A Historical Control Study of a Novel, Non-invasive Perfusion Enhancement System for the Treatment of Stage 2 Sacral and Ischial Pressure Injuries

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Abstract

Purpose

The purpose of this study was to compare the time it took to fully heal long term care patients with existing stage 2 sacral and ischial pressure injuries (PIs) managed with standard of care on a novel, non-invasive perfusion enhancement system with the time it took to heal a retrospective, size-matched cohort data group of patients also with stage 2 sacral and ischial PIs who were managed with standard of care and conventional alternating pressure mattresses.

Design

A historical control non-blinded study of patients with stage 2 sacral and/or ischial pressure injuries was conducted.

Subjects and Setting

The sample comprised 31 consecutively enrolled patients in four community-based, long-term care facilities.

Methods

Subjects were consecutively enrolled to the experimental group. Subjects in the control group received a low-air-loss mattress with alternating pressure, rented per facility protocol for stage 2 PI treatment. Patients in the experimental group received the novel, noninvasive perfusion enhancement (NIPE) system instead of a low-air-loss, alternating pressure surface. The NIPE system was utilized on top of the standard issue static foam mattress and on recovery chairs. Both

groups received an identical standard of care. The primary outcome measure was time to complete healing (in days) of the stage 2 pressure injuries comparing the experimental group to a retrospective, size-matched cohort of stage 2 PI patients who received the same standard of care from the same centers over the previous 12-month period. Kaplan-Meir and log-rank tests were calculated to analyze the time to heal data and generate the comparison results. Patient characteristics were compared using standard t-tests for data sets and Chi-squared tests for proportions to ensure that the differences in average values and ratios between control and experimental groups were not statistically significant.

Results

Nine (9) experimental group patients with fourteen (14) stage 2 pressure injuries completed the trial. Twenty-two (22) historical control group patients with twenty-eight (28) stage 2 pressure injures were identified for comparison purposes. The mean time to fully heal PIs for the historical control group was 26.25 days with a standard deviation of 2.42 days and upper and lower 95% confidence boundaries of 21.51 and 30.99 days respectively. The mean time to fully heal PIs for the experimental group was 10.5 days with a standard deviation of 1.016 days and upper and lower 95% confidence boundaries of 8.51 and 12.49 days respectively. The mean time to fully heal stage 2 pressure injuries in the experimental group was 40% of the mean time to fully heal stage 2 pressure injuries in the control group (p-value<0.0001, Kaplan Meier Log-Rank Analysis). This result was statistically highly significant. The time to fully heal stage 2 pressure injuries was 60% faster in the experimental group than in the control group. Patients in the historical control group took 1.5 times (150%) longer to fully heal their stage 2 pressure injuries than those who were treated with the novel non-invasive perfusion enhancement system.

Conclusion

Patients treated with the novel, non-invasive perfusion enhancement (NIPE) system experienced complete healing of their pressure injuries significantly faster than those treated with low-air-loss, alternating pressure mattresses. These findings suggest that a non-invasive perfusion enhancement (NIPE) system can accelerate the time to complete healing of patients with existing stage 2 pressure injuries when used in place of conventional low-air-loss, alternating pressure surfaces. Further study is warranted.

Introduction

Pressure injuries (PIs) are a common and costly complication impacting patients.[1] A PI is defined as localized damage to the skin and/or underlying tissue, typically over a bony prominence.[2] Pressure injuries range in severity from intact skin to full-thickness skin loss.[3] These wounds occur as a result of pressure that is sustained for a critical duration of time.[3] Pressure injuries result in decreased quality of life, increased mortality, and increased healthcare costs.

