Original investigation

A quality improvement project comparing two treatments for deep-tissue pressure injuries to feet and lower legs of long-term care residents

ABSTRACT

Objective To retrospectively examine clinical outcomes from a feasibility study that compared two treatment options for deep-tissue pressure injuries (DTPIs), including the clinical indicators increasing the risk of deteriorating DTPIs among long-term care residents.

Methods A retrospective chart audit of 40 DTPIs from 33 long-term care residents in two long-term care facilities were conducted to compare 1: polymeric membrane dressings (PMDs) with offloading; and 2: a skin barrier film with offloading.

Results Of the 13 DTPIs treated with PMDs, only 23% deteriorated to a stage 3 or 4 pressure injury (PI), whereas of the 27 DTPIs treated with skin barrier film, 41% deteriorated to a stage 3 or 4 PI. The clinical factors found to increase the risk of developing and deteriorating DTPIs included weight loss, hypoalbuminemia, debility, dementia, coronary artery disease, and cerebrovascular disease.

Conclusions The PMD group's DTPIs evolved into fewer open PIs despite having higher percentages of clinical indicators for DTPIs. The project findings support the use of PMD dressings for DTPIs; however, more robust research is warranted.

Keywords deep-tissue pressure injury, lower-extremity injury, long-term care, offloading, polymeric membrane dressings, pressure injury, skin barrier film

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INTRODUCTION

A pressure injury (PI) is pressure-related damage to a local area of skin and the underlying tissue, generally over a bony prominence.[1] These injuries present a significant challenge for the staff of long-term care facilities (LTCFs) and affect their residents' quality of life, escalating healthcare costs, readmissions, risk of infection, pain, depression, and death.[2,3] Deep-tissue pressure injuries (DTPIs) are PIs that occur under intact skin, which are thought to first develop in the deep tissues of the body and then appear on the skin surface[4] as nonblanchable red, purple, or maroon discoloration or a blood-filled blister.[1]

Despite current treatment, these injuries often rapidly become open wounds.[4] Typically, DTPI treatment aims to prevent further damage and avoid devolution to stage 3 or 4 PI.[4] However, there is limited research on DTPI treatment, so this quality improvement project was implemented to retrospectively analyse the findings of a feasibility study that compared a drug-free polymeric membrane dressing (PMD) with the use of a skin barrier film among residents in two LTCFs with DTPIs on their feet and lower legs. The PMD is a foam dressing designed to reduce inflammatory factors and edema related to skin damage while requiring infrequent dressing changes.[5] The PMD was chosen because of its easy accessibility and supply in the study LTCFs. Skin barrier films come in multiple forms and comprise a transparent coating to protect skin from trauma and moisture.[6] The previous DTPI treatments used in the two facilities were a skin barrier film and

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offloading; despite using the skin barrier film twice a day, the facilities continued to see deteriorating DTPIs, prompting the feasibility study.

Along with the current treatment concerns regarding DTPIs, research is ongoing to ascertain whether there are clinical indicators that influence the evolution of DTPIs into open wounds. In LTCFs, most residents have multiple comorbidities that influence PI risk, including DTPIs.[7] Further studies are needed to conclusively establish the clinical indicators that potentially contribute to DTPIs so they can be mitigated.

Background and Clinical Problem

The prevalence of DTPIs has increased threefold since 2006, presumably because of the classification of DTPIs, which were defined in 2007. This increased the awareness of DTPIs.[4] Changes in regulations and improvements in prevention and treatment have not reduced their incidence, and the number and cost of all PIs continue to increase.[8] In addition to causing pain and suffering for LTCF residents, DTPIs cost LTCFs as much as $3.3 billion annually.[9]

The most common location for a DTPI is on the heel. Heels are mostly bony prominences covered by a thin layer of skin with little padding or protection from pressure.[10,11] Further, other medical conditions, such as respiratory and/or cardiovascular issues, increase the time residents spend supine, and they often require the head of the bed to be elevated, which places additional pressure on the feet and legs.[10-13] The same pressure mechanisms damage the soft tissues of the lateral areas of the foot and toes; because of chronic lateral positioning, these areas often experience sustained, unrelieved pressure.[11]

Shearing is a common risk factor to consider in the evolution of DTPIs.[13,14] The layers of skin stretched against a surface with friction and pressure result in damage on the surface and deeper internal tissues.[14] Shearing risk includes passive repositioning of residents, elevating the head of the bed, and involuntary active movements involving spasms or tremors from medical conditions, which increase the constant positioning/pressure of the feet against the mattress.[14] The risk of pressure and shearing consequently increases the risk of deterioration of DTPIs of the feet and lower legs.[4,14,15]

