Uterine tonus assessment by midwife versus patient self-assessment within the active management of the third stage of labour

UTAMP trial: preliminary results

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****No conflict of interest to declare**

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Introduction – Maternal mortality

[1] Say L, Chou D, Gemmill A, *et al.* Global causes of maternal death : a WHO systematic analysis. *Lancet Glob Heal* 2014; : 1–11.

Postpartum hemorrhage (PPH)

- PPH ≥ 500ml in 24 hours[3]
  - Majority caused by uterine atony

- Active management of the third stage of labour (AMTSL)[3]
  1. use of uterotonic drugs
  2. controlled cord traction
  3. massage of the uterus
  4. monitoring of the uterine tonus

  60% reduction of PPH morbidity and mortality

- Task shifting in care from midwife to patient
  - Health professionals shortage, reach community deliveries
  - Studies showed effective task shifting in distribution of misoprostol, other steps not investigated

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[3] WHO recommendations for the prevention and treatment of postpartum haemorrhage, 2012.

Aim of the UTAMP trial

To assess whether there is a difference in effectiveness of uterine tone assessment when performed by a midwife compared to a patient's self-assessment on mean blood loss and the incidence of postpartum hemorrhage.

Setting: Korle Bu Teaching Hospital in Accra, Ghana

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Methods (1)

- Non-inferiority pragmatic randomized controlled trial (RCT)
- Setting: Korle Bu Teaching Hospital in Accra (Ghana)
- Intervention: uterine tonus assessment every 15 minutes for 2 hours
  - Arm 1: By midwives (intervention arm)
  - Arm 2: By patients (control arm)
- Sample size calculation: 800 women to be included
  - Difference of 5.5% in PPH can be detected
- Ethical approval: Protocol and Ethics Review Committee University of Ghana Medical School
  - Clinicaltrials.gov (NCT02223806)

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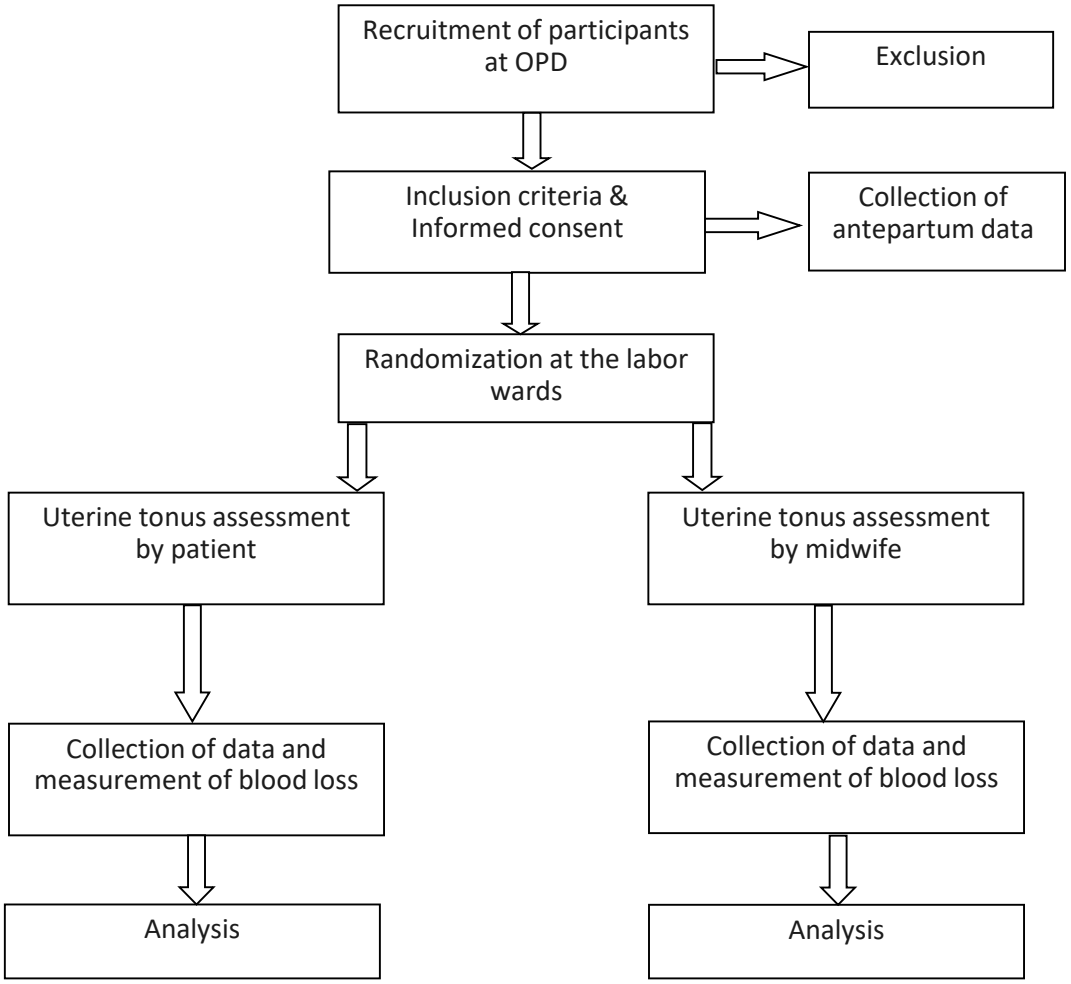
Figure 1: Study flow



