Gold vs. Fool's Gold:

Critically Reading and Evaluating Clinical Research Papers

Presentation



Contents

There are three aspects to a clinical research paper to explore...

The **Context** of a Clinical Research Paper

Critically Reading and Evaluating the **Content** of the Clinical Research Paper

Professional Application of the Information

The Context of a Clinical Research Paper

Before reading a clinical research paper, note the following elements:

1. Publication

The journal in which the paper was published

2. Title

The title should describe the content of the paper clearly and succinctly

3. Authors

Lists the names of individuals who have authored the paper

4. Date

Shows when the paper was published

Trials



Research

A randomized double blind crossover placebo-controlled clinical trial to assess the effects of a mouthwash containing chlorine dioxide on oral malodor

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Abstrac

Background: Previous research has shown the oxidizing properties and microbiological efficacies of chlorine dioxide (ClO₂), however, its clinical efficacies on oral malodor have been evaluated only with organologic measurements (OM) or sulphide monitors. No clinical studies have investigated the inhibitory effects of ClO₂ on volatile sulfur compounds (VSCs) using gas chromatography (GC). The aim of this study was to assess the inhibitory effects of a mouthwash containing ClO₂ on morning oral malodor using OM and GC.

Methods: A randomized, double blind, crossover, placebo-controlled clinical trial was conducted among 15 healthy male volunteers, who were divided into 2 groups. In the first test phase, the group 1 subjects (N = 8) were instructed to rinse with the experimental mouthwash containing $\Box \Omega_2$, and those in group 2 (N = 7) to rinse with the placebo mouthwash without $\Box \Omega_2$. In the second test, phase after a one week washout period, each group used the opposite mouthwash.

Oral malodor was evaluated before rinsing, right after rinsing and every 30 minutes up to 4 hours with OM, and concentrations of hydrogen sulfide (H₂S), methyl mercaptan (CH₃SH) and dimethyl sulfide (CH₃H₂S), the main YSCs of human oral malodor, were evaluated with GC.

Results: The baseline oral condition in the subjects in the 2 groups did not differ significantly. The mouthwash containing ClO_2 improved morning bad breath according to CM and reduced concentrations of H_2S , CH_3SH and $(CH_3)_2S$ according to CG up to 4 hours after rinsing. CM scores with ClO_2 were significantly lower than those without ClO_2 at all examination times. Significant reductions in the concentrations of the three kinds of VSCs measured by GC were also evident at all examination times. The concentrations of the three gases with ClO_2 were significantly lower than those without ClO_2 at most examination times.

Conclusion: In this explorative study, CIO₂ mouthwash was effective at reducing morning malodor for 4 hours when used by healthy subjects.

Trial registration: ClinicalTrials.gov NCT00655772

Page 1 of 8 (page number not for citation purposes)

Critically Reading and Evaluating the Content of a Clinical Research Paper

Clinical research papers typically consist of six major sections:

- Abstract
- Introduction
- Materials & Methods
- Results
- Discussion
- Conclusion
- References

We will examine each of these sections in greater detail.

Content

Professional Application

Content: Abstract

The **Abstract** is a short summary of the research paper, generally containing the four key elements below:

- Objective of the study
- Short description of the methodology
- Short description of major results
- Main conclusions of the study

Context

Professional Application

Content: Introduction

The **Introduction** of a clinical research paper should clearly convey the purpose of the study.

A well constructed introduction will clearly show why the study is important and how it will contribute to the overall body of scientific knowledge.

Content: Introduction

Thinking Critically

After reading the Introduction, ask yourself the following questions to assess your own comprehension:

What research influenced the authors' decision to engage in the described study?

What questions are the authors answering through the study?



