Treatment of Meniere's disease with betahistine in the first trimester of pregnancy

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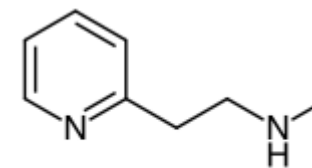
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Introduction

Betahistine is a histamine analogue used as a vasodilator in the treatment of Meniere's disease. However, evidence of benefit is weak. Betahistine has not been adequately tested for reproductive toxicity. In animal studies in rabbits, embryo-fetal losses were higher than in the control group. In humans, a series of 24 prospectively followed pregnancies has been published to date. Three pregnancies were terminated because of concern for fetal harm, and two pregnancies ended in abortion. One in 20 newborns suffered from a major malformation (Buharalioglu et al 2018).
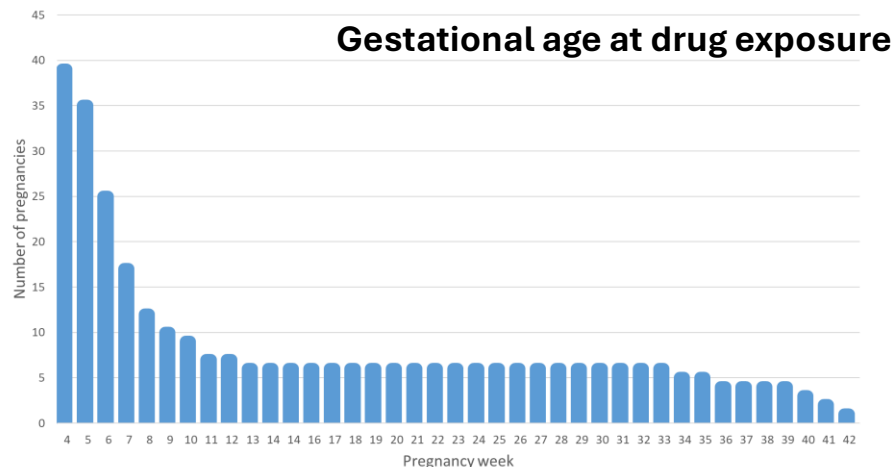
Methods

After contacting our Teratology Information Service (TIS Ulm / Germany) 39 pregnancies were included in a prospective follow-up study between 1991 and 2023. Three months after the estimated date of birth, the inquirers received a structured questionnaire to document the course and outcome of the pregnancy.
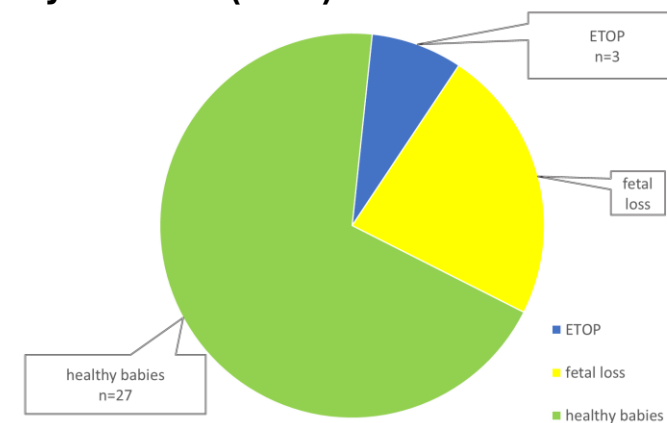
Betahistine

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Results

Gestational age at drug exposure

Pregnancy outcome (n=39)

- Due to the unclear data situation, three patients decided to terminate their pregnancy.
- Nine pregnancies ended in spontaneous abortion (9/36 = 25.0%).
- No fetal malformations were observed in the 27 pregnancies that were carried to term.
- However, only seven patients continued treatment with betahistine until delivery, while the other pregnant women decided to stop the medication in the first trimester due to the manufacturer's warnings.

Conclusion

Our prospectively documented case series showed no evidence of an increased risk of fetal malformations following maternal use of betahistine in the first trimester. However, a high proportion of spontaneous abortions was observed, which is consistent with animal data. Expansion of the cohort is desirable to clarify a potential reproductive toxicological risk.