



Effect of a wearable patient sensor on care delivery for preventing pressure injuries in acutely ill adults: A pragmatic randomized clinical trial (LS-HAPI study)

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ABSTRACT

Importance: Though theoretically sound, studies have failed to demonstrate the benefit of routine repositioning of at-risk patients for the prevention of hospital acquired pressure injuries.

Objective: To assess the clinical effectiveness of a wearable patient sensor to improve care delivery and patient outcomes by increasing the total time with turning compliance and preventing pressure injuries in acutely ill patients.

Design: Pragmatic, investigator initiated, open label, single site, randomized clinical trial.

Setting: Two Intensive Care Units in a large Academic Medical Center in California.

Participants: Consecutive adult patients admitted to one of two Intensive Care Units between September 2015 to January 2016 were included (n = 1564). Of the eligible patients, 1312 underwent randomization.

Intervention: Patients received either turning care relying on traditional turn reminders and standard practices (control group, n = 653), or optimal turning practices, influenced by real-time data derived from a wearable patient sensor (treatment group, n = 659).

Main outcome(s) and Measure(s): The primary and secondary outcomes of interest were occurrence of hospital acquired pressure injury and turning compliance. Sensitivity analysis was performed to compare intention-to-treat and per-protocol effects.

Results: The mean age was 60 years (SD, 17 years); 55% were male. We analyzed 103,000 h of monitoring data. Overall the intervention group had significantly fewer Hospital Acquired Pressure Injuries during Intensive Care Unit admission than the control group (5 patients [0.7%] vs. 15 patients [2.3%] (OR = 0.33, 95%CI [0.12, 0.90], p = 0.031). The total time with turning compliance was significantly different in the intervention group vs. control group (67% vs 54%; difference 0.11, 95%CI [0.08, 0.13], p < 0.001). Turning magnitude (21°, p = 0.923) and adequate depressurization time (39%, p = 0.145) were not statistically different between groups.

Conclusions and Relevance: Among acutely ill adult patients requiring Intensive Care Unit admission, the provision of optimal turning was greater with a wearable patient sensor, increasing the total time with turning compliance and demonstrated a statistically significant protective effect against the development of hospital acquired pressure injuries. These are the first quantitative data on turn quality in the Intensive Care Unit and highlight the need to reinforce optimal turning practices. Additional clinical trials leveraging technologies like wearable sensors are needed to establish the appropriate frequency and dosing of individualized turning protocols to prevent pressure injuries in at-risk hospitalized patients.

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What is already known about the topic?

- Hospital acquired pressure injuries are insidious multifactorial complications of hospitalization.
- Studies have failed to establish the efficacy of routine repositioning of patients for the prevention of pressure injuries.
- Prior studies rely on manual measures to assess care delivery however this limits sampling, is prone to errors, and introduces the potential for significant bias.
- It is not known whether objective data derived from wearable patient sensors can inform preventive care practices and improve related outcomes in intensive care unit patients.

What this paper adds?

- The findings from this study support the use of wearable patient sensors as effective interventions to inform care delivery, improve turning compliant time, and reducing hospital acquired pressure injuries.
- This novel work establishes the efficacy of repositioning and lays the groundwork for developing individualized turning protocols for patients at risk of hospital acquired pressure injuries.

1. Introduction

Hospital Acquired Pressure Injuries are insidious, multi-factorial complications arising from sustained pressure and/or damage caused by shear and friction forces (NPUAP, 2014; Russo et al., 2008; Bauer et al., 2016). In the United Kingdom, hospital acquired pressure injuries occur in approximately 2000 patients per month within the National Health Service (Unit CAS, 2015). In the United States, over 250,000 pressure injuries were subjected to mandatorily reporting in 2007 (Anon, 2015). Between 1993 and 2006, Hospital Acquired Pressure Injuries-related hospitalizations rose by 78.9% (Russo et al., 2008), prompting the US Centers for Medicare and Medicaid to cease reimbursing healthcare organizations for HAPI-related care. In 2011, the National Quality Forum added Hospital Acquired Pressure Injuries to their list of “Never Events” (Serious Reportable Events that are identifiable and measurable) (NQF, 2011). Thereafter, a study of 210 academic medical centers found a rather precipitous reduction in Hospital Acquired Pressure Injuries, from 11.8/1000 inpatient stays in 2008 to 0.8/1000 inpatient stays in 2012 (Padula et al., 2015). It is unknown whether this drop was due to implementing best-practices or administrative influences (Padula et al., 2016). In 2014, the Patient Protection and Affordable Care Act (Rosenbaum, 2011) further incentivized the prevention of Hospital Acquired Pressure Injuries with reimbursement penalties levied against health care organizations with the highest rates of Hospital Acquired Conditions.

Current joint-prevention guidelines (NPUAP, 2014) from the European, American, and Pan-Pacific agency’s for preventing pressure injury recommend individualized care plans, appropriate supportive surfaces, and modulating the frequency of repositioning based on individual patient needs. However only 14% (Black, 2015) of these guidelines were supported by evidence; the majority of which was indirect or expert opinion (NPUAP, 2014). The standard of care for patients in the Intensive Care Unit is redistribution of weight every two hours while in bed, and every hour while in a chair (Improvement IfCS, 2012). However, globally, studies evaluating patient turning reveals poor compliance with turning protocols, and varying rates of pressure injuries (3%–37%) (NPUAP, 2014; Unit CAS, 2015; Barrois et al., 2008; Jiang et al., 2014; Prentice, 2007; Prentice and Stacey, 2002).

