Selected Summaries

Early detection and treatment of postpartum haemorrhage: A game-changing strategy

Gallos I, Devall A, Martin J, Middleton L, Beeson L, Galadanci H, Alwy Albeity F, Qureshi Z, Hofmeyr GJ, Moran N, Fawcus S, Sheikh L, Gwako G, Osoti A, Aswat A, Mammoliti KM, Sindhu KN, Podesek M, Horne I, Timms R, Yunas I, Okore J, Singata Madliki M, Arends E, Wakili AA, Mwampashi A, Nausheen S, Muhammad S, Latthe P, Evans C, Akter S, Forbes G, Lissauer D, Meher S, Weeks A, Shennan A, Ammerdorffer A, Williams E, Roberts T, Widmer M, Oladapo OT, Lorencatto F, Bohren MA, Miller S, Althabe F, Gülmezoglu M, Smith JM, Hemming K, Coomarasamy A. (United Nations [UN] Development Program–UN Population Fund–UN Children's Fund–World Health Organization [WHO]–World Bank Special Program of Research, Development, and Research Training in Human Reproduction, the Department of Sexual and Reproductive Health and Research, and the Concept Foundation—both in Geneva; College of Medical and Dental Sciences, University of Birmingham, Health Education England, and Department of Obstetrics and Gynaecology, Birmingham Women's and Children's NHS Foundation Trust, Birmingham, the Centre for Behaviour Change, University College London, and the Department of Women and Children's Health, School of Life Course Sciences, King's College London, London, and the Institute of Life Course and Medical Sciences, University of Liverpool, Liverpool—all in the UK; the African Center of Excellence for Population Health and Policy, College of Health Sciences, Bayero University, Kano, Nigeria; the Department of Obstetrics and Gynaecology, Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania; Department of Obstetrics and Gynaecology, University of Nairobi, Nairobi, Kenya; Department of Obstetrics and Gynaecology, University of Botswana, Gaborone; KwaZulu–Natal Department of Health, Pietermaritzburg, Department of Obstetrics and Gynaecology, University of Cape Town, Cape Town, and the Effective Care Research Unit, University of the Witwatersrand, Johannesburg—all in South Africa; the Department of Obstetrics and Gynaecology, Aga Khan University, Karachi, Pakistan; the Maternal and Newborn Health Unit, Technical Leadership and Innovation, Jhpiego, and Johns Hopkins University, Baltimore, USA; the Gender and Women's Health Unit, Centre for Health Equity, School of Population and Global Health, University of Melbourne, Melbourne, VIC, Australia; Department of Obstetrics and Reproductive Sciences, School of Medicine, University of California, San Francisco, San Francisco, USA; and the Maternal, Newborn, and Child Health Team, Bill and Melinda Gates Foundation.) Randomized trial of early detection and treatment of postpartum hemorrhage. *N Engl J Med* 2023;**389:**11–21.

SUMMARY

The E-MOTIVE trial was a parallel cluster-randomized trial conducted in secondary-level hospitals in Kenya, Nigeria, South Africa and Tanzania. The baseline control phase evaluated the use of E-MOTIVE intervention—a calibrated drape to measure the exact amount of blood loss for early detection of postpartum haemorrhage (PPH) and WHO's first-response treatment bundle, including routine use of uterine massage, oxytocic drugs, tranexamic acid, intravenous fluids, and a process for examination and escalation, supported by implementation strategies such as involvement of local champions, training, PPH trolleys and audits.

The trial was approved by the Ethics Review Committee of WHO and each participating country. Eligible hospitals included those with 1000–5000 deliveries per year, providing comprehensive obstetrical care, with capability to perform surgery for PPH. Hospitals that had already implemented the PPH bundle care were excluded.

Participating hospitals provided usual care for PPH for 7 months at baseline followed by 1:1 randomization to provide usual care or E-MOTIVE intervention for 7 months. Control hospitals provided only usual care, with use of uncalibrated drapes, and blood loss estimation by visual inspection and management of PPH as per local guidelines. Initial line of management was oxytocic drugs; tranexamic acid was reserved for refractory bleeding only. The primary outcome was a composite of three clinical outcomes, i.e. severe PPH (blood loss ≥1000 ml after vaginal delivery); laparotomy for bleeding, or maternal death due to PPH. The main secondary outcomes included detection of PPH, adherence to treatment bundle, estimation of individual primary composite outcome elements, PPH ≥500 ml, death from any cause, blood transfusion for any cause and for PPH, uterine tamponade, intensive care admission, neonatal death and outcomes of resource-use.

