
a series of fact sheets written
by experts in the field of liver
disease

HCV Advocacy:

A Simple Guide to Reading an Abstract

Alan Franciscus, Editor-in-Chief

Reading – and understanding – an abstract can be very challenging because there are so many pieces of the puzzle to fit together. This article will focus on tips for reading and understanding an abstract.

General Tips for Reading and Understanding an Abstract:

An abstract is usually divided into seven sections. Start by reading the entire abstract quickly – highlight or note any important facts that are key points, such as the number of participants, overall effectiveness, etc. After a quick review go back and read it slowly and carefully. A natural inclination is to just read the conclusion section, but remember that a conclusion, at times, can be what the author wanted to prove and not necessarily the real facts.

The abstract below is from the Association for the Study of Liver Diseases (AASLD) Conference 2007. This particular abstract is about HCV-796 – a drug that is no longer in clinical development due to severe side effects.

1) Title:

A very brief (one brief sentence) description of the study – this will give you an idea of what the study authors are trying to test or prove.

Example:

Phase 1 evaluation of antiviral activity of the non-nucleoside polymerase inhibitor, HCV-796, in combination with different pegylated interferons in treatment-naïve patients with chronic HCV.

2) Authors:

All the authors will be listed and sometimes the affiliations of the authors will also be listed. Look for reputable authors and medical institutions. The author and affiliation carry a lot of weight.

Example:

S. Villano; D. Raible; D. Harper; P. Chandra; L. Bazisotto; G. Bichier.

3) Introduction or background:

A brief history of what is known about the topic under study and why the study is important.

Example:

Background:

HCV-796 is an inhibitor of hepatitis C virus (HCV) RNA-dependent RNA polymerase that has demonstrated clinical antiviral activity across multiple HCV genotypes when administered as monotherapy or in combination with pegylated

interferon alfa-2b (PEG2b). We further evaluated HCV-796 when administered with pegylated interferon alfa-2a (PEG2a).

4) Aim:

This is one of the most important sections because it spells out the original intent or design of the study. The aim should include definite end points that are carefully planned and executed. Look for prospective studies that are designed in advance with certain clinical outcomes.

- *Retrospective* studies are studies that look back over time at a previous study or population. They are important for compiling information for future studies, but they can also be manipulated and do not carry as much weight in evidence based medicine as prospective studies.

As you have probably noticed some abstracts are formatted differently than others. In the example I have listed the ‘aim’ is included in the background information.

5) Patients/Methods:

This section will give you information on patient characteristics, drug dosing and other valuable information.

Important points to ask yourself when reviewing this section:

a. How many patients were enrolled in the study?

- Larger studies carry more weight.

b. Outcomes vary widely depending on many factors.

What were the patient characteristics?

- Were they evenly matched by age, gender, race, genotype, viral load, degree of liver damage, biochemical markers and other important patient information?

c. Was the clinical trial randomized and blinded to prevent bias?

- The gold standard of clinical research on humans is the blinded, randomized control trial. In this type of trial, patients are randomly selected. Randomization means that patients are randomly assigned – usually by a computer program – to a particular study group to receive the test drug, a standard of care drug or a placebo.

d. How did the researchers test their hypothesis and what tools did they use?

- Are they using sensitive diagnostic tools?

e. Was the study designed to compare one drug against another drug, or against the current standard of care?

- Was the dose of medication appropriate in both groups?

Example:

Methods:

Evaluations were performed within a randomized, double-blind, Phase 1 study in adult patients with chronic HCV infection who were naïve to treatment. In one group, patients were randomized to receive oral HCV-796 or placebo Q12h for 14 days, and all were to receive PEG2b (1.5 mcg/kg) on day-1 (one day before start of HCV-796/placebo) and day 7. In another group, the design was the same except the PEG therapy was PEG2a (180 mcg) on day-1 and day-7. In each group 12-16 patients were to receive the active HCV-796 (500 mg Q12h) with one of the PEG therapies.

6) Results:

This section reports on the outcome of the study. It should break the information down by overall results and then by patient characteristics and medication dose. The results should also report the statistical significance, which is an indicator of how well the drug will work un-

der the same circumstances in a different setting. This is usually reported as a p-value. P-value of < 0.05 is considered statistically significant. $P=0.05$ means that there is a 95% chance the drug will work in a similar patient population and a 5% chance that it will not.

If the abstract is testing a new medication, there should also be a brief overview of the side effects.

In this example you will note that the authors reported that the side effects of HCV-796 were typical of the side effects reports for Peginterferon therapy. However, we now know that early studies with small patient populations provide limited information and that studies conducted over a longer period of time with large patient populations give us the best information.

