

IBD LIVE:

A Puzzling Pregnancy

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PIANO

Consensus Statements

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Women with IBD should discontinue:

18. Ozanimod (at least 3 months)

19. Etrasimod (at least 1-2 weeks)

20. Tofacitinib (at least 4 weeks)

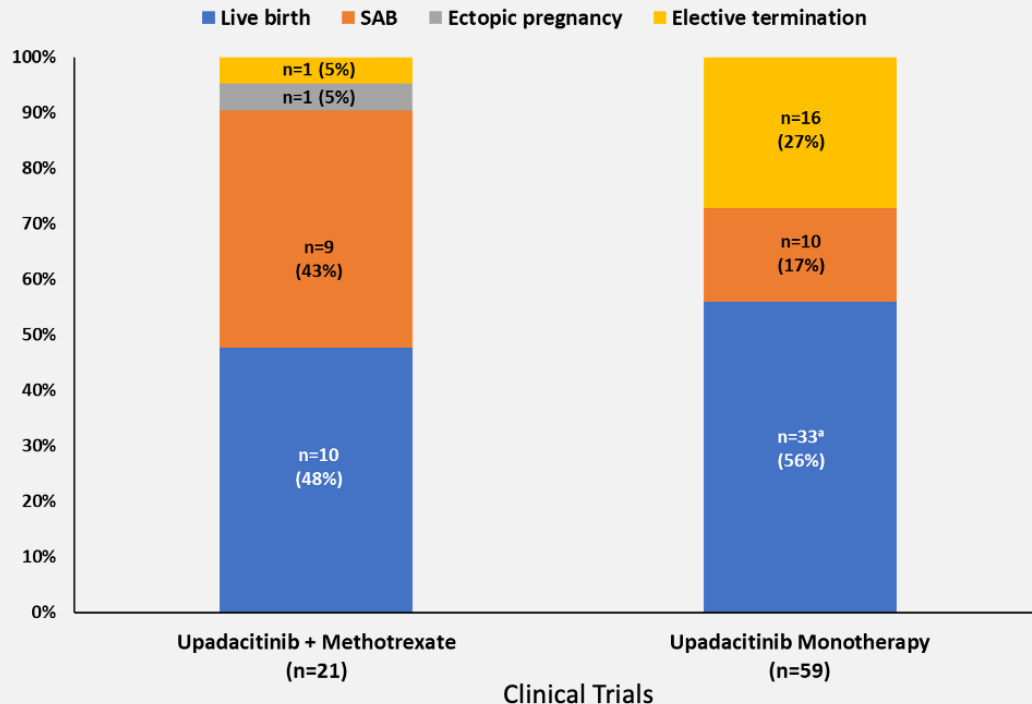
21. Upadacitinib (at least 4 weeks)

22. Filgotinib (at least 4 weeks)

...prior to conception unless there is no effective alternative therapy to maintain maternal health

PIANO – Pregnancy

Pregnancy Outcomes in Patients Treated With Upadacitinib: Analysis of Data From Clinical Trials and Postmarketing Reports



Animal Reprotoxicity Data

- 1.6x, 15x [15 mg QD]
- **0.8x, 7.6x [30 mg QD]**
- 0.6x, 5.6x [45 mg QD]

N= 128 maternal UPA-exposed pregnancies

- Clinical trials n=80
 - Mean *in utero* exposure 5 wks, 3d
 - Live births (54%)
 - SAB (24%)
 - TAB (21%)
 - Ectopic pregnancy (1%)
 - 1 congenital malformation
 - Atrial septal defect
- Postmarketing cases n=48
 - Live births (46%)
 - Spontaneous abortions (38%)
 - Elective terminations (15%)
 - Ectopic pregnancy (2%)

PIANO – Breastfeeding

JAK-inhibitors & breastfeeding

Tofacitinib

- Detectable in breastmilk of 2 lactating women
 - 5 and 10 mg BID, respectively^{1,2}
- "Worst-case": **Relative Infant Dose 3.4%**^{1,2}
- 3 infants exposed to tofacitinib during pregnancy/breastfeeding → normal development^{2,3}
 - 1 infant: normal immunological assessment at 3 months of life.³

Upadacitinib & filgotinib

- No available human lactation data
- **EMA & FDA recommend avoidance of breastfeeding.**^{4,5}

Recommendation

Due to no/limited human safety data including unknown effects on the immune system of the suckling infant, breastfeeding should be avoided in case of treatment with a JAK-inhibitor

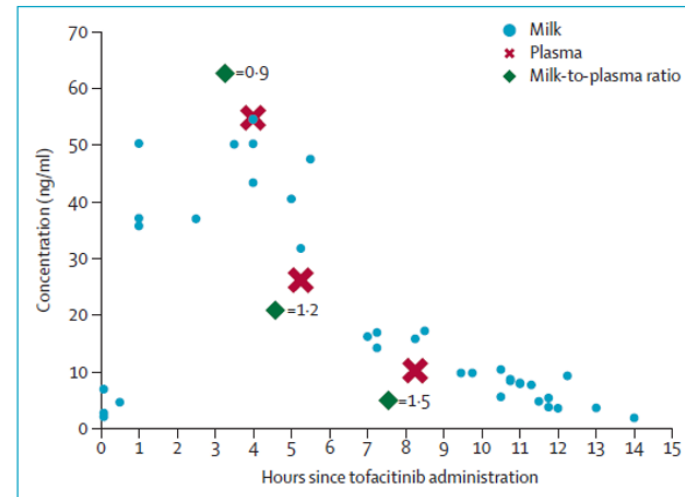


Figure: Tofacitinib concentrations in maternal milk and plasma
37 milk samples collected on 25 individual days during a 63-day period.

Ref. 1

Thank you!

Questions and Comments