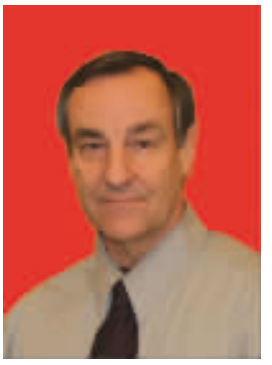
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专家述评

编者按:随着我国生物医学研究者同国际同行的交流日益广泛,越来越多的科技人员希望自己的论文发表在 SCI 收录的国际期刊上。本刊编辑部特邀本刊编委 Tom Lang 先生撰文为中国作者在国际期刊发表临床研究论文提出建设性意见。该文提出的一系列问题非常便于论文撰写者自查自省,是一篇非常实用的投稿指南。



中国作者发表临床研究论文自查列表

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【摘要】 科学研究的最后一步就是在科技期刊发表其研究成果。本文罗列了一系列在论文写作过程中需要注意的问题,包括应参照期刊投稿指南、遵循科技论文格式、遵守署名志谢原则,文题、摘要、前言、方法、结果、讨论是否符合写作要求,以及图表相关问题等,为中国作者撰写高水平的临床研究论文提供帮助。作者特别强调:①论文撰写者应当首先自问:医学是否会因我的研究而不同?只有有意义的研究才能得到期刊编辑和读者的关注。②论文撰写应力求使论文具有"逻辑性、完整性和一致性",并避免对他人论文的某些文字的直接复制。

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A checklist for Chinese authors publishing clinical research in scientific journals

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The final stage of research is to publish the results in a scientific journal. If the results are not published, from a scientific standpoint, the research was never done. Publication is also the beginning of the formal discussion of the research and is usually the most lasting, if not the only, record of the research[1]. And, as most authors in all countries are aware, publication is also required for professional advancement.

Despite the importance of scientific publications, however, few authors have been formally trained in how to prepare them. The purpose of this article is to identify the most important characteristics of a scientific article reporting clinical research and to provide Chinese authors with the information and advice they need to prepare their manuscripts for publication.

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1 General Comments about Your Research

The most important part in getting your research published is doing important research. Before you start your study, ask yourself "How will medicine be different if I can answer my research question?" If you can't answer this question, you may spend a lot of time and money doing research that will not be of interest to journal editors or their readers.

The biggest problem most researchers in all countries have is that they study something that *can* be studied, not something that *needs* to be studied. Be sure you read the literature in your field so that you know what is known about your topic and what needs to be known. If possible, work with colleagues: you can ask more important questions, do larger studies, and probably get more money and resources if you work with a group. In most fields of medicine, it is hard to do important research on your own. In any event, *you need to make sure in your article that you tell readers what you did and why it needed to be*

done. This information is among the most important you need to include in your article.

Be sure you ask for help in designing and interpreting your research if you need it. If possible, talk with a statistician before you start collecting data. Statisticians will help you identify possible sources of error, confounding, and bias that can greatly reduce the quality of your research. A trained medical librarian can also be useful in helping you find articles on your topic that you can include in your literature review. Colleagues can be of great help if they will tell you honestly what they think about your research and your article and how to improve both.

2 General Comments about Your Writing

In the past few years, Western journals have begun to receive large numbers of manuscripts from researchers in developing countries where English is not the native language. Although most journals would like to consider all manuscripts they receive, their resources are limited, so they cannot send every manuscript for review. So, if a manuscript cannot be easily understood by a native English-speaker, it may be rejected immediately, before it is sent for review.

To get manuscripts reviewed under these circumstances, many authors have their manuscripts edited by "language polishing companies," which guarantee that your manuscript will not be rejected immediately *because of poor English*. (These companies do NOT guarantee that your manuscript will be published!) Most companies say they edit thousands of manuscripts a year and that their manuscript editors are native English speakers who have advanced degrees and sometimes several publications in the same field as the author. These qualifications may be helpful, but they do not always mean that the editing will be of high quality. Also, although the editing will be done in a few days, it can be expensive. Be sure to ask your colleagues about any company you might use; quality, costs, and honesty differ greatly among these companies.

"Language polishing" is not the same as copyediting or the more extensive "substantive" editing[1]. Manuscripts that have been well copyedited should have no errors in English, no inconsistencies in terms or numbers, and will meet all the formatting requirements of the journal. Copyediting takes more time than language polishing and fixes more problems; it is also more expensive. Many skilled native English speakers can help you copyedit your manuscript, but a trained editor may provide better service.

