Please note: These studies may involve findings that exceed the claims currently cleared by the FDA for the product. Bravida Medical is not intending to make performance claims about its product. The intent is to disseminate the scientific literature on these 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.

Patient Perspectives on Novel Intervention for Radiation Dermatitis

Phylicia Gawu, D.O.^a, Oluwatomiwa Awobayiku, BS ^b, Alekhya Mitta M.D.^a, Christina Henson M.D.^a

^a The university of Oklahoma Health Sciences Center, Stephenson Cancer Center; ^b New York Institute of Technology College of Osteopathic Medicine at Arkansas State University

Background

- Radiation dermatitis (RD) remains a challenging side effect of radiation therapy, especially for head and neck and breast cancer patients.
- While current strategies have provided some relief, they
 often fall short in effectively managing severe cases of
 RD.
- Silverlon silver plated dressings represent a recent advancement for both the prevention and treatment RD.

Purpose

 The purpose of this study was to measure the effectiveness and patient experience of using Silverlon for the prevention of RD in a group of patients undergoing head and neck and breast radiation therapy.

Methods

- Silverlon was used as prevention for RD on 11 patients undergoing head and neck and breast radiation therapy.
- A total of 7 patients had complete data and were included in the final results.
- Patients were surveyed on their experience after 1 week of use.

Results

Treatement Area	Treatment Received	Fraction Silverlon Initiated	Silverlon Securement	Compliance to Prescribed Use	Easy to Use	Used with Emollients	CTCAE Grade
Breast	50 Gy in 25 fractions	15/25	Bra	Yes	Yes	No	1
Head and Neck	55 Gy in 22 fractions	20/22	Kerlix	Yes	Yes	No	1
Head and Neck	66 Gy in 33 fractions	17/33	Kerlix	Yes	No	No	1
Head and Neck	70 Gy in 35 fractions	31/35	Gator	Yes	No	No	1
Breast	60 Gy in 30 fractions	24/30	Bra	Yes	Yes	No	1
Head and Neck	70 Gy in 35 fractions	21/35	Kerlix	Yes	No	Yes	1
Head and Neck	60 Gy in 30 fractions	012/30	Kerlix	Yes	No	No	1

- · A summary of results are provided in Table above.
- Patients were surveyed after 1 week of use about their experience with using Silverlon.
- Four head and neck patients had difficulty complying with the protocol because the product would not stay in place; 2 stopped Silverlon use after 2 days.
- 2 patients reported adverse: exacerbation of rash in a breast patient and an allergic reaction in a head and neck patient.
- 1 patient reported a cooling effect on the treatment field while another reported that the product appeared to be aiding in wound healing.

Summary and Recommendations for Future Research

- In this limited patient sample, the use of Silverlon appeared to have a positive impact on RD prevention and mitigation.
- · However, it is clear that additional options for dressing securement that are easier for patients to use are needed.
- Ease-of-use was higher in breast cancer patients than head and neck patients, likely because the use of a bra provides a reasonable option for Siverlon dressing securement.
- These preliminary data highlight the need for a larger trial in breast cancer patients.

References

- 1. Singh M, Alavi A, Wong R, Akita S. Radiodermatitis: A Review of Our Current Understanding. Am J Clin Dermatol. 2016 Jun;17(3):277-92. doi: 10.1007/s40257-016-0186-4.
- 2. Bolderston A, Lloyd NS, Wong RK, Holden L, Robb-Blenderman L; Supportive Care Guidelines Group of Cancer Care Ontario Program in Evidence-Based Care. The prevention and management of acute skin reactions related to radiation therapy: a systematic review and practice guideline. Support Care Cancer. 2006 Aug;14(8):802-17. doi: 10.1007/s00520-006-0063-4.
- 3. Hemati S, Asnaashari O, Sarvizadeh M, Motlagh BN, Akbari M, Tajvidi M, Gookizadeh A. Topical silver sulfadiazine for the prevention of acute dermatitis during irradiation for breast cancer. Support Care Cancer. 2012 Aug;20(8):1613-8. doi: 10.1007/s00520-011-1250-5.
- 4. Shanmugasundaram N, Uma TS, Ramyaa Lakshmi TS, Babu M. Efficiency of controlled topical delivery of silver sulfadiazine in infected burn wounds. J Biomed Mater Res A. 2009 May;89(2):472-82. doi: 10.1002/jbm.a.31997.