For example, a study of 39 Intensive Care Units (Goldhill et al., 2008) in the UK revealed the median time to repositioning was four hours, while 5% of patients remained in position for longer than eight hours. A similar study of three Intensive Care Units in the United States found that 97% of patients did not receive standard repositioning every



Fig. 1. Wearable Patient Sensor (courtesy of Leaf Healthcare, Inc.).

two hours, and 50% were supine for up to eight hours (Krishnagopalan et al., 2002). These studies did not assess the association between repositioning and Hospital Acquired Pressure Injuries – a common limitation. To reinforce this point, a recent systematic review concluded that there is little available evidence addressing the question of whether repositioning patients decreases the risk of acquiring pressure injuries (Gillespie et al., 2014). The need to use direct observation and self-reported data to record turning compliance is contributive to this lack of evidence (Goldhill et al., 2008; Krishnagopalan et al., 2002; Gillespie et al., 2014; Lyder et al., 2001; Mazano et al., 2014; Schallom et al., 2005). Current methodologies miss actual care episodes, do not capture the effectiveness of a turn in redistributing pressure, and introduces significant observer and self-report biases.

In environments like the Intensive Care Unit, a wearable patient sensor may overcome these limitations by providing an objective recording of patient turning practices. The Leaf Patient Monitoring System (Leaf Healthcare, Inc.) is a wearable patient sensor (Fig. 1) that measures body position and provides feedback promoting optimal turning practices. In non-experimental implementation trials, this system has been reported to have increased turning compliance (Tarver et al., 2014; Walters et al., 2016; Parker et al., 2015), however the effect on Hospital Acquired Pressure Injuries has not been studied. The purpose of this randomized clinical trial was to assess whether the use of a wearable patient sensor, to promote optimal turning practices, is effective in increasing turning compliance and preventing Hospital Acquired Pressure Injuries in patients admitted to an Intensive Care Unit.

2. Methods

2.1. Study design and participants

This is an investigator-initiated, pragmatic, single site, open label, two arm, parallel, randomized clinical trial conducted from September 2015 to January 2016, for patients admitted to either of two Intensive Care Units at a large Academic Medical Center. Intensive Care Unit A (25 beds) specializes in the care of post-cardiothoracic surgical patients; Intensive Care Unit B (33 beds) specializes in the care of critically ill medical, surgical, and trauma-related patients. Study exclusion criteria were: patients less than 18 years of age; patients with an issue preventing effective sensor adhesion (i.e. a sternal dressing) or known adhesive sensitivity; extreme frailty/acuity as determined by clinicians, precluding study participation; or patients exercising their right of refusal. Ethics approval with a waiver of individual authorization was granted prior to study commencement. A detailed protocol is available (Pickham et al., 2016), and the study is registered with ClinicalTrials.gov, NCT02533726.

2.2. Randomization and intervention

Randomization was performed by the investigators and concealment achieved using individual opaque envelopes. Permuted sizes of blocks of two, four, and six were used to approximate equal sample sizes for each stratum (ICU unit [A and B] and treating service team [medicine and surgery]). A wearable patient sensor was applied to the chest below the suprasternal notch. Once enrolled, group allocation was revealed and the patient monitoring system was selected to function in either a *control* or *treatment* mode. For patients allocated to the *control* group, their sensor was recording but data did not feedback to bedside clinicians. Clinicians caring for patients in the control group relied on standard care practices relying on traditional turning reminders, unaided by sensor data. Patients allocated to the *treatment* group had their sensor data relayed back to a point-of-care dashboard, offering the clinician real-time data on the quality of the turn performed, the patient's current position, and the time-to-next turn (eFig. 1). Patients were blinded to group allocation. Clinicians were not blinded but were independent to the study team.

2.2.1. Care delivery

Prior to the study, nurses were provided up to one hour of education on the functioning of the sensor and the patient monitoring system. To access the system, nurses were required to open the monitoring dashboard at the bedside (a computer is available in each ICU room), by clicking an icon located on the desktop of their computer. All nurses were instructed to open the dashboard for all patients throughout their shift. Patients' sensor data were continually recording and securely stored regardless of whether the bedside dashboard was opened and visible to the nurse. Nurses caring for patients in the *treatment* group would receive visual warnings if the patient was not turned in accordance with established protocols (i.e. turning frequency of two hours and a 20° turning threshold). Once turned the visual advisory would reset automatically and display the new time-to-next turn.

2.3. Measurement of patient turning

The wearable patient sensor measures patient turning by assessing its relative position within a three-dimensional space, and every ten seconds relays these data through a mesh network of antennae to a secure SQL database. To minimize signal noise, offline and prior to analysis, a filter was applied registering a turn only if the patient was in the prior position for one minute, turned to a new position, and held the new body position for at least one minute. Changes in position were then calculated to determine the degree of position change, as well as the duration of time spent in each position.

Minimum thresholds for turning were established based on best available evidence and expert opinion (Herrman et al., 1999; Anon, 2014). For this study these were: turning at minimum every two hours; a minimum turn angle of 20°; with at least 15 min of tissue depressurization – which was a dynamic target. For example, if a patient stayed on his/her newly turned side for half of the minimum expected depressurization time (e.g. seven and half minutes vs. fifteen minutes), then the time-to-next turn was proportionally adjusted (i.e., turn time would be reduced by 50%, such that a turn would be required within one hour instead of two hours). This was performed continuously to achieve at least 15 min of cumulative tissue depressurization time every two hours.

2.4. Clinical outcomes

Development of a hospital acquired pressure injury was the primary outcome. Documentation and staging of pressure injuries was performed by the clinical team independent to the study. Nursing staff routinely perform a head-to-toe skin assessment for each patient, every shift. Any remarkable findings are documented and a daily report is

generated for assessment within 24 h by an independent Certified Wound, Ostomy, and Continence Nurse; This person was independent of the study and blinded to group allocation. If a HAPI was present, the wound was staged using the National Pressure Ulcer Advisory Panel staging criteria (Anon, 2015) and documented in the clinical record using standard documentation procedures.

