Evidence Based Medicine and Case Reports: Study of an optimized method of reporting maternal drug exposure cases

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Objectives

General
To develop an optimized method for case reports and case series of maternal drug exposure, with the goal of increasing the strength of evidence associated with these sources.

Specific
This work has been divided into three main parts, namely:

Part 1 - Research for guidelines
Part 2 - Analysis of clinical data
Part 3 - Optimized Method

Methods

Part 1 - Research for guidelines

PubMed
A search in PubMed was performed using equation ”Case Reports” [Publication Type] AND ”Evidence-Based Medicine” [Mesh]. Then the tools ”Titles with your search items” and ”Related Citations in PubMed” were used, and, from the articles obtained, we proceeded with an analysis of its Mesh terms. The most relevant Mesh terms found were combined with the term ”Case Reports” [Publication Type].

Scientific journals
There was also performed a visit to several websites of scientific journals to analyse their own instruction for authors for the writing and publication of case reports and case series. The selection of the scientific journals was made according to the scope of each journal and the identification of the journals that provided useful articles in the PubMed search.

Part 2 - Analysis of clinical data

The clinical cases of pregnant women provided by the Service of Human Reproduction of the Coimbra Hospital and University Centre permitted the identification of the most relevant information that should be present in clinical records and allowed the focus on clinical cases of depressed pregnant women, as an example of the use of the method to report cases of a specific condition.

Part 3 - Optimized Method

Combination of the guidelines obtained from the scientific literature in Part 1 and the most relevant demographic, clinical and pharmacological information identified in Part 2 to develop the optimized method for the writing of case reports and case series proposed.

Results

Part 1 - Research for guidelines

Scientific Papers - Table 1: General structure recommended by authors.

Section of the report | Description
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Title | Informative, brief, indicating the type of study.
Abstract | Structure similar to that of the case report. Authors sometimes suggest a maximum number of words.
Introduction | Brief, explaining the importance of that report recurring to references from the scientific literature. It may contain a sentence presenting the patient of the report.
Case Report | Description of the patient including demographic information and clinical history. Performed exams and their results, diagnosis and treatments, as well as the outcome obtained vs. expected.
Discussion | Probably the most important section. Transmission of the final message and reflection on the results obtained.
Conclusion | Brief. Summary of the final message.

Scientific Journals

Very different recommendations. Some journals demand structured reports in order to be published, others do not refer a specific structure, and some others simply inform that do not publish case reports nor case series (including journals in the area of gynecology, obstetrics, pediatrics and teratology).

Discussion

Part 1 - Research for guidelines

The recommendations and guidelines found in the different researches showed the importance attributed to case reports and case series. Usually the recommendations were more strict when there was attributed a greater value to these type of studies. There is still a lot to learn from and with case reports, but unfortunately there are still a lot of journals that refuse to publish them, probably because they are associated with a low level of evidence.

In spite of the recommendations found in the literature, there are usually guidelines from each journals so that the cases may be published, and sometimes that recommendations do not lead to complete case reports.

Part 2 - Analysis of clinical data

The more complete the case reports, the more strength of evidence. For that it is of high importance that the clinical records contain all the relevant information for each case, which is not what usually happens.

Part 3 - Optimized Method

There was proposed a method for the writing and publication of case reports and case series. Although the authors are usually restrained to the journals orientations, there is still a lot of information that should be addressed and authors may use this method to consult it.

Conclusion

The method proposed was successfully developed. Given the fragility of the population the method refers to, it is of major importance to generate scientific evidence that support the use of medicines in pregnant women. There is, however, a patent need to provide complete medical records in order to enable the access to all the relevant information related to each case. This method allows the creation of valid reports written with quality, generating a reliable source.

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