An audit to determine how teratogenic risks of carbimazole are considered for patients of child-bearing potential in an acute hospital setting

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Introduction

Carbimazole is associated with an increased risk of congenital malformations when used in pregnancy. In 2019, the Medicines and Healthcare products Regulatory Agency (MHRA) strengthened its advice on risk minimisation.[1] The valproate national campaign raised awareness of risks amongst healthcare professionals and the public.[2] However, within our organisation it was perceived that awareness of teratogenic effects of carbimazole was potentially less well-known. The overall aim was to determine if teratogenic risks associated with carbimazole were considered in patients of child-bearing potential.

Objectives were to measure the percentage of patients that had a documented:

- Acknowledgement of risk (audit standard 70%);
- Pregnancy or contraception status (audit standard 80%)
- Record of provision of patient information (audit standard 70%)

Methods

The setting was an acute NHS organisation comprising two main sites. The prescribing, health record (HR) and pharmacy dispensing systems were electronic. A cluster sample of female patients aged ≤45 years that had carbimazole dispensed between November 2018 and November 2019 were included. A data collection tool was developed and piloted prior to use. A trainee pharmacist reviewed patient HRs and extracted details of prescription, risk conversations, contraception and pregnancy status onto the data collection tool. Patients without a consultation record were excluded. No patient or staff identifiable data were recorded. Data were collated using Microsoft Excel and analysed descriptively.

Results

Seventy-nine of 81 patients aged 11-45 years were included; two patients were excluded because their consultation records were unavailable. Of 79 patients, 35 (44%) had either pregnancy status, contraception, teratogenic risk consideration or discussion documented. For 44 (56%) patients, there was no documented acknowledgement of risk. Twenty-nine (36%) patients had their pregnancy or contraception status documented. For six pregnant patients, provision of advice was unclear. Only fifteen (19%) had specific documentation about risk consideration and six of documented risk conversations with patients. There was no evidence pharmacists had checked risk considerations made by prescribing clinicians or actively provided information to patients.

Conclusion

Findings suggest that consideration of teratogenic risk of carbimazole is inconsistent. Where pregnancy and contraception status were documented in the absence of further information, it was unclear if patients were informed of risks or involved in treatment discussions. Findings have limited generalisability due to the small sample. Although HR were thoroughly reviewed, findings were based on documentation that was potentially incomplete or not representative of detailed discussions during patient consultations. Further research should use methods to explore clinician and patient awareness of teratogenic risk of carbimazole and patient involvement in their treatment decisions.

Recommendations are to:

- Upskill pharmacists so they more actively provide risk information
- Better utilise electronic prescribing to mandate inclusion of contraception status and facilitate standardised risk consideration.
- National bodies should implement formal risk minimisation strategies for all teratogenic drugs.

References:

1. Medicines and Healthcare products Regulatory Agency. Carbimazole: increased riskof congenital malformations strengthened advice on contraception [internet]. London:MHRA; 2019 [cited February 2019]. Available from: https://www.gov.uk/drug-safety-update/carbimazole-increased-risk-of-congenital-malformations-strengthened-advice-on-contraception
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