2020.PIANO

Observ/Biologics&thiopurine/IBD/pregnancy

Pregnancy and Neonatal Outcomes after Fetal Exposure To Biologics and Thiopurines among Women with IBD

Observational study. Pregnant woman with IBD on biologics and/or thiopurine.

Primary endpoint :
Five outcomes (congenital malformations, spontaneous abortions, preterm birth, low birth weight (LBW) and infant infections) among pregnancies exposed versus unexposed in utero to biologics, thiopurines or a combination.

Results:
- Drug exposure did not increase the rate of congenital malformations, spontaneous abortions, preterm birth, LBW, and infections over the first year of life.
- Higher disease activity was associated with risk of spontaneous abortion (HR 3.41, 95% CI 1.51-7.69) and preterm birth with increased infant infection (OR 1.73, 95% CI 1.19-2.51).

Conclusions:
Biologic, thiopurine, or combination therapy exposure during pregnancy was not associated with increased adverse maternal or fetal outcomes at birth or within the first year of life. Therapy with these agents can be continued throughout pregnancy in women with IBD to maintain disease control and reduce pregnancy related adverse events

Table 2: Pregnancy related complications by drug exposure, controlling for maternal age, steroid use and disease activity

Event	No Exposure (n=379)	Biologics* (n=642)	Thiopurine# (n=242)	Combination** (n=227)
Any Pregnancy Complication^	1.0 (Ref)	1.2 (0.8, 1.7)	1.3 (0.8, 2.0)	0.8 (0.5, 1.3)
Spontaneous Abortion (Only Gestation Ages <= 140 Days)	1.0 (Ref)	1.3 (0.5, 3.3)	1.4 (0.4, 4.2)	1.2, (0.4, 3.8)
Spontaneous Abortion (All Gestation Ages)	1.0 (Ref)	1.3 (0.5, 3.0)	1.3 (0.4, 3.8)	1.1 (0.3, 3.3)
Preterm Birth (<37 weeks)	1.0 (Ref)	0.9 (0.5, 1.5)	1.4 (0.8, 2.6)	1.8 (1.0, 3.3)
Small for Gestational Age	1.0 (Ref)	1.1 (0.5, 2.0)	0.5 (0.2, 1.5)	0.7 (0.3, 1.8)
Low Birth Weight (<2500 g)	1.0 (Ref)	1.0 (0.5, 1.8)	0.6 (0.3, 1.5)	1.2 (0.6, 2.5)
Intrauterine Growth Restriction	1.0 (Ref)	0.6 (0.2, 1.4)	0.3 (0.07, 1.5)	0.7 (0.2, 2.3)
Cesarean Section	1.0 (Ref)	1.3 (1.0, 1.8)	1.3 (0.9, 1.9)	1.7 (1.1, 2.5)
NICU at Birth	1.0 (Ref)	1.1 (0.7, 1.9)	1.2 (0.6, 2.2)	1.5 (0.8, 2.8)

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