The total time with turning compliance was the secondary outcome. If a turn was not performed when expected (every two hours), then any past-due time was considered to be non-compliant time, until a satisfactory turn was detected by the monitoring system. For example, if a patient was admitted for five hours and was repositioned after three hours, then the patient's care was considered to be compliant for hours one and two, non-compliant for hour three, and if turned adequately, compliant for hours four and five. Total compliant time would be four out of five hours (80%). For each patient, the duration of Intensive Care Unit stay was classified according to whether care was compliant or non-compliant using the following formula: $[Total\ Monitoring\ Time - Non-Compliant\ Time] / Total\ Monitoring\ Time$.

2.5. Statistical analysis

We planned to enroll 1812 patients to provide 80% power to detect a 50% difference in Hospital Acquired Pressure Injuries between study groups (Anon, 1992) (i.e. 5% with HAPI in the control group vs. 2.5% with HAPI in the treatment group).

Originally, one interim sample-size calibration was planned to be conducted by the principle investigator; to verify whether the study remained sufficiently powered. In data provided by the clinical team, the observed outcomes were less than expected and sample size recalculation demonstrated the need for the enrollment of many more thousands of patients per group. As a pragmatic clinical trial undertaken in two very active intensive care units, it was determined that the additional costs and resources now necessary to complete the trial was prohibitive. The study team deemed the study to no longer be viable. The study was abandoned and enrollment ceased. Soon thereafter it was brought to our attention by the clinical team that the clinical data provided and used in the interim sample calculation were not correct. An error had been made. Thus, the trial had incorrectly been abandoned after 73% of the target enrollment had been achieved. We therefore performed a final analysis on a sample size that had not reached target, for reasons described above, and report the following results herein.

Primary treatment efficacy was estimated based on an intention-to-treat analysis. A Fisher's Exact test was used to test for differences in the development of Hospital Acquired Pressure Injuries between treatment groups. These were adjusted to examine for the possible influence of admitting team (medicine vs. surgery) or unit of admission (ICU A vs. ICU B), as well as risk for pressure injury based on Braden score. The Braden score (Bergstrom et al., 1987) is a validated tool comprised of six sub-scales (eTable 1) and is used to characterize a patient's risk for developing a pressure injury. In this study, Braden Score was used to stratify patients into three groups; low risk (19+), medium risk (13–18), and high risk (< 12). Secondary outcomes were analyzed using an independent samples Mann Whitney *U* test for differences in total time with turning compliance overall, and for high risk patients (mechanical ventilator dependent) – with absolute and relative changes reported. Linear and logistic regression analyses were performed to estimate the unadjusted associations between demographic and clinical factors, and the primary and secondary outcomes. Forest plots were constructed to graphically depict these associations. Sensitivity analyses was also performed comparing the intention-to-treat to per-protocol analyses (Harmonisation ICo, 1998). All tests were conducted at a 0.05 level of significance. Analysis was performed using SPSS Statistics (v.22, IBM).

