

# Prevention of oral mucositis and its consequences

A pilot study of episil® oral liquid in a clinical setting for patients with oral cancer undergoing definitive RT. **Mucositis, Prevention, Barrier-forming lipid**

**K. Söderström** Umeå University Hospital, Cancer centre, Radiation department, Umeå, Sweden.  
**H. Harnesk-Nygren** Umeå University Hospital, Div. of Special Care Dentistry, Umeå, Sweden.

## Conclusion

The major finding in the study is that episil® oral liquid is well tolerated and the trend towards less feeding tube-dependency and a possible reduction in inpatient time is promising. However, as this was a small pilot study of the introduction of a registered medical device into the clinical setting, the aim was descriptive and more prospective studies are needed. Since the mucositis and pain scoring for the controls were done retrospectively there is a substantial risk of misclassification due to unstructured reporting in the patient chart illustrating the need for standardized side effect registration in day to day clinical practise for ongoing/future clinical evaluation.

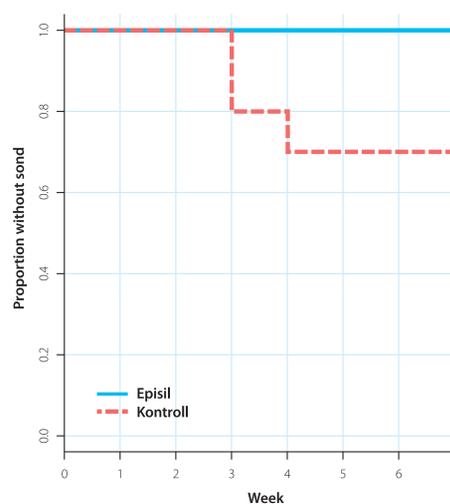
## Purpose/Objective

Oral mucositis is one of the major acute morbidities following RT in oral cancer causing pain and dysphagia for a large fraction of patients and can lead to hospitalization and feeding tube-dependency and has a major impact on quality of life. Different strategies have been put forward to prevent severe mucositis for patients undergoing RT. This study was conducted to evaluate the prevention and management of severe oral mucositis and its consequences with a commercially available bioadhesive barrier-forming lipid solution, episil® oral liquid, in patients with oral cancer treated with definitive RT in a clinical setting.

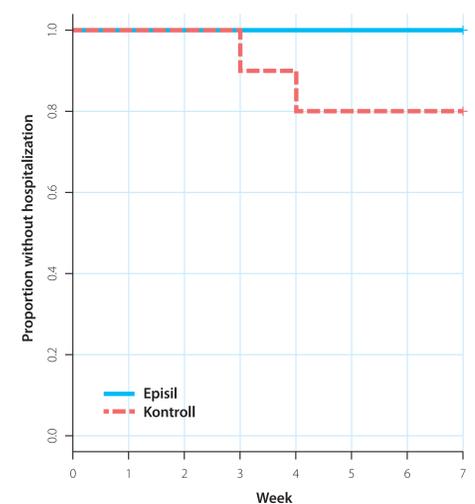
## Material/Methods

10 prospectively collected consecutive out clinic patients with oral cancer treated with episil® oral liquid during RT were evaluated for oral mucositis (WHO grade 0-4), pain (VAS-scale), analgesic consumption, feeding tube-dependency and inpatient time. 10 consecutive out clinic patients at start of treatment undergoing RT for oral cancer before the introduction of episil® oral liquid at the same institution were drafted as retrospective controls. The patients receiving episil® oral liquid

**GRAPH 1: KAPLAN-MEIER CURVES FOR TIME TO FEEDING TUBE; P=0.067**



**GRAPH 2: KAPLAN-MEIER CURVES FOR TIME TO HOSPITALIZATION; P=0.146**



were monitored weekly by dentist and nurse at the radiotherapy ward separately. Data on side-effects for the controls were collected from the patient chart. Feeding tube, analgesic prescription and in hospitalization was managed according to clinical practice at the department by the treating physician.

All patients were treated with a combination of surgery and radiotherapy. Patients enrolled in the study were treated with either standard treatment (2 Gy daily/5 days a week to 60-68 Gy with a total treatment time of 6-7 weeks pre- or postoperatively) or intensified treatment (consisting of either accelerated treatment or chemoradiotherapy). As both of the intensified treatment strategies have been shown to produce a significantly higher proportion of acute mucositis, patients were stratified for treatment protocol (standard vs. intensified) in the analysis. All tests were two-sided and a p-value of <0.05 was considered significant. The mucositis and pain scores were analysed in an ANOVA with baseline as covariate. The Kaplan-Meier method and the log rank test were used to evaluate time to event.

## Result

The mean age for all patients was 62.2 years (range: 31-79), 65.4 years in the controls and 58.9 years for the intervention group. 50 % of the controls and 60 % of the episil® oral liquid group were male. 30 % of the patients, equally distributed between the groups, received an intensified treatment (protocol 2 or 3). Two patients in the intervention group discontinued episil® oral liquid, both due to emesis. There was no significant difference in assessed mucositis, 2.8 ([SD] 0.7) in the controls and 2.5 ([SD] 0.4) in the intervention group, or in assessed pain between the groups. There was no significant difference stratified by background treatment in time (weeks) to continuous opioids (6.4 vs 4.6 (p 0.223)) or hospitalization (2 vs. 0 events (p= 0.404)) between the groups, as illustrated in Graph 2. There was a trend towards improved outcome for feeding tube-dependency with three events in the control group and none in the episil® oral liquid group (p =0.097), as illustrated in Graph 1.

