CE Symptom Management Series
1.0 ANCC Contact Hour

Palliative Care in the Management of Pain, Odor, and Exudate in Chronic Wounds at the End of Life

A Cohort Study

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Palliative care approaches that effectively manage distressful symptoms associated with wounds at the end of life remain elusive. This 4-week study examined a topical wound powder RGN107 for reducing pain, odor, and exudate in 50 patients with pressure ulcers, skin tears, and malignant/fungating and vascular wounds receiving hospice or palliative care and explored quality of life for the caregiver. Through an observational design, the outcomes were measured with visual analog scales, 2 pain questionnaires, and a caregiver quality-of-life instrument. Intent-to-treat analyses were used. Statistically significant reductions in pain ($P = .001$), odor ($P = .04$), and exudate ($P = .00003$) were observed. Caregiver quality of life remained unchanged ($P = .28$); however, improvements were noted in 3 subscales. Findings suggest topical RGN107 reduced pain, odor, and exudate in a highly challenged population with wounds at the end of life. A larger comparative effectiveness trial should be conducted with other wound powder comparators and usual care approaches and should include cost benefits.

KEY WORDS

comfort care, end of life, malignant wounds, pain, palliative wound care

Symptom management approaches for palliative wound care are in critical need as few options exist for individuals at the end of life with wounds. There is a lack of research of wound therapeutics that effectively manage physically distressing symptoms such as pain, odor, or excessive drainage (exudate). These symptoms negatively affect quality of life for both the individual who experiences them and the caregiver who provides wound care. Wounds such as pressure ulcers, skin tears, and vascular lesions develop because of a host of factors including physiological changes associated with comorbid medical conditions, lack of movement, skin fragility, and poor nutrition.[1] Wound prevalence studies of the hospice population have shown wound rates as high as 47%; half are pressure related.[2] Even when life expectancy is merely a few weeks, palliative wound care options should emphasize symptom management to preserve dignity and well-being and promote quality of life of the individual and caregivers.

Pain

Pain is an extremely burdensome symptom, affecting 60% of individuals within the last 4 months of life.[3] Patients and caregivers report wound pain as one of the worst aspects of having a wound because it disturbs sleep, mobility, mood, and relationships,[4] all factors that reduce quality of life.[5] Wound pain during dressing changes and wound cleansing is reported to be the time of greatest pain.[1] Dressing materials adhere to the fragile wound surface because of the glue-like nature of dehydrated

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or crusted exudate. Each time the dressing is removed, and the wound is cleansed, there is the potential to further induce local trauma and elicit pain. Nonadherent permeable dressings, wound gels, and silicone-type products are recommended to reduce pain.[6] Dressings containing active ingredients such as ibuprofen have demonstrated local pain relief in exudating wounds.[7] The efficacy of these dressings on wound pain experienced by patients at the end of life, however, is limited by a lack of research. Feasible methods to augment wound care could result in fewer dressing changes and less exposure to cleansing, 2 major sources of wound care discomfort.

Odor and Exudate

Other sources of distress are wound odor and excessive exudate. Odor from tissue necrosis or infection is reported to cause gagging, vomiting, weight loss, social isolation, and withdrawal among individuals and their caregivers[8,9] and leads to poor quality of life.[5] Research on treatment options for odor management is limited. Both topical metronidazole and activated charcoal are indicated for odor management.[10,11] Activated charcoal dressings, when sealed and kept dry, have been reported to conceal odor from malignant fungating wounds.[12] Odor and exudate associated with malignant wounds were reduced in a study comparing a honey-coated bandage to a silver-coated bandage.[13] Antimicrobial and silver-containing dressings have been reported to reduce odor, but there is limited evidence to support this claim.[14] Wound exudate is an excess of leaking fluid that generally accumulates more readily from injured tissue. Wound exudate poses a serious problem because of the presence of proteases that destroy tissue and contribute directly to wound enlargement.[15] Dressings that are minimally bulky, prevent leakage, are comfortable, and are aesthetically acceptable with high absorbencies and long wear times are best.[16] However, limited evidence is available to guide the selection of one dressing or product over another. Also, these dressings can be expensive.