In addition to the lack of standard treatment for DTPIs, there is concern about whether DTPI deterioration could be affected by certain clinical indicators. In many LTCFs, a large percentage of residents with limited mobility and debility have a higher risk of developing a PI. As residents age, the number of medical conditions they encounter increases.[7] Published studies show that medical conditions such as anemia, diabetes mellitus, fecal or urinary incontinence, vascular disease, or malnutrition increase the risk of developing PIs and (more recently) DTPIs.[3,4,7,16] Of these risk factors, anemia has been most commonly associated with an increased risk of DTPIs.[3,4] A review by Gefen et al[13] notes that variables such as fever, uncontrolled cardiovascular disease, or respiratory acidosis could also increase the risk of DTPIs. Accordingly, this project not only compared two different treatment options for DTPIs, but also considered the resident's clinical indicators and their potential influence on DTPI deterioration.

The treatment of DTPIs generally falls into one of two categories: offloading and application. In a Cochrane systematic review, McGinnis and Stubbs[17] studied heel pressure-reducing devices for offloading in the treatment of heel ulcers. According to their results, there is no single device available that meets all of the criteria for comfort in the prevention and treatment of heel ulcers by removing pressure with offloading. There also is a need for further research into relieving heel pressure and treating PIs with offloading.[17] Van Leen et al[18] reviewed pressure-reducing techniques for PI treatment in a longitudinal study in a Dutch LTCF. Offloading the feet and lower legs led to a statistically significant decrease in PIs from 16.6% to 5.5%, with the most benefit for patients with medium to high risk of PIs. Over the years of the study, 57.8% of the patients at medium to high risk of PI with documented offloading of feet and legs (as well as educational intervention) were less likely to develop a PI.[18]

The other category of treatment is the application of dressings. A randomised controlled study by Sullivan[19] evaluated the treatment of DTPIs with dressings and demonstrated that 74% of DTPIs decreased in size or resolved with the use of a self-adherent, multilayered, silicone-based border foam dressing. Of the 128 DTPIs in this study, only one opened to deeper tissue, and the other injuries either did not open or opened to the dermis with a mean healing time of 17.8 days. Essentially, the multilayered foam dressings decreased deterioration and improved resolution time.[19]

Campbell et al[16] evaluated the use of padded-heel dressings to treat heel wounds. The treatment group showed 100% improvement among the 20 participants, whereas only 13 of 20 wounds in the control group closed. The study also demonstrated that the treatment group required less time and financial expense to heal.[16]

The National Pressure Injury Advisory Panel recommends the use of offloading and preventive dressings on residents who are at high risk of developing heel ulcers.[20] Levy et al[15] observed that prophylactic dressings applied to the heels decreased the risk of DTPIs by reducing stress and shear. Ultimately, the use of dressings to protect skin and offload pressure and shearing is widely recommended, although comparison studies are limited and warranted.

METHODS

The purpose of this project was to retrospectively compare, analyse, and evaluate the documented deterioration of DTPIs to open PI among residents using two different treatments. The secondary purpose was to determine the prevalence of clinical indicators known to contribute to the development of DTPIs in the PMD group versus the skin barrier film group.

This project sought to answer the following research questions:

(1) Do PMDs and foot offloading reduce deterioration of DTPIs for residents 55 years or older better than skin barrier film with offloading?

(2) What was the prevalence of various clinical indicators among residents who developed a DTPI on their foot and/or lower extremity, and would a change in treatment have an impact on the evolution of the DTPI?

Study Initiation and Ethics

An analysis of administrative data collected by the quality assurance and performance improvement team from two LTCFs during 2014 and 2015 showed that 36% of DTPIs evolved into open stage 3 or 4 PIs when treated with offloading and the twice-daily application of a skin barrier film. This finding was the catalyst to perform a feasibility study comparing the skin barrier film with PMDs for DTPIs that developed between October 2015 and May 2017 in the two facilities. The PMD was chosen because it was new to the facilities' formulary lists, was easily accessible, and had evidence of benefit for other types of wounds.

This retrospective comparative analysis project conducted in fall 2017 examined the outcomes for the 33 residents with a total of 40 DTPIs included in the feasibility study. Researchers conducted a systematic chart audit comparing the treatments of PMD or skin barrier film for the sample of residents with DTPIs and based on the type of treatment used from October 2015 to May 2017. Charts were included in the project if the resident had a DTPI to the feet and lower legs, were at least 55 years old, and were treated with either PMDs or skin barrier film with offloading.

