Reviewer's report

Title: A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial.

Version: 3 Date: 5 January 2015

Reviewer: Therese Dowswell

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Re: 'A comparison of inpatient with outpatient balloon catheter cervical ripening: a pilot randomized controlled trial.'

Chris S Wilkinson, Pamela Adelson and Deborah A Turnbull BMC Pregnancy and Childbirth Research article

Thanks for sending me this manuscript describing a pilot study to review. Overall, I thought the article was interesting, well-written, methods were sound and the study covers an important topic. I would request minor essential revisions.

1. Is the question posed by the authors well defined?

In many settings world-wide induction of labour is common, with approximately a quarter of pregnant women undergoing induction in the study setting. Induction of labour can lead to potentially life-threatening complications for women and babies. Induction of labour can be expensive both because of the cost of induction agents and the need for women to remain as inpatients. The pilot study described in the paper therefore addresses a very important topic: the use of balloon catheters for pre-induction cervical ripening in inpatient versus outpatient settings.

The background section sets out the problem and the question addressed by the trial is well defined.

2. Are the methods appropriate and well described?

Yes, the manuscript describes a pilot study for an RCT. I would have liked some more information on some of the issues raised.

I was not clear when randomisation took place. In the background it sounded as though randomisation took place BEFORE the catheter was inserted ("just prior to the intervention") but in the results it was stated three women were not randomised because there were problems with catheter insertion. Would the authors please clarify? Post-randomisation exclusion is potentially a problem.

If women were randomised before the catheter was inserted did this in any way affect the waiting time for catheter insertion, the setting for insertion (clinic or inpatient setting) or insertion technique?

This was a feasibility study; it would be useful to have some further information
on why approximately a quarter of eligible women refused to participate.

3. Are the data sound?
Yes, the data appear sound although (as the authors note) the pilot was under-powered to demonstrate differences between groups for most clinical outcomes. The authors draw attention to a 24% difference in oxytocin group. Other fairly large differences between groups were not mentioned. It seemed more likely that the catheter would be expelled at home – if this is a real difference, what would account for it?
The finding re oxytocin – the study was not blinded – although blinding this sort of intervention is not possible, lack of blinding may nevertheless affect clinician behaviour and introduce bias; it would be good if the authors mentioned this.
It is possible that interventions in the inpatient group are increased simply because they may receive more monitoring.

4. Do the figures appear to be genuine, i.e. without evidence of manipulation?
Yes. The data re neonatal outcomes appears to be repeated in tables 2 and 3. Economic data were not reported here; it would be good to see that for the main trial.

5. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Yes,

6. Are the discussion and conclusions well balanced and adequately supported by the data?
Yes, see above, more discussion of possible bias would improve the paper.

7. Are limitations of the work clearly stated?
See above.

8. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Yes.

9. Do the title and abstract accurately convey what has been found?
Yes.

10. Is the writing acceptable?
Yes.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**
I declare that I have no competing interests.