The purpose of substantive editing is to make sure that your writing is logical, complete, and consistent[1]. Research designs and activities will be described completely, tables and figures will clearly present the data, and all conclusions will be supported by the results. Most substantive editors will call to your attention problems with meaning, consistency, or with the research and may provide comments like those you might get from a peer reviewer at a journal. Substantive editing, which usually includes copyediting, can be done by experienced authors, but again, a professional medical editor may provide better service. Substantive editing is sometimes offered as a "premium" service by language editing companies. It will be more expensive, but I recommend that you use this service if possible; it is a better value for your money than language polishing, which will not uncover or correct the more important problems in your manuscript.

Another important issue for nonnative English speakers is plagiarism, which means using the ideas or words of another person without giving them credit, so that readers will think the idea or words are yours[1]. Science requires that you build on the work of others, so the problem is not using the ideas and words of another person, it is not giving credit to the people whose ideas and words you are using. Many nonnative English speakers will copy parts of someone else's article because the English in the article is better than their own, and they just want to make their article read better (this practice is sometimes called "patch writing")[1]. However, it is best to rewrite the same information in your own words. If you can't, put the information in quotation marks and reference the article where you got it. Many journals now use special computer programs to compare your manuscript with thousands of other manuscripts[2]. If your words are too much like those of another article, the journal may accuse you of plagiarism, reject article, and tell your university that you may be guilty of scientific misconduct.

3 The General Form of the Scientific Article

The general form of a scientific article consists of

four headings: Introduction, Methods, Results, and Discussion. This form is often referred to as the "IMRAD" format (pronounced "ihm raad"), and it is an international standard for reporting research. The text under of these headings should answer a specific question:

Introduction: Why did you start?

Methods: What did you do?

Results: What did you find?

Discussion: What does it mean?

If you can answer these four questions well, you will be well on your way to preparing your article.

4 Questions to Consider when Writing Your article

Below, I have listed several questions you can ask yourself when preparing your article. If you cannot answer these questions, stop writing until you can answer them.

4.1 Did you follow the journal's instructions for authors?

Most journal editors will tell you that *the single best action you can do to get published is to read their journal's Instructions for Authors*. The Instructions will tell you what type of articles the journal wants to publish, who reads the journal, how to prepare your manuscript, what reference style to use, what forms you need to complete, how to submit your manuscript, and several other important pieces of information. Articles that do not follow the Instructions may be rejected simply for this reason. For direct links to the Instructions for Authors for most biomedical journals, see the website of the Raymon H. Mulford Health Science Library at the University of Toledo (formerly the Medical College of Ohio): **http://mulford.meduohio.edu/instr/.**

4.2 Did you follow the reporting guidelines for the type of research you conducted?

The evidence-based medicine movement has led to the development of dozens of reporting guidelines for various types of research. The first and best known are the CONSORT guidelines for reporting randomized controlled trials, but there are many more. Even if the journal does not require that your article meet these guidelines, they are useful checklists for reporting your research. Visit the Equator Network at **www.equator-network.org** to find reporting guidelines for the major types of research designs (cohort studies, surveys, and so on) used in clinical investigations and for several specific medical procedures (such as vision screening studies and intravascular ultrasound studies).

4.3 Do all people listed as authors meet the criteria for authorship?

Did each author make important contributions to 1) the design or conduct of the research AND 2) to the writing or revision of the article AND 3) agree to take responsibility for their part of the research by signing the journal's statement of authorship? *Getting the funding, collecting data, providing patients or samples, or supervising the research group alone are not enough to qualify for authorship*. For more information on authorship, see the Uniform Requirements of Manuscripts Submitted to Biomedical Journals[3].

People named as authors who do not meet these qualifications are called "guest authors," and journals do not want them to be included as authors, although you can list them in the acknowledgments. Some journals will also ask you to tell the contribution of each author to prevent guest authorship, a practice called "contributorship."

4.4 Are the authors listed in order of their contributions, from most to least?

The order of authorship should not be determined by academic rank or seniority but generally by how much each author contributed to the research, although some journals may ask for a different order[4-6]. Do not list the senior author last just because he or she is the senior author. *Ideally, who will be authors and in what order their names will appear will be determined before the article is written*, if not before the research is conducted. Deciding the order of authors in advance is the easiest way to avoid problems with authorship.

4.5 Does the title describe the research accurately enough that readers will know whether or not they might be interested in reading the article?

