An RCT on Support Surfaces for Pressure Ulcer Prevention

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Study protocol

An individual randomized design will be used. Eligible acute care patients will be identified by a wound nurse and recruited within 48 hours of identification of moisture risk. New admissions will be screened for the pressure injury risk factors of Total Braden score≤18 and Braden Moisture sub-scale score 1-constantly moist or 2-very moist, projected length of stay ≥4 days, and absence of pressure injuries. Total Braden ≤ 18 was found to represent a relative risk of pressure injury of 4.26 (95% CI, 3.27 to 5.55) in a meta-analysis of 31 studies. WOCN consensus guidelines for support surface selection indicate provision of a preventive support surface for those at risk, defined as Braden scale score ≤ 18, and use of a surface with low air loss (LAL) features for those with Braden Moisture sub-scale score of 1 or 2. After informed consent, absence of pressure injuries will be confirmed, baseline data (biological and clinical data) will be recorded and participants will be randomized by the Clinical Coordinator (a wound and research nurse dedicated to this project) into one of seven groups differentiated only by the support surface assignment. Seven surfaces were chosen for the trial interventions that can be divided into reactive support surface with LAL or reactive surface without LAL and demonstrate a range of heat and moisture control performance characteristics. The Clinical Coordinator will carry out the randomization at the end of the baseline visit. Participants in all groups will be provided usual care including tissue integrity management according to study site system-wide Skin Integrity Procedures, which address risk assessment (daily), skin inspection (twice daily), regular patient repositioning (every two hours as condition allows), pressure alleviation, moisture control, nutritional support and friction/shear relief applications. This and the other aspects of usual care are adjuncts to the support surface intervention, which will be applied to all groups and documented. Data will be recorded daily by the Clinical Coordinator from assessments, electronic medical records, observations and interviews with clinical staff until pressure injury incidence or hospital discharge. We targeted a minimum projected length of stay of 4 days to allow sufficient time for a pressure injury to develop. Provision of the support surface intervention will be accomplished by coordination with the hospital's bed warehouse and local DME suppliers.

Choice of outcomes: The outcome measures were chosen to ensure direct relevance to patients at risk for developing pressure injuries. We chose the direct clinical outcome measure of pressure injury incidence to assess the clinical effectiveness of the study support surface interventions being compared. Pressure injury status will be monitored and recorded every day (7 days per week) until any of the following endpoints are reached: pressure injury incidence or discharge from hospital. Identification of pressure injury by certified wound nurses who are not part of the research team avoids potential bias and provides quality assurance. These nurses will not be blinded to surface type but will be blinded to surface performance characteristics. After an endpoint is reached, the pressure injury severity will be recorded as the highest stage reached prior to discharge (Stage 1, 2, 3, 4, deep tissue pressure injury (DTPI) or unstageable) as defined by NPUAP. If the pressure injury status was observed to be a DTPI or unstageable and later becomes stageable as 1, 2, 3, or 4, the latter stage will be recorded. Otherwise DTPI and unstageable injuries will be recorded as such.

Choice of covariates: Variables that may be associated with the outcome of pressure injuries were recorded and include:

- Relevant biological variables (recorded at baseline): age, sex, race, ethnicity, weight, height, and underlying health conditions such as diabetes, peripheral vascular disease, nutritional status, and incontinence
- Pressure injury risk factors (assessed and recorded daily until endpoint): Braden score, Braden subscale scores
- Clinical conditions and procedures (monitored and recorded daily until endpoint): layers of linens, type and length of the surgery,
- Length of stay and number of days on the support surface (recorded at study endpoint).

Statistical Analysis Plan

The effectiveness of reactive support surfaces with and without low air loss were compared. This was done using using a Pearson Chi-Square analysis to test for an association between treatment groups (2 levels - low air loss vs without low air loss) and pressure injury incidence.