Reviewer’s report

Title: Surgical and medical second trimester abortion in South Africa: a cross-sectional study

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Reviewer: Josep Lluis Carbonell i Esteve

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General

The manuscript evaluating women’s experiences seeking and undergoing second trimester abortion at public sector hospitals in Western Cape Province, including documenting the efficacy, safety and acceptability of medical and surgical abortion as currently performed is a very interesting study and without any doubt must be published after some corrections. There are very few papers on this topic published in the world. (In the Berlin congress of FIAPAC, if I am not wrong, you could find in the abstract book a piece about this topic: surgical versus medical abortion in 2ª trimester.)

Abstract.

1. It is too long (269 words), it could be condensed.
2. Background could be reduced to: A high percentage of abortions performed in South Africa are in the second trimester. However, there are no studies describing women’s experiences or documenting the efficacy and safety of those services.
3. Objectives form part of the Abstract. Please put in writing them.
4. For example the last paragraph could be eliminated.
5. New sentences must not begin with a number (220 women underwent...)
6. All p values must be written as “p” and not as “P”

Background

1. References [4,5,6,7] must be written as [4-7]. It’s valid for the Discussion section.
2. The last sentence (“Given ..... later abortion care”) of the introduction section could be is not necessary.

Materials and Methods

1. Paragraph starting with “The study ....... were ensured.” Must be located at the beginning of this section (it must be the first). A sentence indicating that the study was carried out in accordance with the revised version of the Helsinki Declaration and with the standards of Good Clinical Practice” must be introduced
in such paragraph.
2. The paragraphs starting in “The remaining … procedures maintained at the facility” must be eliminated from the text. That is not interesting to anybody and authors must be centered on the participating centers.
3. The phrase explaining why the study was extended data collection could be eliminated.
4. The authors affirmed that the primary outcomes of the study were procedure efficacy, safety and acceptability and then proceeded to define each one of those endpoints. It may be better to focus first on efficacy as the main variable to be evaluated and as secondary outcomes. Then, safety and acceptability could be defined as secondary variables to respond to the objectives of the study.
5. The sentence starting with “This sample size …..0.05” must be rewritten. There was not random allocation to one or another method, or random selection of subjects, etc. It must be said that with “the number of subjects recruited was sufficient to detect a difference in efficacy of 85% for induction and 98% for D&E, with 90% power and two-sided alpha of 0.05.
6. Why means ± standard deviations were not use for continuous variables? Number observations allow that. The use of IQ range is not necessary.
7. Why if statistical comparisons were performed by procedure rather than by site because numbers were too small to allow for analysis by site, the results are presented for each site. Instead, it could be worthy to limit the presentation to procedures.

Results
1. Last sentence of first paragraph must be included in M and Methods section.
2. Along this section are given explanations about the reasons because the gestational was more or less advanced in the different methods. Please, limit to present the results; the commentaries on why data are similar or different belong to the discussion section and must be eliminated from this section.
3. In general, what is written in the text must not be in tables and vice versa, it is not necessary to repeat information: this is valid for the whole results section.
4. In tables it is not necessary to give information on age, parity, gestational age by classes; again: means ± standard deviations should be used and again: limit the presentation by procedures, no by centers. It is not interesting be so exhaustive for those variables but for education, housing and languages.
5. The generalized use of IQ range is not justified along the tables, especially in categorical variables. They must be eliminated.
6. The results section must be written in third person and any comment trying to explain anything about the information given must be eliminated from this section. Comments and interpretation belong to the Discussion section.
7. Information on cesarean section must be given rather than vaginal deliveries (higher risk for D/E and for inductions as well)
8. Phrases as “After initiating data collection …… participants’ charts must be moved to Material and methods section. There are some along this section.