The title is the most important part of the article because it is the link between your research and readers' interests. You don't have to trick readers into reading your article by writing an interesting title. In fact, most readers will be happy if you give them enough information to decide that they *don't* need to read the article. Nobody likes to waste time reading something that will not be helpful.

4.6 Does the title include at least the most important explanatory and response variables?

Determining the relationship between explanatory and response variables is generally the purpose of the study, so including these variables in the title will usually indicate what the article is about. The titles of articles reporting clinical research should identify, if possible, the information in "SPICED": the Setting (the place where the study was performed, Patients (the diagnosis studied), Intervention (the treatment), Control condition (the comparison group), Endpoints (the outcomes of interest), and Design of the study (for example, case series, cohort).

Many journals limit the length of the titles they publish. You may need to spend some time shortening your title to meet these limits without losing important information.

4.7 Does the abstract describe the research accurately enough that readers will know whether or not they might be interested in reading the article?

The abstract is the second most important part of the article. Like the title, it is often separated from the full article and so needs to be understandable without reading the article. Most journals limit the number of words in the abstract, and many will specify the type of abstract they want. A **descriptive abstract** may be limited to 150 words and tells readers only what topics the article will include. An **informative abstract** may have up to 300 words and summarizes specific information in the article with four unlabeled sections: introduction, methods, results, and conclusions. A **structured abstract** usually accompanies reports of randomized trials. It consists of 250 to 300 words and a series of headings that identify the major parts of the study.

4.8 Is the information in the abstract consistent with that in the article?

One of the most common errors in a scientific article is that the abstract contains information that is missing or that differs from the information in the article, especially the conclusions[1].

4.9 Does the introduction describe the research accurately enough that readers will know whether or not they might be interested in reading the article?

Few people are aware how useful a good introduction can be in understanding the article. I recommend that you write a four-part introduction. **Part 1 is a background statement** that prepares readers to understand the problem you studied. **Part 2 is a problem statement** that defines the nature, extent, and importance of the problem you studied. *Be sure you tell readers why you studied what you studied and why your work is important.* **Part 3 is an activity statement** that tells in general what you did in your research, and **Part 4 is a forecasting statement** that tells readers what to expect if they continue to read the article (Example 1).

> **[Background Statement]** In patients with atherosclerotic vascular disease, aspirin is recommended to prevent myocardial infarction and graft occlusion. **[Problem Statement]** However, aspirin is also associated with bleeding. Patients are often asked to stop taking aspirin before bronchoscopy, to reduce the risk of bleeding. The effectiveness of this practice has never been tested. **[Activity Statement]** Thus, we sought to determine whether aspirin really does increase the risk of bleeding after bronchoscopy. **[Forecasting Statement]** Here, we report our randomized trial in which we compared the number and severity of bleeding events in those taking aspirin with those who were not and determined that aspirin does not increase the risk of bleeding.

Example 1 An example of a four-part introduction

4.10 Does the methods section provide enough information for readers to determine whether your research design and activities were appropriate and valid?

Authors are often told that a good methods section should allow others to repeat their research. Although this advice is good, most biomedical research is too complicated, and articles are too short, to give all the details necessary to repeat the research. Instead, you need to persuade readers that your methods were the right ones to use for the problem you studied and that you applied these methods well. Below are the important questions to address in the Methods:

Did you confirm that an Institutional Review Board (or IRB) approved the study before you started?

Did you confirm that patients gave informed consent or that animals were treated and cared for appropriately throughout the research? (See Animal Research: Reporting *In Vivo* Experiments (the ARRIVE Guidelines[7])

Did you describe the research design adequately?

Did you identify the explanatory and response variables and tell how they were measured?

Did you tell how you controlled for error, confounding, and bias?

Did you identify the primary and secondary relationships you studied?

Did you tell how the sample was collected and how the sample size was determined?

Did you identify the statistical tests used to analyze your data and confirm that the data met the assumptions of the tests used to analyze them?

Did you identify the alpha level that defines statistical significance (often 0.05) and the statistical software program you used to analyze your data?

4.11 Does the results section tell what you found in your research?

Did you tell readers about important but unplanned events that occurred during the research?

Did you report the data for each of the variables studied?

Did you identify the relationships among the variables you studied?

Did you present your data in figures and tables when appropriate? (Use figures to show overall patterns in the data and tables to show exact values.)

Are your statistical analyses reported correctly[8]?

Did you report 95% confidence intervals instead of, or in addition to, *P* values[8]?

4.12 Does the discussion section explain the importance and implications of your research?

Did you summarize the problem and results in the first paragraph or two?