Quality of Life

Caregivers are distressed by unrelieved symptoms of pain, odor, and exudate associated with large wounds and express frustration and helplessness with being unable to comfort a loved one.[17] Uncontrolled symptoms, coupled with the burden of providing physical care, can also lead to negative caregiving outcomes such as depression and social isolation from loved ones and friends.[18] Nurses and patients report frustration with not having effective methods to control wound pain and odor, especially during dressing changes.[19] Methods to address these negative symptoms, especially pain, odor, and exudate, are critically needed to improve overall quality of life of the caregivers and the patients.

Topical Therapy for Palliative Wound Management

Most therapies available for wound care are specific to manage one symptom such as odor, pain, or exudate; few provide simultaneous "comfort" for all symptoms. The intent of this study was to augment current palliative wound care clinical practices by contributing to the knowledge base of symptom science research, in particular to the management of wounds at the end of life. The topical therapy RGN107 used in this study is a natural powder, applied during each dressing change and intended to form a "crust" seal barrier over the wound, limiting wound manipulation to less frequent direct contact with dressings and exposure to air. The powder is available through major drugstore chains and online and costs on average approximately $7 per 10-g package. It comes in packets or bottles. At present, it is not a reimbursable item. The goal was to reduce pain, manage odor, and control exudate.

Aims

The aims of this 4-week study were to examine a wound care intervention using RNG107 to control wound pain, odor, and exudate in 50 patients receiving home-based or inpatient hospice care. The study also aimed to explore quality of life for both patient and caregiver. We hypothesized the intervention would enhance comfort care and quality of life at the end of life. This observational study was conducted between March 2012 and November 2015.

METHODS

Theoretical Framework

The intent of this study was to supplement evidence for the development of palliative wound management guidelines grounded in symptom management and comfort for individuals at the end of life. The study was underpinned by Kolcaba and Kolcaba's[20,21] comfort theory asserting that when the health care needs of individuals are appropriately assessed and properly intervened the outcome is enhanced patient comfort over time. This study addressed physical discomfort, specifically the sensation of pain, odor, and exudate relief. If the patient is physically content (relief from symptoms), he/she experiences sensations of ease. Enhancing comfort increases quality of life[21] and supports a peaceful death.[22]

Sample

Inclusion criteria included having a life expectancy of more than 1 month but less than 6 months; 21 years or older; presence of a chronic wound with a score of greater than 2 on a 0- to 10-point visual analog scale (VAS) for pain, odor,

or exudate; and a wound caregiver willing and able to perform the required protocol. Individuals were excluded if they or their wound caregivers had known allergies to mint, sandalwood, ragweed, or dogwood; had current wound treatment including negative-pressure wound therapy; or were unwilling to discontinue use of previously prescribed topical creams or ointments, such as antibiotics/antimicrobials applied to the wound bed; or the wound was covered with a tough eschar (powder would not adhere). Enrolled participants remained active in the study until they either completed 4 weeks of powder application, were discharged from the participating hospice, or died; or the participant/caregiver withdrew consent, or they were withdrawn from the study by the principal investigator for medical reasons.

Ethics

The Medical University of South Carolina Institutional Review Board approved the study, and an independent Data Safety Monitoring Board monitored the ethical and safety profile of the study. The study was conducted according to the Declaration of Helsinki II, and written informed consent was obtained from all participants. Participants or legally authorized representatives (LARs) were compensated $175.

Setting

Participants were recruited and enrolled from 7 hospice agencies, 2 of which were inpatient facilities, in the Eastern United States. Agency nurses approached potentially eligible patients and their families about study interest. If interested, and with verbal consent, the study team personnel contacted the patient and/or the LAR and the wound caregiver to set up a face-to-face meeting to discuss the study and conduct pre-eligibility screening. If patients were eligible and willing to participate, they, or their LAR, and their wound caregivers provided written informed consent. Retention methods included weekly caregiver phone calls and joint in-person caregiver/patient visits.

