A Feasibility Study of Intermittent Electrical Stimulation to Prevent Deep Tissue Injury in the Intensive Care Unit

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Objective: The primary goal of this study was to investigate the feasibility of utilizing intermittent electrical stimulation (IES) in an intensive care environment as a potential method for preventing pressure ulcers. Furthermore, we wished to evaluate the practicality of the innovation and end-user acceptability.
Approach: Twenty immobile subjects, age ranging from 19 to 86 years old with a Braden Scale score ranging from 9 to 16 (very high to moderate risk of developing pressure ulcers), were enrolled. Intermittent 35 Hz electrical stimulation was administered through surface electrodes to the gluteal muscles causing them to contract for 10 s every 10 min. Subjects utilized IES on a program that increased from 4 to 24 h per day over 8 days and lasted up to a maximum of 4 weeks.
Results: Bedside nurses reported that IES was simple to use, took an average of 6 min to apply, and 2 min to remove. Furthermore, IES could be easily incorporated into routine patient care. No pressure ulcers occurred in any subject during the study. No untoward reactions or adverse events had occurred directly as a result of IES.
Innovation: IES represents a potential method of preventing bedsores. This study represents a necessary pilot study, investigating safety and feasibility before proceeding with a larger randomized controlled trial to determine efficacy.
Conclusion: Our results suggest that IES is both safe and feasible to implement in intensive care units.

Keywords: pressure ulcer, pressure sore, prevention, intermittent electrical stimulation, intensive care unit

INTRODUCTION

Pressure ulcers are defined as a "localized injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in combination with shear."[1] They commonly lead to infection and in the United States are responsible for ~60,000 deaths annually.[2] Pressure ulcers often affect people with reduced mobility and impaired sensation throughout the continuum of healthcare. An estimated 7.4 million people worldwide have a pressure ulcer at any given time.[3] Given the morbidity, mortality, and economic impact of pressure ulcers, the question arises—can we prevent them?

One form of pressure ulcer termed deep tissue injury (DTI), which originates over the bone, often goes undetected until it breaches the surface. Therefore, prevention is of paramount

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importance. The potential mechanisms for pressure ulcer formation have recently become better understood. External loading, from lying in one position, mechanically deforms the underlying soft tissue and reduces blood flow.[4] Mechanical deformation of soft tissue, particularly muscle, is the first pathway to tissue breakdown.[5,6] Reductions in blood flow and tissue oxygenation further extenuate the resulting tissue necrosis and lead to larger and faster-forming pressure ulcers.[6,7] Tissue breakdown due to mechanical deformation can start within 10 min of loading,[5] and the breakdown often originates in the deep tissue around bone–muscle interfaces. Because these DTIs cannot be detected by routine skin inspections, the injuries progress outward unknown to the affected individual or the caregiver.

While maintaining skin integrity is one of the fundamental goals of the care of hospitalized patients, the prevalence of pressure ulcers would indicate that there are still opportunities to enhance prevention. Traditional approaches to prevent pressure ulcers involve offloading the pressure by turning the patient often, every 2 h. While this interval is longer than the safe margin for the formation of DTIs, there is controversy around the timing of turning, and there are variations in practice around the world. More recent approaches use specialized pressure redistributing mattresses and wheelchair cushions. Despite these commonly applied preventative approaches, the incidence and economic costs associated with pressure ulcers remain substantial.

Economic costs are mainly associated with the treatment of pressure ulcers. These costs are staggering—the United Kingdom spends up to £2.1 billion annually on hospital-acquired pressure ulcers.[8] The United States spends from $9.1 to $11.6 billion annually.[9] Treatment strategies may include dressings,[10–13] debridement,[10] biological therapies,[10,14,15] electric[16,17] and negative pressure wound therapies[3,11,18] to increase wound closure rates, medications to treat infection, skin grafts, and myocutaneous flap surgeries[19] to close the wound. All told, a single pressure ulcer can require years to treat. A stage IV pressure ulcer has been defined as "full-thickness tissue loss with exposed bone, tendon, or muscle."[20] The average hospital treatment cost associated with stage IV pressure ulcers and related complications was $129,248 for hospital-acquired ulcers during one admission and $124,327 for community-acquired ulcers over an average of four hospital admissions.[21] Pressure ulcers are an example where effective prevention strategies may not only decrease morbidity and mortality but also costs to the healthcare system.