Data were analysed by modified intention to treat principle. The E-MOTIVE protocol promoted initiation of treatment bundle at ≥300 ml blood loss if associated with any clinical abnormality. The primary outcome occurred in 794/48 678 patients (1.6%) in the intervention group and in 2139/50 044 (4.3%) in the usual-care group ($p<0.001$). PPH was diagnosed in 93.1% in the intervention group versus 51.1% in the usual-care group. Adherence to the treatment bundle was 91.2% in the intervention versus 19.4% in the usual-care group. The primary outcome risk was markedly reduced from 3.8% at baseline to 1.1% by the last month of implementation. PPH ≥500 ml and ≥1000 ml was diagnosed in 8.5% and 1.6% of the patients in the intervention group, versus 16.7% and 4.3% in the usual-care group, respectively. There were 12/17 maternal deaths attributed to PPH in the intervention and 18/28 deaths in the usual-care group, respectively (Table I). The trial showed that E-MOTIVE intervention reduced the risk of composite primary outcome following vaginal delivery by 60% at secondary-level hospitals, which is an important result.

There were certain limitations of the study. Information about postpartum haemoglobin and experience of patients about care was not collected. The uncalibrated drapes used in the usual-care group were transparent, which would have allowed care providers to assess the blood collected in drapes and might have attenuated the effect of the intervention observed. The power of the study was less to assess maternal mortality. The trial was conducted in low- and middle-income countries (LMICs); further research is required for high-income countries for generalization of findings of the trial.

COMMENT

PPH is a major cause of morbidity and mortality, accounting for 1 death every 6 minutes globally, occurring mainly in LMICs.[1] In India the incidence of PPH after vaginal delivery is 2%–4%, contributing to 19.9% of the maternal mortality rate.[2] PPH is

TABLE I. Outcome parameters of the postpartum haemorrhage (PPH) trial

Outcome measure	Intervention group *n*=49 101 (%)	Usual-care group *n*=50 558 (%)	Relative risk (95% confidence interval)
Primary outcome	794/48 678 (1.6)	2139/50 044 (4.3)	0.40 (0.32–0.50)*
Diagnosis of PPH	(93.1)	(51.1)	1.58 (1.41–1.76)
≥500 ml	(8.5)	(16.7)	0.51 (0.44–0.60)
≥1000 ml	(1.6)	(4.3)	0.39 (0.31–0.49)
Adherence to treatment bundle	(91.2)	(19.4)	4.94 (3.88–6.28)
Median (range) blood loss	160 (100–280) ml	220 (120–380) ml	–
Blood transfusion for PPH in postpartum period	(1.2)	(1.9)	0.71 (0.55–0.90)
Maternal deaths attributed to PPH	12/17	18/28	0.73 (0.40–1.31)

* p<0.001

definitely treatable and the key lies in its early detection and consistent implementation of strategies.

Time to respond in the event of PPH is the golden step to reduce mortality. Visual estimation of blood loss is almost always an under-estimate by ~20% if the estimated volume is <1 L, and by 41% if the estimated volume reaches 2 L.[3] Quantitative estimation of blood loss is better than visual estimation for early detection of PPH as shown in various studies.[4,5] Non-calibrated drapes under-estimated blood loss with worsening of accuracy at larger volumes compared to calibrated drapes.[4] Quantitative estimation of blood loss is recommended.[6]

In 2017, a technical consultation was conducted to develop PPH care bundles based on the clinical interventions taken from WHO's 2012 and 2017 recommendations.[7] The bundle approach was introduced to address challenges to implementation and adherence to evidence-based PPH guidelines. Akter *et al*. identified the following barriers: limited workforce, lack of knowledge, inadequate skills, reduced involvement of healthcare workers, and resistance to task shifting.[8] Gallos *et al*. conducted the E-MOTIVE trial to overcome these barriers and assess the multi-component strategy for diagnosis and treatment of PPH. The various components of E-MOTIVE have been well known since years for their effectiveness. This trial has shown that a composite approach can reduce the primary outcome by 60%. Presently, the use of calibrated drapes is non-existent and tranexamic acid is available only in select secondary and tertiary settings.

After diagnosing PPH, clinicians implement one treatment at a time and add the second treatment if the patient does not respond to the first. The bundle approach is a combination of discrete evidence-based practices used simultaneously rather than one by one involving teamwork, cooperation and coordination thereby providing high-quality care through selected best interventions. Changing the behaviour of healthcare workers (HCWs) in practice implementation is challenging. The care bundle approach will help in implementation of guidelines, change of clinical practices and will improve patient outcome if high compliance is maintained. Repeated trainings of HCWs (including midwives) in the use of bundle approach, time to time audit of incidence, severity, morbidity and mortality due to PPH to determine the fallacies and feedback of HCWs about problems faced during PPH management and back to HCWs about the measures for improvement. Although, this intervention is associated with certain drawbacks such as non-inclusion of misoprost, which is especially critical if the quality of oxytocin is not good, limitation of patient position to recumbent posture by drapes and time consumption in swab counting.[9]

The E-MOTIVE intervention, supported by a multi-component implementation strategy, will help in markedly decreasing the risk of severe PPH, thereby improving the maternal survival from PPH especially in LMICs.

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