EVALUATION OF NEW AND INNOVATIVE FLUID DELIVERY DEVICE FOR WOUND HEALING

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BACKGROUND

Clinical trials are a way to study new products for safety/ effectiveness. Ongoing research on new devices is essential to advance wound care. New therapies are emerging that involve the use of moist wound healing products to deliver antimicrobials, analgesics and a host of bioactive molecules (i.e., growth factors and micrografts).

METHOD

We evaluated an innovative fluid delivery device on aspects that are important to patients and providers. Our study consisted of three components: clinical trial, retrospective chart review, and surveys. After receiving IRB approval, 15 patients were enrolled and 57 separate procedures were performed and evaluated.

This non-randomized, unblinded trial involved placement of a novel fluid delivery system instilling small amounts of either a 3% gentamicin solution, sterile water, or normal saline at a constant flow rate to partially saturate a semi-occlusive dressing. The innovative dressing was applied to the wound and the activated device was left in place for up to 5 days. On each visit, the provider completed a survey to analyze application, removal, and device functionality. A patient questionnaire was also completed a survey to analyze application, removal, and device functionality. A patient questionnaire was also completed.

RESULTS

Safety: No adverse events were reported during the study and no severe incidents between clinic visits. There were varying degrees of maceration of the periwound skin which may have affected wound healing in only 11% of the cases.

Ease of use: Application time decreased to as little as 10 minutes. The providers deemed the device as “intuitive”. Removal of the device received an 89% rating by clinicians as “easy” (Figure 1).

Impact on ADLs: 91% of patients indicated the device posed no limitations on their ADLs; 4% stated the device enhanced their daily activities.

Healing rates: determined to be favorable with 85% of the device applications resulting in wound healing rated “as anticipated” or “better than anticipated”; 14 out of 15 patients (93%) had a reduction in wound surface area.

COMMENTS ABOUT THE PRODUCT:

Patient Perception
- “Amazing how much it has healed”
- Wearing it is “like it is not there, just have to watch the tube”
- No irritation from tape while wearing it.
- Wearing it is “like it is not there, just have to watch the tube”
- “That is healing quick, I can’t believe it”

Physician Assessment
- “It’s looking good”
- “only a little tiny spot in center looks like it doesn’t have epithelialization”
- “The device is easy to apply and the wound is looking good”
- Steroid cream is needed to help with a rash this week

Clinical (RN) Perception
- “I’m amazed that the wound came up because it use to be dented in so deep.”
- Wound looks really good, small areas of possible contact dermatitis, however, it may be from a reaction to the barrier wipes.
- “Best I’ve seen since he came in. Was deep and wound was just sitting there week after week”
- “Best I’ve seen it look, he’s almost done”

REFERENCES


CONCLUSION

The moist wound-healing device was favorable with both the provider and patients due to the ease of use and improved healing rates. The patients enjoyed the ability to perform activities of daily living while wearing the device. The results of the research suggest the device may have an application as an advanced wound care resource.