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Letter to the Editor

The use of MuGard™, Caphosol®, and episil® in patients undergoing chemoradiotherapy for squamous cell carcinoma of the head and neck

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Dear Professor Duxbury,
We have read with interest the prospective audit trial of episil®, Caphosol® and Mugard™ by Pettit and colleagues that was published as a *FirstView* article in the *Journal of Radiotherapy in Practice*[1] and have the following comments.

STUDY DESIGN/METHODOLOGY

Overall, the study design and interpretation of results were not conducted with the scientific rigour one would expect in order to produce an unbiased outcome. Specifically,

- Patients were not randomized to receive one of the four treatment regimens.
- Investigators were not blinded to the treatments that the patients were receiving, thus increasing the potential for investigator bias in favour of the established institutional regimen.
- It is unclear if demographics of the treatment groups were similar in age, oral health status, concomitant meds and comorbid conditions.
- It appears that no minimum threshold pain score was required at baseline for patients to initiate treatment with one of the prescribed regimens.
- No validated pain/symptom assessment tool was utilised.
- There was no established dosing protocol for the individual treatments.
- The trial does not appear to be statistically powered. There were only 15 patients enrolled in the episil cohort, while no more than seven or eight were compliant with their mouth care regimen on a weekly basis.

Nevertheless, despite these design flaws, the authors suggested there was no significant difference between treatments; because the study appeared not to be adequately powered and was not randomised, the lack of a significant difference between treatments is expected.

Other shortcomings of the trial are as follows:

COMPLIANCE

While compliance was an assessment tool in the trial, no definition of compliance was provided by the authors. In addition, no compliance was recorded during the first week of treatment.

ORAL INFECTIONS

The frequency of Candida infections in the episil® cohort (20%) was two-fold less compared to the standard departmental mouth care (40%). Nevertheless, Pettit and colleagues chose

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to ignore this observation and instead stated that, 'Rates of candida were similar among the four mouth care regimes'.

PAIN SCORES

Patients in the episil® and Caphosol® cohorts appeared to have lower mean analgesia scores than patients on standard mouth care regimen and Mugard™; however, this observation was also overlooked and not discussed by the authors. Indeed, standard departmental care, comprising aspirin, glycerin and sucralfate, showed no tendency to decreased mean analgesic score even after 8 weeks of treatment, as compared to episil® and Caphosol®, for which the scores were close to zero at week 8. Instead, the authors only pointed to higher mean analgesic scores for Mugard™ from week 4 to 8. In addition, it is not surprising that compliance was higher for the standard treatment as compared with episil® and Caphosol®, as analgesia score for patients on standard treatment remained high throughout the 8-week study. In contrast, were the low compliance rates in the episil cohort (i.e., mean, 22%; range, 7–53%) related to the degree of pain control these patients experienced?

We conclude that the study was poorly designed and reported. The results were interpreted with an apparent bias to standard departmental mouth care, which, if anything, showed the least favourable treatment outcome in terms of the combination of mucositis score, oral toxicity and oral infections, despite being an unspecified 'cocktail' of at least three components (i.e., aspirin, glycerin and sucralfate) as first line. In addition, it is unclear from the article if standard departmental care used in the study also included second line GelClair®, which would raise additional questions to the comparison and the effect of the standard departmental care regimen. Interestingly, the authors concluded by emphasising the importance of rigorous clinical and financial evaluations before introduction into clinical practice.[1] It is assumed that this statement also pertained to the standard departmental care regimen.

Reference

1. Pettit L, Sanghera P, Glaholm J, Hartley A. The use of Mugard™, Caphosol® and Episil® in patients undergoing chemoradiotherapy for squamous cell carcinoma of the head and neck. Journal of Radiotherapy in Practice available on CJO2013. doi: 10.1017/S1460396912000581.

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