New antioxidant-containing topical formulation for treatment of Hand-Foot Syndrome in cancer patients: physician's and patient's perspective

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INTRODUCTION

Dermatological chemotherapy side effects, especially Hand and Foot Syndrome (HFS), are frequent in cancer patients receiving antitumor therapy, have a negative impact on quality of life (QoL), and sometimes leads to decreasing of cytostatics doses or ceasing the chemotherapy that finally have a negative effect on treatment outcomes. Until now no medications have been established as standard therapy of HFS.
The aim of this multicenter observational QoL study was to investigate the efficacy of the new antioxidant-containing topical formulation (elima®) for HFS treatment in cancer patients from the physician's and patient's perspective.

PATIENTS AND METHODS

Patient characteristics	Total	Treatment groups	
		elima®	SC-F*
Patient number	59	30	29
Sex			
male	21 (35.6%)	11 (36.6%)	10 (34.5%)
female	38 (64.4%)	19 (63.3%)	19 (65.5%)
Age			
mean years (SD)	62.4 (10)	63.3 (9.4)	61.4 (10.7)
range	39-83	45-83	39-80
A***ntitumor therapy***			
Capecitabin, monochemoherapy	19 (32.2%)	10 (33.3%)	9 (31%)
Capecitabin, polychemotherapy	20 (33.9%)	10 (33.3%)	10 (34.5%)
Sunitinib, sorafenib	20 (33.9%)	10 (33.3%)	10 (34.5%)
HFS WHO grades			
1	3 (5%)	1 (3.3%)	2 (6.9%)
2	22 (37.3%)	10 (33.3%)	12 (41.4%)
3	34 (57.7%)	19 (63.4%)	15 (51.7%)

**moisturizing skin care agent containing vitamin F*

Treatment groups were balanced by sex, age and HFS severity WHO grades

Evaluation of HFS changes

HFS changes was evaluated according to WHO grades from physician's perspective 9-10 weeks after HFS treatment start as follows:

- improvement (WHO severity grade has decreased)
- no change (WHO severity grade has not changed)
- worsening (WHO severity grade has increased)

Patient's report of HFS symptoms severity

Comprehensive Symptom Profile In Patients with HFS questionnaire (CSP-HFS) was used to assess severity of 14 HFS related symptoms by a Numeric Rating Scale 0 (no symptom) -10 (worst severity). The total symptom severity was calculated as the sum of severity scores for 14 HFS related symptoms.

Statistical analysis was made using t-test and general liner model with adjustment for HFS grade and base line symptom severity

CONCLUSIONS

Elima® is an effective treatment for HFS from both physician's and patient's perspective and is superior to generally accepted treatment with SC-F.

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RESULTS

HFS changes on elima® vs SC-F: physician's perspective

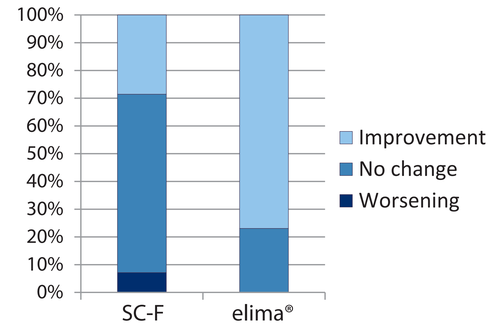

Fig. 1. Distribution of patients according to the HFS changes on elima® vs SC-F

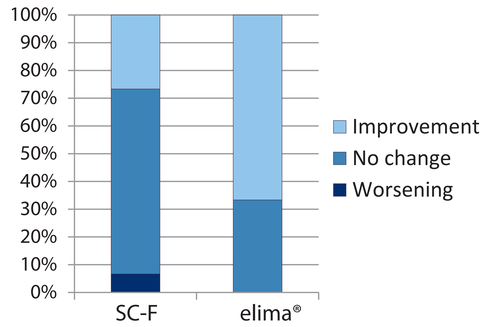

Fig. 2. Distribution of patients with HFS WHO grade 3 according to the HFS changes on elima® vs SC-F

After 9–10 weeks HFS severity according to WHO grades decreased in 77% patients on elima® vs 29% patients on SC-F (p<0.001).
No patients worsened on elima®; 7% had HFS worsening on SC-F.

HFS in patients with WHO grade 3 improved much better on elima® than on SC-F: HFS severity according to WHO grades decreased in 68% vs 27% patients (p=0.03).

HFS symptom severity changes on elima® vs SC-F: patient's perspective

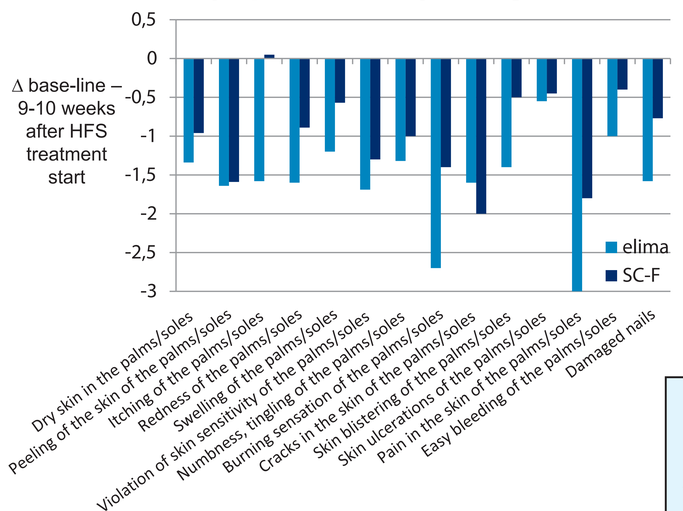

Fig. 3. Changes in symptom severity 9-10 weeks after HFS treatment start on elima® vs SC-F; value with "–" – decrease of symptom severity, value with the "+" – increase of symptom severity

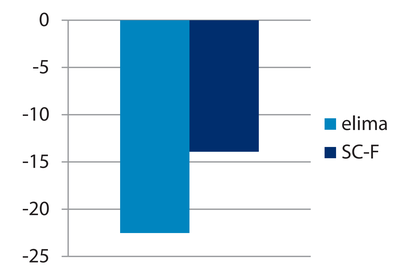

Fig. 4. Changes in total symptom severity after 9-10 weeks of HFS treatment start on elima® vs SC-F, value with "–" – decrease of symptom severity

Severity of all symptoms according to the CSP-HFS decreased significantly on elima® (ES=0.25–0.97) as compared with slight severity reduction of 9 symptoms (ES=0.2–0.73) and increase of itching on SC-F, p<0.01 (Fig. 3). Total symptom severity reduction was more explicit on elima® than on SC-F (Δ22.5 vs Δ13.9, ES=0.38) (Fig. 4).