Some of the highest reported rates of hospital-acquired pressure ulcers come from intensive care units (ICUs) and range from 14% to 42%.[22] Patients in the ICU have a variety of diagnoses that can be associated with pressure ulcer formation such as traumatic brain injury, spinal cord injury, stroke, sepsis, and other acute injuries. These conditions often result in altered levels of mobility and consciousness, which in turn can lead to tissue breakdown due to the increased durations of unrelieved loading around bony prominences.[22,23] Moreover, ICU patients may experience weight loss from poor nutrition or weight gain from edema. This can result in higher pressures over localized areas and eventual tissue breakdown.[22,23] Collectively, these factors make the ICU a prime target for testing pressure ulcer prevention strategies.

CLINICAL PROBLEM ADDRESSED

To address limitations in current treatment strategies, our group has developed a novel method called intermittent electrical stimulation (IES) for the prevention of pressure ulcers.[24,25] Using this technique, low levels of electrical current are applied to the gluteal muscles. These muscles are loaded during sitting or lying down, subjecting them to damaging levels of compressive, shear, and tensile stresses and strains. The stimulation causes the muscles to contract for 10 s every 10 min. These contractions mimic the subconscious postural adjustments performed by able-bodied individuals every 6–9 min in response to discomfort while sitting or lying down. The periodical contractions redistribute pressure around bony prominences such as the sacrum and ischial tuberosities, reduce the mechanical deformation, and increase muscle tissue oxygenation.[6,26–29]

In the present study, we investigated the feasibility of IES in the ICU. The present study was conducted as one part of preparation for a potential future randomized controlled trial to examine the efficacy of IES. We chose to test the device in the ICU for a number of reasons. First, reports from a number of sources[23,30,31] have indicated a high incidence of pressure ulcers in the ICU. Second, the ICU is a fast-paced clinical and highly technical environment in which a host of invasive and noninvasive monitoring and lifesaving interventions are used routinely. We wished to study the practicality of using IES among these other interventions. Third, we were interested in end-user acceptability by healthcare personnel, patients, and families. Finally, most ICU nursing staff are highly skilled technically. For all of these reasons,

the ICU was felt to be a reasonable starting point for using a novel technology into clinical practice. We hypothesized that the use of IES in the ICU environment would be both safe and feasible.

MATERIALS AND METHODS

Study design

A prospective cohort study design was used to investigate the feasibility of applying IES in the ICU. Potential subjects were initially identified by their assigned bedside nurse. The study nurse then met with the potential subject and/or family members to obtain written consent. This study was approved by the Conjoint Health and Research Ethics Board at the University of Calgary.

We sought to include participants with a wide range of diagnoses in the study who were immobile (*i.e.*, bedbound), between the ages of 18 and 90 years old, with no current pressure ulcer and a predicted minimum length of ICU stay of 4 days. We excluded patients with a body mass index >30 given concerns about an inability of the electrical stimulator used in this study to elicit a sufficient gluteal contraction due to adiposity in the region. Furthermore, we excluded patients on neuromuscular blocking drugs and myasthenia gravis as these conditions would theoretically prevent the electrical current from causing an appropriate muscular contraction. Patients with burns or open wounds to the buttocks and/or rhabdomyolysis were excluded because of a potential theoretical risk of exacerbating further tissue breakdown. Finally, patients with unstable spine/pelvic/hip fractures were excluded to avoid the potential of causing displacement of the fracture through contraction of the gluteal musculature.

Clinical assessment

We recruited a convenience sample of 20 study participants. All 20 were evaluated on the Braden Scale[32,33] to assess their risks of developing a pressure ulcer by examining six criteria as follows: sensory perception, moisture, activity, mobility, nutrition, and friction and shear. The Braden Scale has previously been shown to be reliable[34–36] and is widely used in other pressure ulcer studies. The bedside nurse administered the Braden Scale.

