

# FIRST CLINICAL EXPERIENCES WITH R1 AND R2, A LACTOKINE-BASED MEDICAL DEVICE, FOR PROPHYLAXIS OF RADIATION DERMATITIS IN CANCER PATIENTS

K. Potthoff<sup>1</sup>, M. Scharp<sup>1</sup>, L. Fetzner<sup>1</sup>, S. Nejad-Asgar<sup>2</sup>, M. Häfner<sup>1</sup>, W. Klinkner<sup>3</sup>, M. Becker-Schiebe<sup>4</sup>, H. Tonscheidt<sup>5</sup>, I. Schlamm<sup>1</sup>, J. Gilbssen<sup>6</sup>, J. Debus<sup>1</sup>

<sup>1</sup>Radiation Oncology, University of Heidelberg Medical Center, Heidelberg, <sup>2</sup>Center for Radiation Oncology, Goch, <sup>3</sup>Radiation Oncology, Memmingen, <sup>4</sup>Radiation Oncology, Städtisches Klinikum Braunschweig gGmbH, Braunschweig, <sup>5</sup>Radiation Oncology, Medizinisches Versorgungszentrum, Dortmund, <sup>6</sup>Radiation Oncology, Klinikum München-Pasing, Munich, Germany (Contact address: karin.potthoff@med.uni-heidelberg.de)

## Background

Acute radiation dermatitis (ARD) occurs in nearly 95 % of all patients receiving radiation therapy in the head and neck area. Currently, there are no evidence-based regimens for prophylaxis of radiation dermatitis or any standardized treatment recommendations. "R1 and R2" is a novel lactokine-based Class I Medical Device consisting of R1, a water-based gel which offers intense hydration to the skin while providing cooling relief and protecting skin against inflammation, and R2, a soothing lotion with anti-inflammatory properties and high UVB and UVA protection.

## Aim

To provide first clinical experiences with R1 and R2 for prophylaxis of radiation dermatitis in a case series of cancer patients.

## Methods

Between October 2010 and January 2011 21 patients with locally advanced head and neck cancer (HNC) undergoing radiochemotherapy and 8 patients with breast cancer (BC) undergoing radiotherapy applied R1 and R2 to the irradiated skin during radiotherapy. R1 was applied once a day within 2 hours after radiation, R2 was applied four times a day. Clinical response was assessed during and shortly after radiotherapy, including photo documentation. Physicians were asked to document their findings on a standardized questionnaire.

## R1 and R2

R1 and R2 is a new two step treatment to protect the skin during and after radiotherapy. Both products, are classified as a class 1 Medical Device and comply with 93/42/EEC Directive. There are no pharmaceutical ingredients. R1 and R2 are free from parabens, fragrance, benzenes, oxidants, antioxidants or metals. The active ingredient is lactokine which is a milk based protein.

Lactokine fluid contains a network of activated and stabilized signal molecules derived from milk which promotes vitalization of the skin protection system and reduction of melanin synthesis.



Lactokine influences the signal transduction cascade that stimulates proinflammatory response and, e.g., counteracts the formation of the proinflammatory mediator Prostaglandin E2.

# R1

The R1 is a cooling gel that has to be applied on the irradiated skin area once a day after the irradiation. It instantly cools any burning or irritation, gives lasting pain relief and protects the skin against inflammation.

# R2

The R2 is a soothing moisturising lotion that has to be applied on the irradiated and affected skin area 3-4 times a day, at bedtime or whenever the skin feels tight or dry. The R2 continues the pain relief of the R1 cooling gel. It makes the skin smoother and helps stressed skin heal and repair itself faster. It also helps to protect the skin from the damaging effect of UVA and UVB.

## Results

### Patient Characteristics

	Number of pts.	Prophylaxis of ARD	Treatment of ARD	No. of pts. with side effects of R1 and R2	No. of pts. with ARD NCI CTCAE ≥ grade 3
HNC	21	17	4	0	3
BC	8	4	4	0	0

Average duration of the application of R1 and R2 was approximately 6 weeks. Application of R1 and R2 was well tolerated. No side effects were seen. In most of the patients radiation dermatitis was mild.

### Selected Patient Cases



Condition of skin after 10 fractions. Patient did not use R1 and R2 as directed.



Condition of skin after 17 days using R1 and R2 for acute radiation dermatitis. Radiation was continued without any break.

**Treatment of acute radiation dermatitis**



Condition of skin before radiation therapy. Patient did use R1 and R2 from first day of radiation.



Condition of skin after 70 Gy using R1 and R2 for prophylaxis of acute radiation dermatitis. Radiation was continued without any break.

**Prophylaxis of acute radiation dermatitis**



Intensity modulated radiatio GD 69 Gy combined with carboplatin 70 mg/BSA and 5-FU 600 mg/BSA (d1-5 and d29-33). R1 and R2 was applied for prophylaxis of radiation dermatitis starting day 1 of radiation until 1 week after end of radiation.



**Prophylaxis of acute radiation dermatitis**

All physicians asked would recommend R1 and R2 for prophylaxis and/or treatment of acute radiation dermatitis.

## Conclusion

Our case series reveals that the application of R1 and R2 is feasible, safe and effective for prophylaxis and for treatment of acute radiation dermatitis. Patients do much better during radiation. They have a better quality of life.

Currently, we are conducting a randomized, controlled multicenter clinical trial in more than 100 patients examining R1 and R2 for prophylaxis of radiation dermatitis in head and neck cancer patients.

## References

- Archambu JO, Penzer R, Wasserman T. Pathophysiology of irritated skin and breast. *Annals of Plastic Surgery* 2005, 55: 12-15.
- Lilla C, Ambrosone CB, Kopp S, Helmlod I, Shemezer P, von Fournier D, Hasse W, Sautter-Bihl ML, Wenz F, Chang-Clude J. Predictive factors for late normal tissue complications following Radiotherapy for breast cancer. *Breast Cancer Res Treat* 2006; DOI 10.1007/s10549-006-9480-9.
- Glees JP, Mameghan-Zadeh H, Sparkes CG. Effectiveness of topical steroids in the control of radiation dermatitis: a randomised trial using 1% hydrocortisone cream and 0.05% clobetasone butyrate (Eumovate).
- Clin Radiol 1979 Jul;30(4):397-403. Wells, M.&S.Macbride. Radiation skin reaction. In:Supportive care in Radiotherapy. 2004; 135 ff.