MATERIALS AND METHODS

Powder

RGN107 was designed to fill and cover the wound to prevent exposure to contaminants and air and reduce frequent cleansing and dressing changes. The wound powder formulation is a natural powder extract composed of active ingredients *Calendula officinalis* L (International System of Units [SI] 0.1% volume/weight) and *Arnica montana* L (SI 0.01% volume/weight) and inactive ingredients *Mentha arvenis* (mint, 90 weight/weight) and *Santalum album* (sandalwood, SI 10% weight/weight). RGN107 was produced under Good Manufacturing Practice conditions in 10-g packets and ultraviolet sterilized. The ingredients are known to have absorptive, aromatic, antiseptic, anti-inflammatory, and analgesic properties.[23] In our previous study of chronic venous leg ulcers, RGN107 formed a crust or protective seal over the wound, thereby reducing pain during dressing changes.[24] We found that the crust prevented the dressing from sticking to the fragile wound bed and restricted painful exposure to air when the dressing was removed. The powder crust also prevented direct wiping over the wound, which is contraindicated during dressing changes for wounds that require comfort care.[25] This study extends research with patients with wounds at the end of life.

RGN107 Protocol Training

A tailored protocol training model was developed that recognized the variability of wound caregivers (inpatient vs home-based agency and family) and strategies for applying the powder to various types of wounds (ie, sacral pressure ulcers, tumor, vascular ulcers of the lower legs including venous and arterial). Within the inpatient settings, group training was delivered to all 3 nursing shifts over a period of 3 days. In the home setting, small group training was delivered to all caregivers who provided wound care to the participant, including family members, hospice nurses, and home health aides. Study personnel were present at the first application of the powder for each enrolled participant in order to assess wound caregiver learning and advise on any special application techniques. Caregivers were instructed to immediately notify study personnel of all suspected or noted adverse events whether they believed the adverse events were related to RGN107 application.

Intervention

In both settings, a hospice registered nurse established the wound protocol per agency standard of care guidelines and obtained a physician's order to use RGN107. For the first 2 days of the study, standard wound care was maintained, so that baseline measures of odor, exudate, and pain could be collected. On day 3, the dressing was removed, the wound was cleansed according to agency protocol (usual care), and RGN107 was applied liberally to the entire wound bed. Loose powder around the periwound area was removed, and the wound was covered with a nonstick foam-type dressing. A new powder packet was used for each dressing change. The protocol emphasized a palliative "comfort" care approach that reduced physical manipulation of the patient and the wound through infrequent "prn" whenever necessary for dressing changes. The frequency of dressing changes depended on wound characteristics such as exudate, observed as 50% strikethrough on the dressing, contamination from incontinence, or high odor. In these instances, the powder

TABLE 1 Measures

Variables	Instruments/Data Collection Timepoints (in Parentheses)	Internal Consistency
Demographics	Age, sex, race/ethnicity, diagnoses, wound history, life expectancy (baseline)	N/A
Cognitive status	Functional Assessment Staging Test: stage of cognitive impairment/dementia, ranging from 1 (normal aging—no deficits whatsoever) to 7 (severe dementia—no longer able to hold head up) (baseline)	0.87
Functional status	Palliative Performance Scale: levels of ambulation, activity/evidence of disease, self-care, intake, and conscious level, ranging from 100% (normal) to 0% (death), scored in increments of 10% (baseline)	0.96
Pain	Visual analog scale (VAS) = 11-items with 10 = worst possible and 0 = none and classified as <3 = mild, 3-6 = moderate, and 7-10 = high (baseline and each dressing change)	0.99
	McGill Pain Questionnaire–Short Form: 19 items consisting of 5 subscales with 15 descriptors (11 sensory and 4 affective) on a 4-point scale, which rates pain on an intensity scale as 0 = none, 1 = mild, 2 = moderate, and 3 = severe (baseline, week 2, and end of study)	0.95
	Pain Assessment in Advanced Dementia Scale: for unresponsive individuals. Total scores from the 5-item scale range from 0 to 10, 1-3 = mild pain, 4-6 = moderate pain, and 7-10 = severe pain. Higher scores indicated more severe pain (baseline and each dressing change)	0.84
Odor	VAS 11 items with 10 = worst possible and 0 = none and classified as <3 = mild, 3-6 = moderate, and 7-10 = high (baseline and each dressing change)	0.99
Exudate	VAS 11 items with 10 = worst possible and 0 = none and classified as <3 = mild, 3-6 = moderate, and 7-10 = high (baseline and each dressing change)	0.99
Quality of life—caregiver	Quality of Life in Life Threatening Illness–Family Carer Version: the 19-item scale is an 11-point numerical rating scale that ranges from 0 to 10, where 0 = worst situation and 10 = best situation. Used in the home for family caregiver (baseline, week 2, end of study)	0.80

