RESEARCH PAPER

The Use of a No-sting Barrier Film Treatment Protocol Compared to Routine Clinical Care for the Treatment of Stage 1 and 2 Pressure Injuries in Long-term Care

Adrian Chan, BHSc (Hons)^a, Henry Yu-Hin Siu, MD, MSc CCFP (COE), IIWCC^{b,*}

^aToronto General Research Institute, Toronto, ON, Canada; and

^bDepartment of Family Medicine, McMaster University, Hamilton, ON, Canada

KEYWORDS:

Pressure injury;
No-sting barrier film;
Long-term care;
Nursing

Abstract Pressure injuries increase morbidity and mortality in geriatric patients by 400%. Residents in long-term care (LTC) are at high risk of developing pressure injuries because of limited mobility, poor nutritional status, impaired cognition, and incontinence. This study aims to determine whether a no-sting barrier film (NSBF) treatment protocol is more effective than current physician practices for treating stage 1 and 2 pressure injuries in LTC. A retrospective cohort study of 129 residents from one LTC facility was performed after a six-month implementation trial of a NSBF treatment protocol. The six-month incidence rate of stage 1 and 2 pressure injuries was 9% and 38% respectively. There was a statistically significant reduction in healing time in those treated with the NSBF protocol. In summary, the NSBF protocol reduces healing time of stage 1 and 2 pressure injuries; this protocol could be easily incorporated into existing pressure injury treatment strategies in LTC.

© 2016 Elsevier Inc. All rights reserved.

Introduction

The prevalence of pressure injuries in Ontario ranges from 22.1% in community based settings to 29.9% in non-acute care settings¹; pressure injuries also increase the risk of

mortality among geriatric patients by as much as 400%.¹ Residents in long-term care (LTC) facilities are at a higher risk of developing pressure injuries because of factors that may include limited mobility, poor nutritional status, impaired mental functioning, and incontinence. These factors increase the chance of skin breakdown and complicate treatment.^{2–4} Furthermore, because LTC residents have multiple chronic diseases and may have increased medication burden,^{5,6} wounds that may be healable in younger populations are deemed as maintenance or unhealable wounds.⁷

Vital to supporting wound healing, current best practice guidelines for treating pressure injuries recommend off-loading pressure, reducing friction and shear forces, appropriate debridement, proper nutrition, infection

Funding Source: This study was not funded by any research grants or funding agencies.

Conflict of Interest Statement: This manuscript is an original submission and work of the publishing authors. The following authors: Mr. Adrian Chan and Dr. Henry Siu do not perceive any conflict of interests and have none to declare for this study.

* Corresponding author. 1475 Upper Ottawa Street Hamilton ON L8W 3J6, Canada. Fax: +1 905 575 1539.

E-mail address: siuh3@mcmaster.ca

control, and maintaining proper moisture balance.^{1,8} Chronic wound exudates and moisture from fecal or urinary incontinence can damage healthy tissue around the wound leading to peri-wound maceration and infection^{8,9}; this delays pressure injury healing and leads to poor quality of life, longer treatment times, and increased healthcare costs. A 2012 UK study showed the significant economic cost of pressure injuries on the health care system. The study reported the cost of treating a single episode of stage 1 and 4 pressure injuries to be £1214 and £14,108 respectively.¹⁰

One method of maintaining proper moisture balance is the use of barrier products such as no-sting barrier creams and sprays; these have been developed to maintaining appropriate moisture balance.¹¹ No-sting barrier films (NSBF), when applied to intact or damaged skin, have been found to form a long-lasting waterproof barrier to protect the peri-wound skin, and acts as a protective barrier against wound fluids, body wastes, perspiration and friction.¹¹ Despite their routine use in protecting peri-wound skin, there are currently no studies that investigate the effects of NSBF in treating pressure injuries of LTC residents.

Objective

To determine if the application of a barrier cream twice a day (for stage 1 injuries) or a barrier spray twice a day (for stage 2 injuries) is more effective for the treatment of pressure injuries in LTC residents when compared to routine practices.