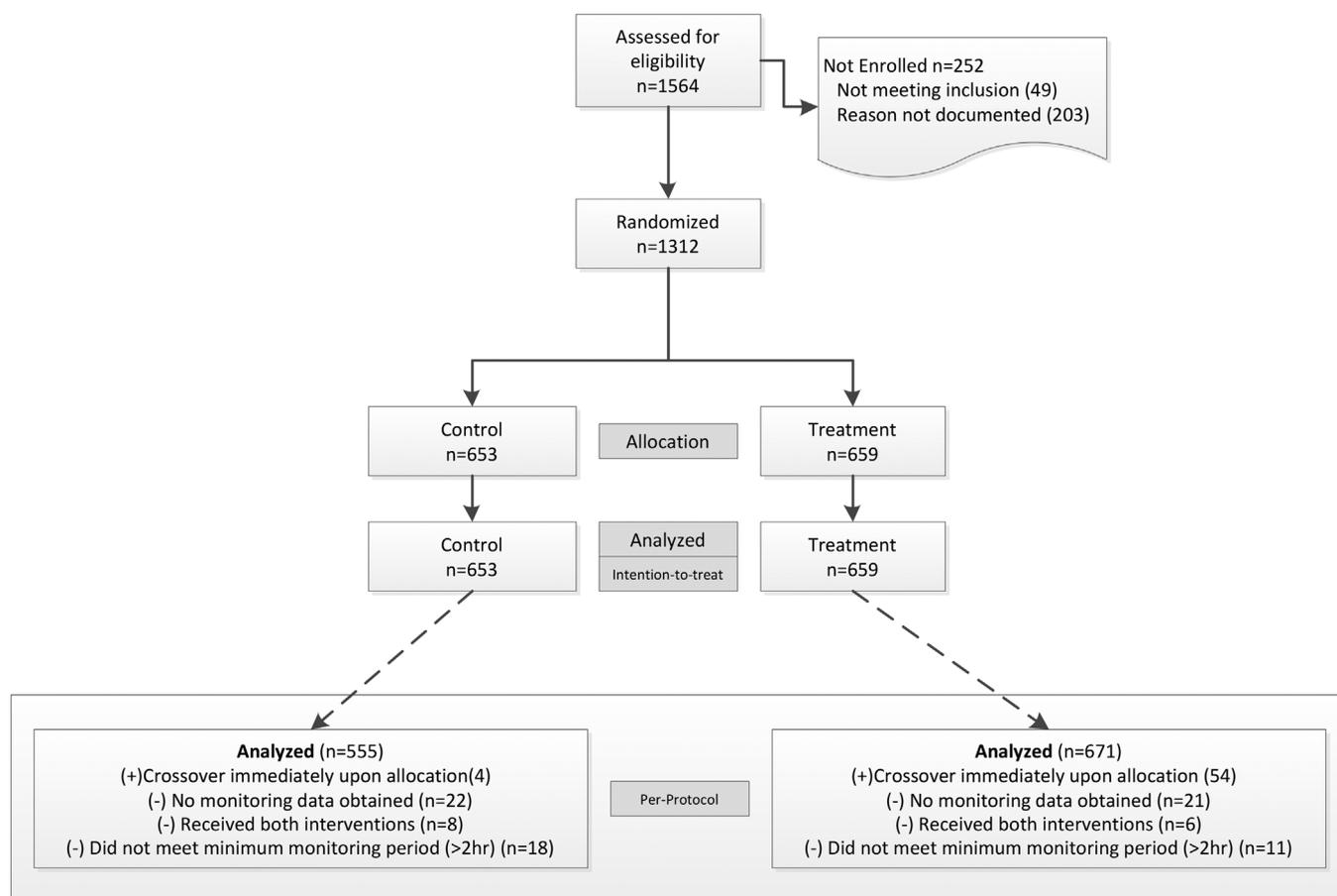


Fig. 2. Consort Flow Diagram.

3. Results

During the study period, 1564 patients were admitted to an Intensive Care Unit; 252 (15%) were not enrolled due to patient/family choice, extreme frailty/acuity, sensitivity or inability to adhere sensor, and for other undocumented reasons. Of the eligible patients, 1312 underwent allocation (Fig. 2 – CONSORT diagram).

3.1. Baseline data

Demographic and clinical characteristics were similar between control and treatment groups (Table 1). Mean age of patients was 60 (SD 17 years), with more men than women (55% v 45%), and with proportions of race and ethnicity representing the served population (White non-Hispanic [54%], Black non-Hispanic [5%], Asian [15%], Hispanic [16%]).

3.2. Pressure ulcer risk

The proportions of high- and moderate-risk patients were similar between groups (High risk [Braden < 12]: treatment 12% vs. control 10%; Moderate risk [Braden 13–18]: treatment 23% vs. control 26%) (Table 1), and for Braden sub scores (eTable 1). Patient acuity measures were also similar between groups (Table 1).

3.3. Outcomes

3.3.1. Primary

Forty-six patients (3.5%) experienced at least one Hospital Acquired Pressure Injury during admission to an Intensive Care Unit. A Certified, Wound, Ostomy, and Continence Nurse determined that sixteen

patients had an injury caused by a medical device and ten patients had an injury present on admission to the Intensive Care Unit. Subsequently, twenty patients (1.5%) developed a total of thirty individual position-related Hospital Acquired Pressure Injuries (eTable 2). The majority of pressure injuries were deep tissue injuries (n = 10) or classified as being of Stage II (n = 9), involving either the sacrum (n = 13) or buttocks regions (n = 7).

Pressure injuries were evident within fifteen patients in the control group (2.3%, [4.3 patients with HAPI per 1000 ICU patient days]) and five patients in the treatment group (0.76%, [1.3 patients with HAPI per 1000 ICU patient days]). The intervention had a significant protective effect against pressure injury (OR = 0.33, 95% CI [0.12, 0.90], $p = 0.031$). This effect remained after adjusting for admitting team, unit of admission, and risk for pressure injury ($p = 0.038$). The Number Needed-to-Treat to prevent one additional Hospital Acquired Pressure Injury was sixty-two. Univariable analysis for developing HAPI demonstrated that older age was associated with reduced odds for Hospital Acquired Pressure Injury, while abnormal Glasgow Coma Scale score, higher lactate values, steroid use, higher APACHE II score and longer length of stay in the Intensive Care Unit, were associated with greater odds for Hospital Acquired Pressure Injuries (Table 2 and eFig. 3).

3.3.2. Secondary

103,000 h of patient positioning data were obtained (Med = 40 h, IQR = 19 h–91 h). There was strong evidence to suggest treatment affected the proportion of time compliant (treatment, 67% vs. control, 54%, $p < 0.001$). In patients at high-risk for pressure injury (Braden Score < 12), relative difference in the total time with turning compliance was 43% (treatment, 67% v control, 47%, $p < 0.001$). In univariable analyses, male sex, greater body mass index, surgical team,

Table 1
Baseline Demographics and Clinical Values.^a

Characteristics	Control n = 653	Treatment n = 659	Overall n = 1312
Male, No. (%)	352 (54)	366 (56)	718 (55)
Age, mean (SD), Years	60 (18)	60 (17)	60 (17)
Race, No. (%)			
White	351 (54)	358 (54)	709 (54)
Black or African American	40 (6)	30 (5)	70 (5)
Asian	98 (15)	92 (14)	190 (15)
Ethnicity, No. (%)			
Hispanic/Latino	98 (15)	113 (17)	211 (16)
Non-Hispanic/Latino	538 (82)	524 (80)	1062 (81)
Body Mass Index, mean (SD)	23 (6)	24 (6)	24 (6)
ICU Unit A, No. (%)	225 (35)	226 (34)	451 (34)
Type of Admission No. (%)			
Medical	251 (38)	245 (37)	496 (38)
Surgery	402 (62)	414 (63)	816 (62)
Monitoring Time, mean (SD), Hours	78 (132)	84 (128)	81 (130)
Length of ICU Stay, mean (SD), Hours	128 (234)	139 (244)	133 (239)
Community Acquired Pressure Injury, No.	0	2	2
HAPI Present on Enrollment, No.	2	6	8
Braden Scale, No. (%) ^b			
High (< 12)	51 (10)	61 (12)	112 (11)
Moderate (13–18)	130 (26)	124 (23)	254 (25)
Low (19 >)	321 (64)	347 (65)	668 (65)
Charlson Comorbidity Index, mean (SD)	3.7 (3)	3.8 (3)	3.8 (3)
Apache II Score, mean (SD) ^b	13 (7)	14 (7)	13 (7)
Nursing Acuity Index, mean (SD) ^b	65 (31)	65 (30)	65 (30)
Glasgow Coma Scale, mean (SD) ^b	13 (3)	13 (3)	13 (3)
ASA Risk Score at 1st Surgery, mean (SD)	3 (1)	3 (1)	3 (1)
Temperature, mean (SD), F nd	99 (1)	99 (1)	100 (1)
Smoking History, mean (SD), Years	7 (13)	8 (13)	7 (13)
Diabetes, No. (%)	149 (23)	147 (22)	296 (23)
Albumin, mean (SD) ^b	3 (1)	3 (1)	3 (1)
Lactate, mean (SD) ^c	4 (3)	4 (3)	4 (3)
Anticoagulants, No. (%) ^c	472 (72)	472 (72)	944 (72)
Antibiotic, No. (%) ^c	481 (74)	484 (74)	965 (74)
Insulin, No. (%) ^c	338 (52)	340 (52)	678 (52)
Sedative, No. (%) ^c	534 (82)	530 (80)	1064 (81)
Steroid, No. (%) ^c	295 (45)	281 (43)	576 (44)
Vasopressor, No. (%) ^c	599 (92)	608 (92)	1207 (92)