Patients in acute care and long-term care settings are likely to have multiple risk factors for developing PIs, including impaired mobility, protein-calorie malnutrition, and chronic health conditions.[4] Furthermore, patients are often of advanced age, putting them at even greater risk of developing PIs.[5] Age-related skin changes include subcutaneous fat loss, decreased collagen and elastic fibers, diminished vascularity, and vessel wall thinning.[5] As a result, oxygen-nutrient delivery and waste removal decreases while skin becomes thinner and less elastic, leading to increased risk of PI formation and delayed healing when PIs occur. [5]

Pressure injuries develop due to the sustained or repeat external application of pressure leading to vascular compression which results in tissue ischemia.[6,7] Ischemic tissues deteriorate from impaired blood flow and subsequent depletion of oxygen and nutrients with an accumulation of toxic metabolites.[7,8,9] Tissue reperfusion is a natural response to ischemia wherein the body supplies an excess amount of blood to the depleted tissues when vascular compression is relieved in order to re-establish oxygen and nutrient delivery.[10-14] Reperfusion has been observed to promote the progression of tissue damage in other organ systems following periods of ischemia, such as following ischemic stroke and myocardial infarction.[15,16] Current research supports that a similar pathogenic process of ischemia and reperfusion injury occurs in the skin.[11,12,17,18]

Wound healing is a complex, multicellular process requiring adequate tissue perfusion and involving a sequential, overlapping process of inflammation, proliferation, and remodeling phases.[19,20] The initial inflammatory phase serves as a protective tissue response involving a delicate balance of pro-inflammatory mediators, which promote necessary tissue-healing mechanisms, such as stimulating inflammation, increasing macrophage produced growth factors, and attracting neutrophils.[21] If the presence of pro-inflammatory mediators reach an unfavorable balance however, the effects can be detrimental to the wound healing process.[21] Research has shown that elevated and/or prolonged levels of pro-inflammatory mediators, such as TNF-α, IL-1β, and IL-8, can lead to delayed wound healing.[21] Furthermore, pro-inflammatory mediators have been identified in high levels in chronic, nonhealing wounds.[21] Reperfusion injury involves the generation of reactive oxygen species, calcium overload, and a complex inflammatory-mediated response which interrupts the homeostasis necessary for optimal tissue healing.[10,15,21,22] Thus, an intervention focused on minimizing vascular compression to enhance tissue perfusion and prevent ischemia and reperfusion injury would be beneficial for PI treatment.[17]

Maintaining adequate tissue perfusion to prevent ischemia and subsequent reperfusion injury in sacral and ischial PI healing is a challenge due to the high-pressure locations of the wounds over bony prominences. Current standard of care protocols focus on pressure-relieving strategies, such as manual repositioning schedules and alternating pressure surfaces, mitigation of contributing factors, such as shear, friction, and microclimate, and the use of

specialized dressings.[1,3] Prior to this study, there had been no report of a technology designed to target underlying ischemia and reperfusion injury and to promote tissue perfusion for the treatment of pressure injuries.

This article presents the findings from a historical control study investigating the effectiveness of a novel, non-invasive perfusion enhancement system for the treatment of stage 2 sacral and ischial pressure injuries in the long-term care setting.

Study Design

This study is a non-blinded, clinical trial using historical data as the control. The research design and informed consent were approved by the Institutional Review Board (IRB) and facility administration. Consecutive adult patients with stage 2 sacral and/or ischial pressure injuries who met inclusion criteria were consented and enrolled into the experimental group.

Inclusion criteria were:

1. Newly diagnosed sacral and/or ischial stage 2 facility-acquired pressure injury (FAPI)
2. Unhealed sacral and/or ischial stage 2 community-acquired pressure injury (CAPI)

Exclusion criteria were:

1. FAPI or CAPI in locations other than sacrum or ischium
2. Stage 1, 3, 4, and Unstageable pressure injuries, and/or Deep Tissue Injuries (DTI)
3. Infected pressure injuries
4. Unstable orthopedic fractures
5. Active psychiatric illnesses

Study Device

The novel, non-invasive perfusion enhancement (NIPE) system (The TurnCare Guardian® System, TurnCare, Palo Alto, CA) consists of two main parts: a computer-controlled pressure sensor and dynamic air pump (the "Controller") and a multi-channel inflatable perfusion enhancing support surface (the "Enhancer"). The Enhancer is placed directly on the support surface beneath all bed linens and absorbent pads. The enhancer spans the patient from the lower back to the mid-thigh region. The enhancer's design is unique in that it has a 3-dimensional shape that both envelops and conforms to the sacral-region anatomy. The enhancer is bordered on both sides by inflatable side supports that center the patient over the pattern of air cells built around a central "epicenter."

