



## Evaluation of Mycophenolate and Pregnancy Risk: A Retrospective Cohort Study

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### INTRODUCTION

- Mycophenolate is a widely used immunosuppressant with **known teratogenic effects**.
- The SFDA has implemented various risk minimization measures to prevent fetal exposure to mycophenolate.
- However, the risk of fetal exposure to Mycophenolate in Saudi Arabia is **unknown**

### OBJECTIVES

This study aims to quantify the pregnancy risk during mycophenolate use compared to azathioprine among women of childbearing age (WCBAs) in Saudi Arabia

### METHODS

#### Study Design & Data Source:

A cohort of women of childbearing age (WCBAs) were identified using King Abdulaziz Medical City (Riyadh) electronic health records between 2016-2021.

#### Study Populations:

Females between the age of 15-59 were included. We excluded females who have undergone any surgery resulting in sterilization, such as a hysterectomy. Females who had evidence of being postmenopausal or infertile were excluded.

#### Exposure Measures:

According to the first prescription WCBAs received, they were grouped into two exposure groups representing mycophenolate users and azathioprine users. The study index date is the date of receiving the 1st prescription. WCBAs were considered exposed until they exhaust days of supply and without a refill dispensing after 30 days. Because both medications are abundantly used for off-label indications such as skin disorders, we included all users, regardless of indications.

#### Outcome Measures:

The primary outcome was defined as an overlap between days of supply and date of pregnancy indication.

#### Statistical Analysis:

We calculated the propensity score of receiving mycophenolate by fitting a logistic regression model using the measured confounders. A generalized linear model using Poisson distribution was then fitted to estimate the adjusted risk ratio and corresponding 95% confidence interval (CI).

### RESULTS

- We included 224 and 457 WCBAs who initiated azathioprine and mycophenolate, respectively.

Figure 1: Prognostic factors distribution in study groups.

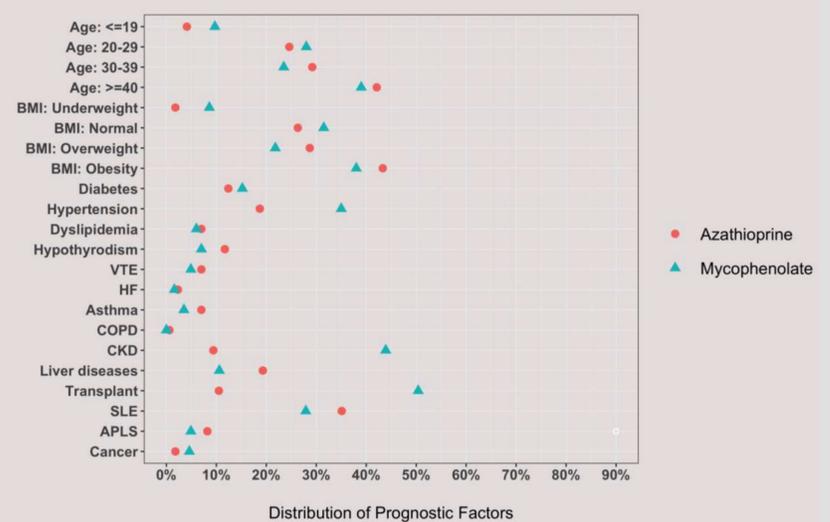
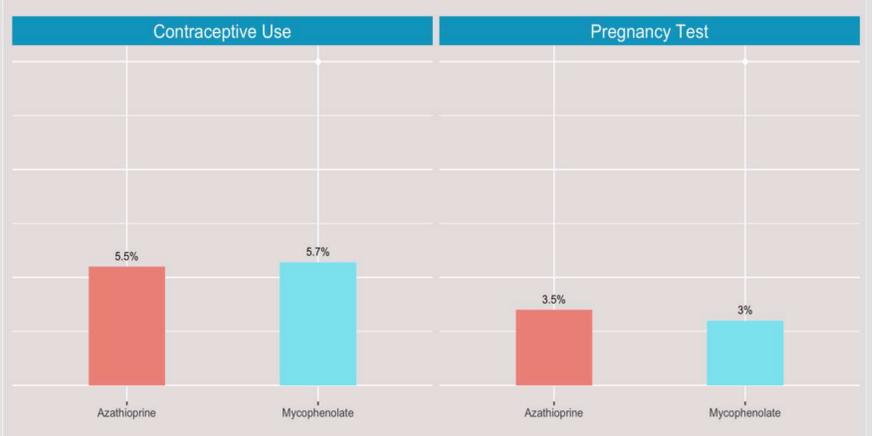


Table 1: Estimated Pregnancy Risk in mycophenolate and azathioprine users

Group	Sample	Event	Cumulative Incidence Per 1000	Crude Risk Ratio (95% CI)	Adj. Risk Ratio (95% CI)
Azathioprine	224	31	178.5	Ref.	Ref.
Mycophenolate	457	10	30.6	<b>0.14</b> (0.09-0.23)	<b>0.10</b> (0.04-0.18)

Figure 2: Distribution of pregnancy tests and contraceptive use



### CONCLUSION

Although mycophenolate users have a significantly lower pregnancy risk compared to azathioprine users, **a considerable size** of pregnancies occurs.