Prospective analysis comparing the use of the VAC-dressing to topical agents in non-diabetic nursing home residents with stage 3 sacral pressure ulcers

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A. Background/Study Purpose/Rationale

Pressure ulcers, a common and significant problem in the elderly and critically ill, have shown to decrease quality of life, increase morbidity and prolong hospital stays. Based on the Norton scale (Norton et al 1989) patients with limited activity, impaired cognitive state, and incontinence are at increased risk for developing pressure ulcers. Patients with pressure ulcers are approximately 2-3 times more likely to die than those without an ulcer (Thomas et al, 1996). Pressure ulcers are classified by depth and categorized as follows: denuded skin, skin tear, stage 1= soft tissue swelling and induration with associated erythema, may be associated with superficial ulceration. stage 2= a full thickness skin ulcer penetrating through the dermis to the junction with the subcutaneous fat. Stage 3: full thickness ulcer extending through the dermis into the subcutaneous fat, limited by the deep fascia and stage 4 are full thickness ulcers extending to bone.

Reports show that 10-35% of patients admitted to nursing homes have pressure ulcers of varying stages, and up to 30% of these ulcers are stage 3-4. Reports show that 8% of long- term facility members will develop at stage 2 or deeper ulcer within the first 6 months of nursing home admission (Spector et al, 1988, Brandies et al 1990). Patients with known stage 3-4 ulcers need pressure relief with frequent position changes, good hygiene and pain control to maximize wound healing. Other factors that contribute to healing time include wound size and depth, nutritional status, weight (Van Rijswijk, et al 1994). Healing time for stage 3- 4 full-thickness pressure wounds treated with standard topical agents vary, with mean healing time ranging from 1.5- 6 months (Bolton et al 2004; Berlowtiz et al).

Full thickness stage 3-4 ulcers are typically treated with surgical and/or enzymatic debridement, with additional agents to promote granulation tissue formation. Additional topical anti-microbials can be added for infected wounds, and systemic therapy is initiated when there is evidence of osteomyelitis or bacteremia. Additional modalities such as electrotherapy, hyperbaric oxygen, direct application of growth factors and negative pressure dressings have been used to for the treatment of pressure ulcers. The vacuum assisted closure (VAQ therapy is a type of negative pressure dressing that has been to heal both surgical and pressure wounds. The VAC system includes a hydrophobic polyurethane foam that is cut to fit the shape of the wound. Special suction tubing is attached to the foam and placed on intermittent suction to remove excess drainage from the wound bed. This system is designed to increase local blood flow, decreases edema and bacterial count and promote the formation of granulation tissue for faster healing in the wound bed (Moues et al 2004) There have been small studies with the use of vacdressing in post-operative and non-surgical patients with diabetic foot ulcers, postoperative patients with abdominal wounds, and pressure ulcers. These small studies have shown that the VAC system promotes decrease in wound size and depth compared to standard wound care (Fabian et al 2000; McCallon et al 2000, Wanner et al). However there are no large, prospective trials to specifically assess the use of the VAC system on healing time to wound closure in full thickness stage 3 pressure ulcers in the non-diabetic population. The purpose of this study is to assess healing time with the use of the vac-dressing in non-diabetic patients compared to topical agents, with the hypothesis that the use of the vac-dressing will promote faster healing.

B. Study design

This will be a prospective, randomized study involving 10 nursing homes in the New York metropolitan region. Written informed consent will be obtained from all subjects or designated research health care proxy. A trained wound care specialist will evaluate residents with a sacral pressure ulcers. All wound care nurse specialists participating in the study will undergo a training session to standardize the method of staging and treating pressure ulcers. Wound care nurses will have to successfully complete a written exam as well as a wound care practical to participate in the study (inter-rater reliability> .8). Nursing home physicians will recruit subjects with single stage 3 sacral pressure ulcers. Recruited subject will undergo a complete physical exam and have all wounds evaluated by the study wound care specialist. Wounds will be classified by depth and categorized as follows: denuded skin, skin tear, stage 1= soft tissue swelling and induration with associated erythema, may be associated with superficial ulceration. Stage 2= a full thickness skin ulcer penetrating through the dermis to the junction with the subcutaneous fat. Stage 3A= full thickness ulcer extending through the dermis into the subcutaneous fat, limited by the deep fascia with light drainage (less than 3 cc), stage 3B= clean full thickness stage 3 ulcer with moderate to heavy drainage (greater than 3 cc). Stage 4 ulcers are full thickness ulcers extending to bone. Full thickness ulcers with areas of necrosis cannot be staged until all the necrotic tissue is removed. Subjects with an ulcer that has less than 10% necrotic tissue will have a trial of enzymatic debridement with accuzyme. After 3 days if the wound did not debride adequately, additional surgical debridement will be implemented to insure that the wound is clean. Subjects with large areas of necrotic tissue will undergo initial surgical debridement followed by 3 days of topical accuzyme. Once the full thickness ulcer is debrided, it can be staged appropriately.

