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EVALUATION OF PRESSURE INJURY PREVENTION CARE BUNDLE APPLICATION IN INTENSIVE CARE UNIT PATIENTS DIAGNOSED WITH INTERNAL DISEASES

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

NCT ID: Not yet assigned

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Objective and Setting

The present study is a quasi-experimental study with a control group conducted in order to evaluate the application of pressure injury prevention care bundle in intensive care unit patients diagnosed with internal diseases.

Hypothesis

H0: The application of the pressure injury prevention care bundle is not effective in preventing pressure injury development.

H1: The application of the pressure injury prevention care bundle is active in preventing pressure injury development

Study Universe and Sample

The universe of the study consisted of patients hospitalized in the intensive care unit patients diagnosed with internal diseases in training and research hospital. The study sample was made up of diagnosed with internal diseases patients who were hospitalized in the intensive care unit between July-December 2021, who met the inclusion criteria, and who agreed to participate in the study. Power analysis was performed in order to determine the number of patients to be included in the study. The power of the test was calculated through G*Power 3.1 software. In order to determine the development status of pressure injuries in the intervention and control groups, 98 patients were included in the study with a minimum number of 49 patients in each group.

Inclusion and Exclusion Criteria

Patients who were 18 years old and above, who did not have any pressure injuries on any part of their body, who were expected to stay in the clinic for at least 24 hours, and who were diagnosed with an internal disease were included in the study. The patients who were younger than 18 years, who had a pressure injury on any part of their body, who were expected to stay in the clinic for less than 24 hours, and who had intensive care indications other than an internal disease were excluded from the study.

The end criteria for the study was determined as follows;

• Death of the patient, reaching the desired number of patients, discharging the patient from the clinic, the development of pressure injury in the patient.

Data Collection Instruments

A. **Patient Information Form**: The form prepared by the researcher includes questions inquiring about the sociodemographic and background information of the patients (age, gender, body weight, height, smoking and alcohol use), clinical characteristics (date of hospitalization, hospitalization diagnosis, duration of stay in intensive care unit, Braden risk assessment tool score, being provided with mechanical ventilation or not, medicines used, development and staging of pressure injury), and laboratory results (hemoglobin, hematocrit, blood glucose level, saturation, prealbumin value).

B. Pressure Injury Prevention Care Bundle Form: The form was developed by the researcher by benefiting from the Prevention and Treatment of Pressure Injury – 2019 Quick Reference Guide, European Pressure Injury Advisory Panel (EPIAP), and National Pressure Injury Advisory Panel (NPIAP) (2016) guidelines **(Figure 2).** The pressure injury prevention care bundle includes risk assessment (risk is assessed using braden risk scale, the assessment is carried out within the first 8 hours, then it's done every day, ıf there is a change in the status of the individual, ıt will be re-evaluated), skin assessment (the skin is evaluated for non-fading redness by printing, localized temperature, edema and humidity, ıt is evaluated in each sift or change of state, pressure zones in contact with the medical device are evaluated every 12 hours), skin care (the skin is clean and kept in normal humidity, the areas of the fritz are not rubbed vigorously, they are not massaged, every 8 hours the barrier feature protects the product and skin, the skin is protected from urine and fecal incontinence, sheets are kept clean, tense and dry), positioning (every two hours, the right-hand side-back-left-side position is given 30°, respectively, the pressure on the bone protrusions is reduced, the heels are prevented from touching the bed and are maintained), regulation of nutrition and liquid management (individual enteral or parenteral nutrition is provided, the patient's fluid intake is evaluated, dehydration is evaluated, weekly albumin/crp values are monitored) .[1,6,9,10]

In intervention of applying each parameter in the bundle, “yes” is marked, and “no” is marked when each parameter is not applied, when each recommendation is applied, it is considered full compliance with the bundle. [11-12] After the bundle has been prepared, 4 intensive care nurses, 2 academics who are qualified in intensive care and internal diseases nurses, and 7 specialist docs were presented to the opinion of the Medical Specialty Education Institution (TUEK), where the study was conducted.

C. Braden Risk Assessment Tool: The tool was developed by Braden and Bergstorm in 1987 by considering risk factors involved in pressure injuries. With this tool, six parameters of the patient’s stimulant perception, activity, mobility, the effect caused on the skin by humidity, friction, and shearing tension are measured. 12 points and below in total are considered high risky, 13-14 points risky, 15-16 points low risky, and for individuals at the age of 75 and above, 15-18 points are evaluated to be low risky. In addition, it is recommended to be used in intensive care units and patients who need long-term care. This tool is routinely used in the clinic where the study was conducted.[13-15]

Data Collection

The study was conducted in three stages. The stages of the study are presented in **Figure 1.**

Stage 1: In the first phase of the study, the pressure injury prevention care bundle, consisting of 5 substances related to risk assessment, skin assesment, skin care, positioning, regulation of nutrion and liquid management, has been developed. After the bundle has been created, a training presentation has been prepared for nurses working in the clinic, including general information on pressure injury within the literature, the pressure injury prevention care bundle and information on how to use the bundle.

Once all of these preparations have been completed, the control group has been included in the study by continuing routine practices for pressure injury in the clinic (using of braden risk scale, positioning, elevation of the heels). After completing the patient acquisition of the control group, an appropriate training schedule has been created to perform the previously prepared training program, taking into account the nurses' work schedule in the clinic. The training program has been carried out to 40 nurses working in ICU between 30-45 minutes in 4 separate meetings. After the training, training presentations were given to the nurses.

Stage 2: After the training, the pressure injury prevention care bundle was applied to the patients in the intervention group who met the inclusion criteria until the determined number of patients was reached.

Stage 3: At this stage, it was examined whether any pressure injuries developed in the patients in the group who were applied the pressure injury care bundle, and the effectiveness of the pressure injury care bundle was evaluated.

Data Evaluation and Statistical Methods

The study data were analyzed through IBM SPSS V23 software. In the categorical comparison of the groups, Yates Correction, Fisher's Exact test, and Pearson χ^2 test were employed. In the two-group comparison of the normally distributed data, Independent Two Samples t test was used, while in the comparison of the data without normal distribution, Mann-Whitney U test was used.

The risk factors affecting the process of disease development were analyzed with Cox regression analysis. In the comparison of survival duration according to VOD status, Log Rank test was employed. The analysis results were presented as mean±standard deviation for the quantitative data and as frequency (percentage) for the categorical variables. Significance level was taken as $p<.05$.

Ethics

In conducting study, universal ethical rules as well as scientific principles were observed. As the use of human beings in the study required the protection of individual rights, the principles of Helsinki Declaration of Human Rights were also observed. Ethics board approval was obtained from the Health Sciences University Hamidiye Interventional Research Ethics Committee **(Decision No: 2021.03.18-33)** and institutional permission was taken from the hospital where the study would be conducted and Medical Specialty Education Authority. Moreover, before collecting the study data, each patient participating in the study or their legal custodian was informed about the content of the study and nurses, voluntary participation, and their verbal and written consents were taken.