Methods

Ethics approval was granted by Hamilton Integrated Research Ethics Board (Study #14-103-C).

Study Design

A retrospective cohort study was performed on all residents admitted to one LTC facility in Hamilton, ON, Canada between September 1, 2013 and February 28, 2014 after a 6-month implementation trial of an NSBF protocol (3M™ Cavilon™ No-Sting Barrier Film) developed by the LTC facility clinical staff.

Sample

One hundred twenty-nine LTC residents admitted to the facility between September 2013 and February 2014 were included in this study. They resided in five home areas of approximately equal size. All residents in each home area were assigned to either the NSBF protocol (interventional protocol), or routine care (control arm). Fifty-six residents from two home areas under one LTC attending physician

were assigned to receive the NSBF protocol; 73 residents from three home areas under two different LTC attending physicians were assigned to routine care, the control arm.

NSBF Protocol

Stage 1 and 2 pressure injuries identified during routine clinical care were assessed by nursing staff and documented on the resident's electronic medical record. If the resident resided in the intervention home areas, the nursing staff initiated the NSBF protocol immediately and noted this on the resident's care plan. The NSBF protocol directs staff to apply a barrier cream twice daily to any stage 1 pressure injury, and a barrier spray twice daily to any stage 2 injury until a stop order was received from the LTC attending physician. For those residents residing in the control home areas, routine clinical care and treatments deemed appropriate by their LTC attending physicians were followed.

Regardless of home area, all identified stage 1 or 2 pressure injuries automatically triggered a referral to the facility's wound care nurse. For those residing on the intervention home areas, the wound care nurse could request termination of the NSBF protocol if the wound was misidentified as a stage 1 or 2 pressure injury. LTC attending physicians were notified of any pressure injuries identified.

Outcomes

The primary outcome for this study was the time to healing for identified stage 1 and 2 pressure injuries in each arm.

DATA Collection

Retrospective data abstraction from resident charts identified demographic data and the weekly documented wound status (e.g. worsening/no improvement, improving/healing, healed) over the course of four weeks by the wound care nurse. Data abstraction was completed by one author, who was blinded to the nature of the intervention, and which home areas were assigned to receive the NSBF treatment protocol.

Each pressure injury identified was considered an independent event, even if multiple pressure injuries were identified on a particular resident at the same time, or at different times during the six-month review. Concurrent stage 3, 4 or unstageable pressure injuries, or other wounds including skin tears, friction, sheer and moisture-related injuries were not counted in the data collection.

DATA Analysis

In the literature, the median time to healing of small stage 2 pressure injuries was 33 days.¹² The authors

Table 1 LTC Resident Demographics.

Demographic information	Treatment	N (total = 129)	Mean (SD)	P (t-test)
Gender (female)	NSBF	38/56 (68%)	–	–
	Control	56/73 (77%)	–	
Age (years)	NSBF	56	86.9 (7.9)	0.542
	Control	73	87.8 (8.4)	
Number of co-morbidities	NSBF	56	6.2 (3.1)	0.170
	Control	73	6.9 (2.5)	
Number of medications	NSBF	56	8.1 (3.4)	0.723
	Control	73	8.3 (3.5)	
BMI (kg/m ²)	NSBF	56	26.7 (6.4)	0.848
	Control	73	26.5 (5.8)	
Pressure injury risk scale (PURS) score	NSBF	56	3 (1.5) ^a	0.669
	Control	73	3 (1.7) ^a	
Number of residents with PURS > 3	NSBF	34/56 (61%)	–	–
	Control	39/73 (53%)	–	
Number of pressure injuries	NSBF	27 (total)	–	–
		7 (stage 1)		
		20 (stage 2)		
	Control	34 (total)	–	
		5 (stage 1)		
		29 (stage 2)		

^aPURS scores are integers; therefore, the median is reported rather than the mean.

therefore used four weeks as the healing benchmark for this study. Residents were analyzed by intention to treat. Pressure injuries that progressed past a stage 2 pressure injury within four weeks of identification were deemed as treatment failure. Pressure injuries that did not heal within four weeks of identification were also deemed as treatment failure. No residents were lost during follow-up. Statistical analyses were performed on collected data using SPSS version 20.

