ventilator duration.

Part two: Patient clinical assessment includes vital signs such as oxygen saturation, albumin, type of nutritional support, level of consciousness, capillary refill, and edema grade.

Part three: skin assessment. The Braden Scale for Predicting Pressure Sore Risk is defined as a pressure ulcer development risk prediction score that is based on a patient's sensory perception, skin moisture levels, activity, mobility, nutrition, friction, and shearing. Scores range from 6 to 23. A score of 15–18 indicates that the patient is at mild risk for developing a pressure ulcer; a score of 13–14 indicates moderate risk; a score of 10–12 indicates high risk; and a score of equal to or less than 9 indicates severe risk.

Two medical devices are used and consist of three parts.

Part one: ICU medical device assessment: this part is used to assess the number of non-invasive and invasive devices and whether they are needed or not. Each site will be assessed for the Pressure Ulcer Staging Form based on classification of Pressure Ulcer Grading:

Grade 1: non-blanchable erythema of intact skin. Discoloration of the skin, warmth, oedema, induration, or hardness may also be used as indicators, particularly in individuals with darker skin.

Grade 2: Partial thickness skin loss involving the epidermis, dermis, or both. The superficial ulcer presents clinically as an abrasion or blister.

Grade 3: Full-thickness skin loss involving damage to or necrosis of subcutaneous tissue that may extend down to, but not through, underlying fascia.

Grade 4: Extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures with or without full thickness skin loss

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Method:

Ethical approval will be obtained from the university committee.

After an explanation of the study's purpose, hospitals administrative authorities' permission to perform the study was acquired from selected hospitals.

The reliability of the tool was established, and it was accepted. A pilot study was done on 10% of the studied population to assess the accessibility of two tools, and necessary modifications were made.

Data collection phase:

A letter was submitted from the Dean of the Faculty of Nursing, Damanhour University, to the director of intensive care units at the Alexandria main university in Alexandria government hospitals in Egypt.

The validity of the instruments was verified by presenting them to five experts in the field of the study, who revised them. The recommended modifications will be made.

On the first admission day, the researchers assessed all newly admitted mechanically ventilated patients to identify the exclusion criteria. They were assigned equally to controlled and intervention groups.

The patients will be assigned to two equal groups: the control (A) and intervention (B) groups.

Group A received routine nursing care for medical devices.

The intervention group (B) received skin care bundle. It includes eight key components:

Secure devices and protect the skin with dressings in high-risk areas.

K: Keep repositioning more frequently than twice daily (if not medically contraindicated); remove the medical device as soon as medically feasible.

Inspect the skin under the device more than twice daily; high-risk patients will require more frequent assessments.

Nutrition and hydration, nutrition deprivation, and insufficient dietary intake are risk factors for medical device-related pressure injuries and impaired wound healing.

Choose the correct size and type of medical device to fit the individual.

A. Avoid placing devices over sites of prior or existing pressure injury or assess the patient's risk status.

Report medical device-related pressure injuries correctly and immediately; monitor incidence and prevalence.

Educate staff on the correct use of devices and prevention of skin breakdown (younger and older patients are at high risk); never apply additional pressure when securing a device; and do not position the patient directly on a medical device unless it cannot be avoided.