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Perinatal and Infant Outcomes After Bictegravir Exposure in Pregnancy: a Canadian Surveillance Study

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BACKGROUND

- Despite limited data, Bictegravir (BIC) was recently upgraded to an alternative regimen in pregnancy in US and European guidelines
- Since BIC's Food and Drug Administration approval in 2018, less than 400 perinatal cases of BIC exposure have been published

OBJECTIVES

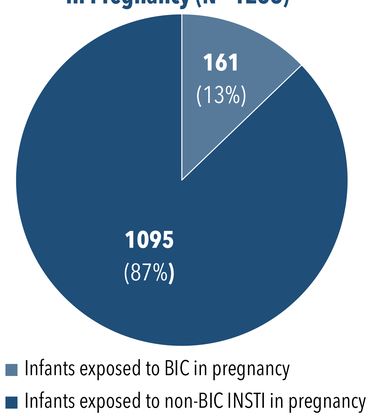
1) Review all Canadian infants exposed to BIC in pregnancy.
2) Compare perinatal and early infant outcomes to infants exposed to other cART in pregnancy.

METHODS

- **Type of Study:** Population-based, retrospective cohort study
- **Data Source:** Canadian Perinatal HIV Surveillance Program (CPHSP)
  - All live births to pregnant people living with HIV within 22 referral centres (estimated 95% of all births in the country)
  - Excludes: Miscarriages, stillbirths, therapeutic abortions
- **Primary Outcome:** Rate of congenital anomalies, preterm births, birth weights, perinatal transmission
- **Data Analysis:** Univariate and multivariate regression analysis using SAS 9.4 compared perinatal and early infant outcomes in infants exposed to either BIC or non-BIC cART

RESULTS

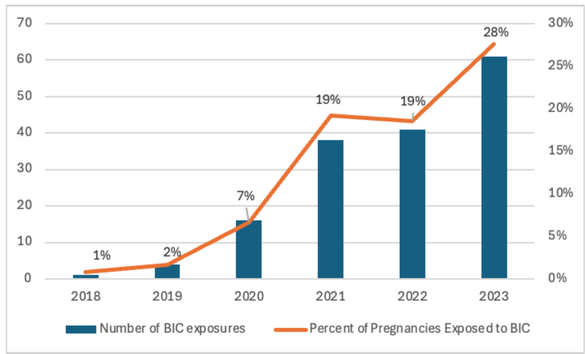
BIC vs. Non-BIC INSTI Exposures in Pregnancy (N=1256)



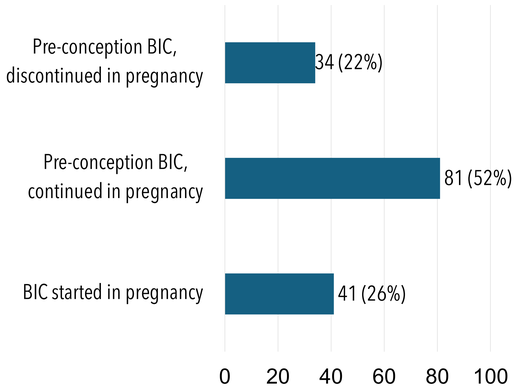
Bictegravir exposure in pregnancy **was not** independently associated with adverse perinatal and early infant outcomes in our Canadian cohort.

Indigenous populations and **people who inject drugs** were disproportionately exposed to BIC use during pregnancy.

Number and Percentage of Pregnancies Exposed to BIC in Canada



Timing of BIC Exposures in Pregnancy



Perinatal Outcomes by Timing of BIC Exposure in Pregnancy

	Preconception BIC with continued use in pregnancy (n=81)	Preconception BIC with discontinuation in pregnancy (n=34)	BIC started in pregnancy (n=41)	P-value
Preterm delivery (<37 weeks), n (%)	17/80 (21.3)	3/34 (8.8)	8/41 (19.5)	0.277
Low birth weight (<2500g), n (%)	15/79 (19.0)	3/34 (8.8)	6/41 (14.6)	0.386
SGA - Birth weight <10th percentile, n (%)	13/79 (16.5)	7/34 (20.6)	7/40 (17.5)	0.869
Child has congenital anomalies, n (%)	5/76 (6.6)	1/31 (3.2)	2/39 (5.1)	0.894
Perinatal HIV Transmission, n (%)	0/67 (0.0)	0/32 (0.0)	1/32 (3.1)	0.489