Abbreviations: ICU, intensive care unit; ASA, American Society of Anesthesiologist physical status classification system score; APACHE II, Acute Physiological and Chronic Health Evaluation II.

^a No statistical differences between groups for all clinical and demographic variables ($p > 0.05$).

^b First measure after admission to ICU.

^c Highest value during hospital admission.

^d Lowest value during ICU admission.

^e One or more administered during ICU admission.

abnormal Glasgow Coma Scale score, lower albumin values, higher lactate values, higher APACHE II score, longer length of stay in the Intensive Care Unit, and surgery duration time, were associated with a lower total time with turning compliance (Table 2 and eFig. 2).

3.3.3. Turning magnitude and depressurization time

Sensors recorded 178,039 position changes; 64,450 (36%) met criteria to be classified as a ‘turn’ (control = 35% [27,566] vs. treatment 37% [36,884]). We analyzed the first 72-h of care provided to ventilator-dependent patients (n = 281, control = 127 vs. treatment = 154). Turning compliance in this subset was greater with the

intervention (67% vs. control = 51%, $p < 0.005$), however the average turn magnitude (21°, $p = 0.923$) and the proportion with adequate tissue depressurization time (39%, $p = 0.145$) were no different.

3.3.4. Sensitivity analysis

Primary and secondary outcomes were compared using a per-protocol analysis (Harmonisation ICo, 1998). Post-randomization exclusions were due to: no sensor monitoring data available (n = 43), patients not meeting a minimum monitoring threshold (> 2 h) (n = 29), and patients receiving both interventions during Intensive Care Unit admission (n = 14), misallocated after returning to the Intensive Care Unit). After accounting for these changes exclusions and adjusting for cross-over 1226 subjects were included in the per-protocol analysis (n = 671 treatment, n = 555 control) (Table 3). Consistent with the intention-to-treat analysis, treatment effects remained significant between groups (Hospital Acquired Pressure Injury, $\Delta + 6\%$, $OR = .27$, $95\% CI [0.10, 0.75]$, $p = 0.012$; Compliant time, $\Delta + 2\%$, $95\% CI [0.08, 0.13]$, $p < 0.001$).

4. Discussion

In this pragmatic randomized clinical trial, optimal patient turning with adults admitted to an Intensive Care Unit was greatest using a wearable patient sensor; improving the total time with turning compliance and significantly reducing the odds for developing Hospital Acquired Pressure Injuries. The intervention was associated with a significant increase in the total time with turning compliance for patients at high risk for pressure injuries.

Hospital Acquired Pressure Injuries are multifactorial, with patients in the Intensive Care Unit possessing an elevated risk profile due to immobility and other clinical factors (Cox, 2011). In our study, over 30% of patients had restricted mobility (eTable 1). Prior studies evaluating the association between patient turning and the development of Hospital Acquired Pressure Injuries have failed to sufficiently establish a benefit (Gillespie et al., 2014). Mazano et al. found that increased turning frequency had no impact on pressure injury formation in patients who are mechanically ventilated (10% v 13%, $p = .730$), but did increase device-related adverse events ($p = .020$) (Mazano et al., 2014). While Chaboyer et al. analysis of a Hospital Acquired Pressure Injury – prevention care bundle with 1600 hospitalized patients, failed to produce sufficient evidence to indicate an effect ($HR = 0.58$, $95\% CI [0.25, 1.33]$, $p = .198$) (Chaboyer et al., 2016). Two other trials assessed dedicated turning teams for reducing Hospital Acquired Pressure Injuries. McGuinness et al. developed a skin and wound assessment team, and conducted bedside consultations and rounding. This intervention reduced HAPI by 48% when compared to historical controls (McGuinness et al., 2012). Similarly, Still et al. deployed a two person turning team in a surgical Intensive Care Unit, resulting in a three-fold reduction in Hospital Acquired Pressure Injuries (15% v 5%) (Still et al., 2013). Despite suggestion of a benefit from patient turning, the implementation was not sustained due to the resource-intensive nature of the intervention. The rate of Hospital Acquired Pressure Injuries was reported to have increased once the focus on the trial subsided (Still et al., 2013).

The pragmatic nature of our study and the comprehensive data obtained from continuous monitoring allows us to make a series of novel observations. It is important to note, as the wearable sensor is placed on the trunk of a patient, it will only detect changes in trunk position and not the off-loading of the heels or other body parts. Notwithstanding, to our knowledge this is the first study to use wearable patient sensors to report data on turning magnitude. To do this we established a minimum turn angle threshold that was based on the best available evidence (20°) (Herrman et al., 1999; Anon, 2014). Although we detected a difference in compliance time, we did not detect differences in turn magnitude between groups. It is probable that the angle

Table 2
Association of Demographic and Clinical Variables to Turning Compliance and HAPI.

