Intercollegiate Specialty Fellowship Examination

Part A

Oral Surgery

Critical Appraisal

Note: Parts of the sections within the original article are not relevant to this examination and have been redacted. Including parts of pages 1643, 1644, 1646, 1647 and 1648.

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

Intercollegiate Specialty Fellowship Examination in Oral Surgery

Part A

Extract – 29 marks

Gholami M., Banihashemrad A., Mohammadzadeh A., and Ahrari F., 2021. The Efficacy of 4% Articaine Versus 2% Lidocaine in Inducing Palatal Anesthesia for Tooth Extraction in Different Maxillary Regions. *J Oral Maxillofac Surg 79:1643-1649.* doi:10.1016/j.joms.2021.02.019.

The Efficacy of 4% Articaine Versus 2% Lidocaine in Inducing Palatal Anesthesia for Tooth Extraction in Different Maxillary Regions - Journal of Oral and Maxillofacial Surgery (joms.org)

1. Which two important elements of the CONSORT checklist regarding the methods (trial design) are missing from this manuscript? For each, discuss how this may affect interpretation of the results of this trial. **(4 marks)**

- Definition of primary/secondary endpoints a priori **(1 mark)** – several outcomes/endpoints are mentioned and it is not explicitly stated which is the primary endpoint and which are secondary ones. This opens the door for post-hoc modification, and may affect the robustness of the results **(1 mark)**
- Samples size calculation **(1 mark)** Unclear if trial, a priori, had sufficient power to detect important differences **(1 mark)**

2. The authors state that they conducted a double-blind study.

a) What does this mean in the context of this trial? (1 mark)
b) Explain how lack of blinding could have biased the results of this study based on the different players involved and how important blinding in this trial would have been (3 marks)
c) What degree of confidence can be placed on the effectiveness of the blinding in this trial based on the information given by the authors? (1 mark)

(5 marks total)

a) Neither the patient nor the treating surgeon/investigator/outcome assessor would have been aware of which patient received articaine or lidocaine **(1 mark)**
b) Subjective pain endpoints, blinding therefore very important **(1 mark)** Subject's knowledge of group assignment may affect pain

rating **(1 mark)** Doctor's knowledge of group assignment may affect stimulus given **(1 mark)**

c) Not very confident as the authors do not give any information on how blinding was achieved. They merely state that patient and outcome assessor were blinded, but given the specifics of this study (repeated injections/assessment over a short period of time, it is difficult to imagine how this was implemented) **(1 mark)**

3. The authors stated that they used stratified randomisation.

   a) What does this mean in the context of this trial and what is the purpose of this stratification here? (2 marks)
   b) What assumption do the authors make? E.g. why do they think stratification is necessary? (1 mark)

   (3 marks total)

   a) Stratification factor is tooth type/region (anterior, premolar, molar), randomisation is done within strata of stratification factor. (1 mark) Purpose is to avoid major imbalances of stratification factor between experimental groups, i.e., to avoid, for example, that (by chance) most of the teeth in lidocaine group are anteriors, while most of the teeth in articaine group are molars **(1 mark)**
   b) The assumption that there are important differences in the effectiveness of local anaesthesia between regions **(1 mark)**

4. The authors recruited 100 patients with anterior teeth,100 patients with premolars and 100 with molars to be extracted.

   Was this 'balancing' crucial to receive an unbiased estimate of the difference between the two local anaesthetics? Give a reason for your answer. **(1 mark)**

   No – randomisation ensures an unbiased estimate, balancing of study population does not have effect on internal validity **(1 mark)**

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Part A

5. The following questions relate to **Table 1**.

   a) What is the purpose of the information in **Table 1**? (1 mark) Why is this kind of table important enough to be listed in the CONSORT statement? (1 mark)

   b) The authors report a p-value for age in **Table 1**. What probability is this p-value describing? (1 mark)

   c) How meaningful are statistical tests to compare the baseline parameters between experimental groups here and why? (2 marks)

   (5 marks total)

   a) Balance of population characteristics at baseline (here age and sex) (1 mark) to check to what extent randomisation has 'worked', i.e., to check that these are balanced between groups (1 mark)
   b) Probability of an age difference as large as found here or larger if in fact there is no difference between groups. (1 mark) [If the candidate gives no interpretation but states that interpretation makes no sense because this is an RCT (see below) (1 mark)
   c) Not meaningful (1 mark), this is an RCT, randomisation ensures balance and by design any differences between groups would be due to chance (1 mark)

6.
   a) Discuss the outcomes chosen by the investigators in terms of their clinical relevance (1 mark) and in terms of the concept of surrogate vs. hard endpoints (2 marks)
   b) Discuss the goal of LA in tooth extraction in this context (1 mark)

   (4 marks total)

   a) Clinical relevance of the endpoints is limited **(1 mark)**. Outcomes could be considered surrogate endpoints **(1 mark)**, as pain response to trigger of periosteal elevator not clinically relevant **(1 mark)**
   b) Goal is to achieve painless XLA of the tooth (hard endpoint), this was not assessed/reported **(1 mark)**

Part A

7. Based on the results presented by the authors, please suggest three clinically relevant conclusions (assuming there is no bias in the reported results). **(3 marks)**

Any three from below

- Articaine 4% is superior to lidocaine 2% in achieving palatal anaesthesia when administered buccally in the maxilla **(1 mark)**
- Articaine 4% can achieve sufficient anaesthesia for the palatal stimulus employed in this study at a variety of doses tested here **(1 mark)**
- However, 17% of patients (a significant proportion, approx. one in five patients or similar) still require a palatal injection to achieve anaesthesia **(1 mark)**
- Lidocaine 2% does not achieve palatal anaesthesia in the vast majority of patients when administered only buccally **(1 mark)**

8. Assuming no bias and based on the data reported in **Table 2**, what proportion of patients can be successfully anaesthetised palatally with the buccal injection of 1.2ml articaine 4%? **(1 mark)**

65% or 65.4% (1 mark)

9. Discuss how the results of this study could impact clinical practice, i.e., as a result of this study should palatal anaesthesia be given when using articaine 4%? Please give reasons. **(3 marks)**

Any three from below

- Unlikely to change practice because: method not 100% effective. (1 mark) [explorative approach acceptable, i.e., 'I discuss this with the patient and offer limited LA to see if it works'
- Endpoint not most clinically relevant, i.e., painless XLA not assessed or reported (1 mark)
- Generalisability to UK population unclear (1 mark)
- Should not change practice based on a single study, unless providing definitive evidence (1 mark)

Total Marks for Extract = 29