TOPICAL PROPHYLAXIS OF ACUTE RADIATION DERMATITIS: INTERIM RESULTS OF A MULTICENTER, RANDOMIZED, CONTROLLED TRIAL (CREAM-1)

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Objectives:
Acute radiation-induced dermatitis (ARD) is a common complication in patients with squamous cell cancer of the head and neck (SCCHN) treated by chemoradiation (CRT). Currently, there is only little evidence concerning prophylaxis and treatment of ARD. Since we had convincing first clinical experiences with the new lactokine containing two-step topical treatment “R1 and R2” in management of ARD we launched a multicenter, randomized, controlled clinical trial in 20 radiation oncologic centers to assess safety and efficacy of the two compounds for prophylaxis of ARD.

Conclusions:
The topical application of cooling “R1” gel and moisturizing “R2” lotion is feasible, safe and effective in prophylaxis of acute radiation-induced dermatitis in patients with squamous cell cancer of the head and neck treated by curative platin-based chemoradiation. Due to promising initial results active accrual will continue.

Study design:
Patients with SCCHN were 1:1 randomized to either receive prophylactic topical “R1 and R2” or the standard skin care of the institution. All patients were treated by fractionated radiotherapy and concomitant platin-based chemotherapy in curative intention. The primary objective is the amount of patients that experience an ARD grade 3 or 4 (NCI CTCAE v. 4.03). According to study protocol, all patients were regularly evaluated and the irradiated skin was photographed and graded according to NCI CTCAE. In addition, patients completed quality of life (QoL) questionnaires.

Results:
From June 2011 to mid of June 2012 a total of 75 patients were randomized in CREAM-1 to either receive ARD prophylaxis with R1 and R2 or skin care according to institutions standards (Fig. 1 + Table 1). As of May 2012 31 patients had at least their first-follow-up examinations and were evaluable for safety. Tumor and treatment characteristics are shown in Table 2 and Fig. 2.

Application of R1 and R2 was well tolerated. No grade 4 toxicities were seen. QoL was maintained in patients applying R1 and R2. Selected photographs to document toxicity at the end of chemoradiation are sampled in Fig. 3. Skin of every patients recovered completely by no later than 8 weeks. Occasionally, skin hypopigmentation remained.

Abbreviations:
ARD: acute radiation-induced dermatitis CRT: chemoradiation IMRT: intensity-modulated radiotherapy SCCHN: squamous cell cancer of the head and neck