Intermittent electrical stimulation

The IES system used in the present study consisted of a two-channel electrical stimulator, Impulse EMS D7 (BioMedical Life Systems, Inc., Vista, CA), connected to hypoallergenic electrodes (7.5×10 cm; Axelgaard Manufacturing Co., Ltd., Fallbrook, CA) applied directly to the skin over the buttocks (Fig. 1). The stimulator sent a 35 Hz electrical pulse for 10 s every 10 min to cause a contraction of the gluteal muscles.

Before electrode application, the patient's skin was cleansed and dried. Patients were positioned on their sides by the nurses with knees and hips positioned at 90 degree angles to help identify the ischial tuberosities. For each buttock, the cathode (stimulating) electrode was placed widthwise 2.5 cm above the ischial tuberosity and the anode (return) electrode was placed widthwise 2.5 cm below the posterior superior iliac crest. Electrodes were connected to the stimulator, and the stimulation intensity was adjusted to achieve a visible, fused muscle contraction of the gluteus maximus at the minimal stimulation setting possible.

Given that we were exploring the feasibility of this device in a new and potentially challenging clinical setting, we implemented a protocol in which the duration a study participant would wear the device increased over several days. On the first day of the study, our protocol dictated that participants should wear the device for 4 h with the skin assessed at the 2-h point to ensure no ill effects had occurred from the stimulation on the first day. The study protocol was conducted in addition to the hospital's ICU nursing standard clinical practice to prevent pressure ulcers. This included turning patients or repositioning them every 2 h and completion of skin assessments at these intervals. These skin assessments served to monitor for the development of any tissue damage. At these 2-h checks, nurses also checked to ensure that device connections were intact and electrodes in place. Day 2 of the protocol involved increasing stimulation to 8 h. If no untoward reactions were observed, days 3–5 consisted of 12 h of stimulation. On day 6,

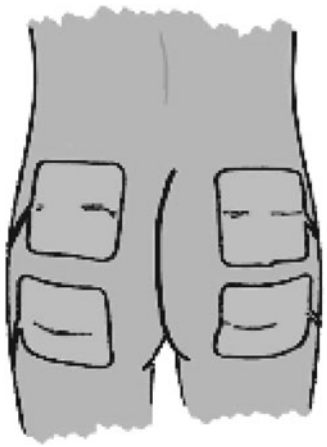

Figure 1. Electrode placement on buttocks.

stimulation was increased to 16 h and again increased to 20 h on day 7. Finally, stimulation was increased to 24 h on day 8 and left on continuously until the subject was discharged, the subject became mobile, had completed 4 weeks of being on the system, or had deceased. Unfortunately, despite the best attempts of the research team to enforce the ramping protocol, on a number of occasions, the research nurse would arrive on the unit to discover that the bedside nurse had unilaterally decided to increase the duration of stimulation much longer than the protocol prescribed, in one case proceeding directly to 24-h stimulation. In cases of breaks from the ramping protocol, we continued the participant progressing along the ramp from the number of hours the participant was receiving when the protocol deviation was discovered by the research nurse. Electrodes were changed only if soiled, partially peeled, or at shift change every 12–24 h.

Clinical staff training

To facilitate the implementation of this research study, many staff who were involved in the day-to-day care of ICU patients were trained to use the device. In collaboration with the charge nurses and nurse educators, the research study nurse provided multiple inservices focusing on the prevention of pressure ulcers and incorporating the IES device into their daily bedside routines when caring for their patients. A total of 71 registered nurses, 6 unit clerks, 4 occupational therapists, 5 physiotherapists, and 4 nursing students were trained over 4 months. Training consisted mainly of brief one-on-one sessions or small group sessions scheduled at convenient times throughout the clinical staff's shift, including evenings and weekends to accommodate all staff who would be involved with participants enrolled in the study. A hands-on approach of positioning the patient, providing instruction on electrode placement, and initiation of a muscle contraction was the most effective training method for the variety of different staff types in the ICU. Supplemental pictorial index cards documenting the steps required to don, doff, and use the system were available at the bedside for a quick overview for staff. In addition, study documentation and video clips were available on the ICU's internal website. A continuing education certificate was given to all nurses participating in the study.

