Cross-network, multicentre cohort study assessing real-world pregnancy and birth outcomes following prenatal dolutegravir exposure in Europe

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Background

- Dolutegravir (DTG) is an HIV integrase strand-transfer inhibitor recommended by WHO for use during pregnancy for viral suppression and prevention of vertical transmission[1]
- The **DOLOMITE**† project, comprising **DOLOMITE-EPPICC** and **DOLOMITE-NEAT ID** studies, assessed safety, effectiveness and pregnancy outcomes of prenatal DTG use in Europe
- We aimed to use pooled data from the two DOLOMITE program studies to assess outcomes with prenatal DTG use
- **DOLOMITE-EPPICC** is a multi-cohort study nested in the European Pregnancy and Paediatric Infections Cohort Collaboration (EPPICC) analysing pooled prospectively-collected individual-patient data from studies in Italy, Romania, Russian Federation, Spain, Switzerland and UK
- **DOLOMITE-NEAT ID** is a multicentre observational study conducted at clinical sites in the NEAT ID Network in Belgium, France, Italy, Poland, Portugal, Spain, UK and Ukraine

† Dolutegravir in pregnant women and exposed infants in Europe; WHO, World Health Organization

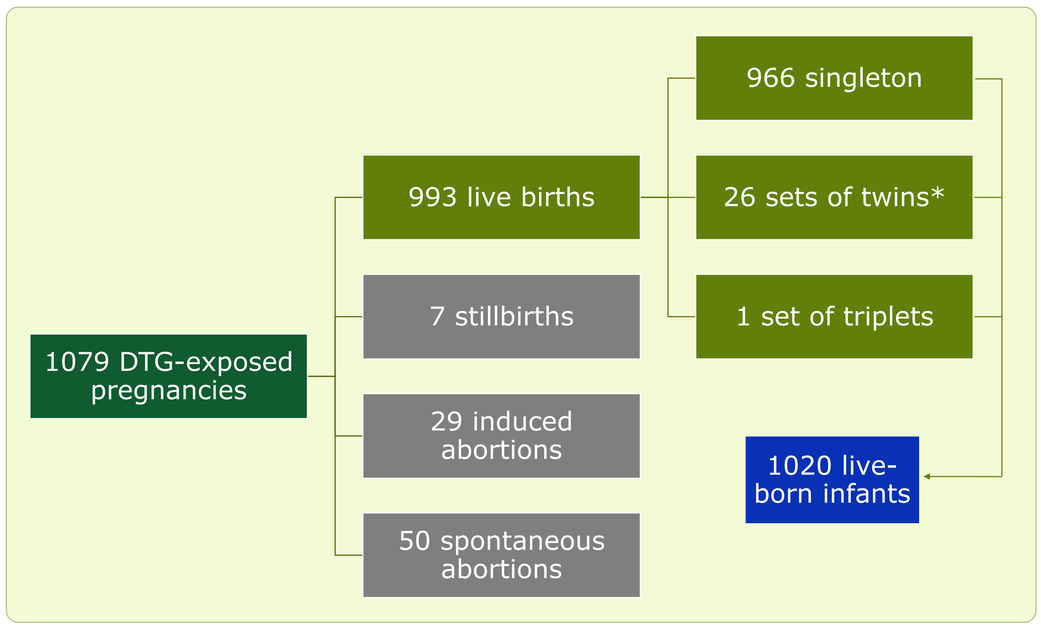
Methods

- Prospectively-collected, pseudonymised individual patient data from the DOLOMITE-EPPICC and DOLOMITE-NEAT ID studies were harmonised and pooled
- Pregnancies with any prenatal DTG exposure and known pregnancy outcome were included in analyses
- Earliest prenatal DTG exposure was classified as first trimester (T1) or second/third trimester (T2/T3)
- Outcomes assessed were congenital anomalies, preterm delivery (PTD) (<37 weeks), very PTD (<32 weeks), low birthweight (LBW) (<2500g), and very LBW (<1500g)
- Congenital anomalies were assessed using the World Health Organization International Classification of Diseases: Tenth Revision
- Prevalence of congenital anomalies was calculated among live-born infants; analyses of PTD and LBW were restricted to singleton live-born infants
- De-duplication of pregnancies from overlapping sites was conducted prior to analysis
- The analysis dataset included pregnancies and infants from:
  - 7 cohorts participating in DOLOMITE-EPPICC
  - 22 sites participating in DOLOMITE-NEAT ID

