AUDIT OF A GENERAL ADULT PSYCHIATRY SERVICE'S COMPLIANCE WITH HPRA GUIDELINES ON VALPROATE PRESCRIBING IN WOMEN OF CHILDBEARING POTENTIAL

Dunne E[1], O'Driscoll E[2], Fernandez C[1]
1. St Vincent's University Hospital, Dublin 2. St Patrick's University Hospital, Dublin

BACKGROUND

Valproate is a mood stabiliser indicated for the treatment and prophylaxis of mania in bipolar affective disorder where lithium is not tolerated or is contraindicated, as well as in the treatment of epilepsy.

Guidelines were published by the HPRA in April 2018 for prescribers of valproate, given the significant risk of teratogenicity associated with its use in women of childbearing potential. Exposure to valproate in utero is associated with a 10% risk of congenital malformation in children, early developmental delay, and lower intellectual abilities.

Prescribers must adhere to the pregnancy prevention programme, which includes discussion of the risk of teratogenicity with valproate and need for reliable contraception. Prescribers should also ensure that the patient signs an Annual Risk Acknowledgment form, has a copy of the Patient Guide , and is reviewed at least annually.

AIMS

The aim of this audit was to identify all women of child-bearing potential currently prescribed valproate and to investigate compliance with HPRA guidelines on valproate prescribing in community mental health teams (CMHTs) based in a South Dublin service.

METHODS

In this audit, all women of childbearing potential on valproate currently attending the service as of December 2019 were identified using an electronic appointment database and a review of healthcare records. Childbearing potential was defined as 18-55 years and pre-menopausal. Patient demographics, medication, primary diagnosis, and compliance with HPRA guidelines were retrieved from healthcare records. Compliance with guidelines comprised documentation of discussion of the risk of teratogenicity, provision of information about the risks to the patient, and documentation of current contraception. Where available, information on whether valproate was initiated by the CMHT, cessation was attempted, and if alternatives were considered was also recorded.

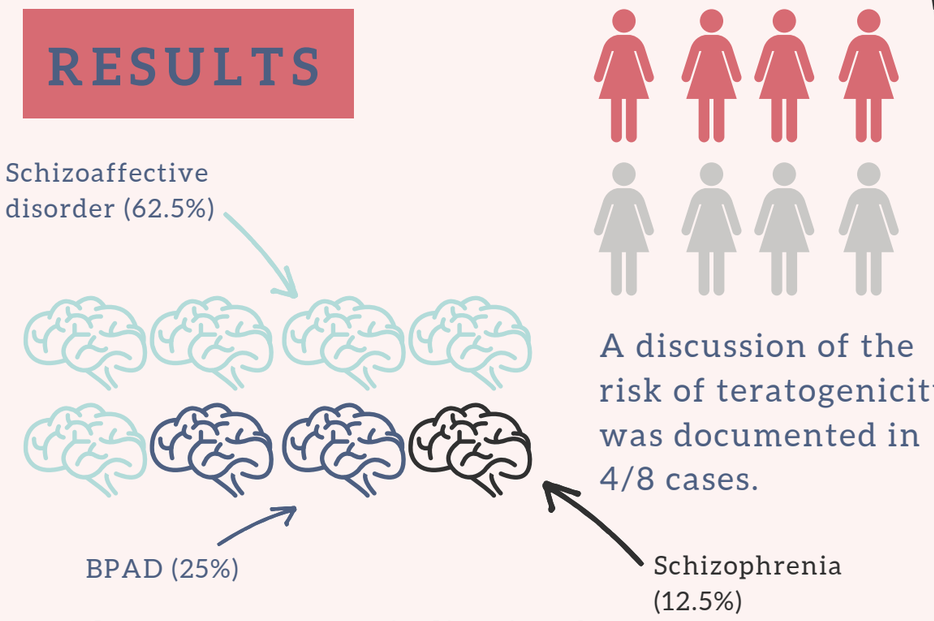
RESULTS

A total of 8 patients of child bearing potential were identified as currently taking valproate. The mean age was 44.1 years (range 33-55yrs).

The mean treatment dose of valproate was 1175mg (range 600-1800mg).
Valproate was initiated by the CMHT in 4/8 cases.
An alternative medication was considered in 5/8, and cessation of valproate attempted in 1/8.

Contraception was used by 2/8 women, with both using intra-uterine devices.
Written information was provided to patients in 3/8 cases, and oral information in 1/8.

RESULTS



A discussion of the risk of teratogenicity was documented in 4/8 cases.

The most common indication for valproate was schizoaffective disorder (5/8), followed by Bipolar Affective Disorder (2/8) and Schizophrenia (1/8).

DISCUSSION

Treatment with valproate in women of child-bearing potential is associated with significant risk of teratogenicity. It is therefore of utmost importance that women exposed to valproate do so with full knowledge of the risks this entails. This audit indicates that there is partial compliance with HPRA guidelines in the service. Notably, valproate is contraindicated unless the conditions of the pregnancy prevention programme are fulfilled. It is concerning that only 25% of patients were using reliable contraception; while some had personal reasons for not using contraception, this was not documented in all cases. A discussion of the risks of teratogenicity was only documented in half of the patients, which again indicates a need for greater compliance with guidelines. Lack of compliance with guidelines has the potential to raise legal and ethical concerns, and as such measures should be taken to increase adherence.

LIMITATIONS

Limitations of the study include small sample size, and possibility of incomplete data due to current use of paper-based healthcare records. Most teams lacked an up to date list of current patients, meaning data on total patient numbers was difficult to ascertain, and hence excluded.

RECOMMENDATIONS

Recommendations following this audit include holding a training session on HPRA guidelines for prescribers, maintaining a register of patients on valproate attending the service and the date that their next Annual Risk Acknowledgement form is due, and re-auditing in 6 months.

ETHICS

Ethical approval was granted by St Vincent's University Hospital Ethics Approval Committee.
Audit approved by Dr Cathryn Rogers, Clinical Director, and SVUH Clinical Audit Department .