Data collection methods

Custom-designed data collection sheets were utilized to collect information pertinent to a number of parameters.

The bedside nurses were responsible for monitoring skin condition as they applied and removed the electrodes. Skin condition was rated using a slightly modified version of the National Pressure Ulcer Advisory Panel scale.[20] This scale has been shown to be reliable.[37] We modified the scale to add in a level (level 1) that was equivalent to no evidence of any skin issue. We then asked the nurses to rate skin condition on a scale from 1 (no redness) to 5 (stage IV pressure ulcer). Furthermore, the nurse was asked to rate the contraction strength on a 4-point scale as follows: 1 (can't see it or feel it), 2 (can't see it, can feel it), 3 (can see weak contraction/feel flicker), or 4 (can see strong contraction). The bedside nurses recorded the time of day IES was used and the duration required for donning and doffing. Furthermore, they recorded when other assistance was needed (*e.g.*, reconnecting leads, changing electrodes secondary to an incontinent episode) and the time required to complete these activities. Nurses were asked to rate the ease of positioning the patients to apply the device among 1 (very easy: participant independently achieves desired position), 2 (easy: desired position achieved by caregiver(s) with minimal effort), 3 (moderate: desired position achieved by caregiver(s) with moderate assistance (due to extremely heavy weight, tone in legs, pain), 4 (difficult: desired position achieved by caregiver with significant effort (due to extreme contractures, poor range of motion, pain), and 5 (very difficult: unable to achieve desired position). Furthermore, the nurses were asked to provide the ease of finding an adequate muscle contraction among 1 (very easy: adequate muscle contraction on first attempt), 2 (easy: adequate muscle contraction with minor adjustments needed to electrodes), 3 (moderate: adequate muscle contraction after several electrode adjustments, 4 (difficult: only able to achieve inadequate muscle contraction), and 5 (very difficult: no visible or palpable muscle contraction found despite numerous adjustments to electrodes). These scales have been previously used in another study of IES for pressure ulcer prevention.[24]

Participants, if capable, were asked daily if the stimulation was distracting, irritating, or uncomfortable. They were also asked about their ability to fall asleep with the system on. Furthermore, they were asked to rate whether IES would be an acceptable part of their daily routine. When participants were incapable of providing this information, feedback from their family members or loved ones was sought regarding whether they believed the stimulation was irritating, whether their loved one was able to fall asleep while the stimulation was on, and whether stimulation was acceptable as part of

the daily routine. This qualitative feedback was sought from family members as they were often making care decisions for their loved ones.

Data analysis and statistics

Data were collated for each study participant for every day they used the IES system. Quantitative data on time and responses to the scales utilized are described below using descriptive statistics, including mean and standard error. When making comparisons of responses before and after stimulation, a Wilcoxon-signed rank test was used. Qualitative data provided in the responses are summarized in the results below.

RESULTS

Participant demographics

The primary focus of this study was to evaluate the safety and feasibility of using the IES intervention in the ICU setting. Over a period of 7 months, 20 patients with a variety of diagnoses (Table 1), who met the study inclusion/exclusion criteria, were enrolled in the study. Participants' age ranged from 19 to 86 years (median 52 years); 65% were males and 35% were females. The Braden Scale score for all participants ranged from 9 to 16, placing them in the moderate- to very high-risk category for developing pressure ulcers. The duration that participants used the system ranged from 4 to 25 days (median 4 days).

Participation in the study was concluded for a number of reasons (Table 1). Nine participants were transferred to other clinical units within the hospital or to another center. Eight participants passed away as a result of their admitting diagnosis. One participant withdrew from the study after requesting the clinical team to provide comfort measures only going forward. In another participant, a cardiac pacemaker was implanted due to rhythm irregularities, and the use of IES was discontinued given the theoretical risk of disrupting a demand pacemaker. Another participant had significant weight gain over the course of the study. His participation was discontinued after 8 days of IES use, as he no longer met our inclusion criteria.

The safety of the system was evaluated by documenting any incident of skin breakdown, loss of muscle contractions during periods of use, and system failure during use. The mean duration of IES use per day per participant varied from 7 to 24 h (Fig. 2). Given the ramping protocol for the duration of IES use deployed in this study, only 5 of the 20 participants reached 24 h per day of IES use.