The epicenter is aligned with the patient by the large side supports of the enhancer such that the epicenter is directly beneath the sacrum providing anatomically correct orientation that maximizes system effectiveness. The enhancer's air channels have a unique shape to enable the delivery of pressure gradient therapy in an anatomically specific and precise fashion.

To start therapy, the patient weight and position (chair or bed) are entered into the controller via a touch screen. The pressure within the air cells of the enhancer is tightly regulated and adjusts automatically every few seconds to within 3mmHg as specified by the therapy algorithm programmed into the controller. The enhancer gently lifts the patient up from the underlying support surface, be it a bed, recovery chair, or wheelchair. Once lifted, a continually changing combination of adjacent pressure spaces and pressure points ("pressure gradients") are created beneath the patient by the sequential inflation and deflation of the enhancer's air cells. The adaptive pressure capabilities continually monitor chamber pressures and adjust the application of pressure to create and rotate a varying series of pressure points and adjacent pressure voids beneath the sacral region. In the mobility impaired patient, these moving pressure gradients mimic the continually-shifting pressure patterns of healthy body movement which prevent sustained vascular compression and therefore enhance perfusion throughout the sacral region. The non-invasive perfusion enhancement system recreates patterns of pressure gradient movement seen in healthy subjects who naturally reposition themselves to avoid pain from prolonged vascular and soft tissue compression.

Research Settings and Standards of Care

The study was conducted in four affiliated long-term care facilities owned and managed by one team and one company (Ryder's Health Management, Stratford, Connecticut). All wound care training, treatment guidelines, and patient care standards were consistent among these facilities. The Standard of Care protocol for stage 2 PI treatment was consistent and maintained at each facility. Standard of care included the use of ointments and dressings managed by the wound care team, as well as intermittent manual repositioning schedules. Standard of care also included the use of rented low-air-loss, alternating pressure mattresses (SpanAmerica PressureGuard® Easy Air™, SpanAmerica, Greenville, SC or similar), ordered at the time of diagnosis of a stage 2 sacral or ischial pressure injury for control group patients. Experimental group patients utilized the NIPE system on top of the standard issue static foam mattresses and chairs. All other standard of care provided to experimental group patients was identical to the standard of care provided to the historical control group from the 12 months prior.

Upon diagnosis of a stage 2 sacral or ischial pressure injury (CAPI or FAPI) patients were assessed for inclusion and exclusion criteria. Eligible patients were consented, enrolled, and provided with the NIPE system by

members of the research team within 24 hours of diagnosis. The research team members were employed by the manufacturer of the NIPE system (Turncare, Inc, Palo Alto, CA).

After enrollment, patients in the experimental group had the NIPE system placed on their beds and chairs by members of the research time and by facility staff. The Enhancer was placed directly on the chair with a sheet placed over it. The Enhancer was placed directly on top of the foam mattress and secured to the bed frame with disposable Velcro straps. The fitted sheet was placed over the enhancer. Patient skin did not come in direct contact with any part of the perfusion enhancement system at any time. The enhancer was cleaned along with the bed surface and recovery chair according to standard hospital practices. The NIPE system was utilized continuously throughout the trial period. No additional support surfaces or alternating pressure mattresses were utilized by experimental patients.

Data Source and Collection

Medical record reviews were conducted for historical control patients with sacral and/or ischial stage 2 pressure injuries within 12 months prior to the initiation of the study. Pressure injury location, size, and healing times were recorded. Patient demographics, including Braden Scales and incontinence status at the time of pressure injury diagnosis were also recorded. (Table 2) Data points were collected on experimental patients twice per week throughout the trial period.

Data Analysis

Kaplan-Meier curves of the time to fully heal the treated stage 2 sacral/ischial PI patients and historical control patients were constructed and analyzed. The log-rank test was used to calculate the p-value.