Results

- 1079 pregnancies (76.7% EPPICC, 23.4% NEAT ID) resulting in 1020 live-born infants were included (**Figure 1**)
  - 66.1% (713/1079) from UK/Ireland
  - 57.6% (619/1074) in persons of Black ethnicity
  - Median age at conception: 32 years (IQR, 27-36)
  - 70.4% (755/1073) had earliest DTG exposure in T1
    - Live births: 671/988 (5 missing timing)
    - Spontaneous abortions: 49/49 (1 missing timing)
    - Stillbirths: 7/7
    - Induced abortions: 28/29
  - Median gestational age of live-born infants: 39 weeks (IQR, 37-39)

Figure 1. Flowchart of included pregnancies and infants

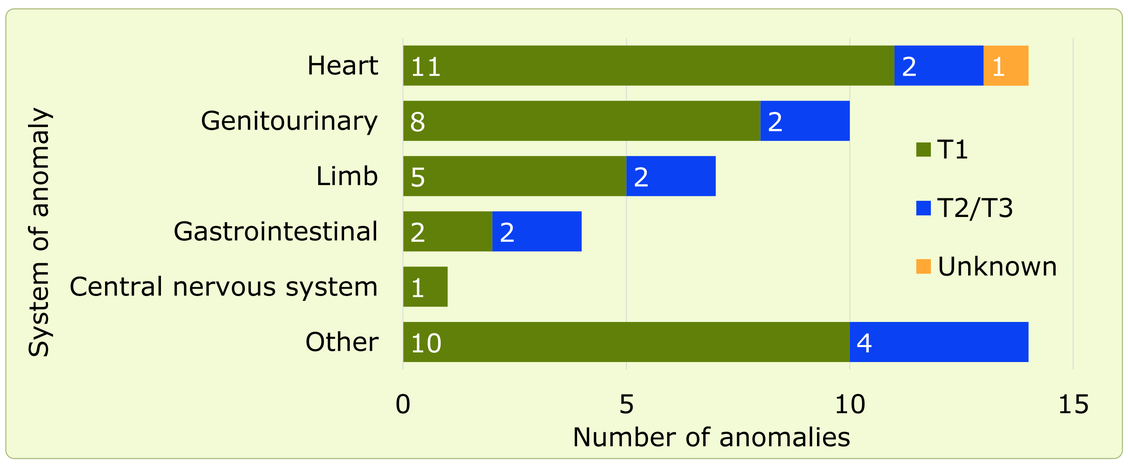


* Includes one set with spontaneous abortion of one twin
DTG, dolutegravir.

Congenital anomalies

- Prevalence of congenital anomalies among live-born infants:
  - Overall: 4.7% (95% CI, 3.5%-6.2%) (47/992)
  - T1 exposure: 5.2% (95% CI, 3.7%-7.2%) (35/669)
  - T2/T3 exposure: 3.5% (95% CI 1.7%-6.1%) (11/318)
- Organ system of anomalies among live-born infants in **Figure 2**

Figure 2. Anomalies by organ system and DTG exposure timing, live-born infants



Note: 3 infants had 2 anomalies.
DTG, dolutegravir; T1, first trimester; T2/T3, second/third trimester.

- Congenital anomalies identified among other outcomes:
  - 1 of 29 induced abortions: neuronal migration disorder and severe microcephaly, T1 DTG
  - 1 of 7 stillbirths: cheiloschisis (cleft lip), T1 DTG

Preterm delivery and low birthweight

- There was no difference in birth outcomes between infants exposed to DTG in T1 vs T2/T3 (**Table**)

Table. Birth outcomes by DTG exposure timing, singleton live-born infants

Outcome	Earliest DTG exposure timing, *N*=961		
	T1 (*n*=652)	**T2/T3** (*n*=309)	*p*-value
PTD (<37 weeks)	87/639 (13.6%)	44/306 (14.4%)	0.750
Very PTD (<32 weeks)	16/639 (2.5%)	7/306 (2.3%)	0.840
LBW (<2500g)	86/635 (13.5%)	36/304 (11.8%)	0.468
Very LBW (<1500g)	17/635 (2.7%)	9/304 (3.0%)	0.804

Note: excludes 5 infants with missing timing of earliest DTG exposure. Data on PTD and LBW missing for 16 and 22 infants, respectively. DTG, dolutegravir; LBW, low birthweight; PTD, preterm delivery; T1, first trimester; T2/T3, second/third trimester.

CI, confidence interval; IQR, interquartile range

Conclusions

- Data from this large cohort of pregnant individuals demonstrate the overall safety of DTG use in pregnancy
- All outcomes were consistent across exposure groups and within expected background rates (e.g., 3-5% prevalence estimated by the Metropolitan Atlanta Congenital Defects Program)
- This study further supports accumulating evidence that prenatal/T1 DTG use has similar maternal and infant outcomes compared to T2/T3 use

Reference

1. WHO updated recommendations on HIV clinical management: recommendations for a public health approach. Geneva: World Health Organization; 2025.

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