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Corresponding authors:
J. Sibiude (jeanne.sibiude@aphp.fr)
J. Warszawski (josiane.warszawski@inserm.fr)

NO INCREASE IN BIRTH DEFECTS IN INFANTS EXPOSED TO INTEGRASE INHIBITORS AT CONCEPTION

Jeanne Sibiude[1,2,3], Jérôme Le Chenadec[4], Laurent Mandelbrot[1,2,3], Stéphane Blanche[5,6], Catherine Dollfus[7], Nathalie Lelong[8], Elisa Arezes[1, 9], Lamya Ait Si Semi[1], Sophie Matheron[10], Christine Rouzioux[5,6], Josiane Warszawski[4,9,11], and Roland Tubiana[12,13], for the ANRS CO1-French Perinatal Cohort Study

[1]AP-HP Hôpital L. Mourier, Colombes; [2]UMR 1137, INSERM, IAME; [3]Univ Paris-Diderot, Paris; [4]CESP INSERM U1018, Le Kremlin-Bicêtre; [5]AP-HP Hôpital Necker-Enfants Malades, Paris; [6]Univ Paris-Descartes, Paris; [7]AP-HP Hôpital Trousseau, Paris; [8]Inserm, UMR S953, Université Paris 6, Paris; [9]Univ Paris Sud/Paris Saclay, Le Kremlin-Bicêtre; [10]AP-HP Hôpital Bichat, Paris; [11]AP-HP Hôpital Bicêtre, le Kremlin-Bicêtre; [12]Univ Paris-Sorbonne, Paris [13]AP-HP Hôpital Pitié Salpétrière, Paris, FRANCE

CESP - Inserm U1018

Institut national de la santé et de la recherche médicale

EPF

INSERM CESP 1018 - Hôpital de Bicêtre AP-HP
82 rue du Général Leclerc
94276 LE KREMLIN BICETRE Cedex
Tél. : 33 1 49 59 53 05/10 Fax : 33 1 49 59 53 00

OBJECTIVE

To compare birth defect rates and other maternal or neonatal outcomes between integrase-inhibitors (InSTI) exposed mother-infant pairs and matched non-InSTI-exposed pairs.

PATIENTS AND METHODS

The National French Perinatal Cohort (EPF, ANRS CO1/CO11)

Prospective national cohort including all pregnant women with HIV and their children in 90 French centres since 1986.
CO1 component of cohort records detailed information during the pregnancy, including immuno-virological data ; CO11 is simplified and represents 1/3 of the cohort.

Study population: Inclusion of all mother-infant pairs exposed to InSTI, categorized into 3 groups: (G1) ongoing at conception, (G2) initiated during pregnancy, as first-line regimen, and (G3) initiated during pregnancy, as second-line regimen.
Matching: Within each group, we matched 1:1 an InSTI-unexposed infant according to other drugs, ethnicity, center, year of delivery, and gestational age at ART-initiation. InsTI exposed women who did not receive PI or NNRTI were matched to women who received darunavir, with the same other drugs.
Statistical analysis: We compared birth defect rates between the 3 InSTI-exposed groups and, for each group, with the respective matched group, using chi2 and McNemar tests.

Table 1 – Baseline characteristics according to exposure group

Maternal baseline characteristics	Exposed at conception G1 N=301		InSTI as 1st line during pregnancy G2 N=183		InSTI as 2nd line during pregnancy G3 N=324		
	n	%	n	%	n	%	p[a]
Age (years)							
<25	21	7.0	33	18.0	32	9.9	<0.01
25-34	156	52.0	114	62.3	195	60.2	
>35	123	41.0	36	19.7	97	29.9	
Nulliparous	79	26.3	45	25.1	66	20.6	0.21
Geographical origin							
Metropolitan France	50	16.6	11	6.0	18	5.3	<0.01
Sub-saharan Africa	198	65.8	133	72.7	242	75.6	
Other	53	17.6	39	21.3	60	18.8	
HIV diagnosis this pregnancy	0	0.0	75	41.9	251	77.9	<0.01
> 10 Years HIV-infected*	76	40.4	8	8.6	52	23.1	<0.01
Viral load at delivery > 50 cp/mL	28	11.0	61	35.9	105	34.7	<0.01
CD4 at delivery < 200/mL	9	4.3	24	16.3	38	14.0	<0.01

