Active management of the third stage of labour without controlled cord traction: a randomized non-inferiority controlled trial

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Abstract:

Background: The third stage of labour refers to the period between birth of the baby and complete expulsion of the placenta. Some degree of blood loss occurs after the birth of the baby due to separation of the placenta. This period is a risky period because uterus may not contract well after birth and heavy blood loss can endanger the life of the mother. Active management of the third stage of labour (AMTSL) reduces the occurrence of severe postpartum haemorrhage by approximately 60–70%. Active management consists of several interventions packaged together and the relative contribution of each of the components is unknown. Controlled cord traction is one of those components that require training in manual skill for it to be performed appropriately. If it is possible to dispense with controlled cord traction without losing efficacy it would have major implications for effective management of the third stage of labour at peripheral levels of health care. Objective: The primary objective is to determine whether the simplified package of oxytocin 10 IU IM/IV is not less effective than the full AMTSL package. Methods: A hospital-based, multicentre, individually randomized controlled trial is proposed. The hypothesis tested will be a non-inferiority hypothesis. The aim will be to determine whether thesimplified package without CCT, with the advantage of not requiring training to acquire the manual skill to perform this task, is not less effective than the full AMTSL package with regard to reducing blood loss in the third stage of labour. The simplified package will include uterotonic (oxytocin 10 IU IM) injection after delivery of the baby and cord clamping and cutting at approximately 3 minutes after birth. The full package will include the uterotonic injection (oxytocin 10 IU IM), controlled cord traction following observation of uterine contraction and cord clamping and cutting at approximately 3 minutes after birth. The primary outcome measure is blood loss of 1000 ml or more at one hour and up to two hours for women who continue to bleed after one hour. The secondary outcomes are blood transfusion, the use of additional uterotonics and measure of severe morbidity and maternal death. We aim to recruit 25,000 women delivering vaginally in health facilities in eight countries within a 12 month recruitment period. Management: Overall trial management will be from HRP/RHR in Geneva. There will be eight centres located in Argentina, Egypt, India, Kenya, Philippines, South Africa, Thailand and Uganda. There will be an online data entry system managed from HRP/RHR. The trial protocol was developed following a technical consultation with international organizations and leading researchers in the field. Expected outcomes: The main objective of this trial is to investigate whether a simplified package of third stage management can be recommended without increasing the risk of PPH. By avoiding the need for a manual procedure that requires training, the third stage management can

be implemented in a more widespread and cost-effective way around the world even at the most peripheral levels of the health care system. This trial forms part of the programme of work to reduce maternal deaths due to postpartum haemorrhage within the RHR department in collaboration with other research groups and organizations active in the field.