



ROYAL COLLEGE OF
PHYSICIANS AND
SURGEONS OF GLASGOW



Intercollegiate Specialty Fellowship Examination

Part A

Oral Medicine

Critical Appraisal

Note: Parts of the sections within the original article are not relevant to this examination and have been redacted. Including parts of the abstract, introduction, pages 134, 135 and 136.

Please note that the sample answer key provided has model answers and they are not exclusive. Other options could be considered as correct answers.

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**Intercollegiate Specialty Fellowship Examination in Oral Medicine
Part A**

Extract - 26 marks

Jorgensen, M.R. and Pedersen, A.M.L. (2017). Analgesic effect of topical capsaicin gel in burning mouth syndrome. *Acta Odontologica Scandinavica* (2); 130-136. DOI: 10.1080/00016357.2016.1269191.

[Analgesic effect of topical oral capsaicin gel in burning mouth syndrome - Result \(ku.dk\)](#)

1. This is an example of a randomised, double blind, crossover study. Discuss whether the study design was appropriate to answer the research question, providing your rationale. **(4 marks)**

- The patients and the clinician were blinded to the treatment **(1 mark)**
- Patients were randomly allocated to treatment groups **(1 mark)**
- There was a washout period between treatments **(1 mark)**
- The crossover ensured that patients acted as their own control **(1 mark)**

2.

- a) Define the term null hypothesis (1 mark)
 - b) What would be an appropriate null hypothesis for this study?
(2 marks)
- (3 marks total)**

- a) Statement which suggests that there is no statistical relationship or significance associated with the intervention **(1 mark)**
- b) In the study, the null hypothesis is that treatment with the two capsaicin gels could not alleviate the burning/stinging symptoms in patients presenting with BMS **(2 marks)**

3. Discuss the adequacy of the inclusion and exclusion criteria for the study. Give your reasoning. **(4 marks)**

Any four of the following:

- The inclusion criteria are adequate, but exclusion criteria are vague and overlook some important issues **(1 mark)**
- There is no mention of whether patients were undergoing active topical treatment for BMS were excluded **(1 mark)**

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- As there were no men taking part in the study where they excluded or is this consistent with the knowledge that BMS is more common in women? **(1 mark)**
 - Where patients allowed to self-medicate during the study if they experienced a flare up of their symptoms of BMS or other comorbidities? **(1 mark)**
 - Where patients on drugs which could cause oral burning excluded e.g., ramipril? **(1 mark)**
4. The authors use computer-generated randomisation allocation. What other methods of randomisation could have been used? **(3 marks)**

Samples of each main group can be accepted as an answer

- Fixed randomisation- e.g. simple randomisation, block randomisation, stratified randomisation **(1 mark)**
 - Quasi-random allocation, - e.g. cluster randomisation, factorial randomisation **(1 mark)**
 - Adaptive randomisation - e.g. minimisation **(1 mark)**
5. Suggest two additional investigations which could have been included as part of the clinical assessment. **(2 marks)**

Any two from below

- Haematological - FBC, B12, red cell folate, HBA1c (any one from list or other reasonable answer) **(1 mark)**
 - Assessment of impact on QOL **(1 mark)**
 - Screen for anxiety and depression **(1 mark)**
6. The authors set alpha at 0.05 and beta at 0.8. What do these terms mean? **(2 marks)**
- α (alpha) is the probability of having a Type I error in any hypothesis test, i.e. incorrectly rejecting the null hypothesis **(1 mark)**
 - β (beta) is the probability of having a Type II error in any hypothesis test, i.e. incorrectly failing to reject the null hypothesis ($1 - \beta$ is power) **(1 mark)**

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7. Provide four comments on the results as presented in the paper.
(4 marks)

Any four from below

- Only 18 patients completed the study which could have led to the study being underpowered **(1 mark)**
- Table 1: Distinction between xerostomia and hyposalivation - how was this made? **(1 mark)**
- Difference in VAS scores between two groups at baseline are quite different which could have influenced the results **(1 mark)**
- Figures in table 3 do not add up **(1 mark)**
- Significant number of patients had systemic conditions which could have contributed to oral symptoms **(1 mark)**
- Twelve patients had abnormalities noted in bloods - reported as insignificant, could these have accounted for some of the symptoms? **(1 mark)**
- A number of patients were on medications for systemic conditions which could have accounted for some of their symptoms e.g. antihypertensives **(1 mark)**
- Reduction in oral burning did not appear to be related to gel strength **(1 mark)**
- Side effects were reported which resulted in a number of individuals withdrawing from the study **(1 mark)**
- Although both strengths of gels caused a reduction in burning symptoms, symptoms progressed to pre-treatment levels of pain once therapy withdrawn **(1 mark)**

8. Suggest four ways in which the study design can be improved.
(4 marks)

Any four from below

- Use of a randomised control study design **(1 mark)**
- Study population reflective of general population e.g. males and females included **(1 mark)**
- Increased sample size **(1 mark)**
- Utilising one concentration of capsaicin gel **(1 mark)**
- Using capsaicin gel for longer periods of time **(1 mark)**
- Stringent inclusion and exclusion criteria **(1 mark)**
- Utilising incomplete data **(1 mark)**
- More frequent VAS **(1 mark)**

Total Marks for Extract = 26