Mycophenolate Use During Pregnancy: An Analysis in the Sentinel Database

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Background

Mycophenolate (MPA) products are immunosuppressants that are approved in the U.S. for use as prophylaxis of organ rejection in kidney/heart/liver transplant recipients. They are also used off-label to treat systemic lupus erythematosus, rheumatoid arthritis, vasculitis, scleroderma, and myasthenia gravis. MPA use during pregnancy is not contraindicated but is warned against due to the previously observed increased risks of pregnancy loss and congenital malformations.

Objective

To examine the frequency and timing of MPA use during pregnancy

Methods

- A descriptive analysis of MPA use before and during pregnancy, stratified by indication, was conducted using data from five Data Partners participating in the U.S. Sentinel System from September 2013 through July 2024.
- Use was identified by the dispensing or administration of MPA products, i.e., Cellcept, Myfortic and MPA generics.
- Pregnancy episodes with live, non-live, mixed, or unclassified birth outcomes among women 10-54 years old were identified using a claims-based algorithm.[1]
- Patients' existing disease and/or organ transplant(s) were identified with ICD, HCPCS, and CPT codes.
- MPA use in a matched comparator NON-pregnant cohort (i.e., without evidence of any pregnancy outcome) was also estimated by indication (i.e., organ transplant, off-label use).

Results

- MPA use any time from 183 days PRE-pregnancy to the end of the pregnancy was identified in 0.02% of all the pregnancy episodes (Figure 1).
- MPA use any time from 183 days PRE-pregnancy to the end of pregnancy was identified in approximately 14% of the episodes of the pregnant cohort and 40% of those of the NON-pregnant cohort in women with organ transplant, and 3% of the episodes of the pregnant cohort and 9% of those of the NON-pregnant cohort in women with off-label use (Figure 1).
- In addition, in pregnancy episodes of patients with organ transplant or off-label use, 90-94% of MPA use was started in the 183 days PRE-pregnancy (Figure 2), and it was continued into the first trimester in approximately 36-37% and into the second trimester in only 2% or less (Figure 3).

[1] Sentinel Bit Bucket.

Results

Figure 1. MPA Use Before/During, or Only During, Pregnancy Time Periods Among the Pregnant Cohort & Comparable Non-pregnant Cohort, by Underlying Indication