was washed out of the wound with a spray wound cleanser and reapplied. For maintenance care, RGN107 was applied over the previously applied powder and covered with clean foam dressing, only as needed. Concomitant pain medications were to be taken as usual during the study.

Outcome Measures

Initial demographic data collected from the medical record at baseline included medical history, pain medications, cognitive status (Functional Assessment Staging Test),[26,27] and functional status (Palliative Performance Scale)[28,29] (Table 1 shows all measures). The main clinical endpoints and pain (wound pain reported by both patient and caregiver), odor, and exudate data were measured with well-validated instruments. Wound pain was measured with a VAS,[30] and the McGill Pain Questionnaire–Short Form[31] was used to collect data from the participant, if able to provide information. On this pain scale, participants rated their overall wound pain (not during dressing changes). Subscales include the Pain Rating Index (S-PRI), Affective Pain Rating Index (A-PRI), and Total Pain Rating Index (T-PRI). Total

descriptive subscales include a single VAS (0-10) for present pain intensity and a verbal rating scale for rating overall pain experience. Three pain scores are derived from the sum of the intensity rank values from the sensory, affective, and total descriptors subscales; the higher the score, the more severe the pain. The Pain Assessment in Advanced Dementia Scale (PAINAD)[32] was used by caregivers to score pain levels for nonverbal individuals. Higher scores indicated more severe pain. Quality of life for the caregiver was measured with the Quality of Life in Life Threatening Illness–Family Carer Version[33] that consisted of 7 subscale scores (environment, patient state, caregiver's own state and outlook, quality of care, relationship, financial worries) and a total score. The lower the score, the poorer the quality of life.

Statistical Analysis

An observational design was used to evaluate the presence of a preliminary "signal" of clinical efficacy in physical wound symptom outcomes of pain, odor, and exudate, and caregiver quality of life. Analysis used the intent-to-treat model. Descriptive statistics for demographic and clinical characteristics were calculated for participants, including inpatients at study sites and outpatients at home. Variables for clinical data recorded on multiple days were defined as averaged weekly or biweekly clinical scores. Changes from baseline of participant pain, odor, and exudate and caregiver total quality of life to end of study (4-week study endpoint, death, or early exit due to dropout) were analyzed using the paired *t* test and nonparametric Wilcoxon (PAINAD) and Sign (McGill A-PRI) tests. Statistical significance was set at $\alpha = .05$. Formal a priori power calculations were not computed; instead, sample size was determined using the "pragmatics of recruitment" for enrollment of inpatients and outpatients, n = 50, to evaluate a signal of clinical efficacy in wound symptom outcomes of pain, odor, and exudate.[34] We did not power to detect statistically significant differences in outcomes; rather, the study aimed for equal representation of participants from the 2 settings. Data were securely stored in REDCap (Research Electronic Data Capture). Statistical analysis was performed using IBM SPSS 23 (IBM, Armonk, NY).

