RCT

Abstracts 31-41

Moderators: Methodious Tuuli, MD; William Grobman, MD

31 Congenital toxoplasmosis prevention by pyrimethamine-sulfadiazine vs spiramycin, a randomized trial

Laurent Mandelbrot[1,2], Isabelle Villena[3], Francois Kieffer[4], Helene Laurichesse-Delmas[5], Norbert Winer[6], Louis Mesnard[7], Alain Berrebi[8], Gwenaelle Le Bouar[9], Anne-Gaelle Cordier[10], Remi Sitta[11], Rodolphe Thiebaut[11]

[1]Hopital Louis Mourier APHP, Colombes, France, [2]Universite Paris Diderot, Paris, France, [3]CHU de Reims, Reims, France, [4]Hopital Trousseau APHP, Paris, France, [5]CHU de Clermont Ferrand, Clermont Ferrand, France, [6]CHU de Nantes, Nantes, France, [7]Hopital d'Orleans, Orleans, France, [8]CHU de Toulouse, Toulouse, France, [9]CHU de Rennes, Rennes, France, [10]Hopital Antoine Béclère APHP, Clamart, France, [11]Université de Bordeaux 2, Bordeaux, France

OBJECTIVE: To compare the efficacy and tolerance of prenatal treatment with pyrimethamine-sulfadiazine (PS) vs spiramycin (S) following primary maternal Toxoplasma gondii infection, to reduce perinatal transmission.

STUDY DESIGN: A randomized, open-label trial in 36 centers in France, compared pyrimethamine (50 mg qd) + sulfadiazine (1g tid), with folinic acid vs spiramycin (1g tid). Pregnant women with confirmed seroconversion were eligible for the trial, after 14 weeks gestation. There was no change in usual procedures for serological screening, prenatal diagnosis or management of infected fetuses and neonates.

RESULTS: 143 women were randomized from 11/2010 to 01/2014, 73 to PS and 70 to S. Baseline characteristics were well balanced between the 2 groups with a median age of 30 years (IQR 26; 32), a gestational age at seroconversion of 19 weeks (14; 25). An amniocentesis was performed in 132 cases, with a positive PCR for T. gondii in 7/68 (10.3%) in the PS group vs. 13/64 (20.3%) in the S group. Two pregnancies were terminated for fetal toxoplasmosis with cerebral abnormalities. Children with undefined infection status were excluded from primary analyses (N=18). The transmission rate was 12/65 in the PS group (18.5%), vs 18/60 in the S group (30%): OR = 0.53 (95% CI 0.23-1.22, p=0.15). The prenatal treatment effect was similar (OR=0.47; CI 0.18; 1.23; p=0.12) after adjustment for gestational week at seroconversion (OR=1.18 per additional week, CI=1.08-1.28 ; p<10-3) but tended to be stronger when started within 3 weeks of seroconversion (p=0.08 for interaction). Three SAE were possibly related to the study drugs, 2 toxidermias and one liver enzyme elevation, all in the PS group.

CONCLUSION: This is the first RCT to study prenatal prophylaxis to prevent congenital toxoplasmosis. There is a trend towards lower transmission with PS, but it did not reach statistical significance, possibly due to lack of power because of premature termination of enrollment. This encourages further research to determine the efficacy of chemoprophylaxis following maternal primary toxoplasmosis.

Rates of mother-to-child transmission of T gondii infection according to treatment group

Study group	Spiramycin		Pyrimethamine/Sulfadiazine		p
	N=60		N=65		
	n	Transmission rate [95%CI]	n	Transmission rate [95%CI]	
Infant with congenital toxoplasmosis	18	30.0%[18.8;43.2]	12	18.5%[9.9;30.0]	0.147
Infant not infected	42	70.0%[56.8;81.2]	53	81.5%[70.0;90.1]	

32 Knotless barbed suture closure of the uterine incision at cesarean - a randomized controlled trial

David Peleg[1], Ronan Said Ahmad[1], Steven L. Warsof[2], Naama Marcus-Braun[1], Yael Sciaky-Tamir[1], Inbar Ben Shachar[1]

[1]Ziv Medical Center, Faculty of Medicine in the Galilee, Bar-Ilan University, Zefat, Israel, [2]Eastern Virgina Medical School, Norfolk, VA

OBJECTIVE: Knotless barbed sutures are becoming increasingly available for surgical procedures in obstetrics and gynecology. Our purpose was to determine if the use of the knotless barbed suture reduces closure time of the uterine incision at cesarean delivery.

STUDY DESIGN: This was a prospective randomized controlled trial. The primary outcome was closure time of the uterine incision. In order to show a decrease of 25% from 6 min to 4.5 min using the knotless barbed suture with a power of 0.9 and type 1 error of 5%, at least 34 women would be needed in each group. Women were randomized by sealed envelope to uterine closure with either a bidirectional knotless barbed suture or polyglactin 910 braided (conventional) suture. Secondary outcomes included blood loss during incision closure and the number of additional hemostatic sutures needed.

RESULTS: Patients were enrolled from August 2016 until March 2017. 102 women were randomized. Fifty-one had uterine closure with knotless barbed suture and 51 with conventional suture. The groups were similar for demographics as well as number of previous cesareans. Uterine closure time using the knotless barbed suture was significantly shorter than the conventional suture by a mean of 1 min 43 sec (P<0.000, 95% CI 67.69 - 138.47 sec). Blood loss estimated during incision closure was significantly lower (mean 221 ml versus 268 ml, P<0.005) and the use of hemostatic sutures was significantly less (median 0 versus 1, P<0.0001).

CONCLUSION: The use of a knotless barbed suture significantly reduced closure time of the uterine incision. There was also less need for additional hemostatic sutures and slightly reduced estimated blood loss.

Primary and secondary outcomes

	Knotless Barbed Suture N = 51	Conventional Suture N = 51	P (95% CI)
Closure time	3 m 37 s ± 1 m 17 s	5 m 20s ± 1 m 41 s	< 0.0001 (67.69 - 138.47 s)
Operation time (min)	20.6 ± 5.4	23.1 ± 7.4	0.0618 (-0.1212 - 4.945 s)
Blood loss during uterine closure (ml)	220.9 ± 89.9	268.2 ± 77.1	0.005 (14.395 - 80.194 ml)
Estimated Total Blood loss (ml)	500 ±168.5	600 ± 145.6	0.0018 (38.129 - 161.87 ml)
Number hemostatic sutures	0.5 ± 0.9	1.5 ± 1.5	< 0.0001