Variable	n	Compliance to Turning ^a				Development of HAPI ^b			
		Proportion Difference	95% CI		P Value	OR	95% CI		P Value
			Lower	Upper			Lower	Upper	
Treatment v Control	1312	0.13	0.10	0.15	< 0.001	0.33	0.12	0.90	0.031
Age [60+ v < 59yrs]	1312	0.02	-0.01	0.04	0.124	0.39	0.15	1.01	0.039
Gender [Male v Female]	1312	-0.05	-0.07	-0.02	< 0.001	1.55	0.61	3.90	0.356
Body Mass Index [18.5–24.9]	1258				0.001				0.572
BMI [< 18.5]		-0.01	-0.04	0.03		1.82	0.35	9.51	
BMI [25–29.9]		-0.04	-0.07	-0.01		0.97	0.20	4.73	
BMI [> 30]		-0.08	-0.11	-0.04		1.89	0.38	9.48	
Team [Surgery v Medicine]	1312	-0.03	-0.05	-0.02	0.035	1.43	0.54	3.73	0.470
Braden Scale [Low]	1131				0.336				0.010
BSS [Moderate]		0.01	-0.03	0.04		7.58	1.94	29.7	
BSS [High]		-0.03	-0.08	0.02		1.00	0.71	9.81	
Glasgow Coma Scale [Normal]	1090				< 0.001				0.018
GCS [Moderate]		-0.05	-0.09	-0.02		1.84	0.48	7.02	
GCS [Severe]		-0.10	-0.15	-0.06		5.17	1.66	16.1	
Albumin [Low v Normal]	1020	-0.04	-0.07	-0.01	0.013	1.96	0.64	5.81	0.244
Lactate [Normal]	571				0.007				0.002
Lactate [Moderate]		-0.04	-0.07	0.00		2.12	0.35	12.8	
Lactate [High]		-0.05	-0.09	-0.02		10.0	2.21	45.3	
Vasopressor ^c [Yes v No]	1267	-0.04	-0.09	0.01	0.079	N/A			
Sedation [Yes v No]	1312	-0.02	-0.05	0.02	0.348	4.50	0.60	33.7	0.144
Steroid [Yes v No]	1312	-0.02	-0.04	0.01	0.232	7.43	2.17	25.5	0.001
APACHE II [1–10]	1310				< 0.001				0.001
APACHE II [11–20]		-0.03	-0.05	0.00		7.88	0.98	63.2	
APACHE II [21 >]		-0.08	-0.12	-0.05		25.7	3.30	200	
Temperature [Normal]	1232				0.163				0.347
Temp ^c [Low]		-0.08	-0.20	0.05		0.00	0.00	N/A	
Temp [High]		-0.02	-0.05	0.01		2.28	0.75	6.91	
Surgery Time [< 1 h]	1045				0.001				0.454
Surg Time [1–4 h]		-0.06	-0.09	-0.03		0.36	0.09	1.39	
Surg Time [4–8 h]		-0.05	-0.09	-0.02		0.36	0.09	1.47	
Surg Time [> 8 h]		-0.04	-0.08	0.01		0.32	0.05	1.98	
Length of Stay [< 3 days]	1312				< 0.001				< 0.001
LOS [3–6 days]		-0.06	-0.10	-0.03		3.38	0.68	16.88	
LOS [6–10 days]		-0.05	-0.09	-0.01		1.91	0.20	18.53	
LOS [> 10 days]		-0.09	-0.13	-0.05		21.3	5.88	75.64	

Abbreviations: BMI, body mass index; BSS, Braden Skin Scale; GCS, Glasgow Coma Scale; APACHE II, Acute Physiological and Chronic Health Evaluation II; Temp, temperature in Fahrenheit; Surg, surgical time as listed in operating room report; LOS, length of stay.

^a Unadjusted linear regression used to estimate relationship between variables and turning compliance.

^b Unadjusted logistic regression used to estimate associations with hospital acquired pressure injuries.

^c Insufficient data.

Table 3
Sensitivity Analyses.

	Intention-to Treat				
	Control n = 653	Treatment n = 659	Effect	Unadjusted	
				95% CI	p
Development of HAPI	0.023	0.007	0.33	[0.12, 0.90]	0.031
Turning Compliance	0.56	0.67	0.11	[0.08, 0.13]	< 0.001
	Per Protocol				
	Control n = 555	Treatment n = 671	Effect	Unadjusted	
				95% CI	p
Development of HAPI	0.027	0.007	0.27	[0.10, 0.75]	0.012
Turning Compliance	0.54	0.67	0.13	[0.11, 0.16]	< 0.001

Intention-to-Treat analysis performed based on group allocation. Per-Protocol analysis includes all patients who received treatment, intended or not. Unadjusted estimates are the difference in odds for developing Hospital Acquired Pressure Injury during Intensive Care Unit admission and the difference in turning compliant time reported as a percentage of monitoring time.

threshold used in this study already mimics current turning practices in the Intensive Care Units, and was therefore too conservative. Increasing the turn angle threshold to the recommended 30° (Barrois et al., 2008; Jiang et al., 2014) may have driven higher magnitude turns in the treatment group, thus increasing the likelihood of detecting measurable differences between groups.

Similarly, overall adequate tissue depressurization time was low. Only 39% of turns were sustained for at least 15 min. To minimize signal noise associated with frequent changes in patients' body position, a one-minute filter was applied to each body position change. Beyond the placement of a sensor, the intervention did not include positioning-aids to assist patients with maintaining a stable body position (i.e. foam wedges or fluid-positioning devices). Consequently, the intervention increased the frequency of turning for Intensive Care Unit patients, but once turned, patients in both groups performed similarly; up to 60% were unable to maintain their body position and meet target time for tissue depressurization. Future research assessing the dose and delivery of patient turning should include position-stabilizers to maintain the quality of patient turns.

