

Retrospective case-control observational study.

Aim: To assess pregnancy and child outcomes of VDZ pregnancies and to compare these results to anti-TNF exposed (TNFE) or both immunomodulatory & biologic unexposed (CON IBD) pregnancies

Results:

- No significant difference in miscarriage rates (VDZ and TNFE: 16% vs 13%, $p = 0.567$; VDZE and CON IBD: 16% vs 10%, $P = .216$).
- In live-born infants, median gestational age and birthweight were similar between groups.
- Median Apgar score at birth was numerically equal.
- Prematurity was similar among groups.
- The frequency of congenital anomalies was comparable between groups as were the percentages of breastfed babies.
- During the first year of life, no malignancies were reported and infants' infection risk did not significantly differ between groups

Conclusion:

No new safety signal was detected in VDZ pregnancies.

TABLE 2 Baseline characteristics live-born children ($n = 389$)^a

	VDZE group ($n = 64$)	TNFE group ($n = 162$)	CON IBD group ($n = 163$)	P-value (VDZE vs TNFE)	P-value (VDZE vs CON IBD)
Gender (F) (%)	39/64 (61)	86/144 (60)	77/150 (51)	1.000	0.231
Median (IQR) gestational age (wk)	39 (38-40)	39 (38-40)	39 (38-40)	0.084	0.433
Median (IQR) Apgar score at birth	9 (9-10)	9 (9-9)	9 (9-9)	0.001*	0.002*
Median (IQR) birthweight (grams)	3290 (2848-3563)	3215 (2835-3555)	3237 (2867-3500)	0.786	0.709
Premature born children (%)	10/64 (16)	14/162 (9)	12/163 (7)	0.151	0.079
Small for gestational age (%)	2/64 (3)	2/162 (1)	3/163 (2)	0.318	0.622
Breastfeeding (%)	39/63 (62)	85/142 (60)	88/138 (64)	0.877	0.875
Congenital anomalies (%)	3/64 (5)	4/162 (2)	3/163 (2)	0.407	0.354
Infections during the first year of life (%)	3/64 (5)	7/67 (10)	7/59 (12)	0.326	0.193
Malignancies during the first year of life (%)	0	0	0	NA	NA

Note: Fisher's exact test used for categorical data and Mann-Whitney *U* test for continuous data.

Abbreviations: CON IBD: immunomodulatory and biologic unexposed; F: female; IQR: interquartile range; TNFE: anti-TNF-exposed; VDZE: vedolizumab exposed.

^aOnly in children born alive. All preterm deliveries occurred between gestational week 33 and 36.

*means a P-value of <0.05 and thus a statistical significant result.

