

33 Postpartum maternal administration of oxytocin and volume of placental transfusion, an RCT



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OBJECTIVE: Background: Delayed umbilical cord clamping is recommended in vigorous infants to allow for passage of blood from the placenta to the infant. Oxytocin is administered to mothers soon after birth to decrease the risk of postpartum hemorrhage. It is not known whether oxytocin administered postpartum influences placental transfusion. Objective: To assess the volume of placental transfusion when oxytocin is administered immediately after birth (group A) compared with oxytocin given after clamping the umbilical cord at 3 minutes (group B).

STUDY DESIGN: Randomised control trial. Study population: Healthy term infants born vigorous by vaginal delivery with informed consent provided in early labor. Methods: Random numbers were generated by computer program and allocation concealment was performed by opaque, sealed, sequentially numbered envelopes. Oxytocin (10 IU) was given IV within 15 sec. of birth in Group A and after clamping the umbilical cord 3 minutes after delivery in Group B. Soon after birth all infants were weighed at the level of the vagina using a 1g precision scale and subsequently placed on the mother's abdomen or chest. At 3 minutes, in both groups, the cord was clamped and cut and weight was obtained again on the same scale. The primary outcome (volume of placental transfusion) was estimated by the difference in weights (1cc of blood equals 1.05g). T-test and chi-square test were used for group comparison

RESULTS: A total of 144 patients were included from May 2016 to November 2016. There were no differences in the primary outcome: infants in group A (n: 70) gained 86g (SD 48), 95% CI 74-97 and in group B (n: 74) 87g (SD 50), 95% CI 75-98, p=0.92. Hematocrit was 57% (SD 5) in group A and 56.8% (SD 6) in group B. No differences were found in any secondary outcomes including jaundice, polycythemia and maternal postpartum hemorrhage. No clinically relevant adverse events in mothers or infants were recorded.

CONCLUSION: When umbilical cord clamping is delayed for 3 minutes infants receive a clinically significant placental transfusion which is not modified by the administration of IV oxytocin immediately after birth.

34 Th Pre-eclampsia Intervention with Esomeprazole trial (PIE trial)



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OBJECTIVE: Preeclampsia is a major pregnancy complication globally responsible for thousands of deaths. We have shown in preclinical

studies that esomeprazole can potently decrease sFlt secretion and mitigate endothelial dysfunction. We therefore set out to examine whether esomeprazole could prolong pregnancy in women diagnosed with very preterm preeclampsia.

STUDY DESIGN: We performed a double blind, randomised, placebo controlled trial at Tygerberg Hospital in South Africa. Women with a singleton pregnancy who were diagnosed with preterm preeclampsia (gestational age (GA) of 26+0 to 31+6) were randomised (stratified to GA above or below 29 weeks) to 40 mg daily esomeprazole or an identical placebo until delivery. The primary outcome was prolongation of gestation. Secondary outcomes included maternal and neonatal composites and individual outcomes. Serial samples were taken for circulating sFlt and other biomarker levels. Pharmacokinetics were performed on 19 participants. To assess whether esomeprazole would prolong the gestation with an additional 5 days we needed to recruit 120 women.

RESULTS: Between January 2016 and April 2017 we randomised 120 women. One participant was excluded due to incorrect randomisation (59 esomeprazole vs 60 placebo). Baseline characteristics were comparable with a median GA at enrolment of 29+4 weeks in both groups. Median time from randomisation to delivery was 12.9 days in the esomeprazole group versus 13.1 days in the placebo group (P-value 0.92, Figure 1). Secondary outcomes are shown in Table 1. There was a statistically significant reduction in the incidence of abruptio placenta (0/59 vs 6/60 esomeprazole vs placebo (p=0.01)). sFlt1 levels among both arms were very high, with no difference between the groups on serial samples, no obvious decline (or further increase) among either group, and a rapid decline post delivery. In the intervention group, esomeprazole was detectable in maternal blood and the cord blood levels were extremely low.

CONCLUSION: In women with preterm preeclampsia, 40 mg daily esomeprazole did not prolong pregnancy.



Secondary outcomes					
		Esomeprazole (n=39)	Placebo (n=40)	P- values	RR or MD (95% CI)
MATERNAL OUTCOMES	Eclampsia	0 (0%)	3 (5%)	0.24	RR 0.15 (0.01-2.75)
	Pulmonary Oedema	1 (2%)	1 (2%)	0.99	RR 1.0 (0.1-15.9)
	HELLP Syndrome	5 (8%)	3 (5%)	0.49	RR 1.7 (0.4-6.8)
	Severe Ascites	7 (12%)	4 (7%)	0.36	RR 1.8 (0.5-5.8)
	Placental Abruption	0 (0%)	6 (10%)	0.01	RR 0.08 (0.00-1.36)
	Major Postpartum Haemorrhage	0 (0%)	3 (5%)	0.24	RR 0.15 (0.01-2.75)
	High Care and Intensive Care Unit Admission	3 (5%)	6 (10%)	0.32	RR 0.5 (0.1-1.9)
NEONATAL OUTCOMES	Birth weight (grams)	1344 (SD 466.5)	1379 (SD 441.3)	0.67	MD -35.00 (-198.07-128.07)
	Perinatal death within 6 weeks of the due date	8 (14%)	9 (15%)	0.51	RR 0.9 (0.4-2.2)
	Intraventricular Haemorrhage Grade III/IV	2 (3%)	0 (0%)	0.24	RR 5.08 (0.25-103.68)
	Necrotising Enterocolitis	4 (7%)	3 (5%)	0.72	RR 1.4 (0.3-5.8)
	Hyaline Membrane Disease Grade III/IV	7 (12%)	9 (15%)	0.79	RR 0.8 (0.3-2.0)
	Neonatal Intensive Care Unit Admission	8 (14%)	4 (7%)	0.24	RR 2.0 (0.6-6.4)

