36th ENTIS Conference 11th – 14th Sept 2025
ARISTOTLE UNIVERSITY'S RESEARCH DISSEMINATION CENTER (KEDEA)
THESSALONIKI, GREECE
E-Poster 59

Agomelatine Exposure During Pregnancy

An Australian Observational Cohort Study

Kwok S[1], Kennedy D[1, 2]

Introduction

Agomelatine is a melatonergic agonist (MT1 and MT2 receptors) and 5-HT2C antagonist and is used often in conjunction with other psychotropic agents e.g. antidepressants for the treatment of major depression and generalised anxiety disorder. There are very limited published cases of agomelatine use in pregnancy. The objective of this study was to follow-up pregnancies with an exposure to agomelatine.

Methods

Women who called MotherSafe regarding the safety of using agomelatine were followed up by a MotherSafe counsellor. Data were collected between 2011 and 2023

Results

From 2013 to 2023 MotherSafe received a total of 600 calls regarding agomelatine.

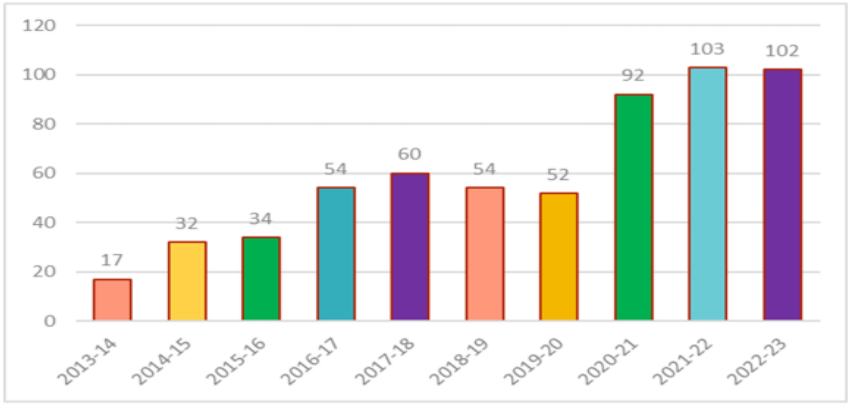

Figure 1: The number of agomelatine calls to MotherSafe have been steadily increasing.

Data from 47 agomelatine-exposed pregnancies were compared with 74 age-matched control pregnancies exposed to non-teratogens. Most (45/47) pregnancies were exposed to agomelatine in the first trimester with a mean dose of 25mg daily. Almost half (45%) of the women continued agomelatine throughout pregnancy, including four women who had taken agomelatine in two separate pregnancies.

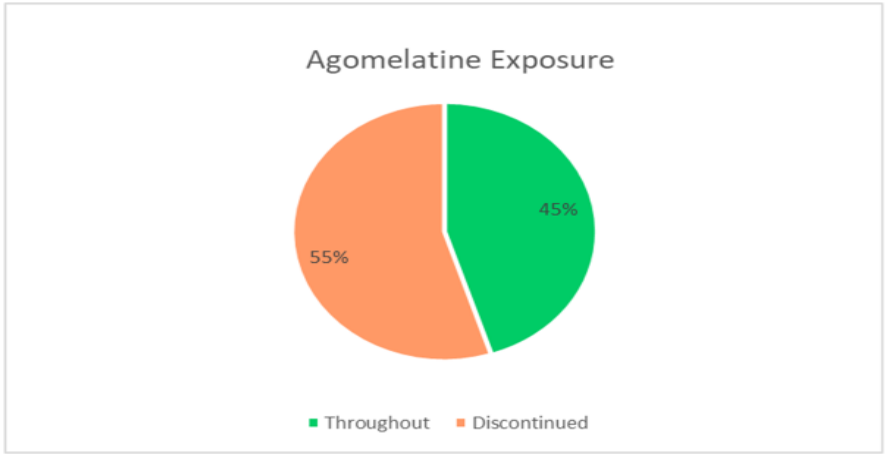

Figure 2: Almost half (45%) of women continued taking agomelatine throughout pregnancy.