* Only available for CO1 component N=506, a: Chi2 test

Fig 1 – Selection of study population

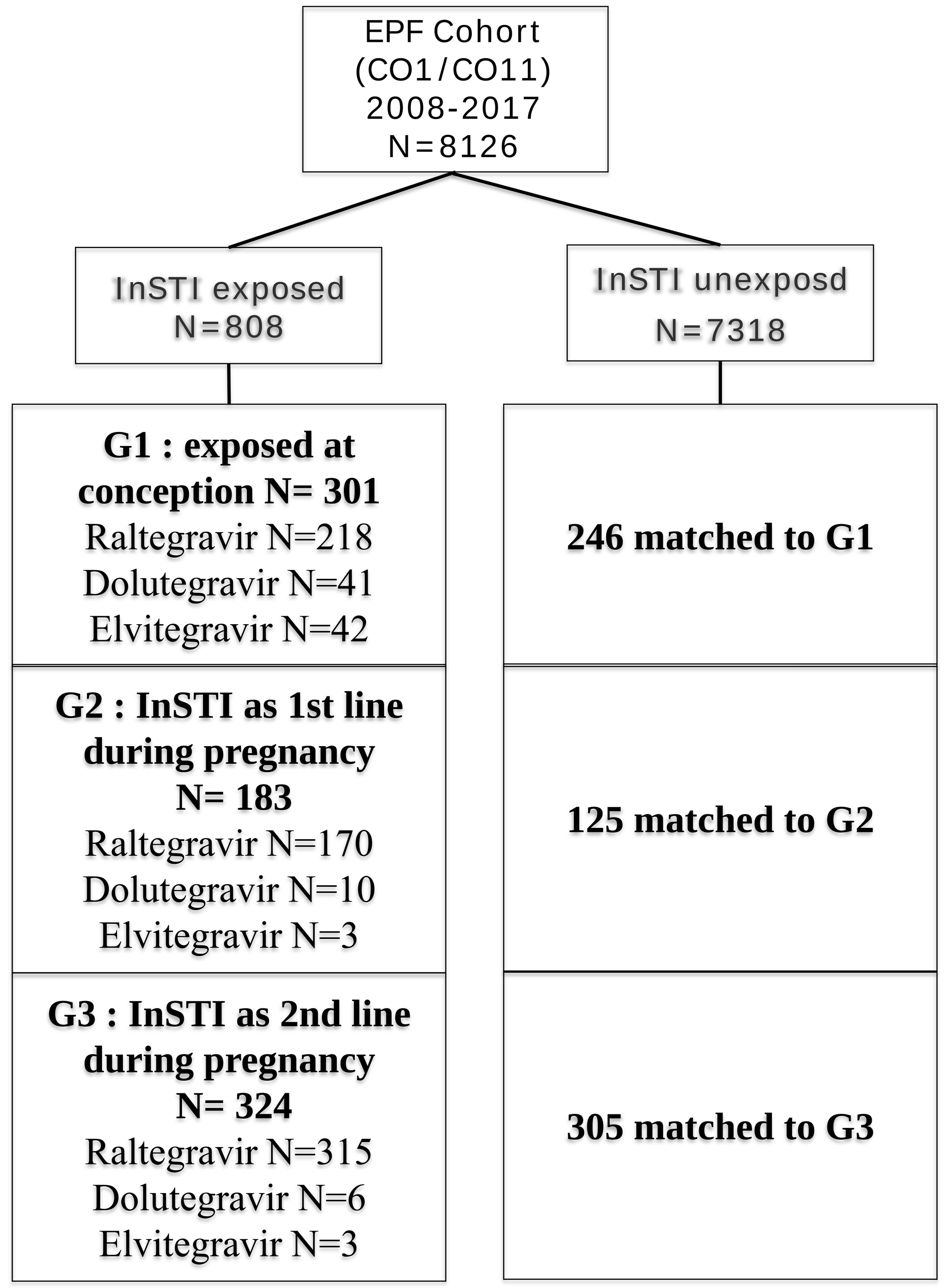

Table 2 – Perinatal outcomes according to exposure group

Perinatal outcomes	Exposed at conception G1 N=301		InSTI as 1st line during pregnancy G2 N=183		InSTI as 2nd line during pregnancy N=324		
	n	%	n	%	n	%	p[a]
Birth defect	18	5.8	5	2.7	9	2.7	0.09
Stillbirths	7	2.4	2	1.1	1	0.3	0.07
Preterm Birth	50	16.8	22	12.1	47	14.6	0.36
Birthweight < 3rd centile	9	3.0	6	3.4	20	6.2	0.13
Length < 3rd centile	12	4.4	9	5.5	14	4.5	0.86
Head circumference <3rd centile	8	2.9	8	4.8	11	3.5	0.56