Content: Materials & Methods

The **Materials and Methods** section provides technical information on the materials and methods used within the study

The section will often addresses the following:

- Research Subjects
- Treatment
- Study Design
- Treatment Groups
- Treatment Group Assignment
- Data Collection
- Endpoint
- Statistical Design

Content: Materials & Methods

Research Subjects

Information on the research subjects include:

- Demographic characteristics of the subjects
- Sample size
- Subject screening criteria used to include, exclude or withdraw research subjects from the study



Content: Materials & Methods

Treatment

Treatment refers to the specific clinical procedures and/or test material administered to research subjects during a study. The authors will typically provide information on the following:

- Description of treatment provided
- Treatment dosage
- Frequency of treatment provision
- Duration of treatment phase

Content: Materials & Methods

Study Design

There are several types of clinical study design:

Parallel Design

Subjects within each group simultaneously receive their respective treatment.

Treatment A



Treatment B



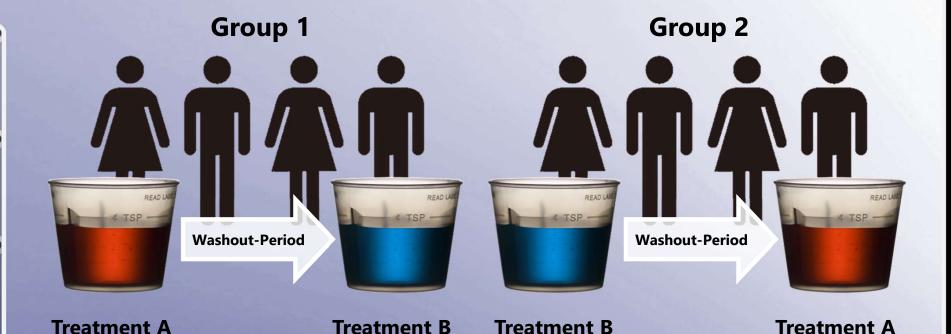
Abstract

Professional Application

Content: Materials & Methods

Crossover Design

Subjects within each group simultaneously receive their respective treatment. After a washout period, the groups switch treatment.

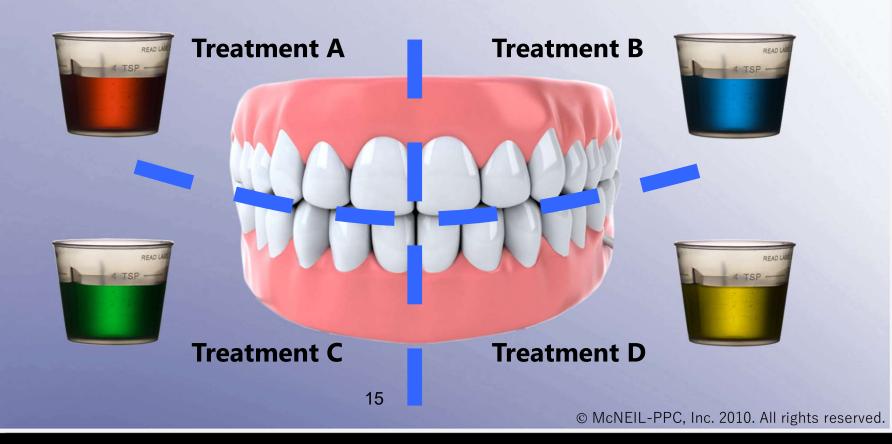


Content: Materials & Methods

Split Mouth

- An example of a more specific dental design study

Within the split-mouth design, each subject's mouth is divided into units (i.e., quadrants) and each subject receives all treatments within the study.



