Intercollegiate Specialty Fellowship Examination

Part A

Restorative Dentistry

Critical Appraisal

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 Restorative Dentistry

Part A

Extract - 30 marks

Seong, J., Newcombe, R., Matheson, J., Weddell, L., Edwards, M. and West, N., 2020. A randomised controlled trial investigating efficacy of a novel toothpaste containing calcium silicate and sodium phosphate in dentine hypersensitivity pain reduction compared to a fluoride control toothpaste. *Journal of Dentistry,* 98, p.103320. DOI: 10.1016/j.jdent.2020.103320.

A randomised clinical trial to determine the effect of a toothpaste containing enzymes and proteins on gum health over 3 months - PubMed (nih.gov)

1. The authors have provided a null hypothesis for this study.

   a) What is a null hypothesis? (1 mark)
   b) Provide a suitable alternate hypothesis for this study (2 marks)

   (3 marks total)

   a) In statistical analysis, a null hypothesis proposes that there is no significant difference between the specified populations in the study. Any observed difference being down to sampling or experimental error **(1 mark)**
   b) The alternate hypothesis for this study could be:

      'The calcium silicate and sodium phosphate (CSSP) containing toothpaste is more efficacious at reducing dentine hypersensitivity (DH) than the fluoride control toothpaste' **(2 marks)**
      OR
      'There is a difference in efficacy at reducing dentine hypersensitivity between the calcium silicate and sodium phosphate (CSSP) containing toothpaste and the fluoride control toothpaste' **(2 marks)**

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Part A

2. This study has used a negative control.

   a) What is a negative control? (1 mark)
   b) Why is a negative control sometimes included in a study? (1 mark)
   c) Comment on the appropriateness of the negative control used in this study (2 marks)

(4 marks total)

a) A negative control is an intervention or sample included in the study that is not expected to change due to any variables with the experiment **(1 mark)**
b) A negative control is included to eliminate the possibility of a non-causal association between exposures and outcome, which could threaten the validity of the study. It ensures that the experimental results are valid **(1 mark)**
c) In this study, a fluoride toothpaste was used as a negative control, which is inappropriate **(1 mark)**. Fluoride toothpastes have properties that could reduce dentinal hypersensitivity (as seen in this study) and therefore is not a true negative control **(1 mark)**

3. What is the evidence level for this study? (1 mark) Where does it sit in the hierarchy of evidence? Explain your answer. (1 mark)

(2 marks total)

- This study is a randomised controlled trial and would therefore be identified as Level II **(1 mark)**
- This study sits between Level I (systematic review of all relevant RCTs) and Level III (controlled trials without randomisation) **(1 mark)**

4. Within the study methodology:

   a) How were participants recruited to this study? (1 mark) What sampling technique was used? (1 mark)
   b) In general terms, provide three ways by which the possibility of errors or bias in the recruitment process could be reduced. (3 marks)

(5 marks total)

a) Patients were recruited by a local advertisement and through a database held at the study site. No details were provided about the advertisement or database. **(1 mark)**
The sampling technique is unclear but appears to be a self-selecting convenience sample **(1 mark)**
b) In general terms, the possibility of errors or bias within the recruitment process can be reduced by:

Any 3 of the following

- Ensuring that information on the study and the opportunity to participate is widely advertised to the population of interest **(1 mark)**
- Participants should be selected using pre-determined, well defined criteria to avoid confounding **(1 mark)**
- Researchers responsible for selection should be standardised and educated about the possibility of selection bias **(1 mark)**
- The study design and structure should be checked for flaws to ensure that participants are truly representative of the population being studied **(1 mark)**

5. Within the study methodology:

a) Discuss the sample size calculations used in this study (2 marks)
b) How could the method used to determine sample size be improved? (1 mark)

(3 marks total)

a) The authors state that no previous data exists to estimate sample size accurately, given the fact that new technology was being used. Therefore, data was obtained from other studies investigating DH technology. **(1 mark)** The authors state that 100 participants per group were selected, which appears to be a reasonable size. They also stated that this sample would permit 80% power to detect a difference of 0.40 standard deviations at a 5% significance level, which is the routinely accepted level **(1 mark)**
b) Given that no previous data was available for this technology, the authors could consider conducting a pilot study to collect some initial data, which could be used to determine the final sample size **(1 mark)**

6. With regards to exclusion criteria:

   a) What would have been an appropriate reason for excluding participants with certain medical conditions? (1 mark)
   b) What other medical conditions could have caused participants to be excluded? (1 mark)
   c) Comment on the exclusion of smokers. Was this appropriate? (2 marks)

(4 marks total)

a) Medical conditions that could heighten or alter the patients pain perception would need to be eliminated. This could be the reason behind the exclusion of patients with diabetes (due to related neuropathy) **(1 mark)**
b) Other conditions that could affect pain perception such as Fibromyalgia, ME, general neuropathy, Stroke and other cerebrovascular accidents, multiple sclerosis, Facial palsy (or any other reasonable medical condition) could be excluded **(1 mark)**

c) There is a well-known association between smoking and periodontal disease, and it can be assumed that smokers will have greater gingival inflammation, recession and possibly brush harder to remove stains. Therefore, the exclusion of smokers was appropriate. **(2 marks)**

7. The authors collected Schiff and VAS data. How would these data be classified? (1 mark). Describe the distribution of these data. (1 mark)

(2 marks total)

- Schiff and VAS scores are ordinal variables as there is clear intrinsic ordering to the scores **(1 mark)**
- These data are usually not normally distributed **(1 mark)**

8. Within the statistical analyses:

   a) Describe the uses of the statistical tests, the ANOVA and the ANCOVA. (2 marks)
   b) Discuss whether the use of ANCOVA was appropriate for this study. (1 mark)

(3 marks total)

a) ANOVA - Analysis of Variance. This is a test used to compare and contrast the means of two or more populations **(1 mark)**
ANCOVA - Analysis of CoVariance. This is used to compare one variable in two or more populations, while considering/eliminating other variables that may not be of interest **(1 mark)**

b) ANOVA assumes that the data being analysed is normally distributed. The data collected here was ordinal and therefore presumable not normally distributed. Therefore, the use of ANOVA was probably incorrect.
ANCOVA was used to control variables that were not of interest (also known as co-variables)
ANCOVA can determine how the dependent variable (in this case pain from Schiff Test/VAS score/etc) is affected by the independent, categorical variables (e.g. The toothpaste being given to the participants), whilst controlling for variables not of interest/nuisance variables /covariates (which in this case is gender, etc.).

This seems to be correct for this study and therefore use of ANCOVA seems correct

(1 mark to be awarded if the answer fits in with the description above)

9. Summarise the findings and comment on the validity of the conclusions of this study.

(4 marks total)

- The data and statistical analyses seem to suggest that using the CSPS toothpaste seems to improve symptoms of sensitivity from the study teeth, relative to the control teeth **(1 mark)**
- The methods and statistical tests seem reasonable **(1 mark)**
- From a whole mouth and QOL point of view, there seems to be no major difference between the two treatments **(1 mark)** Although the control used probably was a positive control, the test toothpaste did seem to decrease symptoms of sensitivity more, suggesting that it may be of merit to help patients with sensitivity in the short/medium term by asking them to apply it to the offending, painful teeth **(1 mark)**

Total Marks for Extract = 30