Results

The intervention and control arm demographics are listed in Table 1.

During the trial, 61 stage 1 and 2 pressure injuries were identified in total in the LTC facility. Thirty-four pressure injuries were identified in the control arm and 27 pressure injuries were identified in the intervention arm. The majority of pressure injuries identified in both arms were stage 2. The six-month incidence rates were 9% and 38% respectively for stage 1 and 2 pressure injuries. There were no significant differences with respect to mean age, number of co-morbidities, medications, BMI, and pressure injury risk scale (PURS) score between the two treatment groups. The monthly incidence rate for the total number of stage 1 and 2 pressure injuries for the overall study, NSBF protocol group (intervention), and the control group are shown in Fig. 1.

The PURS score was developed to be a risk assessment tool for pressure injuries in LTC; with a PURS score of three, the odds ratio of developing a pressure injury was

reported to be 7.11.⁴ The median PURS score for this LTC facility was three (Fig. 2a). Fifty-six percent of residents ($n = 73$) had a PURS score of three or higher. In addition to having a higher incidence of stage 1 and 2 pressure injuries residents with higher PURS scores also had a higher number of injuries over the study period (Fig. 2b).

For those stage 1 and 2 pressure injuries that healed during the six-month observation period, the healing time for the intervention group was 2.15 weeks vs. 2.59 weeks in the control arm ($p = 0.015$) using a two-tailed Independent Samples *T*-test with unequal variance assumption. The mean difference in healing rates between the two groups was 0.44 (95% CI 0.091–0.79) weeks. Overall, 23% ($n = 14$) stage 1 and 2 pressure injuries did not heal in four weeks; unhealed pressure injuries were predominantly

Figure 1 Monthly incidence of stage 1 and 2 pressure injuries in the overall study, as well as separately for the no-sting barrier film (NSBF, intervention) and routine clinical care (control) groups.

Figure 2 (a) The frequency of study LTC residents by pressure injury risk scale score (PURS score). (b) The average number of stage 1 or 2 pressure injuries per resident by pressure injury risk scale score (PURS score).

stage 2, and occurred in residents with higher admission PURS score (Fig. 3). The intervention group had one out of seven stage 1 pressure injuries, and six out of 20 stage 2 pressure injuries not heal in four weeks. The control group had one out of five stage 1 pressure injuries, and six out of 29 stage 2 pressure injuries not heal in four weeks. It should be noted that the intervention group had a higher proportion of residents with PURS scores greater than three relative to the control group (61% vs. 54%).

Discussion

The NSBF protocol resulted in a faster rate of healing in the stage 1 and 2 pressure injuries that healed in the intervention arm. This rate was found to be statistically significant over the rate of healing in those injuries that healed in the control arm. However, despite a quicker healing time, it was observed that the intervention group had a higher proportion of unhealed stage 1 and 2 pressure injuries during the study period. This could be due to the intervention group having a higher proportion of residents with PURS score greater than three (Table 1).

The monthly incidence rate in this LTC facility was consistent with existing findings in literature; there appears

to be a decrease in monthly incidence during December and January. This decrease may be due to increased family presence during the holiday season resulting in more frequent mobilizing of their loved ones, thereby reducing the deleterious effect of pressure on those residents that are normally bed-bound or wheelchair bound.

Informal interviews with nursing staff revealed that standardization of the treatment protocol made communication with the physician easier and allowed for treatments to be initiated immediately rather than waiting on a physician assessment. Informal interviews with administrators identified that the role of the wound care nurse evolved to include an educational and mentoring component rather than clinical assessment alone.