RESULTS

Fifty patients and their caregivers were consented and enrolled, including 42 home-based patients and 8 inpatients over the 7 study sites. Forty-five of the participants (90%) successfully completed the study, with 5 (10%) exiting early (4 patients withdrawn per caregiver request and 1 patient because of transfer to a nonparticipating hospice site). The Functional Assessment Staging Test scores for cognitive decline indicated that of the 35 participants with documented scores upon admission to the hospice 22 participants (63%) were very severe, 9 (26%) were severe, 1 (3%) was moderate, and 3 participants (9%) were mild or very mild. The average age of the participants was 80 (SD, 12.92) years. The evaluation of functional abilities of 44 participants with Palliative Performance Scale scores upon hospice admission indicated that more than half, 31 (77%), were scored at levels of 30% to 10%, indicating they were totally bedbound and unable to do any activity and required total care. Nine participants (23%) were scored 40% or 50%, indicating they were mostly in a bed or chair or unable to do any work or most activities and required considerable assistance. The most common types of wounds were pressure ulcers (n = 36 [72%]), followed by malignant/fungating tumors, skin tears, and chronic venous ulcers (n = 9 [18%]). One wound healed during the study. Weekly frequency of dressing changes over the 4 weeks showed no significant difference for these data. On average, dressings were changed twice weekly. Based on the end of study survey, this frequency was substantially reduced from frequency of dressing changes prior to enrollment in the study, reported by caregivers to be at least daily. Caregivers who provided wound care included family members, licensed and nonlicensed aides, and registered nurses and are referred to as providers (Table 2).

Pain

Among 21 participants who were able to provide their own ratings of pain, mean VAS pain scores showed a statistically significant decrease in average pain scores from baseline to last assessment ($P = .001$). Similarly, PAINAD average scores for 35 participants (some also with VAS ratings) rated by the provider showed a significant decrease from baseline to last assessment ($P = .001$). Measurement summary statistics for average baseline and last assessment are shown in Table 2.

Average subscale pain scores for 9 participants able to complete the McGill Pain Questionnaire decreased from baseline to last assessment, although changes were not statistically significant for the following data: S-PRI ($P = .13$), A-PRI ($P = .38$), and T-PRI ($P = .11$).

Odor and Exudate

Comparison of odor rated by the providers using the VAS for 46 participants showed a significant decrease from baseline to last assessment ($P = .04$). Moreover, VAS exudate average scores showed a statistically significant decrease for 45 participants ($P = .00003$).

Quality of Life for Caregivers

Results for comparison of the Quality of Life During Serious Illness for Family Carers from baseline to last assessment for 23 family caregivers in the home are reported in Table 3. There was no significant change in caregivers'

TABLE 2 Demographics and Characteristics of Participants and Providers

	n/Mean	Percent
Participants (n = 50)		
Gender		
Female	30	60.0
Male	20	40.0
Age, y	80.12	
Race		
Black	17	40.5
White	32	57.1
Other	1	2.4
Diagnosis (top 5)		
Dementia	19	38.0
Cancer	8	16.0
Neurological	6	12.0
Cerebrovascular	4	8.0
Chronic heart failure	4	8.0
Providers (n = 50)		
Gender		
Female	45	90.0
Male	5	10.0
Race		
Black	11	22.0
White	36	72.0
Other	3	6.0
Employed at hospice	34	68.0
Holds licensure/certification	39	78.0
Family	23	46.0

quality of life for these data (P = .28). However, slight improvements were reported in several subscales, with the most notable being caregiver's own state and financial relationships, although these were not statistically significant.

DISCUSSION

We believe this is the first project of its kind to explore a topical powder on the 3 most debilitating symptoms, pain, odor, and exudate associated with wounds in a population at the end of life. Patients at the end of life who develop wounds often experience distressful symptoms that reduce quality of life for them and their caregivers. Findings support the hypothesis that application of RGN107 reduced pain, odor, and exudate. It did not, however, enhance quality of life of the caregivers. Best practice wound care approaches that simultaneously control the most distressful symptoms, pain, odor, and exudate, remain elusive, but this trial demonstrated that the powder provided relief for all 3 symptoms, many of which co-occurred in this patient population. This effect was consistent for various types of wounds including vascular and pressure ulcers. Data were analyzed and reported independently for each symptom because patients may have had 1 or more of the 3 symptoms. All 3 symptoms improved over the study period.