Example:

Results:

The mean baseline HCV RNA level was 6.4-6.5 log₁₀ in each group and 71% of patients were infected with HCV genotype 1. For both PEG therapies, combination with HCV-796 reduced plasma HCV RNA levels to a greater extent than either PEG alone. At day 14, the mean reduction in HCV RNA for HCV-796+PEG2b was 3.4 log₁₀ vs. 1.6 log₁₀ for PEG2b alone. The mean reduction for HCV-796+PEG2a was 3.7 log₁₀ vs. 1.1 log₁₀ for PEG2a alone. For both groups, activity differed by HCV genotype. Mean HCV RNA reductions at day 14 for genotype 1 was 2.9 log₁₀ for HCV-796+PEG2b and 3.2 log₁₀ for HCV-796+PEG2a. For genotype non-1 the respective reductions were 4.4 vs. 4.7 log₁₀. Combination of HCV-796 with either PEG therapy was generally well-tolerated. Common adverse events in all groups were those typically associated with interferons, including headache, chills, and myalgia.

7) Conclusion:

Be careful because the conclusion can be greatly manipulated to fit the author's needs. Refer back to the results and compare the results with the author's conclusions.

The example we used is very straight forward and appropriate for the intent of the study. Always be careful, though, reading the conclusion – it is always better to understand the information in an abstract and come to your own interpretation and conclusion.

Example:

Conclusions:

The combination of HCV-796 with either PEG2b or PEG2a provides similar antiviral activity across multiple HCV genotypes over 14 days of therapy. Results support clinical studies of more long-term administration of HCV-796 with either PEG therapy.

The more you practice reading an abstract the more you will be able to understand the information presented. Always use your critical mind when trying to interpret scientific data or any other source of information. And don't be afraid to ask questions!

Recommended links:

- Medline's Understanding Medical Research www.nlm.nih.gov/medlineplus/understanding-medicalresearch.html
- National Institutes of Health (NIH) www.nih.gov
- Craig Hospital www.craighospital.org/SCI/METS/articles.asp
- New York Online Access to Health www.noah-health.org/en/ebm
- Patient Inform www.patientinform.com/understanding-medical-research
- United States National Library of Medicine www.nlm.nih.gov
- PubMed <http://www.ncbi.nlm.nih.gov/sites/entrez>
- MedlinePlus <http://medlineplus.gov/>

Glossary of Terms

THE GLOSSARY BELOW LISTS SOME OF THE TERMS MOST COMMONLY USED IN CLINICAL TRIALS

Blind or double-blind study

BLINDING: a method of conducting clinical trials in which participants do not know who is taking an experimental treatment, a standard (control) treatment, or a placebo. In a blinded study, the volunteers do not know what treatment (if any) they are receiving. In a **double-blind study**, neither the volunteers nor the researchers administering the treatment know who is receiving what. Blinding is done to reduce bias in drug trials. In the case of medical necessity, a study may be unblinded to reveal who is receiving what treatment.

Control group

- **CONTROL ARM:** a comparison group in a clinical trial that is used to verify an experimental result. A control group is typically given an older standard treatment or a placebo rather than the new experimental treatment under study.
- **CONTROLLED TRIAL:** a clinical trial in which a group receiving an experimental treatment is compared to a control group that is given a standard treatment or a placebo.

Exclusion criteria

conditions that disqualify someone from participating in a clinical trial. Contrast with inclusion criteria.

Inclusion criteria

conditions that a person must meet in order to be eligible for a clinical trial. Contrast with exclusion criteria.

Placebo

an inert, inactive agent (e.g., pill, injection) that has no treatment value.

Protocol

a written plan for a clinical trial, which typically includes details such as the hypothesis to be tested, who can participate, length of the trial, how the treatment under study will be administered, endpoints, and potential risks and benefits.

Randomization

RANDOMIZED TRIAL: a clinical trial arranged to produce a chance distribution of participants into different arms (e.g., experimental treatment, standard treatment, or placebo). Randomization is done to minimize bias

Study Arm

Patients in clinical trials are assigned to one part or segment of a study—a study “arm.” One arm receives a different treatment from another.

For more information about hepatitis C, hepatitis B and HCV coinfections, please visit www.hcvadvocate.org.

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Executive Director

Editor-in-Chief, HCSP Publications
Alan Franciscus

Design

Paula Fener

Production

C.D. Mazoff, PhD

Contact information:

Hepatitis C Support Project
PO Box 427037
San Francisco, CA 94142-7037

alanfranciscus@hcvadvocate.org

The information in this fact sheet is designed to help you understand and manage HCV and is not intended as medical advice. All persons with HCV should consult a medical practitioner for diagnosis and treatment of HCV.

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