Reviewer's report

Title: Pattern recognition in menstrual bleeding diaries by statistical cluster analysis

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Reviewer: Antonio Cano

Reviewer's report:

This manuscript aims at finding clinically meaningful bleeding patterns as reported in bleeding diaries from clinical studies with steroidal hormones, either contraceptives or hormone therapy. The topic is of much interest since there has been considerable heterogeneity in studies reporting bleeding/spotting episodes in studies on women using hormones. Given this relevance, the own World Health Organization has issued recommendations for analyzing bleeding patterns in clinical trials, as adequately cited by the authors. Additional strengths of the manuscript include a good definition of the objectives, a well-selected list of references, and an adequate total length.

The main problem, however, is that the concrete content and conclusions will perhaps be of little interest for clinicians. The analysis is focused on cluster algorithms that many clinical investigators/practitioners may find difficult to understand due to the lack of familiarity with these research tools.

Another point refers to the limitation imposed by the fact that actually 27.9% of the women never bled during the period analyzed, and an additional 68.8% experienced a bleeding pattern that occurred only once. Authors should include in the manuscript an indication on whether this may, or may not, affect the consistency of their conclusions.

In summary, I think this is a well designed and developed study, but perhaps it will be more adequate to submit it to journals with a more specialized profile on this type of analytical models.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no conflict of interest relative to this paper.