The study population was representative of the percentage of patients receiving home-based and inpatient hospice care. At enrollment, the majority were 65 years old, severely cognitively impaired, and bedbound and required total care. The powder was well tolerated by the participants, and no adverse events related to the powder were noted. The effect of the powder may be explained by its synergistic mechanism of action on reducing inflammation, edema, and antimicrobial activity for reducing symptoms. There was decreased frequency in wound care over the study, consistent with the goals of comfort care where reduced manipulation of the wound is preferred.

Theoretical Framework

Kolcaba's "Enhanced Comfort Theory," within the context of physical comfort that concerns bodily sensation (wound symptoms of pain, odor, and exudate), provided an appropriate framework for this study. This theory has guided several studies of comfort interventions[35–37] and was practically applied to a population with wounds.

Pain

Participants able to rate their wound pain during dressing changes (n = 21/50) indicated pain was of moderate severity. Caregivers rated pain similarly for those they assessed. The patients experienced a significant reduction in wound pain for the 4-week study, with mean wound pain scores decreasing by almost half for both participant-rated (VAS) and caregiver-rated (PAINAD) pain. Scores on the McGill Pain Questionnaire showed similar decreases during this period, although not statistically significant. The explanation for the decrease in pain could be attributed to the active ingredients in the powder. *Arnica Montana* (arnica) is known for its analgesic, antiedematous, and anti-inflammatory properties. Arnica contains sesquiterpene lactones, flavonoids, and

TABLE 3 Results of Pain, Odor, and Exudate Measures, and Caregiver Quality of Life

Scores/Participants (n)	Baseline		End of Study		
	Mean	SD	Mean	SD	*P*
VAS pain (n = 21)	4.48	3.19	2.32	3.11	.001
VAS odor (n = 46)	3.89	3.41	2.83	2.73	.04
VAS exudate (n = 45)	5.71	2.77	3.52	2.92	.00003
PAINAD (n = 35)	3.22	2.76	1.70	2.15	.001
McGill pain (n = 9)					
Subscale S-PRI	9.78	7.17	4.56	8.57	.13
Subscale A-PRI	3.44	3.28	1.11	1.83	.38
Subscale T-PRI	13.22	10.05	5.67	9.99	.11
Carers QOL (n = 23)					
Total score	7.81	1.42	8.05	1.76	.28
Environment	8.26	1.36	8.72	1.23	
Patient state	8.09	2.47	8.39	2.08	
Carer's own state	6.45	2.23	7.11	2.16	
Carer's outlook	7.99	1.85	8.23	1.80	
Quality of care	9.20	1.17	8.98	1.71	
Relationships	7.89	2.09	7.98	2.13	
Financial worries	6.78	3.32	7.52	2.92	

Abbreviations: A-PRI, Affective Pain Rating Index; PAINAD, Pain Assessment in Advanced Dementia Scale (PAINAD); QOL, quality of life; S-PRI, Pain Rating Index; T-PRI, Total Pain Rating Index; VAS, visual analog scale.

triterpene alcohols that have been found to interfere with various metabolic inflammatory pathways including the inhibition of nuclear factor κB, one of the primary mechanisms of action to reduce pain and edema.[38] There are few studies in humans directly related to arnica for symptom management; the majority of studies using topically applied arnica reported positive associations with treating bruising, swelling, or pain associated with various procedures such as open rhinoplasty[39]; burns,[40]; and conditions such as tendinitis[41] and acute ankle injury.[42]

Odor

Mentha arvenis (Japanese mint) and sandalwood are the 2 constituents of the powder that have a major effect on wound odor. These extracts' mechanisms of action are due to their antibacterial properties in which there is inhibition of the proliferation of bacteria, including *Staphylococcus aureus*, which are highly odor producing.[43] Most of the wounds in our study had some degree of necrotic (dead) tissue such as slough, which also produces odor and harbors bacteria. While none of the wounds were believed to be infected, most wounds are critically colonized, and in the presence of dead tissue, odor is highly prevalent.[44] The findings of reduced odor in this study indicate the powder was effective.