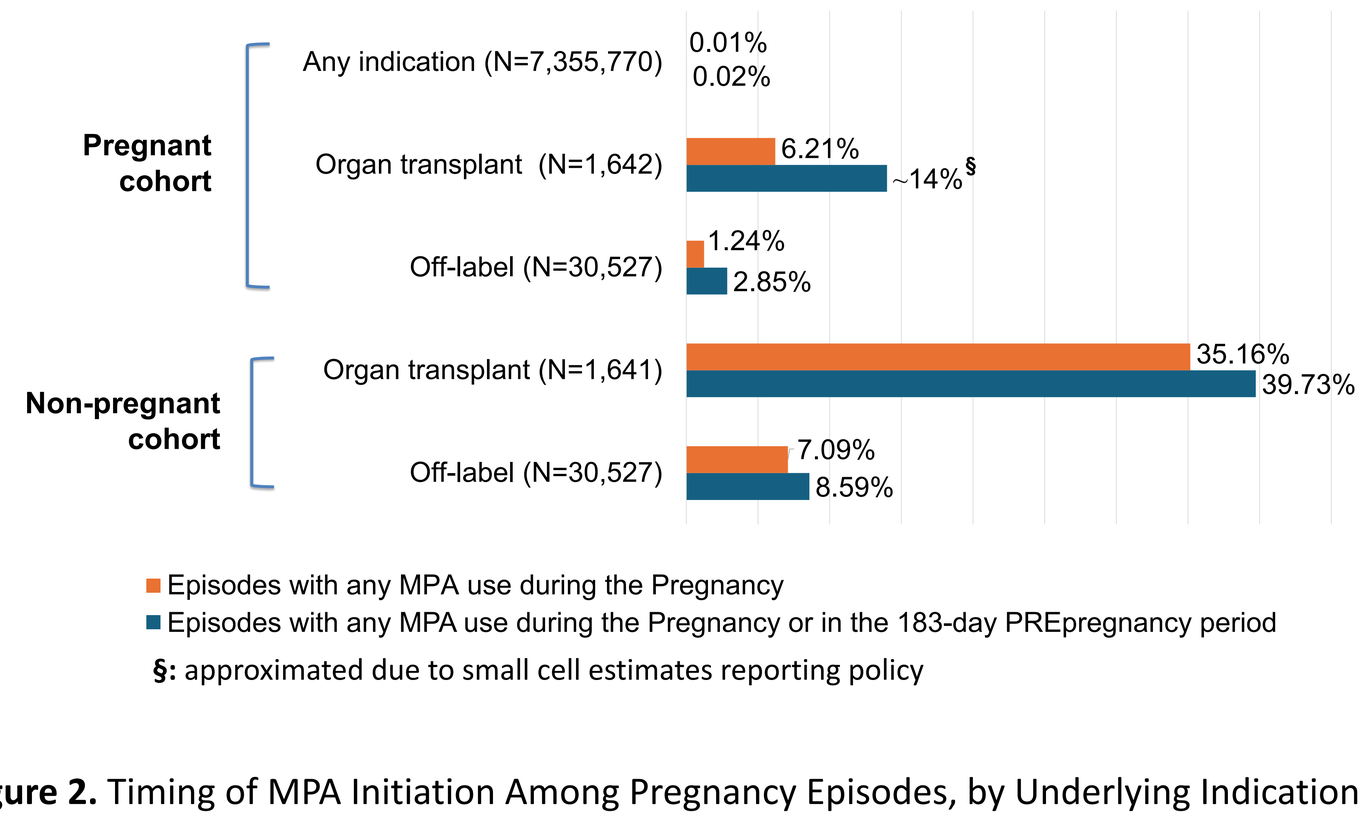


Figure 2. Timing of MPA Initiation Among Pregnancy Episodes, by Underlying Indication

