Harm and Study Design

Nancy Skehan, MD FACP
Sheri Keitz, MD, PhD
Objectives

• Identify common types of study design (randomized controlled trial, cohort studies, case-control studies)
• Identify strengths and weaknesses in study design in answering harm questions
• Define odds ratio
• Compare odds ratio to risk ratio
• Identify the use of structured comparison and scaffolding techniques for teaching study design and odds ratio
• Review the use of breakout rooms, annotation and polling for effective virtual teaching of the above concepts
Study Design

- Meta-Analysis
- Systematic Reviews
  - Synthesized evidence
  - Experimental studies
- Observational studies
- Quality of information
- Amount of Information

- Randomized Controlled Trials
- Cohort Studies
- Case Control Studies
- Cross-Sectional Studies
- Case Series / Case Reports
- Animal Studies / Laboratory Studies
Our PICO

In children ages 3 to 12 years, does eating gummy bears increase the risk of dental caries?
Prospective Cohort

Exposure present

Exposure absent

Outcome - Yes

Outcome - No
Retrospective Cohort

Exposure present

Exposure absent

Outcome - Yes

Outcome - No
Randomized Controlled Trial

Exposure present

Outcome - Yes

Exposure absent

Outcome - No

RANDOMIZE!

MEASURE HERE
Case-Control

Exposure present

Exposure absent

Outcome - Yes

Outcome - No

MEASURE HERE
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<th>Study Design</th>
<th>How do you select your starting population? (Assembling study cohort)</th>
<th>Comparison group</th>
<th>What will you Assess or Measure? What is the Direction of inquiry?</th>
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Abstract

**Objective:** We aimed to study the long-term associations between sucrose intake (SI), selected representatives of the cariogenic oral flora, and the dental health of children from 3 to 16 years of age.

**Methods:** At 7 months of age 1,062 infants (540 intervention; 522 controls) were included in the prospective, randomised STRIP-project aimed at restricting the child's saturated fat and cholesterol intake to prevent atherosclerosis when they become adults. At 3 years of age, every fifth child was invited (n = 178) to an oral sub-study, and 148 (78 boys) children attended. A restudy was conducted on 135 children aged 6, 127 aged 9, 114 aged 12 and 88 aged 16. SI using 4-day food records, plate-cultured mutans streptococci (MS), salivary lactobacilli (LB) and yeasts using commercial kits (Orion Diagnostica, Espoo Finland), toothbrushing frequency using fluoridated toothpaste and dental health expressed as d 3 mft/D 3 MFT were regularly recorded.

**Results:** The SI of children whose intake was ≥ 10 E% (high SI) at 3 years remained high throughout the entire follow-up (p < 0.001, GLM for repeated measures) period, and they had higher salivary MS and LB counts (p = 0.024 and p = 0.068, respectively, GLM) than their counterparts whose SI was below 10 E% (low SI). No differences in toothbrushing habits were found between the high and low SI-groups. Caries-survival was strongly associated with low 6-year-counts of MS (p = 0.008, Cox regression analysis), and the d 3 mft/D 3 MFT scores of the high SI-group were higher than those of the low SI-group (p = 0.046, GLM).

**Conclusions:** High SI at 3 years was associated with high MS-counts (≥ 10 5 cfu/ml) and with a high risk for caries.
Background/aims: The aim of this longitudinal case-control study was to investigate variables associated with caries development from birth to 36 months.

Methods: Children (n = 1,017) who were followed up every 6 months from birth to 36 months were grouped into those that developed caries by age 30 and 36 months, respectively, and compared with children without caries.

Results: By 30 months (n = 608) there were 24 children (4%) who had caries and an additional 23 developed first caries at 36 months (n = 552), giving a total prevalence of 47 children with caries (9%) at 36 months. Children who showed caries by 30 months were more likely to be mutans streptococci (MS) colonised by 18 months (p = 0.001) compared to those who developed caries at 36 months, and showed the following variables: MS counts of >10(5) CFU/ml at 12 months (p = 0.005), missing enamel (p = 0.001), sugar in pacifier at 18 months (p = 0.02), child sleeping next to mother at 6, 18 and 24 months (p = 0.001 to p = 0.02), and exposure to household cigarette smoke at 24 months (p = 0.02). Caries at 36 months was associated with pregnancy problems (p = 0.024), mother having dental cavitations (p = 0.001) and MS presence at 36 months (adjusted odds ratio, AOR = 0.1, p = 0.01 for counts <10(5) CFU/ml). Caries at both 30 and 36 months was associated with MS presence at 18 months (AOR = 6.3, p = 0.005 and AOR = 4.9, p = 0.01).

Conclusions: Children who developed caries by 30 months are colonised by MS at younger ages and with higher MS counts compared with children who develop caries at 36 months.
Teaching Time Out!

• Complex Concepts can be reinforced by using sequential strategies to build on the fundamental principles

• Polling can be used to check for understanding
Throwback Thursday

• Remember the old days?
Risk 0.8 vs. Odds 4
Risk 0.5 vs. Odds 1
Risk 0.01 vs Odds 0.01
Brain Melt Math Turns 10!

Brain Melt 2021-style
Summary

• Identification of study design is important to understand the risk of bias in the study results
• Case-control or cohort studies may be best suited to answer questions related to harm
• Odds = # with events/# without events; Risk = # with events/all in the cohort
• With small numerators and large denominators, odds ≈ risk
Teaching strategies

- Start with a ridiculous case before using a medical one
- Compare risk, which is conceptually easier to understand, to odds
- Use annotation and polling to get learners to commit and to perform a needs assessment
- Structure longer lectures into shorter segments with small group work to minimize cognitive load