During the feasibility study, each resident in each group had an ongoing order for offloading to the DTPI. The residents chosen for the PMD group either provided consent for the new treatment or permission was granted by the resident's responsible party. Treatment with PMD included cutting the PMD to a size slightly larger than the DTPI as well as the application of a transparent medical dressing to cover the PMD once applied. The dressing was changed twice a week. The skin barrier film wipes were applied twice daily, and skin was allowed to dry following the application. The university's institutional review board deemed the current project exempt. The LTCFs' corporate holding company, administrative leadership teams, and medical providers' board members approved the project.

Setting and Participants

The two participating LTCFs are Medicare and Medicaid approved, with private pay residents and a bed capacity of approximately 90 and 110 residents, respectively. They are in the southeastern US. These facilities provide short- and long-term care services that include rehabilitation and complex medical care for residents with reduced physical and mental functioning and multiple comorbidities such as PIs and DTPIs.

Data were extracted, deidentified, audited for the inclusion criteria, and given to the principal investigator by chart auditors. The sample was developed based on resident treatment, with the skin barrier group comprising 23 residents with 27 DTPIs, and the PMD group, 10 residents with 13 DTPIs.

Data Collection and Outcome Measures

Trained medical records experts from each facility extracted previously recorded data from the electronic medical record program called the Electronic Charting System. The data collectors were trained by the principal investigator as to what specific data to extrapolate and code for data entry. The data collectors received standardised training from the investigator to ensure the accuracy of the data collection and the systematic retrieval of the information. Data were retrieved from the electronic medical record on each resident for every DTPI documented. The generated data reports were deidentified and transferred into a private, secure PDF file by the data collectors. The PDF file was then coded and converted into a Microsoft Excel form and organised into a secure database and stored in a password-protected file for retrieval by the principal investigator for analysis.

Data extracted from the medical charts consisted of both demographics and clinical indicators. Demographics included resident age, sex, and ethnicity. The clinical indicators included laboratory test results (anemia and hypoalbuminemia screening), chronic diseases/comorbidities, health history, functional status, and Braden Scale scores.

The Braden Scale is an assessment tool used to determine the risk of developing a PI. The Braden Scale scoring ranges from less than 9 to 32. The lower the Braden Scale score, the higher the risk of developing a PI.[21] Residents with albumin levels less than 3.2 g/dL (reference range, 3.5-5.2 g/dL) demonstrated hypoalbuminemia, which may reflect a decrease in nutrition status in certain patient populations.[7] Anemia was identified as a hemoglobin level below the reference range of 12 to 15 g/dL. Chronic diseases and comorbidities were identified with a diagnosis or *International Classification of Diseases, 10th Revision* code and included peripheral vascular disease, dementia, coronary artery disease, and/or cerebrovascular disease.

Further data included history of previous PI and recent orthopedic history such as any fracture or surgery to the lower half of the body. In addition, information on the resident's level of activities of daily living support and any history of chronic involuntary movements was retrieved. Weight changes were also noted, that is, whether each resident had weight gain or weight loss prior to the identification of the DTPI(s).

Any diagnosis of peripheral vascular disease noted in the residents' chart was captured in the data collection. Because no residents had a documented ankle-brachial pressure index to confirm diagnosis, residents with peripheral artery disease were excluded. In addition, residents with previously diagnosed diabetic or arterial ulcers were excluded.

The outcome variables included DTPI deterioration and PI stage at the time of opening, if applicable.

Statistical Analysis

The Microsoft Excel Descriptive Statistics Tool (Redmond, Washington) was used to analyse the data from the two groups. Descriptive statistics were used to describe the sample. Independent χ^2 tests were used to compare each group with the clinical outcomes of opening or not opening. $P < .05$ was considered statistically significant.

RESULTS

The majority of participants were White women with a mean age of 84 years. The PMD group was slightly older than the skin barrier film group (Table 1).

A simple statistical analysis compared the primary outcome measure between groups; according to the independent χ^2 test, the difference was not statistically significant ($P = .3160$). In the PMD group, 23% of the DTPIs deteriorated to an open PI, whereas 41% of the DTPIs in skin barrier film group opened to a stage 3 or 4 PI. Of the DTPIs that opened, only two of the PMD group wounds opened to a stage 3 PI, and only one opened to a stage 4 PI. Of the DTPIs in the skin barrier film group, seven DTPIs opened to a stage 3 PI, and four opened to a stage 4 PI (Table 2).

Descriptive data were generated for the clinical indicators that increased the risk of developing a DTPI (Table 3). The PMD group had more residents with known clinical indicators for DTPIs. The number of residents needing two people to

Table 1. Demographics of Residents with deep-tissue pressure injury by treatment group

Variable (n = 33)	Dressing Group (n = 10)	Skin Barrier Group (n = 23)
Age, mean, y	85	83
Female, n (%)	8 (80)	13 (57)
Ethnicity, n (%)		
African American	4 (40)	9 (39)
White	6 (60)	14 (61)

Table 2. Wound outcomes

Outcomes (n = 40)	Dressing Group (n = 13)	Skin Barrier Group (n = 27)
Opened, n (%)	3 (23)	11 (41)
Stages when opened, n (%)		
Stage 2	0	0
Stage 3	2 (15)	7 (26)
Stage 4	1 (8)	4 (15)

Independent $\chi^2 = 0.3160$, $P > .005$.

