

# Review of: "Comparative Study between Using Only Vaginal Misoprostol and Using Vaginal Misoprostol and Estradiol Cream for Induction of Labour: Randomized controlled trial"

Justin Konje<sup>1</sup>

<sup>1</sup> University of Leicester

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This was a randomised controlled trial of misoprostol versus misoprostol and vaginal estradiol for the induction of labour in women with an unfavourable cervix. 120 women were randomised - 60 received misoprostol alone and 60 received a combination of misoprostol and estradiol. The main findings were no differences in outcomes - although the emergency CS rates in both groups were exceptionally high. This study while may add to what is already known in the literature suffers from several problems that undermine the study.

1. The language in the manuscript needs to be revised/edited by an English editor as there are so many grammatical errors within the manuscript.
2. There is no evidence that this study was registered. It is the expectation that any prospective clinical trial nowadays must be registered with any of the international trial's registry. Why was this not registered? If it was provide the details please
3. The abstract is very light - any study on induction of labour must present data on induction to delivery interval, failed inductions and augmentations. These are missing in the abstract which focuses mainly on high CS rates most of which were secondary to failed induction.
4. The abbreviation IOA in the first line of the abbreviation should be corrected to IOL.
5. The authors make so many vague statements that should be qualified or referenced - for example the sentence which states that "IOL is an essential vital intervention that reduces undesirable effects. What does this mean and using vital and essential is stating the same thing twice.
6. How does IOL reduce the risk of infections?
7. How does attempting induction on an unripe cervix increase the use of instruments?
8. Levels of satisfaction of delivery - for who the mother? State so please
9. In the 4th paragraph of the introduction it is stated that "... unique dosage or administration method has been recorded without causing such side effects" Which are these side effects? They have not been mentioned before so you cannot be referring to them.
10. In the Patients and methods - change 'pregnant female patients' to either 'pregnant women' or 'pregnant patients'. You cannot have pregnant males!
11. The last sentence of the 2nd paragraph under "patients and methods" is incomplete.
12. In the 4th paragraph it is stated that Bishop score was used to assess cervical dilatation, effacement, consistency and

station. This is incorrect as the variables were used to generate a Bishop score.

13. Why was blood group done at the time of induction of labour presumably in women who had had their antenatal care at the hospital?
14. What was the justification for using 150mg of estradiol? In the study by Dasgupta and Singh (2012), 50 ug of estradiol was used. 150 mg is a very high dose compared to 50ug.
15. Reference is made to dose being given adjusted by a digital scale (Figure 1). There is nothing in Figure 1 to indicate this.
16. Misoprostol was repeated every 4 hours until a maximum of 5 doses. Was this same in multiparous as well as primiparous women?
17. Under Results
  1. You cannot say causes of induction - you should say indication for induction.
  2. Change fetal kicks to fetal movements
  3. In the 2nd paragraph of the results reference is made to "There were no statistically significant difference between the two groups at ( $p=0.151$ )". What is this comparison for?
  4. You cannot present the number of misoprostol given as a fraction (e.g. 2.19); this is best presented as median and range.
  5. Table 1 should be revised and shortened by deleting the data from 'abortion times'
18. In the discussion
  1. It is stated that the most common indications for induction of labour were severe pre-eclampsia and decreased fetal movements. Is this really the case? Surely those with severe pre-eclampsia and an unfavourable cervix would be offered a CS. The authors then go on to state that these indications were similar to that of other published studies - this is not factually correct as the other studies simply referred to pre-eclampsia which in this case was mild including gestational hypertension.
  2. It would have been useful to have a table with the indication for IOL or at least present them in the results (this is missing).
  3. Provide a reference/references to the statements made about the possible mechanism of action of estradiol
  4. What are postmenopausal women used for comparison when justifying the use of estradiol - 4th paragraph of the discussion?
  5. The CS rate is overall very high. How do we explain this?
19. Why is reference 6 preceded by the suffix a etc?