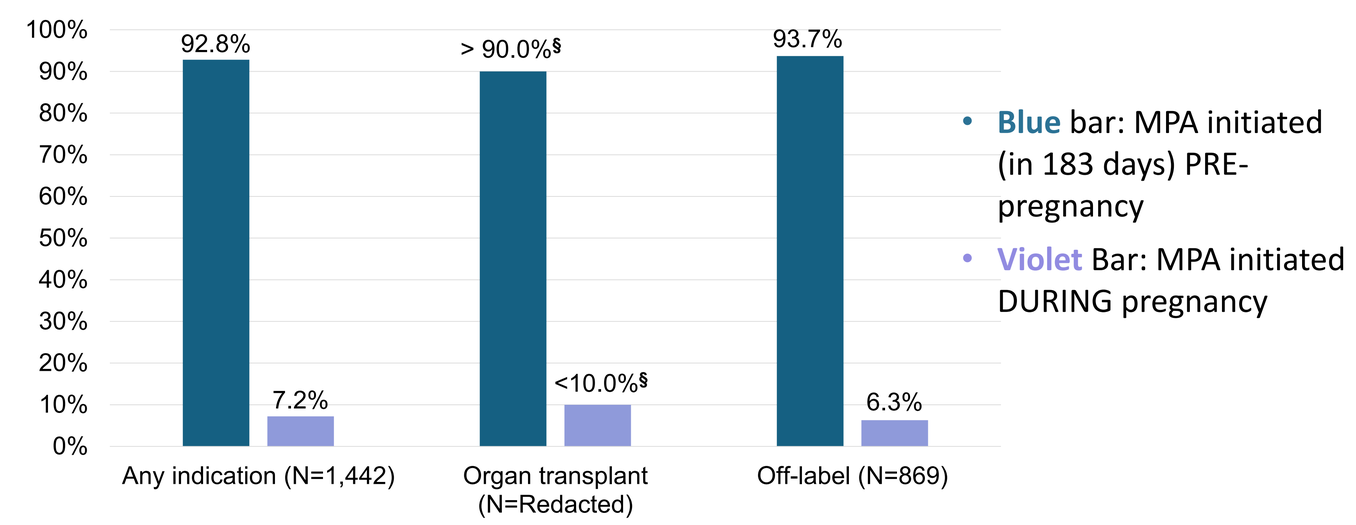
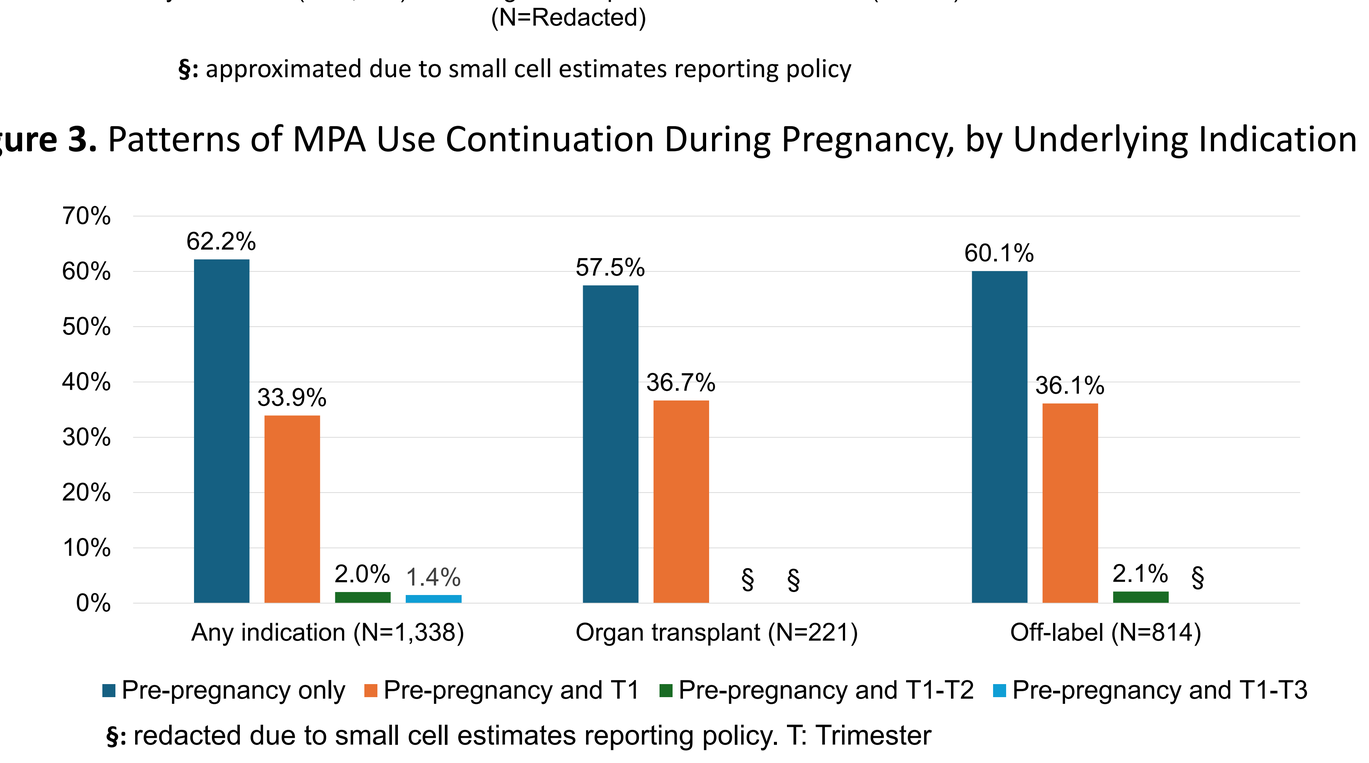


Figure 3. Patterns of MPA Use Continuation During Pregnancy, by Underlying Indication



Conclusion

Our analyses from 2013-24, in the U.S. health care insured population, showed that MPA use during pregnancy or the 183-day PRE-pregnancy period was infrequent, except in women with a prior organ transplant. Regardless of indication, the majority of that MPA use was started PRE-pregnancy and did not appear to continue during the pregnancy. We believe this may reflect the medical community's awareness of embryo-fetal risk associated with MPA use during pregnancy.