C. Study procedure

Subjects with a cleaned stage 3 sacral pressure ulcer will be eligible to participate in the study. A designated computer program will do randomization with stratification based on nursing home, stage 3A, 3B, and age to receive either daily topical treatment or vac-dressing. At the time of randomization all stage 3 A and 3B pressure ulcers will be cleaned with normal saline. All wounds will have a punch biopsy that will be sent for bacterial culture. If positive, appropriate antimicrobial agents will be added. Initial size and depth of the ulcer will be recorded. Those randomized to receive a vac- dressing will have the device placed within 24 hours of randomization. The vac system will be placed on intermittent suction at 125 mm Hg. The vac-dressing foam will be changed three times a week on a set schedule of Monday, Wednesday and Friday. At the conclusion of two weeks, the size, depth of the ulcer and presence of granulation tissue will be recorded. If there is no evidence of that the wound has decreased in size or depth or granulation tissue has started to form, the vac-dressing will be discontinued. Sub ects, who fail the vacj dressing at 2 weeks will be undergo additional topical and/or surgical debridement and can cross over to the topical agent group. For subjects who show improvement at week 2, the vac-dressing will remain until there is evidence of greater than 95% granulation tissue with ulcer depth of less than or equal to I cm, and width less than 4 cm wide. Once these criteria are met, the vac-dressing can be removed and topical agents such as hydrogel with a thin dressing will be used until the wound closes to skin.

Subjects in the non-VAC group with stage 3 A will have topical hydrogel applied to the ulcer bed and then covered with gauze and tegaderm, with dressing changes on a daily basis. Subjects with stage 3 B ulcers will have calcium alginate applied to the wound with a gauze and tegaderm covering. This dressing will also be changed on a daily basis.

All subjects will be placed on oral zinc 220 mg daily and vitamin c 500 mg daily. Special flexicare beds will be provided to all subjects. Nurses at each facility will be instructed to turn patients in bed q2 hours. Fecal and urinary incontinence will be managed with placement of texas catheters/Foley catheters or rectal tubes to avoid wound contamination. A nutritionist will evaluate each subject and make recommendations for possible dietary modification and/or supplementation. Study wound care specialists will make bi-monthly rounds on all study members. Study endpoint: Time to healing to full skin closure. The study will last a total of 9 months. Statistical analysis: The study is 80% powered to detect a statistically significant difference of 10% between the two treatment groups (predicted that at 3 months

90% of people in the VAC group will achieve full closure compared to 80% in the topical dressing group). 222 subjects in each group will be needed to detect this difference. Continuous variables will be calculated with mean and standard deviation. T-test will be used to compare the means of the two groups.

D. Study drugs

This study does not involve any study drugs

E. Medical device

The VAC is a foam and tubing system that produces uniform negative pressure across a sealed wound bed. It is indicated for chronic open wounds (diabetic ulcers and stage 3 & 4 pressure ulcers), acute and traumatic wounds, flaps and grafts, sub-acute and dehisced wounds and partial thickness bums

F. Study questionnaire

This study does not involve any questionnaire

G. Study Subjects

Nursing home residents with one clean stage 3 pressure ulcer, ages 18 and older will eligible for this study. Subjects with diabetes, pre-albumin less than 12, on chronic anticoagulation, allergies to polyurethane sponge, and presence of underlying primary skin conditions or rashes will be excluded from the study.

H. Recruitment

Designated nursing home physicians' will help recruit subjects to the study

I. Confidentiality

All subjects will be given a unique number to preserve that all data is confidential. Data will be stored securely and accessible to the investigators only.

J. Potential conflict of interest

None anticipated

K. Location of the study

The study will involve 10 nursing homes in the New York metropolitan region.

L. Potential risks

Subjects in the vac-dressing treatment group may have an undetected allergy to the polyurethane foam that is used. Furthermore, the vac system is an involved apparatus . Any problems with the system may take hours to days to fix and in turn prolong healing time.

M. Potential benefits

Subjects will all benefit excellent wound care as trained specialists will closely monitor the progress of their wound healing. Furthermore, all subjects will benefit from nutritional optimization, which in turn will promote improved wound healing. They will have the chance to use a device that may decrease healing time

N. Compensation to subjects

There will be no monetary compensation to the subjects or their families during this time.

O. Cost to subjects

There will be no additional costs for the subjects participating in the study. 0. Nfinors as research subjects: there are no minors involved in this study P. Radiation or radioactive substances: this study does not involve either and is therefore not applicable at this time.

P. References

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