Table 3. Clinical Indicators of Residents with deep-tissue pressure injury by treatment group

Variables (n = 33)[a]	Dressing Group (n = 10)	Skin Barrier Group (n = 23)
Weight loss	9 (90)	10 (43)
Hypoalbuminemia (<3.5 g/dL)	6 (60)	5 (21)
Anemia (<12 g/dL)	4 (40)	9 (39)
Peripheral vascular disease	6 (60)	7 (30)
Severe dementia	6 (60)	7 (30)
Coronary artery/cardiovascular disease	9 (90)	18 (78)
Previous pressure injury	5 (50)	9 (39)
Orthopedic history (lower extremities)	3 (30)	12 (52)
Activity of daily living support	8 (80)	14 (61)
History of abnormal movements (spasms or tremors)	7 (70)	2 (9)
Braden Scale score, mean	15	15

[a]n (%), unless otherwise noted.

assist in their activities of daily living was a significant factor, representing 80% of the PMD group and 61% of the skin barrier film group. Residents in both groups had an average Braden Scale score of 15, indicating at least a moderate risk of developing a DTPI. Weight loss and lower albumin scores were implicated, especially for the PMD group, with 90% seeing weight loss and 60% hypoalbuminemia. The residents with severe dementia (PMD, 60%; skin barrier film, 30%) also demonstrated a higher risk of DTPI, as well as residents with a diagnosis of coronary artery disease or cerebrovascular disease (PMD, 90%; skin barrier film, 78%). To investigate shearing, data were collected on residents who had abnormal lower extremity movement such as tremors or spasms. In the PMD group, this clinical indicator may have contributed to the development of DTPIs in 70% of the residents. Interestingly, anemia was an indicator for DTPIs (PMD, 40%; skin barrier film, 39%), although not to the significance level noted in other studies.

DISCUSSION

This retrospective project concluded that skin barrier film and offloading did not prevent the deterioration of DTPIs. Only three DTPIs evolved into an open wound in the PMD group, compared with 11 of the DTPIs in the skin barrier film group. Although this project did not have the statistical power to demonstrate significance, results indicate a possible benefit to changing the current treatment from the skin barrier film with offloading to PMDs with offloading.

This project found a higher risk of deteriorating DTPIs in the residents with more clinical indicators, in accordance with previous studies.[7,16] Many of the LTCF residents' medical conditions continue to be significant indicators, including weight loss, lower albumin levels, abnormal movements such as spasms or tremors, coronary artery disease, and cerebrovascular disease.[4,16] Indicators such as anemia, previous orthopedic surgeries or fractures, peripheral vascular disease, and severe dementia were associated with a moderate risk of deteriorating DTPIs; previous studies found these were high-risk indicators.[4,7,16] Interestingly, the PMD group had more clinical indicators for DTPI deterioration on average and yet had better outcomes. This demonstrates that treatment and management can outweigh the effects of clinical indicators for DPTI progression.

Limitations

The convenience sample size was small because of the total number of residents with diagnosed DTPI during the feasibility study period. Although all of the data collectors were trained by one person at the same time, there was no interrater reliability testing. Further, the diagnosis of DTPI was extracted by the data collectors based on provider diagnosis, because an *International Classification of Diseases, 10th Revision* code for DTPI was not established until 2019. Finally, it is important to note that PMDs may not be available in all healthcare settings, limiting the generalisability of the findings.

Implications for Clinical Practice

Offloading and repositioning of LTCF residents continue to be the recommended treatment for DTPIs. However, complications related to deteriorating DTPIs affect LTCF residents and strain the healthcare system. This project compares two different treatments for DTPIs, while considering the clinical indicators that may increase the risk of DTPI deterioration. Although further evidence is needed to address the cost-effectiveness of these treatments, PMD likely reduced the deterioration of DTPIs. Therefore, PMDs may be attractive to facilities striving to deliver efficient healthcare for their residents, especially those with high-risk residents.

CONCLUSIONS

Although prevention is crucial, once a DTPI has developed, having a fast and reliable treatment option to prevent further deterioration is of the utmost importance. By addressing DTPIs with offloading and screening for clinical indicators of deterioration, along with a preventive treatment such as PMD, the trajectory for these injuries could be vastly improved.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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