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The Proof of the Pudding: How to Report Results and Write a Good Discussion

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CHEST Postgraduate Education Corner

MEDICAL WRITING TIP OF THE MONTH

The Proof of the Pudding*

How to Report Results and Write a Good Discussion

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Scientific manuscripts are structured using the introduction, methods and materials, results, and discussion (or IMRaD) format. For certain types of manuscripts, such as randomized, controlled clinical trials, additional guidelines exist.[1] Scientific manuscripts also have abstracts and references. During the past 2 years, in this "Medical Writing Tips" series, we have explored the organization of the abstract, introduction, and methods and materials sections of the manuscript.

- The abstract, in a sense, is an abbreviated paper with a format that parallels the full paper. Abstracts can be structured or unstructured.[2]
- The introduction gives the background to the subject, provides the gap in the literature, and, most importantly, asks the research question.[3]
- The materials and methods section includes the prospectively defined end points or outcome measures and provides enough information for an investigator in the same field to replicate the published work.[4]

This article will discuss the remaining two sections of a research article, results and discussion. These are often the most difficult sections to write clearly and concisely. I will be using the same fictional study as presented in earlier articles[2–4] to illustrate how the entire manuscript flows logically. Again, I caution, I am offering suggestions and food for thought, not a template, for manuscripts based on clinical hypothesis-testing trials.

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Results

Main Considerations

The function of the results section is to provide the results for all end points and measures stated in the materials and methods (or patients and methods) section. The results section of a clinical hypothesis-testing manuscript typically includes tables and figures for presenting detailed data in as compact and readily understood a form as possible and is usually devoid of references. The results section should report the results of your study only.

Potential Problems

One of the most common problems with the results section occurs when an author provides data but no results, or results but no data. Data are numbers, often best presented in a table or figure. The text of the results section gives meaning to the data, but without "excuses." When reporting results, just provide the facts; discussion and explanation of why results are different than expected belong in the discussion section. The discussion section will also provide a forum for explaining why the results are different from what the researchers had hoped for, either good or bad.

Another potential problem in writing the results section is failure to report all end points that were listed in the materials and methods (or patients and methods) section. Every method must have a result and, conversely, every result must have a method. Results should be reported in the same order as the methods for them were given.[5] Include only results of the prespecified end points; *ad hoc* analyses are not permitted.

Explication

What does a good results section look like? The following sections contain my fictional example, which includes some of the most important items required in the results section, along with my brief comments in parentheses. In a real research paper, many of these points would be expanded with more statistical data provided than the few fictional results given. Remember, the materials and methods section has subsections, generally patients, study design, study drugs/interventions, study end points, and statistical analysis.[4] All of these sections should appear in the results section. The statistical analysis section, however, is not a free-standing entity here, but all measures predefined in the statistical analysis section (mean, median, range, and 95% confidence interval, for example) would be provided in the appropriate sections (*eg*, patients and study end points sections).

First Section: Patients

A total of 315 patients were randomly assigned to treatment, and all patients received at least one dose of a blinded study drug (drug N, n = 156; drug S, n = 155) [Fig 1]. The groups were well matched for baseline characteristics of demography, disease history, disease severity, and previous radiation (Table 1). The patient population was predominantly men (76%) and white (66%), and the mean age was 52 years. Thirty-three patients did not complete the study and withdrew after withdrawal of consent (n = 11), death (n = 3), or other adverse events (n = 19).

(In this section, I provided not only the total number of patients but also the number of patients assigned to each treatment group. Figure 1 would show the CONSORT Group Flow Diagram,[1] the use of which allows the reader to quickly grasp the fate of the patients in terms of their progression through the study. Table 1 would provide baseline demographic and clinical information, and should be formatted to allow easy comparison between the two treatment groups in this study. This section might also include the number of patients in each group who completed each of the proposed five 14-day cycles. This information would also be provided in the CONSORT diagram. I have included information on the number of patients who did not complete the study and will elaborate on death and withdrawals due to adverse events in the safety end point section.)

Second Section: Efficacy End Points

The time to progression, the primary efficacy end point, was 4 months for patients who received drug N compared with 1 month for patients who received drug S ($p < 0.001$) [Table 2]. Overall survival, a secondary efficacy end point, also was longer for patients who received drug N compared with patients who received drug S (22 vs 18 months, respectively; $p < 0.01$) [Table 3]. Treatment with drug N reduced the need for palliative radiation when compared with treatment with drug S (2% vs 10%, respectively; $p < 0.001$) [Table 4].