Limitations

First, wound assessments were performed on a weekly basis as per routine facility protocol by nursing staff; however, pressure injuries that develop and resolve in-between assessments may have been missed. This would most impact the incidence and observed healing rate of stage 1 pressure injuries. However, with the majority of pressure injuries observed being stage 2 (80%), this impact on overall healing rate is minimal. Second, documentation would ideally occur on the date that pressure injury healing was observed; however, as this was a pragmatic NSBF treatment trial, the facility administrators felt that the established wound care documentation protocols were sufficient. Lastly, the pressure injuries in this study were not further classified as healable, maintenance or unhealable wounds during their initial assessment. Some of the unhealed pressure injuries observed in this study may actually have been maintenance or unhealable; therefore, full healing would not have been expected regardless of treatment.

Conclusions

The study demonstrated that using an NSBF protocol significantly impacted pressure injury healing time. This

Figure 3 The percentage of unhealed in the overall study. The percentage of unhealed stage 1 and 2 pressure injuries are also reported by pressure injury risk scale score (PURS score) during the study.

protocol could be implemented in other LTC facilities in combination with best practice guidelines for the primary prevention and treatment of pressure injuries. Future considerations for LTC facilities could also include utilizing the admission PURS score more effectively as an opportunity to initiate primary prevention strategies earlier in those LTC residents at higher risk. Lastly, this study was an evaluation of a pragmatic clinical idea in one LTC facility; larger interventional studies are required to determine the true effect size and the economic impact from faster pressure injury healing.

Acknowledgements

The authors would like to acknowledge the administrators of Regina Gardens Nursing Home for their support and collaboration during this study. Special acknowledgements go to Amie Vahrmeyer, Assunta Fovonic, and Janna Verma for their work in implementing the NSBF protocol with on-site nursing staff.

References

1. Health Quality Ontario: Management of Chronic Pressure Ulcers: An Evidence-based Analysis. 2009. Contract No.: 3.
2. Narayanan S, Van Vleet J, Strunk B, Ross RN, Gray M: Comparison of pressure ulcer treatments in long-term care facilities. *J Wound Ostomy Continence Nurs.* 2005;32(3):163–170.
3. Pham B, Stern A, Chen W, et al: Preventing pressure ulcers in long-term care: A cost-effectiveness analysis. *Arch Intern Med.* 2011;171(20):1839–1847.
4. Poss J, Murphy KM, Woodbury MG, et al: Development of the inter-RAI Pressure Ulcer Risk Scale (PURS) for use in long-term care and home care settings. *BMC Geriatr.* 2010;10:67.
5. Mangin D, Heath I, Jamouille M: Beyond diagnosis: Rising to the multimorbidity challenge. *BMJ.* 2012;344:e3526.
6. McCarthy L, Dolovich L, Haq M, Thabane L, Kaczorowski J: Frequency of risk factors that potentially increase harm from medications in older adults receiving primary care. *Can J Clin Pharmacol.* 2007; 14(3):e283–e290.
7. Sibbald RG, Goodman L, Woo KY, et al: Chronic Wound Care: A Clinical Source Book for Healthcare Professionals, 5th ed. Malvern PA: HMP Communications; 2012.
8. Registered Nurse Association of Ontario: RNAO Best Practice Guideline: Risk Assessment & Prevention of Pressure Ulcers. 2011. Guideline Supplement.
9. Sibbald RG, Kraser DL, Woo KY: Pressure ulcer staging revisited: Superficial skin changes & deep pressure ulcer framework. *Adv Skin Wound Care.* 2011;24:571–580.
10. Dealey C, Posnett J, Walker A: The cost of pressure ulcers in the United Kingdom. *J Wound Care.* 2012;21(6):261–262. 4, 6.
11. Schuren J, Becker A, Sibbald RA: A liquid film-forming acrylate for peri-wound protection: A systematic review and metaanalysis (3MTM Cavilon™ no-sting barrier film). *Int Wound J.* 2005;2(3):230–238.
12. Bergstrom N, Smout R, Horn S, Spector W, Hartz A, Limcangco MR: Stage 2 pressure ulcer healing in nursing homes. *J Am Geriatr Soc.* 2008;56(7):1252–1258.