In addition to the novelty of this study, the pragmatic nature has many advantages over prior studies. First, this study used a wearable patient sensor to capture detailed measurements of the frequency and for the first time, the dose of patient turning. No other study has been able to record dosing data, such as turning angle and tissue depressurization time in hospitalized patients. The finding that only 36% of patient turns reach a minimum turn angle threshold of 20° and only 39% of patients maintain their new position for at least 15 min of tissue depressurization, are the first quantitative data on turn dosing in Intensive Care Units. Second, randomization was completed at the point-of-care, providing for contemporaneous comparisons within the same patient population and care environment. Other studies, due to limitations, have to randomize at the unit level, due to the difficulty maintaining fidelity with individual patient treatment regimens (Goldhill et al., 2008; Krishnagopalan et al., 2002; Moore et al., 2011; Bergstrom et al., 2014). Third, as a pragmatic trial, very few patient exclusion criteria were applied, and standard clinical care practices and documentation were used. Unlike studies that introduce study-specific treatment protocols and documentation, the pragmatic trial maximizes the interpretability and applicability of study findings (Califf, 2016).

In considering the clinical implications of this system, we report the number needed-to-treat to prevent one Hospital Acquired Pressure Injury in this study to be sixty-two patients, though the valid clinical number is yet to be determined. As the first study to utilize a wearable patient sensor to assess care delivery in Intensive Care Units, we applied a sensor to *all* consecutive patients, regardless of their risk for pressure injury. Consequently, the risk of Hospital Acquired Pressure Injury within our cohort is highly variable, including up to 65% of patients being at low risk. In clinical practice this technology would be limited to patients at moderate or high risk for Hospital Acquired Pressure Injury, likely increasing the incidence density and subsequently reducing the number needed-to-treat. Dedicated studies are needed to further establish this clinical number.

The results of this study should be interpreted in relation to the following limitations. First, clinical data related to support surfaces was incomplete. There is a potential threat to internal validity due to confounding variables, however as a pragmatic study we did not alter or change the bed utilization protocol and therefore assume this to be random across groups. Second, due to differences between the study units, we randomized individual patients vs. performing unit cluster randomization. As such there are potential threats to external validity due to reactivity to the experimental situation and treatment diffusion. Third, as a pragmatic trial the organizations technical implementation plan required nurses to launch the monitoring application manually using a two-step login. Eliminating this step would have increased adherence to the study intervention, potentially increasing the difference in time with turning compliance between groups. Fourth, the study was

abandoned prior to enrollment reaching target based on clinical outcome data that were later identified to be incorrect. After receiving the corrected data, a final analysis was performed and there was evidence to suggest a significant treatment benefit. Assuming the null hypothesis is correct, the probability of obtaining these findings or findings more extreme is approximately 3%.

5. Conclusion

Among acutely ill adult patients requiring admission to an Intensive Care Unit, optimal turning was greater with a wearable patient sensor, increasing the total time with turning compliance and demonstrating a statistically significant protective effect against the development of Hospital Acquired Pressure Injuries. These are the first quantitative data on turn quality in the Intensive Care Unit and highlight the need to reinforce optimal turning practices. Additional clinical trials leveraging technologies like wearable sensors are needed to establish the appropriate frequency and dosing of individualized turning protocols to prevent pressure injuries in at-risk hospitalized patients.

Registration

[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02533726), NCT02533726, Registered August 17th, 2015.

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Competing interests

Mike Pihulic is employed by Leaf Healthcare, Inc.

Role of funder/sponsor

This study is an investigator initiated clinical trial. The funders had no role in the design of the study and provided limited technical support and hardware to conduct the study; including analyses of proprietary turning data derived from the monitoring system. To exclude potential for bias, the engineer (MP) was blinded to group allocation and clinical outcomes. The funder had no role in clinical data collection, management, analysis and interpretation of the data; manuscript preparation and the decision to submit for publication.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.ijnurstu.2017.12.012>.

References

- Anon., 1992–2013. G*Power [computer program]. Version 3.1.7: University of Dusseldorf.
- Anon., 2014. Preventing Pressure Ulcers in Hospitals. Agency for Healthcare Research and Quality, Rockville, MD.
- Anon., 2015. NPUAP Pressure Ulcer Stages. (Accessed 23 March 2015).
- Barrois, B., Labalette, C., Rousseau, P., et al., 2008. A national prevalence study of pressure ulcers in French hospital inpatients. *J. Wound Care* 17 (9), 373–379.

