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Abstract Title

Safety of Vedolizumab and Ustekinumab in Pregnant Patients with Inflammatory Bowel Disease: A Systematic Review and Meta-analysis

Authors

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Background

In pregnant individuals with inflammatory bowel disease (IBD) that is refractory to conventional therapy, disease control often necessitates biologic agents such as vedolizumab or ustekinumab, yet safety data during pregnancy remain limited.

Objective

To systematically evaluate maternal and fetal safety outcomes associated with vedolizumab and ustekinumab versus anti-tumor necrosis factor (anti-TNF) in pregnant patients with IBD.

Methods

We searched MEDLINE, Embase, Web of Science, and ClinicalTrials.gov from January 2010 to June 16, 2025. Randomized controlled trials and observational studies reporting pregnancy outcomes following in-utero exposure to vedolizumab or ustekinumab were included. Outcomes included congenital malformations (CM), preterm birth (PTB), severe infant infection, caesarean section (CS), pregnancy loss, low birth weight (LBW), and small for gestational age (SGA). Random-effects meta-analyses were performed, and study quality was assessed using the Newcastle-Ottawa Scale and the Cochrane Risk of Bias tool.

Results

Fifteen studies met the inclusion criteria. Compared to anti-TNF, vedolizumab showed no significant increase in congenital malformations (RR 1.28, 95% CI 0.77-2.15; $I^2=0\%$) but was associated with higher risks of preterm birth (RR 1.42, 95% CI 1.06-1.91; $I^2=0\%$) and low birth weight (RR 1.93, 95% CI 1.08-3.44; $I^2=0\%$). Ustekinumab was associated with congenital malformations (RR 1.96, 95% CI 1.23-3.14; $I^2=0\%$) but not preterm birth or low birth weight. Neither agent was associated with other perinatal outcomes.

Conclusion

Vedolizumab and ustekinumab use during pregnancy was not associated with increased risks of most

adverse maternal or fetal outcomes. Elevated risks in CM, PTB, and LBW may reflect residual confounding.