Darunavir in Pregnancy
A Multicentre Retrospective Analysis

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Background
Protease inhibitors in pregnancy:
- No increase in teratogenicity observed1
- Transplacental passage is low2
- Plasma concentrations reduced particularly in 3rd trimester3
- Reports of increased pre-term delivery4

Darunavir in pregnancy:
- No increased risk of birth defects reported by APN in >200 T1 exposures
- Reduced plasma concentrations in second and third trimesters
- Concerns regarding 800/100mg once daily dosing5
- Recommended as an alternative to Atazanavir or Lopinavir

Limited experience in pregnancy: tolerability, safety and efficacy data are scant.

Aim
To describe current use, efficacy and tolerability of Darunavir in pregnancy.

Methods
Case notes from HIV-1 infected women prescribed Darunavir/Ritonavir during pregnancy between October 2007 and October 2014 reviewed across 8 sites in London and Brighton. Demographics, history of and risk factors for preterm delivery (PTD), antiretroviral therapy (ART) including dosing, treatment switches and discontinuations, virological response, gestational age (GA) at delivery, maternal and infant outcomes were collected. Categorical variables assessed by Chi Square Test.

Results

Demographics

- 55 women
- 59 pregnancies
- 3 multiple pregnancies (2 twins, 1 triplet)
- 2 pending live births
- 65% Truvada backbone

Conclusions
Our data support the use of Darunavir in pregnancy and reflect its increasing use.

Our data are novel by including PTD risk factors not routinely collected by APN.

Well tolerated: Increased ALT associated with high plasma Darunavir concentration where measured (1 out of 2 cases)

Virologically active: Suppression at median 30 days from initiation and no MTCT (including with once daily dosing in those conceiving on Darunavir)

93% virologically suppressed at delivery (exceeds 80% suppression rate with other protease inhibitors6)

Safety: The association of PTD seen with other Protease Inhibitors was also observed in our cohort with Darunavir, but not if commenced pre-conception.

Further work: Analysis of PTD risk with multiple regression analyses needed.

References
5. Drachenberg C et al. BMJ 2007 Dec;335(7622):1126

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Results—Efficacy
- 93% (n=55/59) HIV undetectable at delivery and no cases of MTCT

Results—Safety
- 7/59 (11.8%) PTDs in cohort
- PTD risk factors most commonly found in pregnancies conceived on Darunavir
- Commencing Darunavir after conception was associated with PTD (p<0.05) and low birth weight (p<0.05)