Results

Thirty (30) patients with a total of forty (40) stage 2 sacral and ischial PIs were enrolled in the historical control group. Twenty-two (22) patients from the historical control group, with a total of twenty-eight (28) stage 2 sacral and ischial PIs, were selected to match the average PI sizes of the experimental group. Ten (10) patients were enrolled in the experimental group. Two (2) patients expired prior to complete healing. Both expired patients suffered from significant co-morbidities (coronary artery and valvular diseases, stroke, renal failure). One (1) patient voluntarily withdrew from the clinical trial for reasons not stated. Thus, nine (9) patients with fourteen (14) sacral and ischial PIs were treated with the NIPE system and completed the trial. The mean healing time in the historical control group was 26.25 days (standard deviation 2.42, 95% lower bound 21.50, 95% upper bound 30.99). The mean healing time in the experimental group was

10.5 days (standard deviation 1.016, 95% lower bound 8.508, 95% upper bound 12.492). This meant that patients on the NIPE system completely healed their stage 2 pressure injuries an average of 15.75 days (60%) faster than those on low-air-loss, alternating pressure beds. Patients in the historical control group took 1.5 times (150%) longer to fully heal their stage 2 pressure injuries than those who were treated with the novel non-invasive perfusion enhancement system

Kaplan-Meier curves of time to fully heal stage 2 sacral and ischial PIs in the experimental and historical control groups were constructed and analyzed. The log-rank test led to a p-value less than 0.0001 which is considered highly statistically significant. (Fig. 1)

The NIPE system received positive feedback from test subjects as well as the clinical care team. Patients reported increased comfort with use of the NIPE system. The nursing staff reported that the NIPE system was easy to set up and operate and did not interfere in any way with the delivery of care to the patients or create additional work for the staff. There were no safety events or concerns reported during this clinical trial.

Discussion

The purpose of this study was to determine the effectiveness of a novel, non-invasive perfusion enhancement system in helping to accelerate the time to complete healing of stage 2 sacral and ischial pressure injuries (PIs) as compared to results of a retrospective, size-matched cohort data group, managed with standard of care and low-air-loss, alternating pressure mattresses. The 60% reduction in time to total healing ($p<0.0001$) of stage 2 sacral and ischial pressure injuries in the experimental group suggests that a non-invasive perfusion enhancement system may be a more effective treatment for stage 2 pressure injuries than low-air-loss, alternating pressure mattresses.

In 2018, Bergstrom and colleagues studied the healing times of stage 2 pressure injuries specifically.[23] Of the 1,241 stage 2 pressure injuries studied, 762 (61%) pressure injuries were in the truncal or non-extremity sites.[23] Using the Kaplan-Meier survival analysis, the researchers determined that median days to heal the small ($<1\ CM^2$) stage 2 pressure injuries was 33 days.[23] In 2015, Palese and colleagues studied 270 stage 2 pressure injuries, of which 174 (64%) were sacral, 41 (15%) were trochanteric, and 16 (6%) were ischial, totaling 131 (86%) of the pressure injuries.[24] The average healing time of stage 2 pressure injuries in this study was 23 days.[24] The authors also concluded that smaller pressure injury sizes were associated with faster healing times.[24] These results demonstrate that the average healing time of 26 days for stage 2 sacral and ischial pressure injuries in the historical control group is consistent with previously published healing times and is therefore likely indicative of typical healing times.

Current standard-of-care protocols focus on pressure-relieving strategies, such as manual repositioning schedules and alternating pressure surfaces, mitigation of contributing factors, such as shear, friction, and microclimate, and the use of specialized dressings.[16,17] Prior to this article, there has been no study of a NIPE system for PI treatment. The statistically significant decrease in the healing times for stage 2 sacral and ischial pressure injuries may be due to the prevention of ischemia and subsequent reperfusion injury experienced when patients are repositioned. It is believed that by preventing underlying ischemia and subsequent reperfusion injury, excess pro-inflammatory mediators are avoided, allowing an optimal wound healing environment. Based on these findings, a NIPE system should be considered for the treatment of pressure injuries in addition to current standard measures.

Limitations

The sample size in this historical control study was relatively small (N=31). It would be beneficial to perform a larger study using a randomized, control group and include a more evenly distributed patient population between control and experimental groups.