Did you attempt to explain why you got the results that you got?

Did you compare your results with those of similar studies in the literature? (When describing other studies in the literature review, did you remember to give the sample size and the results in addition to the conclusions?)

Did you tell how your results might be generalized to other places or patients?

Did you discuss the implications of your results? (That is, did you discuss how science or medicine might be different as a result of your research?)

Did you discuss the limitations of your study? (All studies have limitations, even yours!)

Did you list your conclusions? (Example 2)[1]

Did you distinguish between biological importance and statistical significance when you interpreted your findings? (*P* values have no clinical meaning; were the differences you found large enough to be clinically important?)

Did you distinguish between supported conclusions and speculation when talking about your research?

Conclusions

We conclude that Tamoxifen reduced the incidence of DMH-induced colon cancer in rats. We also showed that DMH induced the expression of estrogen receptors in colonic mucosa, but that the number of estrogen receptors in the colonic mucosa was not correlated with blood levels of estradiol, polyamine, or ornithine decarboxylase. Finally, we found no relationship between blood levels of estradiol and tumor incidence.

Conclusions

Our data support the following conclusions:

Tamoxifen reduced the incidence of DMH-induced colon cancer in rats.

DMH stimulated the expression of estrogen receptors in colonic mucosa.

Blood levels of estradiol, polyamine, or ornithine decarboxylase were not correlated with the number of estrogen receptors in the mucosa.

Tumor incidence was not related to blood levels of estradiol.

Example 2 Listing your conclusions is more effective than presenting them in a paragraph.

4.13 Did you acknowledge the people who helped you but who did not qualify for authorship?

Did you get written permission from each of these people to include their names in the article?

Other Questions to Consider:

4.14 Is the literature review current and comprehensive?

Check the dates of your references and make sure they are as current as possible.

Did you make sure the references are complete and accurate by checking them at the US government's PubMed website? (**http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed**)

Have you cited original references that you have read in full yourself? (Try not to cite abstracts as references; use full articles.)

Are the references listed and formatted as required by the journal's Instructions for Authors?

4.15 If you use tables, are they constructed specifically to communicate your data?

Does the title identify the data in the table?

Have you put the data or the row or column headings in a sensible order?

Have you put ellipses (…), in empty cells to show that data were not left out by mistake?

4.16 If you use graphs, are they constructed specifically to communicate your data?

Does the caption identify the data in the graph?

Have you labeled the axes and provided the units of measurement?

Will the graph be readable if the journal has to reduce it to fit on a page?

Are all lines, words, labels, and plotting points necessary to communicate the data?

4.17 If you use photographs or drawings, do they clearly show the information?

Is there good contrast between the subject and the background of the image?

Are all important structures and regions labeled correctly?

Does the image have the right resolution (the number of dots per inch) required by the journal and is it in an acceptable file format (such as *.jpg or *.pdf)?

4.18 If you use diagnostic or analytical images (radiographs, Western blots), are they presented specifically to communicate your data?

Does the caption identify and describe the patient or substance shown in the image?

Did you give the technical details of how the image was taken?

Did you indicate on the image (with arrows or circles) those features of interest to readers?

If applicable, did you include a measurement scale or give the magnification of the image?

Did you explain what the image means?

Does the image have the right resolution (the number of dots per inch) required by the journal and is it in an acceptable file format (such as *.jpg or *.pdf)?

4.19 Did you write a cover letter to the journal editor when you submitted your manuscript?

Did you tell the editor that you are submitting a new manuscript (as opposed to a revised manuscript) and, if necessary, the section of the journal where your manuscript belongs (original research, review, and so on)?

Did you tell the editor briefly what you did and why you think readers will be interested in your research?

Did you tell the editor that your manuscript has not been published before and is not currently being considered by another journal? (You do not need to say if your article was rejected by another journal.)

Did you tell the editor that all of the authors have approved the manuscript as submitted?

Did you tell the editor if the research has been presented at a conference or as a meeting abstract?

Did you list as the corresponding author the author who is best able to communicate with the editor? (In Western journals, no importance is attached to being the corresponding author. The corresponding author is just the person who communicates with the journal, such as the author who understands English the best.)

Did you keep the letter less than one page long?

5 Conclusions

Publishing the results of your study is a long and difficult process, even if everything goes well. You will get better with practice. The questions listed here are not the only ones that journal editors will ask, but they are the most important. If you remember before you start that publishing your research is as important as conducting it and that it requires as much patience and skill, you will be better prepared for the process.

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