DI-062

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 - To identify guidelines for the writting and publication of case reports and case series;

Part 2 - To analyse clinical cases of pregnant women exposed to drugs in order to identify the most relevant data which should be included in clinical records, which permits subsequent publication.

Part 3 - To develop the optimized method proposed from the combination of the information obtained in part 1 and part 2.

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 writting 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 permited 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 writting of case reports and case series proposed.

Results

Part 1 - Research for guidelines

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

Section of the report	Description
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).

Working Groups

ICMJE - Don't refer specific recommendations for case reports nor case series.
ISPE and ISoP - Recommendations for the publication of case reports only for adverse reactions.
CARE - Guideline that recommends a similar structure as that found in scientific papers (table 1).

Part 2 - Analysis of clinical data

From the analysis of clinical data of pregnant women, the most relevant information required for the writting of a case report or case series was compiled as follows:

Clinical information from the mother: identification, demographic information, present health condition, present obstetric condition, physical exam, obstetric history, health history, family background.

Clinical information from the foetus: pre-natal exams and physical exams.

Pharmacological, diagnosis and risk factors exposure information: Treatment(s) used before and after conception, diagnosis interventions, pharmacological history (previous exposures from both parents), potencial exposures to risk factors (environmental or occupational).

Part 3 - Optimized Method

Case Report Sections	Specifications
Title	Brief and concise. Refers the type of study of the report, the drug(s) involved and the maternal exposure, as well as the outcome of the exposure if negative.
Abstract	Less than 200 words. Reference only to the most relevant information of the report: diagnosis, drug(s) involved, and outcome for both the mother and the baby. May be structured into Introduction, Presentation of the Case and Conclusion.
Introduction	Brief. Justifies the relevance of the case and why it should and is being published. Reference to the scientific literature, including the safety information of the drug(s) used.
Case Presentation	Pregnant woman information: Identification and demographic information. Present health condition. Obstetric condition: First appointment status (e.g.: already pregnant?), previous pregnancies and outcomes, gestational age at the time of the first exposure. Performed exams and results. Pharmacological information: Medication administrated before pregnancy: why was it prescribed, generic and commercial name, dose, frequency and route of administration, pharmaceutical form, and duration of treatment. Medication used through pregnancy: addressing the issues of the previous topic, plus duration of treatment before and during pregnancy. Pharmacological history: treatments to previous health conditions, including paternal exposures. Exposures to other risk factores from both parents (e.g.: radiation, alcohol). Information related to the pregnancy - mother: Symptoms development. Pregnancy evolution. Information related to the pregnancy - foetus: Performed exams and results. Complications? Information related to the pregnancy - new born: Characteristics (sex, size and weight, Apgar score, complications?) Performed exams and results.
Discussion	Reflection on the related case: safety and efficacy of the treatment from the perspective of the mother and baby. Generated hypothesis . Reflection on the type of study used and its flaws. Suggestion for future research.
Conclusion	Brief. Summary of the final message to be transmitted to the reader.

Discussion

Part 1 - Research for guidelines

The recommendations and guidelines found in the different researches showed the importance atributed 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 countain all the relevant information for each case, which is not what usually happens.

Part 3 - Optimized Method

There was proposed a method for the writting 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 adressed 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.

Acknowledgements

I would like to thank Professor Ana Cristina Ribeiro Rama for her guidance and support through all the development of this project. I would also like to thank Professor Ana Teresa Almeida Santos for her encouragement and cooperation with the Human Reproductive Service of the Coimbra Hospital and University Centre.