Methods (2)

Recruitment at the outpatient department (OPD) and antenatal ward

Inclusion criteria

- Age ≥ 18 years
- Expected vaginal delivery
- Gestational age of ≥ 28 weeks (OPD) and ≥37 weeks antenatal ward
- Informed consent
- Received antenatal instruction(s)

Exclusion criteria

- Operative delivery
- Severe anemia (<8g/dL)
- Risk factors for PPH: antepartum hemorrhage, history of previous PPH, palpable myoma, anticipated breech delivery, multiple pregnancy, intra uterine fetal death

Methods (3)

Randomization at labor wards

- Block randomisation process Data Management University of Medical Centre Utrecht (UMCU)
- Allocation of one of two trial arms through opaque sealed envelopes

Blinding

- Both midwifes and patients were aware of allocation of trial arm due to nature of intervention

All included women received the same standard of care during and after their delivery

- Including if PPH would occur

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Methods (4)

Blood loss measurement:

- INCO pad was placed after delivery of the infant before placental delivery
- Collecting of blood during two hours after delivery
- Pads were replaced when soaked
- Weighed with a calibrated scale

Statistical analysis (preliminary):

- Descriptive for participant characteristics and outcomes
  - Student's T test, Chi Square Test and Fisher Exact Test
- A two-sided P value < 0.05 was considered statistically significant.

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Results: socio-demographic baseline

	All (n=815)	Midwife (n=390)	Patient (n=425)	P value
Sociodemographic information				

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Results: socio-demographic baseline: comparable arms

	All (n=815)	Midwife (n=390)	Patient (n=425)
Age	29.93 ± 5.4	29.73 ± 5.6	30.12 ± 5.22
Residence			
Accra Metropolitan Area	767 (95.0)	364 (95.0)	403 (95.1)
Other urban area	11 (1.4)	2 (0.52)	9 (2.1)
Rural and other	29 (3.6)	17 (4.4)	12 (2.8)
Marital Status			
Single, divorced or widowed	110 (13.6)	51 (13.3)	59 (13.9)
Married	657 (81.4)	315 (82.6)	342 (80.7)
Engaged or living together	40 (5.0)	17 (4.4)	23 (5.4)
Education level			
No education	68 (8.6)	32 (8.4)	36 (8.5)
Primary School	287 (35.7)	129 (33.8)	1558 (37.4)
Secondary School	243 (30.2)	132 (34.6)	111 (26.2)
Tertiary School	182 (22.6)	75 (19.6)	107 (25.3)
Vocational / Religious School	25 (3.1)	14 (3.7)	11 (2.6)
Employment			
Formal employment	125 (15.3)	67 (17.5)	58 (13.7)
Not formally employed	680 (84.5)	315 (82.5)	365 (86.3)