(In this section, I reported the results of the primary end point and two secondary efficacy end points. More information would be provided in the referenced tables, such as the 95% confidence interval. Some data might be better showcased in a figure rather than in a table.)

Third Section: Safety End Points

Reported adverse events were similar between the two treatment groups, and the adverse events reported were typical of those in a patient population with advanced NSCLC who were receiving treatment with biological therapies (*ie*, fever, flu-like symptoms, or skin rash) and occurred in similar proportions of patients in each group during the study. Most events were of mild or moderate intensity (Table 5).

During the study, 19 patients withdrew because of adverse events (drug N, n = 9 [5.8%]; drug S, n = 10 [6.5%]). The primary reason for study withdrawal was disease progression (drug N, n = 2 [1.3%]; drug S, n = 4 [2.5%]). One patient treated with drug N died, and two patients treated with drug S died; all three deaths were attributed to disease progression and not to the study drug.

No substantial changes from baseline were noted in the serum chemistry analytes alkaline phosphatase, alanine transaminase, aspartate transaminase, lactic dehydrogenase, or uric acid (data not shown).

(In this section, I have given the results for the two safety end points, adverse events [which include death], and changes in laboratory values. If no clinically significant changes occur, it is acceptable to state this result and not provide the data in tabular format.)

Discussion

Main Considerations

The function of the discussion section is to discuss how the results answer and support the research question posed in the introduction and to compare and contrast the results with other studies in the field.

Potential Problems

The discussion section is fraught with potential problems. It is the most difficult section of the

hypothesis-testing paper to write. Often, the discussion section dissolves into a repetition of the results and the introduction of new and inappropriate information, such as additional or repeated background information (from the introduction), *ad hoc* analyses, and discussion of unrelated studies. The discussion is meant to include only information relevant to the current study. The discussion section rarely has tables or figures, but should contain references, as references are the way scientists validate their work and credit the work of other scientists properly.[6] Although subsections can be used for structuring complicated discussion sections, subsections stop the flow of the writing, so it is better to write using transitions for moving between and relating ideas.

Explication

The main function of the discussion section is to answer the research question posed in the introduction and to use the results to support that answer. The cleanest way to start the discussion and to answer the research question is by stating, "The results of our study suggest . . . . . ." or something of that nature. The topic does not need to be reviewed again, nor do the results need to be presented again; however, the author should use the results (and may refer to a specific table or figure) to support and explain the answer. It is always acceptable to remind the audience of the uniqueness or newness of your data (as first suggested in the introduction). It is generally wise, however, to avoid the claim of being first (*ie*, same or similar work may have been reported in an article published in another country and in a language other than English; modesty is always a good virtue to emulate).

In the "middle" portion of the discussion, you should discuss your results as they relate to other work in the field. Any conflicting or unexpected results should be explained, and limitations for the study should always be given (*ie*, the results are appropriate only for the small patient population studied, not all patients at large).

It is tempting, particularly when the results are not as robust as one had hoped for, to provide the results of *ad hoc* analyses. However, remember, no new data can be introduced in the discussion section. If the results were not as expected, it may be disappointing, but not a sign of failure. Reporting the results as obtained from the original hypothesis may allow you or another group to refine the hypothesis and proceed with more testing.

Finally, the discussion should end with a good sentence that summarizes the study, such as, "Thus, the results of our study suggest that drug N has a clear clinical advantage over drug S, including a statistically significant increase in time to progression and overall survival coupled with an acceptable safety profile for drug N." Often, I see concluding sentences that say something like, "The results of this study suggest that more work needs to be done." These sorts of sentences bewilder me, as the hypothesis that was tested, the end points, and the statistical analyses had nothing to do with the concept of requiring further testing. Avoid these types of sentences.

Take-Home Lesson

The results section simply reports the findings of the study, and uses tables and figures to compare and contrast (or at least to organize) data, but the proof of the pudding, as it were, is in the discussion. A careful author will ensure that only results are presented for which there was a corresponding method and that only the results of the current study are presented as per the prespecified analysis.

The discussion section requires careful organization, writing, and editing to ensure that no new topics are introduced, that the limitations of the study are included, and that the section does not become a repeat of the results section without explanation of what the data mean or how they add to the body of scientific knowledge. No excuses should be offered for unexpected data.

So, the proof of the pudding is in the eating: in other words, results count. Being able to present the results succinctly and discuss them logically will help produce an hypothesis-testing paper worthy of publication.

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