- Bauer, K., Rock, K., Nazzari, M., Jones, O., Qu, W., 2016. Pressure ulcers in the United States' inpatient population from 2008 to 2012: results of a retrospective nationwide study. *Ostomy Wound Manage.* 62 (11), 30–38.
- Bergstrom, N., Braden, B., Laguzza, A., Holman, V., 1987. The Braden scale for predicting pressure sore risk. *Nurs. Res.* 36 (4), 205–210.
- Bergstrom, N., Horn, S., Rapp, M., et al., 2014. Preventing pressure ulcers: a multisite randomized controlled trial in nursing homes. *Ontario Health Technol. Assess. Ser.* 14 (11), 1–32.
- Black, J., 2015. Pressure ulcer prevention and management: a dire need for good science. *Ann. Intern. Med.* 162 (5), 387–388.
- Califf, R., 2016. Pragmatic Clinical Trials: emerging challenges and new roles for statisticians. *Clin. Trials* 13 (5), 471–477.
- Chaboyer, W., Bucknall, T., Webster, J., et al., 2016. The effect of a patient centred care bundle intervention on pressure ulcer incidence (INTACT): a cluster randomised trial. *Int. J. Nurs. Stud.* 64, 63–71.
- Cox, J., 2011. Predictors of pressure ulcers in adult critical care patients. *Am. J. Crit. Care* 20 (5), 364–375.
- Gillespie, B., Chaboyer, W., McInnes, E., Kent, B., Whitty, J., Thalib, L., 2014. Repositioning to prevent pressure ulcers. *Cochrane Database of Systematic Reviews.*
- Goldhill, D., Badacsonyi, A., Goldhill, A., Waldmann, C., 2008. A prospective observational study of ICU patient position and frequency of turning. *Anaesthesia* 63 (5), 509–515.
- Harmonisation ICo, 1998. In: Administration USDoHaHSFaD (Ed.), *Guidance for Industry. E9 Statistical Principles for Clinical Trials.* Administration USDoHaHSFaD, Washington, D.C, pp. 28.
- Herrman, E.C., Knapp, C.F., Donofrio, J.C., Salcido, R., 1999. Skin perfusion responses to surface pressure-induced ischemia: implication for the developing pressure ulcer. *J. Rehabil. Res. Dev.* 26 (2), 109–120.
- Improvement ICS, 2012. *Pressure Ulcer Prevention and Treatment Protocol.* Health Care Protocol. Institute for Clinical Systems Improvement (ICSI), Bloomington.
- Jiang, Q., Li, X., Qu, X., et al., 2014. The incidence, risk factors and characteristics of pressure ulcers in hospitalized patients in China. *Int. J. Clin. Exp. Pathol.* 7 (5), 2587–2594.
- Krishnagopalan, S., Johnson, E.W., Low, L.L., Kaufman, L.J., 2002. Body positioning of intensive care patients: clinical practice versus standards. *Crit. Care Med.* 30 (11), 2588–2592.
- Lyder, C.H., Preston, J., Grady, J.N., et al., 2001. Quality of care for hospitalized medicare patients at risk for pressure ulcers. *Arch. Intern. Med.* 161 (12), 1549–1554.
- Mazano, F., Colmenero, M., Perez-Perez, A., et al., 2014. Comparison of two repositioning schedules for the prevention of pressure ulcers in patients on mechanical ventilation with alternating pressure air mattresses. *Intensive Care Med.* 40 (11), 1679–1687.
- McGuinness, J., Persaud-Roberts, S., Ramos, J., Toscano, D., Policastro, L., Epstien, N., 2012. How to reduce hospital-acquired pressure ulcers on a neuroscience unit with a skin and wound assessment item. *Surg. Neurol. Int.* 3 (138).
- Moore, Z., Cowman, S., Conroy, R., 2011. A randomised controlled clinical trial of repositioning, using the 30° tilt, for the prevention of pressure ulcers. *J. Clin. Nurs.* 20 (17–18), 2633–2644.
- National Pressure Ulcer Advisory Panel EPUAPaPPPIA, 2014. *Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline.* National Pressure Ulcer Advisory Panel EPUAPaPPPIA, Osborne Park, Western Australia.
- (NQF) NQF, 2011. *Serious reportable events in healthcare. Update: A Consensus Report.* NQF, Washington, D.C.
- Padula, W., Makic, M.B., Wald, H., et al., 2015. Hospital-acquired pressure ulcers at academic medical centers in the United States, 2008–2012: tracking changes since the CMS nonpayment policy. *The Joint Commission Journal on Quality and Patient Safety* 41 (6), 257–263.
- Padula, W., Gibbons, R., Valuck, R., et al., 2016. Are evidence-based practices associated with effective prevention of hospital-acquired pressure ulcers in US academic medical centers? *Med. Care* 54 (5), 512–518.
- Parker, C., O'Neill, M., Tam, N., 2015. *Strive Towards CALNOC Excellence: Adopting Innovation to Improve Bedside Nursing Care.* California Alliance for Nursing Outcomes (CALNOC), California.
- Pickham, D., Ballew, B., Ebong, K., Shinn, J., Lough, M., Mayer, B., 2016. Evaluating optimal patient-turning procedures for reducing hospital-acquired pressure ulcers (LS-HAPU): study protocol for a randomized controlled trial. *Trials* 17 (190).
- Prentice, J., Stacey, M., 2002. Evaluating Australian clinical practice guidelines for pressure ulcer prevention. *Eur. Wound Manage. Assoc. J.* 2 (2), 11–15.
- Prentice, J., 2007. *An Evaluation of Clinical Practice Guidelines for the Prediction and Prevention of Pressure Ulcers.* School of Surgery and Pathology, Faculty of Medicine, Dentistry and Health Science, The University of Western Australia, Perth.
- Rosenbaum, S., 2011. *The patient protection and affordable care act: implications for public health policy and practice.* Public Health Rep. 126 (1).
- Russo, C.A., Steiner, C., Spector, W., 2008. In: (HCUP) HCaUP (Ed.), *Hospitalizations Related to Pressure Ulcers Among Adults 18 Years and Older, 2006.* Agency for Healthcare Research and Quality (AHRQ).
- Schallom, L., Metheny, N.A., Stewart, J., et al., 2005. Effect of frequency of manual turning on pneumonia. *Am. J. Crit. Care* 14 (6), 476–478.
- Still, M., Cross, L., Dunlap, M., et al., 2013. The turn team: a novel strategy for reducing pressure ulcers in the surgical intensive care unit. *J. Am. College Surg.* 216, 373–379.
- Tarver, C., Schutt, S., Pezzani, M., 2014. We're sensing you! A multiphase clinical trial examining innovative technology to improve patient-turning compliance. In: ANCC National Magnet Conference. Dallas, Texas.
- Unit CAS, 2015. In: Center HSCI (Ed.), *NHS Safety Thermometer: Patient Harms and Harm Free Care.* National Health Service, United Kingdom, pp. 19.
- Walters, B., Jamison, K., Zafer, D., Sanders, T., 2016. *Transforming Pressure Ulcer Prevention in the ICU with Patient Wearable Technology and Nursing Leadership.* Texas Organization of Nurse Executives, Texas.