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Uterine balloon tamponade as an adjunct to misoprostol for the treatment of uncontrolled postpartum haemorrhage: a randomised controlled trial in Benin and Mali

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Critical analysis of the Dumont et al. uterine balloon randomized controlled trial in Benin and Mali

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As postpartum hemorrhage (PPH) researchers, and leaders in education and care of maternal health emergencies, from the United States, UK, Canada, India, Peru, Honduras, Zambia, India, Kenya, Tanzania, Colombia and Nepal, we read the Dumont et al paper with great interest. We would like to share our review:

The most fundamental flaw of this paper is that the authors confuse an intention-to-treat study of a clinical pathway of interventions and behaviors, with the efficacy of a device. These are two very different research questions. In order to test the latter via a randomized controlled trial (RCT) the two groups would

need to be the similar and subjects that did not even receive the device (or received it in desperation two hours after the diagnosis of uncontrolled PPH) certainly could not be included in the intervention group. Thus, this study attempts to test intention-to-treat, not the efficacy of the uterine balloon tamponade (UBT) device.

The second most obvious flaw is that degrees of illness are not accounted for. Clinically defined "uncontrolled PPH" is in no way a homogeneous group. For example, someone that has been referred in and is moribund from their advanced shock is an entirely different subject than someone who has mild uncontrolled PPH. Since this is not controlled for, these two groups are likely incomparable.

Even taking into account the two issues described above, the two groups are different and heavily favor the non-intervention group. For example, in the intervention group the following were considerably worse than in the non-intervention group: late uterotonics (54% vs 37%) and retained products of conception/placenta (19% vs 10%). Additionally, UBTs were placed more than 30 minutes after diagnosis of uncontrolled PPH in 58% of cases

Therefore, while this study truly does not test the UBT device, what it does do is tell us that the care providers were not able to provide quality care to women defined as having uncontrolled PPH, despite being within the framework of a study that encouraged best practice. This is indeed extremely important. This study adds to the growing literature describing that performance of health care providers may often be inconsistent and suboptimal in maternal health emergencies, and, that these poor practices may contribute to the flawed nature of RCTs in maternal health interventions.

Prof Burke, Prof Arulkumaran, Prof. Rogo, Dr. Manasyn, Susana Ku, RMW, Monica Oguttu, RNMW, Dr. Thapa, Prof Ochoa, Prof. Tarimo, Dr. Eckardt, Dr. Suarez and Dr. Garg,

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Conflict of Interest:

None declared.

Back to top

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