Values are expressed in n=(%) or means (sd), where applicable

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Results: pregnancy and health baseline: comparable arms

	All (n=815)	Midwife (n=390)	Patient (n=425)
Gestational age at delivery*		40 (31-41)	38.6 (38.6-41)
Gravida	3.01 (1.7)	2.99 (1.6)	3.04 (1.8)
Primigravida	160 (19.6)	66 (16.9)	94 (22.1)
2-4 pregnancies	516 (63.3)	260 (66.7)	256 (60.2)
Grand multigravida, >=5	139 (17.1)	64 (16.4)	75 (17.7)
Vaginal delivery			
Uncomplicated vaginal delivery	621 (76.6)	299 (77.1)	322 (76.1)
Episiotomy	174 (21.5)	85 (21.9)	89 (21.0)
Vacuum	16 (2.0)	4 (1.0)	12 (2.8)
No medical history	748 (92.7)	353 (92.2)	395 (93.2)
Medical history of:			
Diabetes mellitus	4 (0.5)	1 (0.3)	3 (0.7)
Asthma	22 (2.73)	12 (3.1)	10 (2.4)
Hypertension	18 (2.2)	10 (2.6)	8 (1.9)
HIV	15 (1.8)	7 (1.8)	15 (1.9)
Post partum hemorrhage in previous pregnancy	17 (2.4)	8 (2.3)	9 (2.5)

Values are expressed in n=(%), means (sd), or median with IQR (*), where applicable.

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Results: No difference between arms for primary outcomes of blood loss and PPH

	All (n=792)	Midwife (n=379)	Self-assessment (n=413)	P value	Difference with 90%CI
Blood loss and complications					
Blood loss in ml	306.5 (232.0)	303.0 (239.9)	309.7 (223.8)	0.68	-6.68 (-20.6-33.9)
No PPH	86.3 (681)	85.6 (323)	86.9 (358)		
PPH >500ml	111 (14.0)	56 (14.8)	55 (13.3)	0.55	0.1 (-2.6-5.5)
PPH >1000ml	23 (2.9)	12 (3.2)	10 (2.7)	0.67	0.5 (-1.5-2.5)
Other complications					
Sepsis	3 (0.4)	1 (0.3)	2 (0.5)	1.00	
Neonatal outcomes					
Apgar score <7 at 1 minute	139 (17.7)	60 (16.1)	79 (19.2)	0.25	
Apgar score <7 at 5 minutes	43 (5.5)	17 (4.6)	26 (6.3)	0.27	
Stillbirth or early neonatal death	8 (1.0)	3 (0.8)	5 (1.2)	0.73	

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Results: no difference between arms in required blood loss management

	All (n=792)	Midwife (n=379)	Self-assessment (n=413)	P value
Uterotonics				
Oxytocin (primary)*	345 (99.4)	174 (99.4)	171 (99.4)	0.99
Misoprostol tablets (primary)#	330 (43.6)	155 (42.6)	175 (44.5)	0.50
Oxytocin/misoprostol (secondary)&	70 (20.5)	29 (17.1)	41 (23.8)	0.12
Blood transfusion^	2 (0.6)	1 (0.6)	1 (0.6)	1.00
Other blood loss management interventions				
Manual placenta removal	11 (1.4)	5 (1.3)	6 (1.5)	0.76
Condom taponade	1 (0.1)	1 (0.3)	0	
Other surgical intervention (not specified)	1 (0.1)	1 (0.3)	0	

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Discussion

- Preliminary analysis; analysis by intention-to-treat (matched with randomization lists) will follow

- Uncertainty about role and effect of uterine tonus assessment in AMTSL?
  - But; it is currently gold standard, occupying midwife's time, competing for their attention with other tasks.

- Majority of patients are able to self-assess uterine tonus.
  - But, re-instructions necessary for ±10%

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Conclusion

- No significant differences were observed for mean blood loss or incidence of PPH when women self assess their urine tonus postpartum compared to midwife assessment.

- Evaluation in larger trial and other (clinical) settings will be necessary

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Thank you

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