Content: Materials & Methods

Treatment Groups

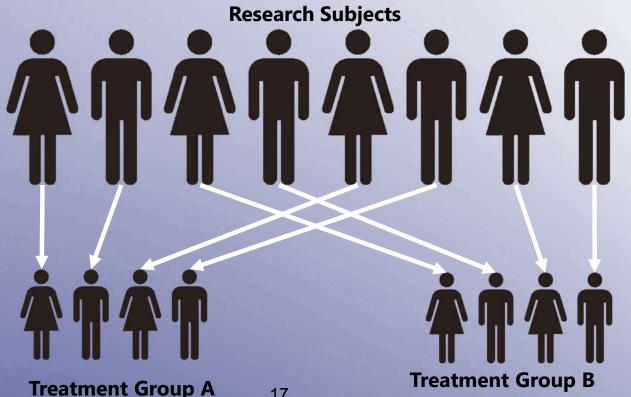
Clinical studies are divided into treatment groups and each group receives a different treatment:

Placebo Control		Positive Control	Negative Control	Experimental Treatment	
	READ US	READ US	READ US	READ US	
	Placebo Control Group	Positive Control Group	Negative Control Group	Experimental Group	
	Subjected to inert treatment	Subjected to treatment known to yield a positive result	Subjected to treatment known to yield no result	Subjected to the treatment under investigation	

Content: Materials & Methods

Treatment Group Assignment

Prior to the administration of treatments, researchers will randomly divide research subjects into treatment groups. Doing so helps ensure that the particular grouping of subjects is not the cause of observed results



Abstract

Introduction

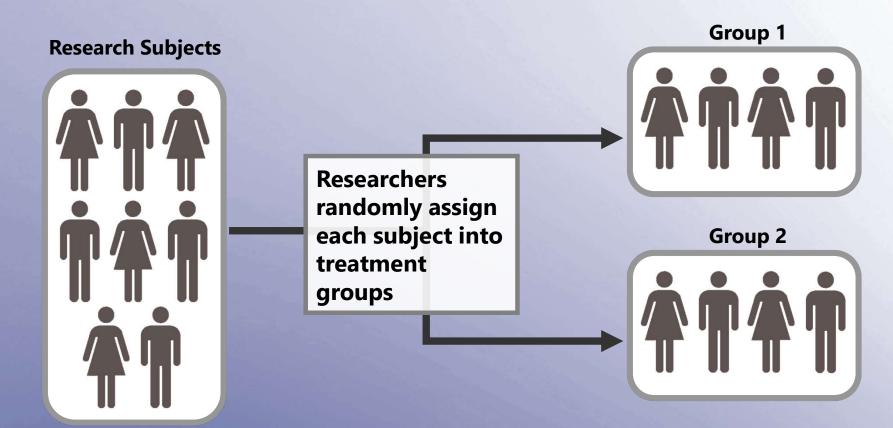
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Content: Materials & Methods

Treatment Group Assignment

Simple Randomization

is one assignment method researchers may use



Abstract

Introduction

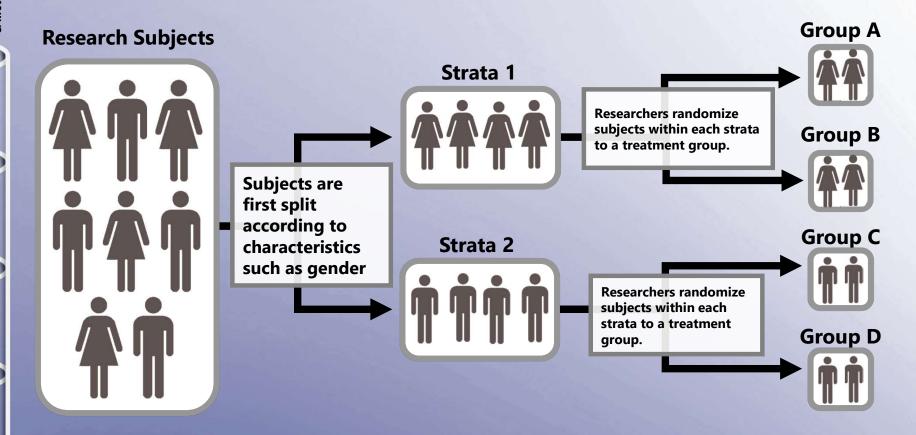
Professional Application

Content: Materials & Methods

Treatment Group Assignment

Stratified Randomization

is another assignment method researchers may use



Content: Materials & Methods

Blinding

is a technique used to minimize the impact of psychological bias on study results by ensuring that the subject and/or investigator/researcher do not know which treatment is received by which subject.