Exudate

A majority of participants experienced moderately to highly exudating wounds that at the start of the study required frequent, at least daily, dressing changes. This frequency was reduced to twice weekly throughout the 4-week study. Arnica, as noted previously, is known for its antiedema and anti-inflammatory properties, which could explain, in part, the reduction in wound exudate. *Calendula officinalis* flower extract (calendula) is a species of the marigold plant that is also noted for its antiedema effects and plays a role in healing chronic wounds. The presence of flavonol glycosides as the major compounds in calendula causes stimulation, proliferation, and migration of fibroblasts in a PI3K-dependent pathway, leading to positive effects on wound healing.[45]

Results of a 7-week study of chronic leg ulcers showed that a combination of extracts in an ointment that contained calendula increased wound epithelialization and reduced edema and exudate.[46] In addition, and although data are limited, positive absorptive effects of the combination of calendula and arnica on wound exudate have been observed.[47]

Caregiver Quality of Life

Caregivers' quality of life did not change notably with respect to care of the wound. We anticipated that as the condition of their loved one deteriorated caregivers would experience poor quality of life; however, this was not evidenced in our findings. This study showed no significant changes over time in overall quality of life; however, in the subscales, some improvements were noted. Change in subscale caregivers' own state from baseline suggests a decrease in caregivers' distress in caring for their loved one. Similarly, change in the subscale financial worries from baseline suggests there was improvement. These results could be explained by the fact that patient life expectancy was short, 1 to 6 months, and caregivers were anticipating the imminent death of their loved one. Having an option to reduce suffering through management of the wound symptoms may have contributed to these improvements. However, the scale was not designed to measure changes in quality of life related to wound improvements over time; thus, a more appropriate scale that measures burden of wound care may be considered.

Limitations

There are several limitations to this study. Primarily, there is a lack of research on topical powder preparations for wound care to which we could compare our findings. We did not study an active comparator; thus, it is unclear whether the powder performed any better than, for example, honey-based, silver-coated, hydrocolloid, or other "usual care" dressings. The study was conducted with a small sample of patients, and the sample was further reduced because 38% of patients died prior to the 4-week study end because of the nature of their underlying condition. Findings may not be representative of a larger cohort of patients with wounds at the end of life. We originally anticipated an even distribution of patients receiving home-based or inpatient hospice care; however, many of the recruited inpatients were ineligible because of having an anticipated survival time of less than 1 week. This was often the case as well for patients receiving hospice care in the home. Numerous staffing and administrative changes in the hospice agencies led to interrupted enrollment. For example, 2 small agencies were purchased by a larger group that required us to seek approval at their corporate level, further delaying enrollment. Nurses and caregivers had difficulty with rating odor, despite frequent training from the study personnel. For example, we noted inconsistencies in the timing of rating of odor (before or after bandage removal and at what distance from the wound such as in the room or up-close to the wound). We also encountered much variability in the amount of powder applied; sometimes, there was more than needed, and other times, there was not enough; therefore, our study personnel provided frequent retraining to ameliorate these inconsistencies. There was only 1 quality-of-life measure for the caregivers, and perhaps, it had low validity and reliability. A burden scale might be a better measure for this outcome in future trials.

CONCLUSIONS

Few topical powder palliative wound care approaches exist to reduce the concomitant symptoms of wound pain, odor, and exudate at the end of life. Wound symptom management remains a challenge despite the availability of numerous topical agents and dressings, because the use of many of those available requires frequent application and can be difficult to obtain and costly. The goal of palliative wound care is to provide comfort, ease symptoms, and reduce the burden of care for the patient and caregiver. RGN107 powder was found to improve symptoms and should be considered when these wound symptoms are present.

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