Skin inspections were performed every 12 h when electrodes were replaced or when there was an incontinent episode (typically one additional time per day). We observed no untoward reactions or adverse events occurring as a result of IES during the study. No signs of skin breakdown were encountered in any of the study participants throughout their enrollment in the study. Bedside nurses reported three incidents of blanchable erythema where the electrodes had been applied, which resolved rapidly within 3–5 min in all cases.

Table 1. *Subject data*

#	Age	Gender	Primary Diagnosis	Admission Date	Consent Date	Time from Admission to Consent # of Days	Braden Scale	Days on System	Mean Hours on Stim	Disposition/Outcome
1	68	M	CABG	30-Jun-13	05-Jul-13	5	14	8	13.6	Transferred
2	46	F	Decomp Cirrhosis	27-Jul-13	01-Aug-13	5	12	3	8	Deceased
3	21	F	Neuromyelitis Optica	18-Jul-13	01-Aug-13	13	9	25	21.1	Transferred
4	83	M	Altered LOC	15-Aug-13	21-Aug-13	6	14	4	19	Device D/C–pacemaker
5	36	M	Metastatic Sarcoma	10-Aug-13	21-Aug-13	11	14	5	9.6	Deceased
6	18	M	Pulmonary Vasculitis	20-Aug-13	25-Aug-13	5	14	4	10	Transferred
7	78	M	Hypoxic Resp Failure	25-Aug-13	31-Aug-13	5	12	4	8	Transferred
8	74	M	Stroke	08-Sep-13	12-Sep-13	4	16	4	10	Deceased
9	34	M	Polytrauma	03-Sep-13	13-Sep-13	10	16	4	9	Transferred
10	73	M	Brain Tumor	03-Sep-13	13-Sep-13	10	15	4	9	Transferred
11	51	M	Perforated Viscous	20-Oct-13	30-Oct-13	10	10	5	24	Deceased
12	60	M	C4 Fracture	04-Oct-13	10-Oct-13	6	16	8	17	Deceased
13	38	F	Subarachnoid Hemorrhage	19-Oct-13	31-Oct-13	12	10	4	10	Comfort measures
14	19	M	Brain Tumor	05-Nov-13	07-Nov-13	2	10	4	11	Transferred
15	22	M	Gun Shot Wound	15-Nov-13	03-Dec-13	18	11	8	20.5	Device D/C–BMI increased
16	64	F	Empyema	01-Jan-13	08-Jan-14	7	14	8	17	Transferred
17	53	F	DVT Pneumonia	28-Dec-13	08-Jan-14	11	10	5	19	Deceased
18	53	F	Polytrauma—	10-Jan-14	19-Jan-14	9	9	4	9	Deceased
19	86	F	Cardiogenic Shock	14-Jan-14	21-Jan-14	7	12	4	9	Deceased
20	61	M	Pneumonia	20-Jan-14	30-Jan-14	10	14	6	14.7	Transferred

BMI, body mass index; CABG, coronary artery bypass graft; D/C, discontinued; DVT, deep vein thrombosis; LOC, level of consciousness.

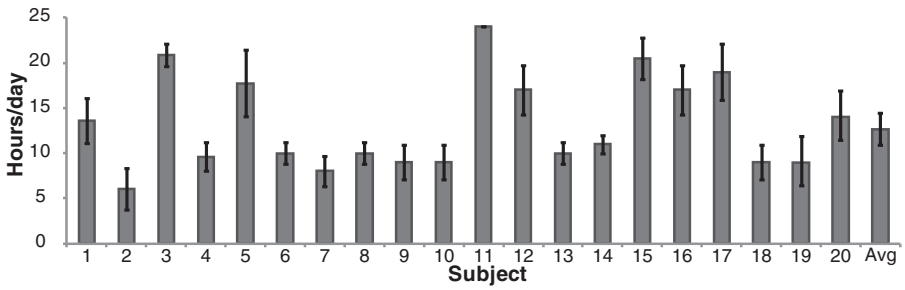

Figure 2. Mean time per day per participant that the IES was used. Error bars are SEM. IES, intermittent electrical stimulation; SEM, standard error of the mean.