Blinding Type	Single Blind	Examiner Blind	Double Blind	Open
Subject				
Examiner				

Content: Materials & Methods

Data Collection

The clinical research paper should describe the study's data collection design by providing information on the following:

- Description of the data that was collected
- Method of data collection
- Instruments used for data collection
- Timing of data collection

To help demonstrate that the results are reproducible, researchers should also provide information on the following:

- Validity and reliability of data collection instruments
- Intra-rater & Inter-rater reliability

Content: Materials & Methods

Endpoints

The criteria used to determine whether a treatment is effective.

If you are testing the effectiveness of a mouthrinse . . .

... then the endpoint could be reduction of gingivitis





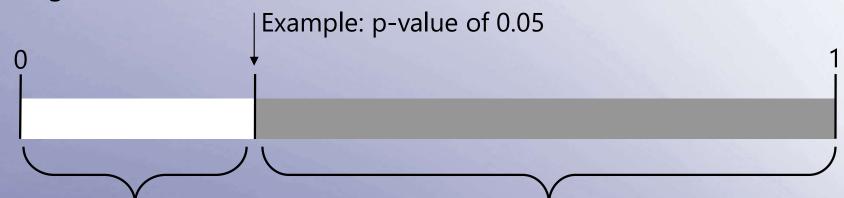
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Content: Materials & Methods

Statistical Design

To ensure the applicability of a study's findings to the general population, a variety of statistical techniques are applied during data analysis.

The **P-value** is used to assess whether a result is statistically significant



5% probability that observed results were due to chance

95% probability that the treatment was responsible for the observed results

Context

Content: Materials & Methods

Statistical Design

The size of the sample is another important consideration. The table below provides a general guideline for determining when a large or small sample size should be used.

Sample Size Guide						
Situation	Large sample size	Small Sample Size				
Assessing rare occurrences	X					
Homogeneous populations / little variability exists within the population		X				
Heterogeneous populations / great variability/diversity	X					
Assessing for small differences	X					
Pilot study		X				

Content: Materials & Methods

Thinking Critically

After reading the Materials & Methods section, ask yourself the following questions to assess your own comprehension:

- What is the number of study subjects?
- What is the duration of treatment?
- Is there a control? If so, what is it?
- Are the subjects randomized into treatment groups?
- What type of study was used?
 Double blinded, single blinded, crossover, etc?



Abstract

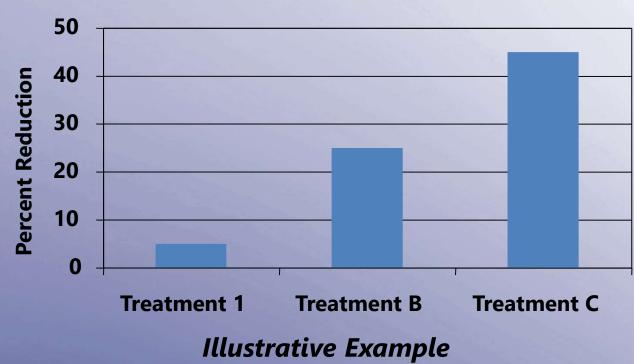
Introduction

Professional Application

Content: Results

The Results section should summarize the study's findings without introducing interpretations of the data.

Reduction in Gingivitis Compared to Positive Control Group



Content: Results

Thinking Critically

After reading the Results section, ask yourself the following questions to assess your own comprehension:

- What were the main study findings described in the Results section?
- Was a statistical method used to ensure an adequate sample size?



Content

Professional Application

Content: Discussion

The Discussion section identifies the major findings within the study and also provides the authors' interpretation of the study results.

