Reviewer’s report

Title: Characterization and preventability of Adverse Drug Events as cause of Emergency Department visits: a prospective 1-year observational study

Version: 0 Date: 05 Oct 2018

Reviewer: Lucien Roulet

Reviewer's report:

Disclosure

I have no conflict of interest that could be construed as relevant to the assessment of this manuscript.

General

The text is clear and understandable.

Contribution to the field: weak

The interest of the article is very limited by its essentially descriptive aspect.

As the literature discussed in this article shows, these results do not provide anything compared to what is already known: we have known for years that

- ADEs are frequent in ED
- increasing age is associated with multimorbidity and thus with polytherapy and thus with ADEs
- a significant proportion of ADEs are preventable
- drugs with a narrow therapeutic range are at higher risk of ADEs
- antibiotics and NSAIDs are among the most responsible classes of ADEs

⇒ in the end, these results are of interest to the Sicilian health authorities, but they bring nothing new at the general level.
Title
The title accurately reflects the study design and content of the article.

Abstract
The abstract is informative, providing the essence of the article.

Introduction
The objectives of the study are not clearly defined.

The introduction does not succeed in raising the issue. It gives the impression of a patchwork of quotations from the literature, without constructing logical reasoning. The consequence is that we do not understand the objective of this work and what justifies its realization, apart from describing the situation in Sicily.

P2, L50: the authors regard as limited the studies carried out previously that did not assess the preventability of ADEs.

In our experience, assessing the preventability of an ADE in the context of emergencies is extremely difficult given the limited information available, especially if no follow-up after discharge is carried out. We are therefore still very sceptical about the assessment of the preventability of ADEs in ED, and these difficulties are not discussed in this article.

P2: the authors refer indifferently to ADR and ADE. However, these terms do not have the same definition, and it makes no sense to compare their prevalence.

Methods
It is very unusual and methodologically very questionable to include both adults and children in a study.

This is the very first time we have encountered such a study design. The typology of drug iatrogeny in adults and children is totally different.

The source of the data collected is not mentioned, what is a major deficiency.

This information is crucial, as it is impossible to interact with a significant proportion of patients in ED - especially when using these data to calculate prevalence rates.
How were OTC drugs collected?

Self-medication in ED is a subject in its own right, which requires a rigorous investigation methodology: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3834162/

Logistic regression methods are unclear

The construction of multivariate models is based on univariate analysis, but which should not be limited to the 3 mentioned factors (gender, age, number of drugs taken). No other variables seem to have been tested, which would be totally insufficient.

It is also well known that there is a strong correlation between age and the number of drugs taken.

Results

Several exclusion criteria are described, but the result section do not provide any evidence (i.e. flow chart) to assess excluded patients.

Again, this information is crucial, especially when using data to calculate prevalence rates.

The authors do not mention the proportion of patients under 18 in the total number of ED visits.

Discussion

Discussion interest: low

The discussion is in accordance with the results, but confirms their lack of interest: little is learned, the considerations remain very descriptive. The discussion is not broadened towards other perspectives.

Miscellaneous

Too large number of references (69): it corresponds rather to a review article than to an original research article

Incomplete quotation for many references

Many figures are provided in comparison with what the article brings. In particular, table 3 is of very little use since the classes presented are very general: a sentence in the result section to quote the 3 main classes would be sufficient
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
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