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Active management of the third stage of labour with and without controlled cord traction: a randomised, controlled, non-inferiority trial

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Summary

Background

Active management of the third stage of labour reduces the risk of post-partum haemorrhage. We aimed to assess whether controlled cord traction can be omitted from active management of this stage without increasing the risk of severe haemorrhage.

Methods

We did a multicentre, non-inferiority, randomised controlled trial in 16 hospitals and two primary health-care centres in Argentina, Egypt, India, Kenya, the Philippines, South Africa, Thailand, and Uganda. Women expecting to deliver singleton babies vaginally (ie, not planned caesarean section) were randomly assigned (in a 1:1 ratio) with a centrally generated allocation sequence, stratified by country, to placental delivery with gravity and maternal effort (simplified package) or controlled cord traction applied immediately after uterine contraction and cord clamping (full package). After randomisation, allocation could not be concealed from investigators, participants, or assessors. Oxytocin 10 IU was administered

immediately after birth with cord clamping after 1–3 min. Uterine massage was done after placental delivery according to local policy. The primary (non-inferiority) outcome was blood loss of 1000 mL or more (severe haemorrhage). The non-inferiority margin for the risk ratio was 1·3. Analysis was by modified intention-to-treat, excluding women who had emergency caesarean sections. This trial is registered with the Australian and New Zealand Clinical Trials Registry, ACTRN 12608000434392.

Findings

Between June 1, 2009, and Oct 30, 2010, 12 227 women were randomly assigned to the simplified package group and 12 163 to the full package group. After exclusion of women who had emergency caesarean sections, 11 861 were in the simplified package group and 11 820 were in the full package group. The primary outcome of blood loss of 1000 mL or more had a risk ratio of 1·09 (95% CI 0·91–1·31) and the upper 95% CI limit crossed the pre-stated non-inferiority margin. One case of uterine inversion occurred in the full package group. Other adverse events were haemorrhage-related.

Interpretation

Although the hypothesis of non-inferiority was not met, omission of controlled cord traction has very little effect on the risk of severe haemorrhage. Scaling up of haemorrhage prevention programmes for non-hospital settings can safely focus on use of oxytocin.

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