9. All tables are not easily understood, they must be simplified.

10. Doses and protocol administration must be referred in material and methods section, not in Results. Authors must, after or better before publishing this paper to hold an agreement meeting or conference or symposium which includes all participant centers: medical directors, chiefs of gynecology services and doctors to make them aware of the absolute chaos and protocol disaster existing just in one province of South Africa. It is unacceptable that every doctor uses a different dose, administration interval and total doses in second trimester pregnancy terminations. That must be well regulated and organized; besides there are high level published reports on the topic which establishes the necessary guidelines and rules. (Guidelines of World Health Organization published 2 years ago in International Journal of Obst Gynecol). Besides, they cannot say that several centers used the D&E technique if they administer previously the most powerful abortifacient (even more that mifepristone) known to date (several doses of misoprostol 6 – 13 hours before the procedure, it is false that they were performing D&E. Or, they are using a new mixed method not yet scientifically documented although practiced in some centers or they are using DyE in those cases that did not abort with the medical protocol used, (6-8-10-13 hours) and that it is the 43. 3% of the scheduled cases for D&E, almost half of the total. In other words, if the woman aborted or expelled the products of conception using misoprostol alone (without surgical interventions) that cannot be considered as a D&E case. They could only say that such cases were programmed to D&E. It is “vox populis” that one single 400-µg misoprostol dose could provoke a second medical trimester abortion in 2-4 hours. Furthermore, the mean time for cervical priming before a D&E (without previous mifepristone) is in the range 1.5 – 3 hours maximum according to cervical conditions: length, cervix position, consistency, dilation of external os, etc (abortion Bishop test). (See bibliography Carbonell et al, Contraception ..........................) If this time is exceeded then they could have spontaneous medical inductions or abortions.

11. Was D&E performed with local anesthesia only? Please clarify that in contrast with the majority of countries they not use “general sedation”.

12. Regarding the medical induction method a post expulsion revision of the uterine cavity must be performed, this could lead to avoid the too high percentage of post abortion complications. Or, at least, to perform an US exam and depending on the results they could perform the post expulsion revision of the uterine cavity. This is obviously depending on the conditions of the country but not having the enough resources justifies that a method should be impoverished or being malpracticed because that removes its prestige. Misoprostol doses should not be administered 3-4 hours before entering a medical center for second trimester abortions because there is a high risk of aborting at home or in the way to hospital, this could very dangerous and stressing to women. Perhaps this is the explanation for the high percentage of discomfort in that group. In fact, authors must separate the cases that aborted before D&E and add them to the group of medical inductions or at least treat
them separately from those who really underwent a D&E. I know and I understand the sanitary situation in South Africa but that is not a justification to rigorously criticize data.

13. Authors should have a thought in the increasing of safety that could represent the use of mifepristone in D&E as well as in inductions, mainly in the most advanced gestations (Mifepristone is very expensive in Exelgyn but South Africa could buy it in China or India (a 200 mg tablet is about 3 euros)

14. Regarding the reported increased pain in the D&E group it is without any doubt due to that 43% of the cases were not D&E but medical inductions, and that D&E must done under general sedation and not only with paracervical blockade.

15. It is true that there are few publications defending the use of misoprostol for cervical priming before a D&E instead of the antiquated but efficacious although slow laminaria tents (if funds are sufficient Dilapan tents must be used, they give the same effect than laminaria tents but it is only needed 2 of them instead of 10-12 of laminaria tents, the price is very high). Any expert in second trimester medical abortion doubts that the most efficacious, rapid and economical cervical priming agent is misoprostol that is worldwide used, independently than the number of scientific publications on the topic. For example, in Spain, where the biggest experience on the use of misoprostol (21 years) with more than 100 000 second trimester abortions performed to date. Unfortunately, there are non serious publications on this matter but the experience exists (See Symposium “Avances en Gineco-Obstetricia, Valencia, España, 1995)

Discussion

1. The paragraph starting with “Since …… public sector services” could be eliminated.
2. A paragraph stating the difficulties and disadvantages of comparing different methods and dose protocols and the limitations of this must be included.

Quality of written English: Needs some language corrections before being published