One-third of the women who took agomelatine were on concomitant psychotropic medications. The women who remained on agomelatine throughout pregnancy were more likely to be on other psychotropic medications, indicating more severe mental health.

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Pregnancy Outcome

There was one birth defect reported in each group, an undescended testis in the agomelatine group, and a baby born with Pierre Robin Syndrome with cleft palate in the control group. The average birth weight was identical in both groups (3.4kg).

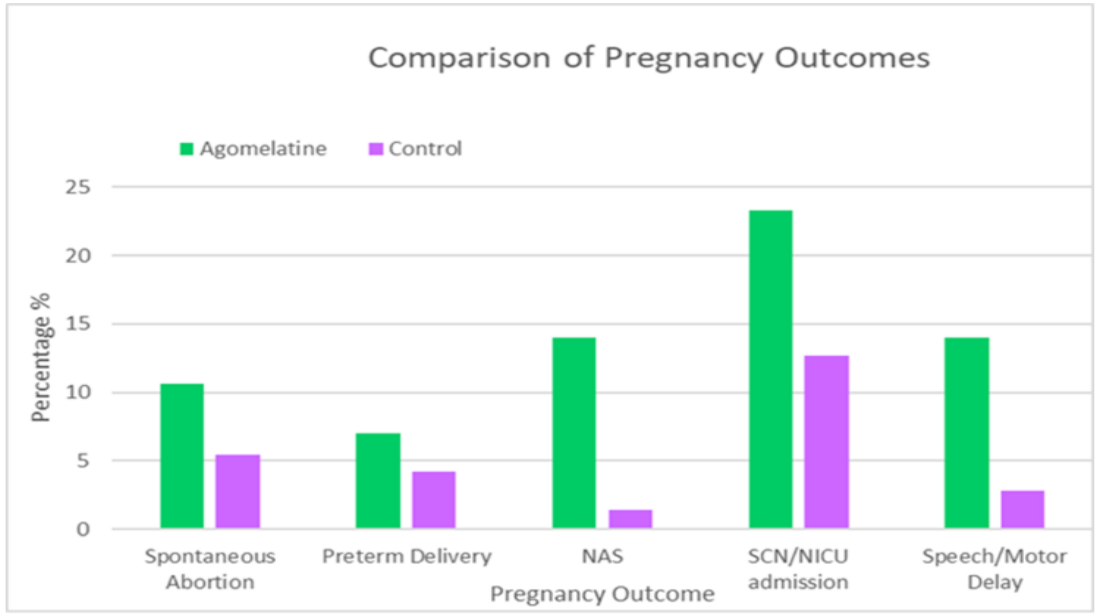

Figure 3: The agomelatine group were more likely to have an adverse pregnancy outcome compared to the control group. (NAS: neonatal abstinence syndrome, SCN: special care nursery, NICU: neonatal intensive care unit). NAS symptoms included self limiting episodes of jitteriness, respiratory distress and hypoglycaemia.

Most of the children (n= 6) in the agomelatine group with speech/motor delays were exposed to concomitant psychotropic medications for the treatment of more significant mental health.

The average age at follow up was 18 months for the agomelatine group, and 35 months for the control group.

Conclusion

This study demonstrated a higher rate of adverse pregnancy outcome following exposure to agomelatine compared to the control group who took non-teratogensl. Maternal anxiety and/or depression and its impact on pregnancy outcome and neurodevelopment is well-documented in the literature. Therefore, the maternal condition in the agomelatine group appears to be an important confounding factor to the results.

Future Research Opportunities

The main limitations of the study include the small number of pregnancy follow-ups, concurrent medication exposures, lack of disease-matched controls and single follow-up session. Further studies with more follow-ups, disease-matched controls and a longer period of infant follow-up are required to corroborate our findings.

Acknowledgements

1. MotherSafe, The Royal Hospital for Women, Randwick, Australia.
2. Womens and Childrens Division, The University of New South Wales, Sydney, Australia.