Decreasing Intraoperative Skin Damage in Prone Position Surgeries

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Study Protocol and Study Analysis Plan

Study Protocol

Recruitment

Patients from neurological and orthopedic surgery groups were recruited for the study at a 281-bed academic Medical Center in the greater Los Angeles area. Per approval by the University of California, Los Angeles, Office for Human Research Protection Program, research staff identified scheduled participants for surgery in the prone position, sent them an information sheet about the study, and then contacted them by phone to determine their interest in the study. Participants were eligible for the study if they were scheduled to undergo orthopedic or neurological surgery in prone position, 18 years of age or older, and able to provide verbal informed self-consent. Exclusion criteria were less than 18 years old, inability to provide verbal informed consent, and scheduled for surgery only in a position other than prone position.

Skin Assessments

On the day of surgery, research staff obtained written HIPAA consent from participants and confirmed consent to participate in the study. Research staff collected visual skin assessment and sub-epidermal (SEM) measures for all participants at the anterior chin, upper cheeks, mid forehead (face), right and left upper chest above nipple line, and iliac crest, both pre-operatively in the Pre-Post Anesthesia Care Unit (PACU) and post-operatively in the PACU or after transfer to the floor unit. Once the pre-operative assessments were completed for intervention participants, research staff placed the multidimensionally flexible silicone foam (MFSF) dressings to the face (chin, cheeks, forehead), chest and iliac crest. Following surgery, research staff removed the MFSF dressings in the PACU or on transfer to the floor unit and then visual skin assessment and SEM measures were obtained. For all participants, visual skin assessments

and SEM measures were obtained daily on the floor unit until post-operative day five or discharge from hospital (whichever occurred first).

Visual Skin Assessment. Trained research staff assessed skin health through direct independent visual assessments. Eight anatomic locations were assessed: mid forehead, chin, and right and left upper cheek, upper chest above nipple line and iliac crest. Areas of visual skin discoloration were palpated for blanchability in persons with light skin tones and any pressure injuries (PrIs) were assessed for size and stage. Training for visual skin assessment emphasized identification of stage 1 PrIs and deep tissue injury (DTI) because these conditions may be difficult to detect. Skin discoloration severity was graded as slight (pink or slight redness in persons with light skin tones and increase in normal skin color in persons with dark skin tones), minimal (redness in persons with light skin tones and deepening of normal skin color in persons with dark skin tones), moderate (bright redness in light skin tones and purple in dark skin tones), or severe discoloration (dark red to purple in light skin tones and black to blue-grey in dark skin tones). In persons with light skin tones, blanchability based on finger palpation was defined as blanchable or non-blanchable; blanching was not considered for persons with dark skin tones. Stage 1 PrIs were defined as skin discoloration with severity of minimal or greater. PrIs more severe than Stage 1 were classified using the NPIAP's 2019 classification system. For skin that demonstrated none of the above visual characteristics, the assessment was considered normal skin. The presence or absence of scar tissue, dry skin, rashes, skin tears, tatoos, and extensive or thick hair was also recorded.

Subepidermal Moisture Measures. Subepidermal moisture (SEM) was measured at each anatomic location on clean dry skin using the Provizio ® SEM Scanner (BBI LLC, Bruin Biometrics, Los Angeles, California, US) dermal phase meter. Using dielectric parameters, the

device transmits high-frequency, low-power electromagnetic waves of 32 kHz via an electrode that requires light skin touch. In the skin, the induced electrical field interacts mainly with water molecules closest to the electrode, with depth of interaction depending on the diameter of the circular electrode (in this study depth was 4 mm). The portion of electromagnetic energy that is not absorbed by tissue water is reflected and measured by the device and displayed in three seconds in the measuring unit picoFarads (pF) (range, 0-7 pF). The electrical properties of free and bound water are nearly identical and thus the measure is reflective of total water content in the tissue.

Definition Intraoperative Acquired PrIs. Intraoperative acquired PrI (IAPrI) was defined two ways for each anatomic location. First, as erythema/skin discoloration of minimal or greater severity by visual skin assessment. Second, by calculating the difference between pre-operative and the post-operative SEM value (hereafter SEM Delta); SEM Deltas greater than or equal to 0.6pF were considered indicative of IAPrIs.

Medical Record Data

Research staff extracted medical, surgical, and demographic information was extracted from participants' electronic health records (EHR) using an investigator-developed abstraction tool. Data abstracted included demographic data (gender, age, race/ethnicity), medical data (height, weight, body mass index, comorbidities such as diabetes, hypertension, peripheral vascular disease and, smoking status, medical diagnoses, Braden Scale for predicting Pressure Sores (Braden) score, use of any PrI preventive strategies such as support surface use, repositioning schedules), surgery type, surgery length, use of vibration machines or other instruments in surgery, length of time in PAR unit, anesthesia used, use of vasopressors during surgery, estimated blood loss, volume of fluids provided during surgery, blood pressure during

surgery, American Society of Anesthesiologists physical status score and documentation of any skin damage. Using EHR data, a Scott-Triggers IAPrI risk assessment score was calculated for each participant. The Scott-Triggers tool examines four characteristics: age 62 years or older: albumin less than 3.5mg/dL or BMI less than 19 or greater than 40; American Society of Anesthesiologists physical status classification system (ASA) 3 or greater; and estimated surgery time over 3 hours. Each characteristic affirmed scores a point and scores greater than 1 indicate high risk for IAPrIs (37).

Study Analysis Plan

The two outcome measures, IAPrI incidence by visual assessment and SEM Deltas indicative of PrI, were compared between participants undergoing prone surgery with standard care (no dressings, pressure reduction positioning on the operating table) and those with standard care and the intervention (use of MFSF dressings placed on chest, iliac crest, and face). Using Fisher's Exact test statistics, the percent of participants with IAPrI on face, chest, and iliac crest as defined above were compared between the two groups for initial post-operative assessment and postoperative days 2 and 3 assessments. There were insufficient participants to evaluate postoperative days 4 and 5.

Using binary logistic regression analyses, demographic, medical and surgical factors were compared for prospective participants who did and did not develop skin damage or IAPrIs controlling for group. Factors that increase risk for IAPrIs were evaluated including: hospital length of stay, surgery length, body mass index (BMI), and skin tone. Cochran Mantel-Haenszel statistics were used to compare the groups.