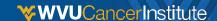


Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the products. We encourage you to read these studies to understand the strengths and limitations of the data. For some claims, Bravida is seeking to broaden the indications with the FDA in the future using data, such as these studies, to provide the substantiation.

Silver-Plated Wound Dressings for the Management of Radiation Dermatitis in Head and Neck Cancer

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Significance

- Acute radiation dermatitis (RD) affects over 90% of patients receiving radiotherapy for cancer, making it one of the most common side effects.
- Radiotherapy causes structural tissue damage to both the epidermis and dermis, increasing the risk for infection and delayed wound healing.
- Patients with head and neck cancer are at particularly high risk because of the higher radiation doses required for prevention or treatment.
- While RD is widely recognized as a significant clinical issue, there is currently no gold standard for treatment.

Purpose

The purpose of this study was to evaluate the use of pure silver-plated wound dressings for the management of RD in head and neck cancer patients receiving radiotherapy.



RD on a patient undergoing treatment for H&N cancer

Methods

- Between 9/6/2023 and 10/30/2023, 7 patients undergoing definitive treatment for head and neck cancers, consisting of oropharyngeal, oral cavity, nasopharynx and laryngeal, were evaluated.
- Pure silver-plated wound dressings were provided at the onset of therapy or once RD was observed and continued without interruption throughout the duration of radiotherapy.
- Patients were instructed to keep the dressings in place continuously, except for when bathing or during treatment.
- The pure silver-plated wound dressings were replaced weekly by the clinical team during on-treatment visits, and NCI CTCAE version 5.0 for adverse event reporting was used to quantify RD.



Pure silver-plated wound dressing application for patient undergoing treatment for H&N cancer

Results

- This initiation evaluation included 7 patients.
- One patient discontinued the trial early due to fitment issues and developed grade 1 RD upon completion of radiotherapy.
- Grade II RD was observed in one patient around laryngectomy without RD in bilateral neck.
- Grade II RD was reported in one patient despite compliance.
- In the other 4 patients, no RD was observed.

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Conclusions

- In this limited sample of high-risk patients, the use of pure silverplated wound dressings appeared to reduce the incidence of RD in patients receiving radiotherapy for the treatment of head and neck cancer.
- Patient who experienced grade II RD despite compliance had significant weight loss during RT, which likely effected dose distribution, thus leading to more toxicity.
- Data collection on additional patients is continuing and will be reported at a later date.

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