Within this section, the authors may:

- Explain how their results fit within the existing body of scientific knowledge
- Address the clinical significance of the results
- Describe limitations of the study
- Suggest topics for further research

Content: Discussion

Thinking Critically

After reading the Discussion section, ask yourself the following questions to assess your own comprehension:

- What were the key findings?
- What limitations, if any, were described about the study?



Content: Conclusion

The Conclusion section provides the authors' conclusions from the study.

The conclusions should be logical and supported by data presented and analyzed in the Results and Discussion sections.

Content: Conclusion

Thinking Critically

After reading the Conclusion, ask yourself the following questions to assess your own comprehension:

 Did the results support the conclusion?

Content: References

The References section lists sources of information cited within the clinical research paper. It can help you:

- Look up additional information on the subject
- Understand the types of sources that the author relies on most heavily

Content: References

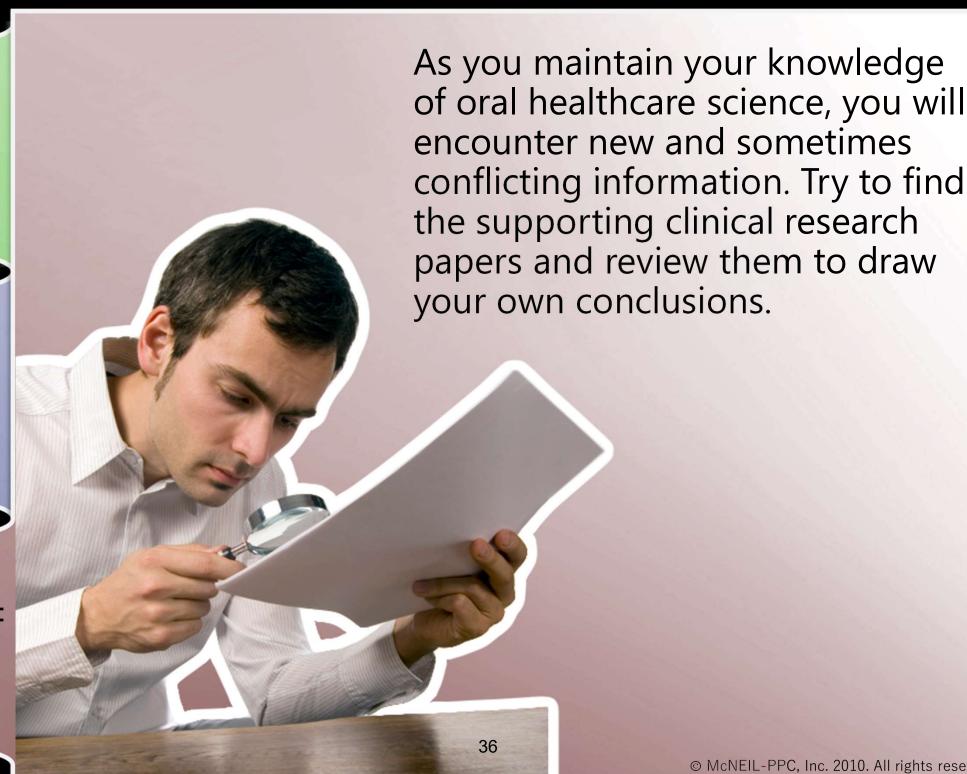
Thinking Critically

The following questions can be used to critically examine the references section:

 Are the references recent and up to date?



Science is evolving every day and the ability to critically read and evaluate clinical papers is a key skill needed in the professional world.



As a student or dental professional, product representatives will visit you to introduce products that can be very beneficial. During these visits, request references and data results supporting the products' efficacy and safety.

As with any other skill, critically reading and evaluating clinical research papers may be a challenging experience at first.

But these skills will help you lead an evidence-based practice, ensuring that you can give your patients the best possible care and recommendations.