Gluteal muscle contractions were visualized and scored on a scale of 1–4 to estimate contraction intensity upon donning and doffing of the device. Contractions were typically rated in the range of 3–4 (Fig. 3). Across all subjects, there was no significant difference in visible contraction strength between the beginning and end of stimulation over the course of each day (Wilcoxon-signed rank test $p > 0.05$).

The feasibility of deploying the new IES system to prevent pressure ulcer formation in the ICU was evaluated by determining the ease of its application and acceptability of its use by the caregiver. Total caregiver time required for application of the system ranged between 4 and 10 min with the average being 5.9 min (±0.3 standard error of the mean [SEM]), which also included continence care (Fig. 4). Time to remove the system ranged between 1 and 5 min with the average being 2 min (±0.1 SEM) (Fig. 4). Qualitative reports from the bedside nurses indicated that the device was simple to use, took minimal time to apply and remove, and could be easily incorporated into their routine patient care.

We were able to obtain participant or surrogate feedback on the device from 15 of 20 participants. All responded positively when asked if they could sleep with the system, as all participants did sleep with the system on. All subjects responded positively when they were asked if receiving IES would be an acceptable part of their daily routine. Two respondents stated that the stimulation was "very little" distracting, while all others felt it was "not at all" distracting. One respondent felt the stimulation was "very little" bothersome, while all others felt it was "not at all" bothersome. No respondent reported the stimulation was either painful or cumbersome.

DISCUSSION

Hospital-acquired pressure ulcers have been identified as a significant problem in many health systems. Despite years of traditional nursing intervention such as turning patients and more recent interventions such as advanced mattress surfaces and nutritional supplementation, the prevalence rates of pressure ulcers remain high.[22,30,38,39] We would suggest that many of these pressure ulcers are preventable, but some may be inevitable. In the United States, some healthcare organizations have taken a more polarized view. Hospital-acquired pressure ulcers have been deemed a medical error because of their preventable nature and the U.S.

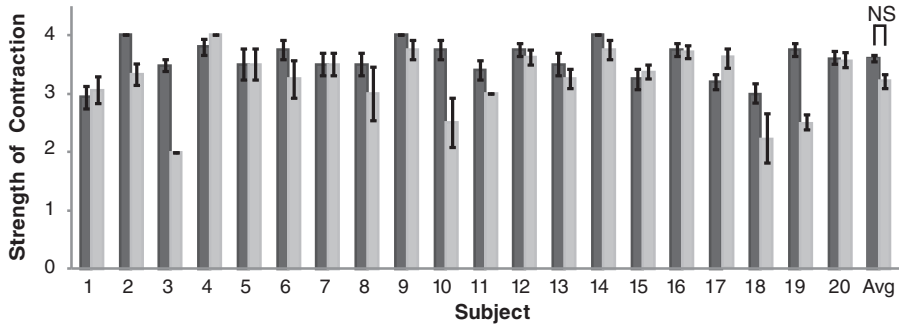

Figure 3. Mean contraction strength per participant. *Dark gray bars* represent contraction strength at the time of electrode application, *light gray bars* represent contraction strength at the time of removal. Error bars are SEM. NS represents a nonsignificant difference.

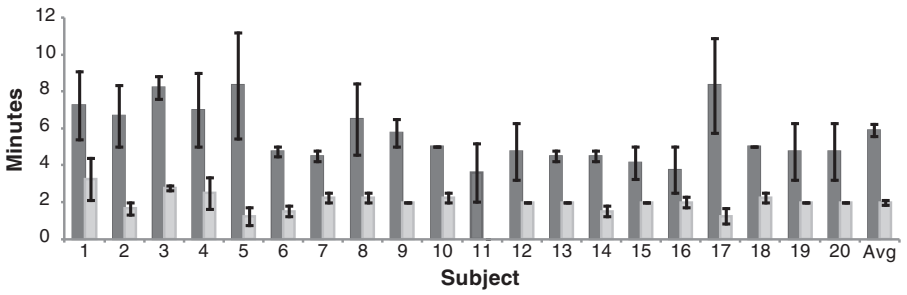

Figure 4. Mean time to apply (*dark gray bars*) and remove (*light gray bars*) the IES system. Error bars are SEM.

