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Safety Enclosures' Clinical Utility Research (SECURE Study)- A randomized trial of safety bed net with that of usual hospital restraint in agitated hospitalized patients.

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Purpose: The purpose of this study is to compare the currently used restraints system with newer and innovative restraints for agitated hospitalized patients to compare the safety, length of stay, health care professional's satisfaction, acceptability, ease of use, and comfort with the two types of restraint systems in hospitalized patients. There are no previously reported trials.

Methods: We report preliminary finding from a ongoing randomized controlled trial of 22 patients age ≥18 to compare SOMA safe enclosure system vs. the standard physical restraint system. We included agitated, acutely confused, and delirious hospitalized patients who were being considered for physical restraints. Patients were excluded for: 1) lack of consent; 2) being critically sick (requiring intravenous vasopressors, intubation and ventilatory support, septic or cardiogenic shock; 3) having a terminal condition; 4) already on restraints >48 hrs. Outcomes included: 1) perception & acceptability of both restraint types on a structured survey from nursing staff, physicians, & family; 2) length of stay; 3) amount of sedatives & hypnotics; 4) total duration of restraints; 5) injuries to patients or staff.

Results: Out of 22 enrolled subjects, (41% were female, mean age 81.5 years) 48%, 33%, 62%, 14%, 14%, 33%, 19% had history of Alzheimer's dementia, CAD, HTN, stoke, Diabetes, alcohol abuse, respectively. Ten patients were randomized to Soma safety and 12 to standard restraints (Posey vest 32%, soft 4 points 5%, soft 2 points 5%, Posey vest plus 2 point soft restraints). Two groups did not differ in mean age or gender distribution. Safety net arm had lower mean length of stay (4.6 days vs. 6.7 p=0.13) and total duration of restraints (3722.8 vs. 5875 minutes). Safety net arm had higher nursing score for ease of use of bedpan (8 vs. 5.5 p=0.03). Patient relatives' rated safety net higher for perceived calmness of patient (8.2 vs. 5.9 p=0.04); reduced risk of injury (9.3 vs. 7.8 p=0.017); hastening recovery from illness (8.9 vs. 5.8 p=0.007); and it being more ethical (7.9 vs. 5.9 p=0.09). Survey scores were highly correlated between physicians and nursing 9r=0.8 p=0.015) while relative's score did not correlate with that of nursing staff. There were no injuries reported resulting directly from restraints.

Conclusions: Based on preliminary findings, it appears that Soma Safety Net is safe, and its use is associated with reduced length of stay, reduced total time on restraints, and higher satisfaction and acceptability from patients' relative.