Perinatal and Early Infant Outcomes with BIC vs. Non-BIC cART Use

		All infants (n=1256)	BIC-exposed infants (n=161)	Non-BIC infants (n=1095)	p-value
Maternal age, median (IQR)		33 (29.0, 37.0)	33.0 (29.0, 37.0)	33 (29.0, 38.0)	0.178
Maternal race, n (%)	Unknown	16	3	13	<0.001
	Indigenous	284 (22.9)	60 (38.0)	224 (20.7)	
	White	161 (13.0)	18 (11.4)	143 (13.2)	
	Black	713 (57.5)	71 (44.9)	642 (59.3)	
	Other	82 (6.6)	9 (5.7)	73 (6.7)	
Maternal risk category, n (%)	Unknown	178	20	158	<0.001
	IDU	171 (15.9)	40 (28.4)	131 (14.0)	
	Mother to Child	52 (4.8)	5 (3.5)	47 (5.0)	
	Sexual	822 (76.3)	93 (66.0)	729 (77.8)	
	Other	33 (3.1)	3 (2.1)	30 (3.2)	
Maternal years since HIV diagnosis, median (IQR)		7.0 (3.0, 11.0)	6.0 (2.0, 12.0)	7.0 (3.0, 11.0)	0.263
Maternal viral load nearest delivery	Unknown	371	46	325	0.125
	<50	806 (91.1)	101 (87.8)	705 (91.6)	
	50-400	52 (5.9)	7 (6.1)	45 (5.8)	
	>400	27 (3.1)	7 (6.1)	20 (2.6)	
Maternal cART adherence in pregnancy	Unknown	46	4	42	0.014
	Excellent	1066 (88.1)	129 (82.2)	937 (89.0)	
	Suboptimal	144 (11.9)	28 (17.8)	116 (11.0)	
Maternal cART continuation at delivery, n (%)		1228/1235 (99.4)	155/158 (98.1)	1073/1077 (99.6)	0.049
Maternal cART continuation postpartum, n (%)		1091/1118 (97.6)	132/139 (95.0)	959/979 (98.0)	0.031
Congenital anomalies, n (%)		66/1208 (5.5)	8/151 (5.3)	58/1057 (5.5)	0.924
Preterm birth, n (%)		170/1241 (13.7)	31/160 (19.4)	139/1081 (12.9)	0.025
Low birth weight (<2500g), n (%)		154/1230 (12.5)	27/159 (17.0)	127/1071 (11.9)	0.069
Small for gestational age, n (%)		204/1227 (16.6)	28/158 (17.7)	176/1069 (16.5)	0.692
Mode of delivery, n (%)	Unknown	11	1	10	0.514
	Caesarean Section (elective)	353 (28.4)	43 (26.9)	310 (28.6)	
	Caesarean Section (emergency)	188 (15.1)	29 (18.1)	159 (14.7)	
	Vaginal (spontaneous and assisted)	704 (56.5)	88 (55.0)	616 (56.8)	
Perinatal HIV transmission, n (%)		7/1162 (0.6)	1/136 (0.7)	6/1026 (0.6)	0.583

Multivariate Analysis on Risk Factors for Preterm Birth (n=741)

Variable		Odds ratio (95% confidence interval)	p-value
ART exposure	BIC	1.39 (0.78, 2.49)	0.261
	Non-BIC	1	
Maternal race	Indigenous	1.66 (0.77, 3.57)	0.195
	Black	0.82 (0.40, 1.68)	0.592
	Other	0.39 (0.09, 1.60)	0.190
	White	1	
Maternal risk category	Sexual transmission	1	
	Injection drug use	1.94 (1.02, 3.71)	0.044
	Perinatal transmission	0.72 (0.19, 2.68)	0.619
	Other	0.63 (0.12, 3.47)	0.598
Maternal viral load nearest delivery	<50	1	
	50-400	1.67 (0.77, 3.65)	0.196
	>400	4.44 (1.84, 10.74)	<0.001

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WOMEN'S HEALTH RESEARCH INSTITUTE AT BC WOMEN'S

CPARG Canadian Pediatric & Perinatal HIV/AIDS Research Group / Groupe canadien de recherche pédiatrique et périnatale sur le VIH/SIDA

ctn+ CIHR Pan-Canadian Network for HIV and STBBI Clinical Trials Research