Centers for Medicare and Medicaid Services have developed nonpayment policies as a result.[40,41] Ultimately, new and innovative interventions need to be sought to prevent pressure ulcers. The goal of this project was to test the feasibility of one such technology in the ICU in a wide range of subjects. This project serves as a necessary stepping-stone before consideration of future clinical trials that could evaluate efficacy.

The ICU is a complex and fast-paced environment where much emphasis is placed on the management of acute life-threatening situations. Despite high nursing staff levels, data from a number of studies report extremely high prevalence rates of pressure ulcers (range 14–42%).[22] Unfortunately, individuals who develop pressure ulcers in the ICU often continue to suffer from them as they are moved onto acute-care wards, rehabilitation wards, and into the community. We believe that preventing pressure ulcers early on during a patient's illness experience, during high-risk periods, will help curtail downstream morbidity and costs related to prolonged hospitalizations and community-related care.

Within the ICU, nurses, occupational therapists, and physiotherapists accepted the IES system and saw the value in utilizing it potentially to prevent pressure ulcers in the early stages of immobility. After a brief demonstration of the device by the research nurse, most clinical staff required minimal-to-no assistance from research staff with device application and removal. The time taken to apply the device averaged 6 min, with only 2 min required for removal. Our findings speak of the acceptability and the relative ease of training and deployment for the IES device in complex clinical environments.

In addition to studying clinical staff's acceptance and the feasibility of incorporating device usage into the daily routine, we wanted to ensure that there were no incompatibilities with other procedures or medical devices in the ICU environment. We had previously tested another version of the device that uses an underwear-based system, long in rehabilitation, long-term care, and community settings.[24] Continence regimens in the ICU included the routine use of urinary catheters, rectal tubes, and abstinence from the use of garment incontinence products, and so, we modified the system to apply electrodes directly to the skin on all study participants. Despite this, no issues with skin breakdown were observed. Moreover, no issues related to interference to or from other medical devices were encountered. It is important to note, however, that at the outset of the study, we chose to exclude subjects with cardiac demand pacemakers, as a small electrical pulse such as the one produced by the IES device could theoretically interfere with this type of pacemaker. Demand pacemakers monitor the heart's natural electrical activity and discharge only when the heart's own rate is too slow or the heart misses a beat. While this may indicate one potential limitation of the device, it warrants further exploration in a carefully controlled environment to determine if the theoretical risk is real.

The use of IES in the ICU setting was safe. We observed no adverse medical event resulting from the use of the system, and it was well tolerated by all study participants. Nonetheless, 9 of the 20 subjects in the study eventually succumbed to their original illness or complications thereof. High mortality is an unfortunate consequence of the serious illnesses that require ICU stays. Published ICU mortality rates from a recent study from our center taking all admissions ranged between 17 and 18%,[42] while an older study at our center had indicated an in-hospital ICU mortality rate of 32%.[43] As a feasibility study, part of our mandate was to evaluate patients from a heterogeneous group to help determine which types of patients might or might not be appropriate for a future, larger efficacy study. We suspect the mortality rate of our sample was higher partly because of the fact

that we intentionally recruited individuals who were quite ill and immobile secondary to their illness. The ICU clinicians we partnered with had suggested that based on their experience, these patients were more likely to develop pressure ulcers if they survived their acute illness.

Importantly, none of the study participants developed a pressure ulcer during the study period. One might argue that we should have continued to follow subjects as they left the ICU to various hospital wards and then into the community to determine whether they developed a pressure ulcer after discharge from the ICU. Nonetheless, this was beyond the scope of the present study, which focused on the safety and feasibility of the device within the ICU. Eventually, larger studies using control groups will need to be conducted to examine the efficacy of IES in the ICU, and these will also need to include further safety outcomes.