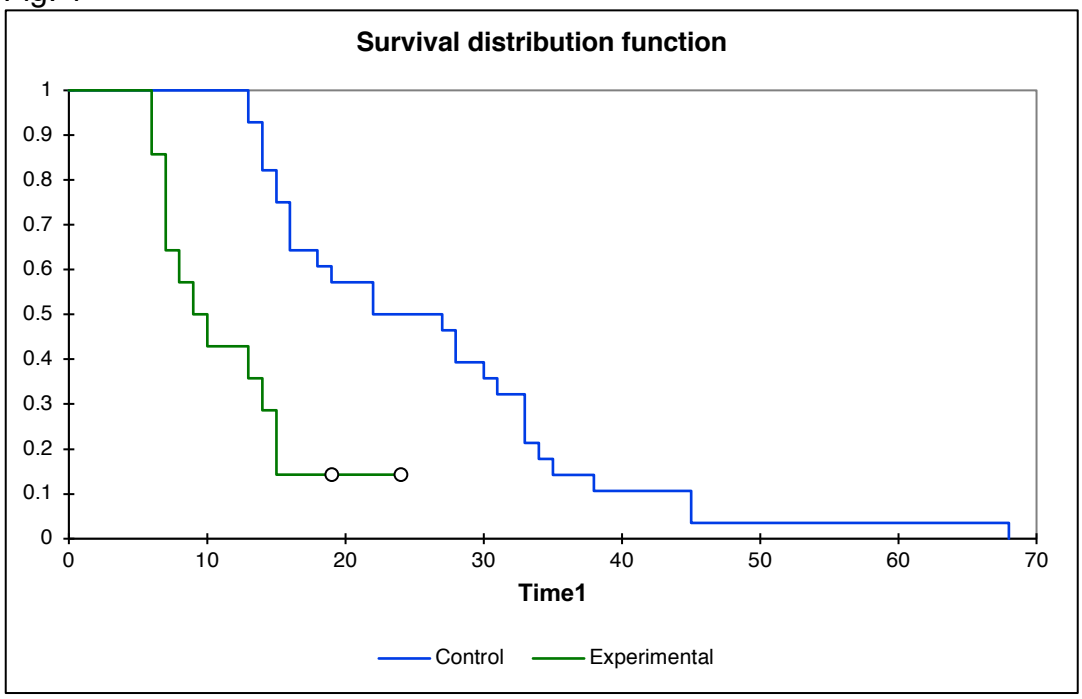
Conclusion

We found that a non-invasive perfusion enhancement system used in supplement to foam mattresses and current standard of care treatment measures in the long-term care setting reduced the time to completely heal stage 2 sacral and ischial pressure injuries by 60% ($p<0.0001$) when compared to conventional low-air-loss, alternating pressure mattresses. Patients who used the NIPE system experienced complete healing of their PIs in an average of 10.5 days compared to 26.25 days in the control group. Patients on the NIPE system fully healed their stage 2 pressure injuries 60% faster than those on low-air-loss, alternating pressure beds. Patients in the control group took 150% longer to fully heal their stage 2 pressure injuries. The findings from this study not only support the use of a non-invasive perfusion enhancement system for treating PIs, but also suggest that ischemia and reperfusion injury may have a negative impact on the healing trajectory of sacral and ischial PIs. Further research is need

Table 1: Trial Participants			
	Control Group	**Experimental Group**	**Total**
Patients Enrolled	22	10	32
Patients Withdrawn	0	1	1
Patients Completing Trial	22	9	31
Number of Stage 2 PIs	28	14	42

Table 2: Patient Characteristics				
	Control Group	**Experimental Group**	**P-Value**	**Difference between groups statistically significant?**
Mean Age (Years)	82	84.86	P=0.46	No
Mean PI Size (CM^2)	1.8	1.5	P=0.64	No
Mean Braden Scale	16.04	15.50	P=0.61	No
Male Patients %	45.5%	11.11%	P=0.07	No
Wheel Chair Use %	86.36%	100%	P=0.25	No
Incontinent %	77.27%	66.67%	P=0.55	No

Fig. 1



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