35 Early-term deliveries are associated with a reduced likelihood of exclusive breastfeeding

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OBJECTIVE: Higher rates of adverse outcomes have been reported for early term (37⁰ to 38⁶ weeks) versus full term (\geq 39⁰ weeks) infants, but differences in breastfeeding outcomes have not been systematically evaluated. Breast milk confers short and long term health benefits, and exclusive breastfeeding (EBF) is a widely-used perinatal quality indicator. We sought to determine whether frequency of breastfeeding initiation (BFI) and EBF differed for early term versus at least full term infants and to identify factors associated with these breastfeeding outcomes.

STUDY DESIGN: This retrospective cohort analysis included participants from two study populations: 743 geographically- and racially-diverse subjects from the Measurement of Maternal Stress Study (MOMS) cohort, and 303 patients from a quality assessment at a hospital-based clinic in Evanston, IL. Participants were included in the analysis if they delivered \geq 37 weeks and had no documented contraindications to breastfeeding. BFI and EBF were assessed by reviewing electronic medical records after discharge. Associations of BFI and EBF with gestational age, maternal age, race, parity, mode of delivery, insurance status, and baby NICU admission were assessed via univariate analysis and multivariable logistic regression.

RESULTS: Of the 875 women eligible for inclusion, 82.9% initiated breastfeeding and 42.5% had EBF. Although early term birth was not associated with any difference in frequency of BFI ($p=0.78$), it was associated with significantly lower odds of EBF (unadjusted OR 0.51, 95% CI 0.38-0.68, $p<0.001$). This association remained (adjusted OR 0.56, 95% CI 0.39-0.80, $p=0.002$) after adjusting for key covariates, including maternal age, parity, mode of delivery, Medicaid status ($p<0.001$), race ($p<0.001$), and maternal smoking during pregnancy ($p=0.001$).



CONCLUSION: Early term infants were half as likely to be exclusively breastfed as full term infants. These data suggest that women with early term infants may benefit from counseling regarding the potential for breastfeeding difficulties as well as additional breastfeeding support after delivery.

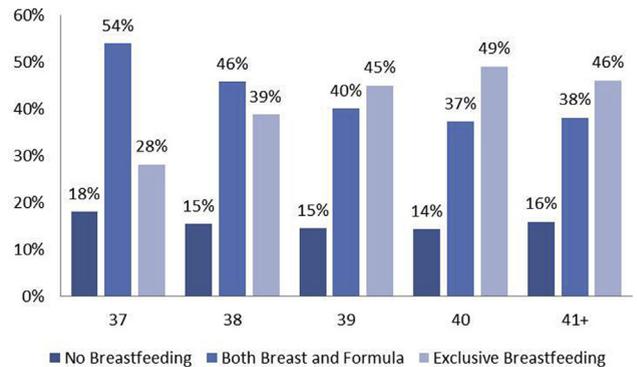


Figure 1: Infant feeding method by weeks gestation for term infants

36 A randomized controlled trial of salpingectomy versus standard tubal ligation at the time of cesarean delivery

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OBJECTIVE: Salpingectomy (SPG) at the time of gynecologic surgery in women who have completed childbearing is recommended for ovarian cancer risk reduction. As the post-reproductive fallopian tube serves little biologic purpose, it may be sensible to perform SPG in lieu of standard tubal ligation (TL) at the time of cesarean delivery (CD). Our objective was to evaluate the feasibility and safety of SPG compared with standard TL at the time of CD in women with undesired fertility.

STUDY DESIGN: The SCORE RCT (NCT02374827), included women \geq 35 weeks GA desiring permanent sterilization at the time of CD. Subjects were randomized after skin incision to SPG or TL by a computer-generated scheme. If SPG was unable to be completed on one or both sides, TL was attempted. Primary feasibility outcomes were total operative time and bilateral completion of randomized procedure. Secondary safety outcomes included clinically estimated blood loss (EBL) and surgical complications up to 6 weeks postpartum (Table). We estimated that 80 subjects (40 per group) would provide $>80\%$ power to identify a 10-minute difference in the primary outcome (time) with a standard deviation of 15 minutes and 2-sided α of 0.05. Analysis was by intent-to-treat.

RESULTS: Of 221 women screened from 6/2015-4/2017, 115 (52.0%) consented to the study; 80 were randomized, 40 to SPG and 40 to TL. Groups were similar at baseline without differences in BMI, number of prior abdominal surgeries or CDs, and medical