a: Chi2 test

Table 3– Perinatal outcomes: comparison of InSTI-exposed and matched pregnancies

Perinatal outcomes	InSTI-exposed matched		InSTI-unexposed matched			InSTI-exposed unmatched	
	n	%	n	%	p[a]	n	%
Exposed at conception (G1)							
	N=246		N=246			N=55	
Birth defect	14	5.7	7	2.9	0.13	4	7.3
Stilllbirth	6	2.5	6	2.5	1	1	1.9
Preterm birth	41	16.8	39	16.1	1	9	17.0
Unexposed to any ART at conception. InSTI as 1st line during pregnancy (G2)							
	N=125		N=125			N=58	
Birth defect	4	3.2	10	8.0	0.12	1	1.7
Stilllbirth	2	1.6	1	0.8	0.57	0	0.0
Preterm birth	16	12.8	14	11.2	0.70	6	10.5
InSTI as 2nd line during pregnancy (G3)							
	N=305		N=305			N=19	
Birth defect	8	2.6	14	4.6	0.21	1	5.6
Stilllbirth	0	0.0	0	0.0	1	1	5.3
Preterm birth	45	14.8	41	13.5	0.65	2	10.5

a: McNemar test for matched data

Table 4 – Description of birth defects according to exposure

InSTI-Exposure at conception	N	InSTI-Exposure at conception	N
Raltegravir		Dolutegravir	
Chromosomal abnormalities (T21 N=1, T18, N=2)	3	Chromosomal abnormalities	1
Polydactyly	4	Patent ductus arteriosus	1
Patent ductus arteriosus	2	Elvitegravir	
Anomalous pulmonary venous drainage	1	Polydactyly	1
Coartctation of the aorta	1		
Corpus callosum agenesis	1		
VACTERL syndrome	1		
Hip dislocation	1		
Posterior urethral valves	1		

RESULTS

Since 2008, 808 women were exposed to InSTI, during pregnancy, 301 were exposed at conception (G1), 183 started an InSTI-based treatment as 1st line during pregnancy (G2) and 324 were treated with an InSTI-based treatment as second-line (intensification) (G3).

Women from the 3 groups differed significantly : women on InSTI at conception were older, and had been living with HIV for a longer time (Table1).

The rates of birth defects and of stillbirths tended to be higher among women on InSTI at conception vs InSTI later in pregnancy, without reaching significance. Other perinatal ouctomes did not differ (Table 2).

Exposed and matched InSTI-unexposed groups did not differ in rates of birth defects, stillbirths or preterm birth (Table3).

Among birth defects reported in women InSTI-exposed at conception, we found no neural tube defects (Table 4).

CONCLUSION

We found no evidence of a higher birth defect rate among 301 women exposed to InSTI at conception, mostly exposed to raltegravir, however in the current context, surveillance must be pursued for this class of ART.

ABSTRACT

Background : Integrase inhibitors (InSTI) are increasingly used by HIV-infected women during pregnancy. Following an alert on the association of dolutegravir with neural tube defects, we evaluated the risk of birth defects in case of exposure to this antiretroviral class.
Methods The French Perinatal Cohort is a multicenter national cohort including all HIV-infected women in 90 maternities. We studied all mother-infant pairs exposed to InSTI, categorized into 3 groups: (G1) ongoing at conception, (G2) initiated during pregnancy, as first-line regimen, and (G3) initiated during pregnancy, as second-line regimen. Within each group, we matched 1:1 an InSTI-unexposed infant according to other drugs, ethnicity, center, year of delivery, and gestational age at ART-initiation. InsTI exposed women who did not receive PI or NNRTI were matched to women who received darunavir, with the same other drugs. We compared birth defect rates between the 3 InSTI-exposed groups and, for each group, with the respective matched group, using chi2 and McNemar tests.
Results : Overall, 301 women were exposed to InSTI at conception (G1): 218 exposed to raltegravir, 41 to dolutegravir and 42 to elvitegravir. Rates of birth defects for InSTI-exposed infants at conception (G1: 5.8% 18/301) did not significantly differ from those of InSTI-exposed infants of the two other groups: 2.7% (5/183) in G2 and 2.7% (9/324) in G3, p=0.09. There was no neural tube defect among infants exposed to InSTI at conception. There were only two birth defects among the 41 infants exposed to dolutegravir (a case of Down syndrome, and a persistant ductus arteriosus).When restricting to matched infants, birth defect rates in G1 were not significantly different from the matched InSTI-unexposed group (5,7%, 14/246 vs 2,9%, 7/246, respectively, p=0.13). The EUROCAT types of birth defects were similar for InSTI-exposed at conception and matched infants. There was no difference in stillbirth rates (2,5% vs 2,5%, p=1), nor in preterm birth rates (16,8% vs 16,1%, p=1) between pregnancies exposed at conception and the matched pregnancies. Among women exposed at conception, 65% were still receiving InSTI at delivery. Similarly, there was no difference in birth defect rates between InSTI-exposed infants in G2 and G3 and the matched unexposed infants.
Conclusion We found no evidence of a higher birth defect rate among 301 women exposed to InSTI at conception, mostly exposed to raltegravir, however in the current context, surveillance must be pursued for this class of ART.

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