Conducting this study in the ICU presented some unique opportunities and challenges. In the ICU, nurse/patient ratios were 1:1 unlike many other areas of the hospital. This allowed constant and direct nursing supervision of all study participants. Nursing technical skill levels in the ICU tended to be quite high, which was advantageous when training them on using the new technology. Furthermore, the ICU nursing staff tended to include many recent graduates who readily embraced novel methods of care, which may have helped with acceptability. Nonetheless, the bedside nursing staff also required close vigilance from the study nurse to ensure that the ramping protocol was followed and data collection sheets were completed. On the few occasions when the bedside nurses unilaterally elected to accelerate the ramping protocol (*e.g.*, subject #11 who was immediately started on 24 h of stimulation), the research staff inquired as to the reason. Almost uniformly, the bedside nurses felt their patients required 24 h protection against pressure ulcers.

One of the challenges in the current study was obtaining informed consent in a timely manner. Given that many individuals are admitted to the ICU in an unconscious state, we frequently relied on surrogate consent. Because voluntary participation in a research study was often seen as unrelated to the patient's primary concern, it typically took 3–4 days after admission before consent was obtained for any study participant. When considering that a preventative measure for pressure ulcers would ideally be administered as soon as possible postadmission, future testing of efficacy of the device needs to consider a deferred consent process to ensure better generalization to what would likely be considered optimal timing for clinical implementation of preventative measures. Deferred consent involves waiting until the participant can make a decision about his/her participation in a study and is often used in emergency or ICU studies. After discussion with our own ethics board, they have permitted us to use deferred consent going forward in a future study on pressure ulcers in the ICU.

In the present study, we also chose to use a protocol that gradually increased the amount of stimulation provided over a number of days. This was done simply to maximize safety in a new clinical environment. Because many study participants only spent a few days on the device, a number of them were unable to use the device continuously for 24 h. Given our experience in the current study, future studies should consider applying IES for 24 h from the onset, with regular skin checks every 4–8 h.

INNOVATION

The IES system presents a novel method for potentially preventing pressure ulcers. Our results suggest that IES is both safe and feasible to implement in the ICU clinical setting. IES was also acceptable to clinical staff as well as the patients and their families. To determine whether IES is truly efficacious at preventing pressure ulcers, future studies should focus on the efficacy of the intervention in similar clinical populations and consider its cost–effectiveness compared to existing standard of care.

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AUTHOR DISCLOSURE AND GHOSTWRITING

Authors A.K., R.W., M.C., and S.P.D. have no conflict of interest to declare. Author V.K.M. is the inventor of the IES system and oversaw the foundational investigations of the concept in animal models and human volunteers leading up to this study. Recently, she cofounded Prev Biotech, Inc. with author R.S. as a start-up company for commercializing the invention. V.K.M. and R.S. were not involved in the collection or analysis of the data, but did contribute to study design and were involved with preparation of the article. No competing financial interests exist for C.H.

ABOUT THE AUTHORS

Angela Kane, RN, is the nurse research assistant, who was responsible for recruiting patients, training healthcare providers in the use of the IES system, and drafting the manuscript. **Robyn Warwaruk-Rogers, BN,** is the nurse research assistant, who was responsible for assisting with study design and data analysis. **Chester Ho, MD, Ming Chan, MD, PhD,** and **Richard Stein, PhD,** all have academic appointments at the University of Calgary or University of Alberta and are part of an interdisciplinary team called Project SMART that provided support for the present study. **Vivian K. Mushahwar, PhD,** is the inventor of Smart-e-Pants—the device used in the present study. **Sean P. Dukelow, MD, PhD,** is an Associate Professor in the Division of Physical Medicine and Rehabilitation at the University of Calgary and was responsible for the overall conduct of the study from inception to completion.

KEY FINDINGS

- No patient developed a pressure ulcer during testing
- IES was found to be easy to use and incorporate into work in the ICU
- IES was found to be safe for use with patients in the ICU

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Abbreviations and Acronyms

BMI = body mass index
CABG = coronary artery bypass graft
D/C = discontinued
DTI = deep tissue injury
DVT = deep vein thrombosis
ICU = intensive care unit
IES = intermittent electrical stimulation
LOC = level of consciousness
SEM = standard error of the mean