Summarizing a Study ...in One Paragraph

Lecture Objectives

By the end of this lecture you should be able to
• describe the four main parts of a journal article.
• identify the most commonly-used study designs.
• outline important elements of a study that should be included in a paragraph-long study summary.
• define key words used when describing a study.

The Four Main Parts of a Journal Article

• Introduction
• Methods
• Results
• Discussion
• IMRaD
• the abstract
• Can you find these elements in the RCT you brought with you?

Introduction

• Should introduce the purpose of the study.
• Explains why the study was important and unique.
• Often contains good background information which will help you put a study into context.
• Why is the RCT unique and important?
What was the purpose of the study?

Methods

• Design. Look for key words such as trial, study, randomized, controlled.
• Subjects. Determine the sample population, which will include identifying the setting. Examine the inclusion criteria and exclusion criteria. All of these will define who makes it into the study. The group of people in the study is called the sample.

Methods

• It is good to tell the study purpose, year of publication, setting, and size of sample in your first sentence.
A blinded, placebo-controlled, randomized controlled trial published in 2000 examined the comparative effectiveness of ramipril and vitamin E in 9297 adults from 267 centers in North America, South America, and Europe.\(^1\)
Methods

• You can mention inclusion criteria in the second sentence.
Patients aged 55 years or older who had a history of coronary artery disease (but no history of heart failure), stroke, peripheral vascular disease, or had diabetes and one other risk factor…

Methods

• Description of intervention or measurements. Includes
  – subject allocation to treatment group
  – clear description of treatments
  – follow-up done to collect event and risk factor data
  – any needed validation of measurement tools, so you are assured of their reliability

Methods

• You can finish with the treatment regimen in the second sentence. Use a third sentence if needed.
Patients aged 55 years or older who had a history of coronary artery disease (but no history of heart failure), stroke, peripheral vascular disease, or had diabetes and one other risk factor were randomized to ramipril plus vitamin E, ramipril plus placebo, vitamin E plus placebo, or placebo plus placebo. All subjects took either ramipril 10mg or a matching placebo daily, and vitamin E 400 international units or matching placebo daily.

Methods

• Primary and secondary outcome measures. The primary outcome measure, also called the primary endpoint, is the main measure the investigators designed the study to examine. Examples of outcome measures include
  – event rates
  – relative risk, odds ratios, or hazard ratios, which measure magnitude of association
  – percent change over time

Methods

• In the third or fourth sentence, you can identify the endpoints.
The primary outcome measure was occurrence of, or death from, myocardial infarction (MI) or stroke, and this particular publication focused only on the ramipril versus placebo arm of this study.

Methods

• The last section of the methods will describe the data analysis, which may include
  – sample size calculations
  – whether data from all patients or just treatment-adherent patients were analyzed
  – additional data analysis information
  – statistical analysis, including variables included in the multivariate model
• The statistical analysis section of our paper contains information about 2 of these 4 elements.
Results

• There are two types of results:
  – patient results
  – outcome results
• Patient results tell you
  – how many subjects completed the study (and
    often how many dropped out and why); study
    flow diagram useful here (not in our study)
  – baseline characteristics of study groups (usually
    in Table 1)

Results

• Outcome results tell you what the investigators found
  out about the primary and secondary outcomes.
• The most important information is often in tables or
  figures.
• You want know the raw numbers (ratios, means,
  proportions, percent change, risk/odds/hazards); the
  difference between the groups is the effect size.
• You will also want to know the statistical results, so
  look for P-values and confidence intervals.

Results

• Raw numbers for primary outcomes in this RCT are
  in Table 3.
• The first numbers to examine in this table are the
  rates, which here are reported as % of each group
  experiencing the event.
• The second numbers to examine in this table are the
  risk numbers, reported here as relative risk. Risk is
  the number of events in a group, divided by the total
  number of people in that group. Relative risk
  describes the risk seen in the treatment group
  relative to the risk seen in the control group.

Results

• Statistical numbers for primary outcomes in this RCT
  are also in Table 3.
• The next numbers to examine in this table are the 95%
  confidence intervals, which describe a range in which
  you can say with close to 100% confidence contains
  the true population risk.
• Relative risk is a ratio, with treatment group risk in
  the numerator, and control group risk in the
denominator. If the risk in the treatment and control
groups are the same, what will the ratio be? Look for
this number in the 95% CI.

Results

Also from Table 3:
• The final statistical number to examine is the p-value.
  P-values represent how probable it is you would see
  these results if the null hypothesis were true. Question:
  what is a null hypothesis?
• The most common p-value used for cutoff between
  statistical significance and non-significance is .05.
• How would you explain the p-value in death from
  cardiovascular causes and the p-value for death from
  non-cardiovascular causes?

Results

• In your paragraph, report the 2-3 most important
  outcomes. Here are the 1° outcome results:
  Fourteen percent of the ramipril group and 17.8 percent
  of the placebo group experienced a primary outcome
  event, with a relative risk (RR) of 0.78 and 95%
  confidence interval (CI) 0.7 to 0.86 (p < 0.001).
Results

• I go into more detail in the next sentence.
  This risk reduction was significant for the individual events of myocardial infarction (RR 0.8; 95% CI 0.70, 0.90), stroke (RR 0.68; 95% CI 0.56, 0.84), and death from cardiovascular cause (RR 0.74; 95% CI 0.64, 0.87), but not for death due to non-cardiovascular cause (RR 1.03; 95% CI 0.85, 1.26).

• Also include any results you thought noteworthy, and which you might remark on in evaluation (optional for you at this point).
  There was a slightly higher percentage of patients with a prior MI and receiving calcium channel blockers in the placebo group. Fewer people in the ramipril group developed heart failure (9.0%) versus the placebo group (11.5%): RR 0.77; 95% CI 0.67, 0.87). The investigators also noted a statistically significant reduction in the new diagnosis of diabetes in subjects receiving ramipril (3.6%) versus placebo (5.4%).

Conclusion

• In one sentence, note the investigators’ conclusion: the single most important thing they think they found. This is usually in the first paragraph of the discussion section.
  The investigators concluded that the use of ramipril significantly lowers cardiovascular event rate and mortality.
• You will not usually include discussion points made by the authors in such a short study summary.

Evaluatory Remarks

• You do not have to include evaluatory remarks in your study paragraphs for this paper. If you want to try doing so, however, be sure that
  – the evaluatory remarks come after the investigators’ conclusion but before your final paragraph summary sentence.
  – you balance strengths and limitations.
  – your remarks are supported by evidence in the study outline part of your paragraph (so don’t introduce new facts in the evaluation part of the paragraph).

Paragraph Summary Sentence

• End your paragraph with an overall assessment statement that summarizes the usefulness of the study in answering the study question.
  This trial suggests that ramipril may lower the risk of cardiovascular events, including death.

Study Designs

• randomized, controlled trial
• pilot study/uncontrolled trial
• cohort study
• case-control study
• cross-sectional analysis
• meta-analysis
• pharmacoeconomic study
• case study/case series
• non-human studies
Questions? Concerns?