Abstracts 1-8

1 Tranexamic acid for the prevention of postpartum hemorrhage after cesarean delivery: the TRAAP2 trial

Loïc Sentilhes[1], Marie-Victoire senat[2], Maëla Le Lous[3], Norbert Winer[4], Patrick Rozenberg[5], Gilles Kayem[6], Eric Verspyck[7], Florent Fuchs[8], Elie AZRIA[9], Denis Gallot[10], Diane Korb[11], Raoul Desbriere[12], Camille Le Ray[13], Céline Chauleur[14], Fanny De Marcillac[15], Franck Perrotin[16], Olivier Parant[17], Laurent Salomon[18], Emilie Gauchotte[19], Florence Bretelle[20], Antoine Benard[1], Aurore Georget[1], Astrid Darsonval[21], Catherine Deneux-Tharaux[22]

[1]Bordeaux University Hospital, Bordeaux, France, [2]Kremlin Bicètre, Ile-de-France, France, [3]Rennes University Hospital, Rennes University Hospital, France, [4]Nantes University Hospital, Pays de la Loire, France, [5]Poissy Saint Germain Hospital, Poissy Saint Germain Hospital, France, [6]Armand-Trousseau Hospital, Paris, France, [7]Rouen Univesity Hospital, Haute-Normandie, France, [8]Montpellier University Hospital, Languedoc-Roussillon, France, [9]INSERM UMR 1153, Obstetrical, Perinatal and Pediatric Epidemiology Research Team (Epopé), Centre for Epidemiology and Statistics Sorbonne Paris Cité, Paris Descartes University, Paris, France, [10]Clermond-Ferrand University Hospital, Centre, France, [11]Robert Debré University Hospital, Paris, [12]St Joseph Hospital Marseille, Provence-Alpes-Cote d'Azur, France, [13]Port Royal Maternity Hospital, Ile-de-France, France, [14]Saint Etienne University Hospital, Rhone-Alpes, France, [15]Strasbourg University Hospital, Alsace, France, [16]Tours University Hospital, Centre, France, [17]Toulouse University Hospital, Languedoc-Roussillon, France, [18]Necker University Hospital, Necker University Hospital, France, [19]Nancy University Hospital, Lorraine, France, [20]Marseille University Hospital, Provence-Alpes-Cote d'Azur, France, [21]Angers University Hospital, Angers, France, [22]INSERM U1153, INSERM U1153, France

OBJECTIVE: To test the impact of 1g of tranexamic acid after cesarean delivery on the incidence of postpartum hemorrhage (PPH).

STUDY DESIGN: In a multicenter, double-blind, randomized controlled trial, we randomly assigned women with a cesarean before or during labor at ≥ 34 gestation weeks to receive a prophylactic uterotonic and 1 g of tranexamic acid (TXA) or placebo. The primary outcome was an objective calculated blood loss > 1000 ml or a red blood cell transfusion by Day 2 after delivery. Secondary outcomes were other measures of postpartum blood loss and potential adverse effects of TXA up to 3 months after delivery.

RESULTS: Of the 4551 randomized women, 4431 had cesareans, 4153 of whom (93.7%) were assessed for primary outcome. The primary outcome occurred in 556 of 2086 women (26.7%) in the TXA and in 653 of 2067 (31.6%) in the placebo group (adjusted risk ratio, 0.84; 95% confidence interval [CI], 0.75 to 0.94; P<0.01). Mean rates for blood loss-related laboratory outcomes were lower in the TXA than the placebo group: mean calculated blood loss (680±748 versus 787±750 ml) and mean peripartum change in hemoglobin and hematocrit (all adjusted P-values <0.001). There were no significant between-group differences in the rates of these hemorrhage-related outcomes: mean gravimetrically estimated blood loss, provider-assessed clinically significant PPH, use of additional uterotonic agents, and postpartum transfusion (all adjusted P>0.05). Vomiting or nausea was more frequent in the TXA than the placebo group (42.7% versus 35.9%, adjusted P<0.001). At 3 months postpartum, thromboembolic events had occurred in 0.4% (8/2079) of the TXA and 0.1% (2/2086) of the placebo group (adjusted risk ratio, 3.99; 95% CI, 0.85 to 18.81; adjusted P=0.08).

CONCLUSION: Among women with cesarean receiving prophylactic uterotonics, tranexamic acid treatment resulted in a significantly lower rate than placebo of calculated blood loss > 1000 ml or transfusion by day 2, but did not reduce hemorrhage-related secondary clinical outcomes (ClinicalTrials.gov numberNCT03431805).

2 Pessary plus progesterone to prevent preterm birth in women with a short cervix (P5 trial)

Rodolfo C. Pacagnella[1], Thaís Silva[2], José Guilherme Cecatti[2], Renato Passini-Jr[3], Tatiana Fanton[3], Anderson Borovac-Pinheiro[3], Cynara Pereira[3], Marcelo S. França[4], Wentao Li[5], Ben Mol[5]

[1]UNICAMP, Sao Paulo, [2]UNICAMP, Sao Paulo, Brazil, [3]Unicamp, Sao Paulo, Brazil, [4]Federal University of Sao Paulo, Sao Paulo, Brazil, [5]Monash University, Melbourne, Australia

OBJECTIVE: While there it is known that progestogens reduce spontaneous preterm birth in women with a mid-trimester short cervix, studies on cervical pessary show conflicting results. We compared the additional effectiveness of cervical pessary for the prevention of preterm birth in women with a mid-trimester short cervix already using progesterone.

STUDY DESIGN: We performed a multicenter randomized controlled trial in 18 perinatal centers in Brazil (RBR-3t8prz UTN:U1111-1164-2636). Asymptomatic women with a singleton or twin pregnancy and a CL ≤ 30mm, measured at 16+0 − 22+6 weeks gestation, were randomized to cervical pessary + vaginal progesterone or vaginal progesterone (200mg daily) alone. Treatments were used from randomization to 36 weeks of gestation or delivery. The primary outcome was a composite of neonatal mortality and morbidity. Secondary outcomes were among others delivery <37 weeks and delivery <34 weeks. We planned subgroup analysis according to cervical length (≤ 25 mm), parity and the number of fetuses (singletons or twins).

RESULTS: Between July 15, 2015 and March 29, 2019, we measured cervical length in 8,490 women, of which 475 women were randomized to receive pessary + progesterone and 461 women to progesterone alone. The primary composite perinatal outcome occurred in 89/463 19.2% versus (91/436) 20.9%, respectively (RR 0·85, 95% CI 0·55 to 1·1). Delivery rates < 37 weeks were 29·1% versus 31·4% (RR 0·86 CI 0·72 - 1·04) while < 34 weeks, delivery rates were 9·9% versus 13·9% (RR 0·66 CI 0·47-0·93). In women with a nulliparous singleton pregnancy and cervical length ≤ 25 mm, the composite perinatal outcomes occurred in 20% versus 33% of the women (RR 0.59, 95% CI 0.37 − 0.94, p-value 0.02).

CONCLUSION: In asymptomatic women with a short cervix, the combination of cervical pessary + vaginal progesterone did not statistically significantly improve perinatal outcome over vaginal progesterone alone. However, delivery <34 weeks occurred significantly less, specifically in nulliparous women with a CL <25 mm