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JAK inhibitors during Pregnancy and Adverse Drug Reactions: A Pharmacovigilance Disproportionality Analysis in VigiBase

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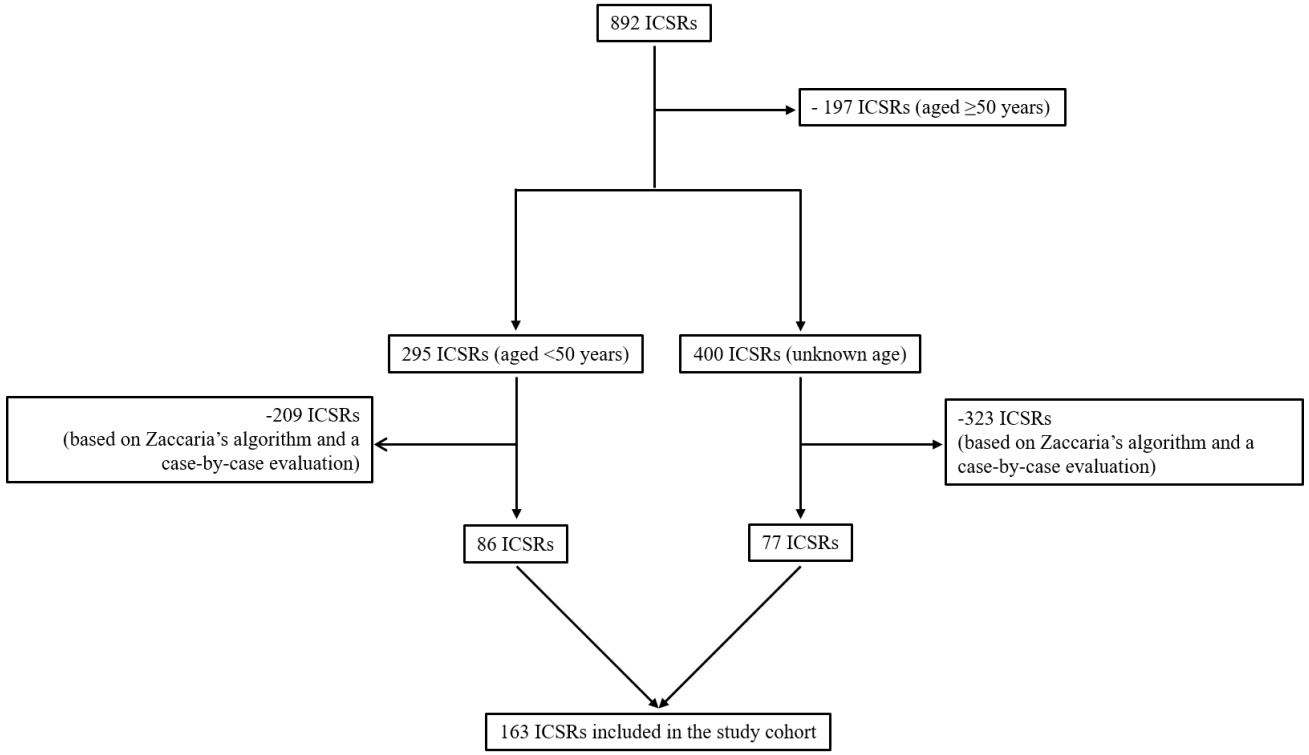
Background & Aim

- JAK inhibitors (JAKIs) treat autoimmune/inflammatory diseases in women of childbearing age.
- Placental transfer is expected; human safety data remain limited.
- Aim: assess pregnancy safety signals for systemic JAKIs in VigiBase.

Methods

- **Data & selection:** VigiBase de-duplicated individual case safety reports (ICSRs) (01.2012–26.05.2024). Pregnancy cases identified via SMQ "Pregnancy and neonatal topics—broad" + adapted Zaccaria algorithm[1]; exclusion criteria: age ≥50, paternal-only, exposure without maternal/neonatal ADRs; two-reviewer adjudication.
- **Drugs & comparator:** Systemic JAKIs as suspected drugs; comparator = all other drugs in VigiBase excluding JAKIs (same age rule).
- **Analysis:** reporting odds ratio (ROR, 95% CI); signal of disproportionate reporting (SDR) = lower 95% CI > 1 with ≥10 ICSRs; sensitivity analysis: JAKI-only reports.

Selection process of the study population



[1]Zaccaria, C. *et al.* Identification of pregnancy adverse drug reactions in pharmacovigilance reporting systems: a novel algorithm developed in EudraVigilance. *Drug Saf.* 47, 1127-1136 (2024).

Results

- Most frequent JAKIs: tofacitinib 44.8%, upadacitinib 34.4%, primarily indicated for rheumatoid arthritis (29.4%).
- Spontaneous abortion: 78/163 (47.9%); no signal of disproportionate reporting (SDR) (ROR 0.37; 95% CI 0.30–0.46).
- Prematurity: 15/163 (9.2%); no SDR (ROR 0.07; 95% CI 0.04–0.11).
- Congenital anomalies in 26 ICSRs (16.0%), no consistent organ-specific pattern.
- Sensitivity analyses confirmed absence of SDRs.

Conclusions

- No disproportional reporting for spontaneous abortion or prematurity.
- Reported anomalies were heterogeneous without a clear pattern.
- Further studies are needed to fully characterize the safety profile of JAKIs during pregnancy and provide evidence-based recommendations for clinicians and health authorities.