

DIRECT-ACTING ANTIVIRAL EXPOSURE IN PREGNANCY: INITIAL FINDINGS FROM THE “TIP-HEPC” CLINICAL CASE REGISTRY



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Introduction

- An estimated 21% of the global population infected with HCV are women of reproductive age.¹
- Treatment for HCV during pregnancy has the potential to:
 - Increase HCV treatment coverage in persons of reproductive age
 - Prevent mother-to-child transmission in current and future pregnancies
 - Improve HCV-related outcomes for mother and infant
- HCV treatment is not currently recommended in pregnancy due to a lack of safety data
- Pregnancy and infant outcomes after DAA exposure are not systematically reported, and only one phase II trial has been completed.

Method

- Clinicians reported outcomes of maternal-infant pairs exposed to DAAs during pregnancy to the registry through a secure web-based portal
- Patients exposed to interferon or ribavirin were excluded
- Primary adverse pregnancy outcomes: preterm delivery (<37 weeks GA), stillbirth or fetal demise, maternal death
- Primary adverse birth outcomes: low birth weight (<2500g, LBW), small for gestational age (SGA), neonatal intensive care, congenital anomalies
- Descriptive analysis was conducted for cases through October 31, 2022

Results

- 23 case reports submitted, all from the USA
- 20 (87%) treated after 1st trimester, of which all were previously published, and 9 were part of a clinical trial
- 3 cases with 1st trimester DAA exposure, of which outcomes available for 1 case: live full-term birth with no adverse pregnancy or infant outcomes

Table 1. Exposures during first trimester (<13 weeks)

Median age (range) (n=3)	32 (22-35)
Treatment regimen (n=3)	G/P=2, SOF/VEL=1
Treatment completed (n=3)	Yes=3, No=0
Median number of days of exposure in pregnancy (range) (n=2)	50.5(45-56)
Maternal HCV outcomes (n=1)	No pregnancy or delivery complications=1
Pregnancy outcomes (n=1)	No pregnancy or delivery complications
Any NICU admission or reported infant complication (n=1)	Yes=0, No=1
NICU admission(n=1)	Yes=0, No=1
Frequency of infant complications	None reported
Congenital anomalies (n=1)	No congenital anomaly detected = 1
Infant outcome (n=0)	No data

Abbreviations: G/P = glecapravir/pibrentasvir; SOF/VEL = sofosbuvir/velpatasvir

Conclusions

- Registry provides timely and valuable real-world data on pregnancy and birth outcomes follow DAA exposure in pregnancy
- Data is needed to guide safe and reliable HCV treatment pathways to improve outcomes among mother-child dyads for HCV elimination
- In complement to much needed phase III trials, further accrual of case reports to TiP-HepC registry will better inform shared decision-making by patients and providers on the optimal approach to HCV in pregnancy

Table 2. Exposures after first trimester (>=13 weeks)

Median age (range)	31.5(18-44)
Baseline comorbidities or substance use	IVDU=10, opioid use=6, tobacco=6, marijuana=4, cocaine=4, mental/behavioral disorders related to OUD=4, methamphetamine=2
Median gestational age (days) at treatment initiation (range)	186.5 (158-270)
Treatment regimen	SOF/LOV=14, SOF/VEL=6
Maternal HCV treatment completion (n=16)	Completed=17, Not completed=0, Unknown=3
Maternal HCV outcomes (n=16)	Cured=14, Not cured=2
Pregnancy outcomes (n=19)	Live-term(>37 week GA)=14, Live-preterm (34--37 week GA)=4, Unknown=1
Delivery type (n=19)	Vaginal delivery=11, C-section=5, Unknown=1
Any NICU admission or reported infant complication (n=17)	Yes=9, No=8
NICU admission(n=17)	Yes=7, No=10
Frequency of infant complications	Neonatal abstinence syndrome=4, Large birthweight=1, Large for GA=1, Brachial plexus injury=1, Respiratory distress syndrome=1
Congenital anomalies (n=19)	None=16, Unknown=3
Infant HCV status (by PCR 6mo or anti-HCV 18mo)	Negative=13, Positive=0

Abbreviations: SOF/LOV = sofosbuvir/ledipasvir, SOF/VEL = sofosbuvir/velpatasvir

The TiP-HepC Registry was launched in June 2022 as the first global registry for direct-acting antiviral exposures in pregnancy.

Submit your cases to the registry at: <https://www.globalhep.org/evidence-base/treatment-pregnancy-hepatitis-c-tip-hepc-registry>

Contact information

For more information, please contact: ngupta-consultant@taskforce.org



References

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4. Abdallah et al., Liver International, 2021.