Management of women on Dolutegravir: an audit against 2018 BHIVA recommendations on prescribing in women of reproductive age

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Introduction

In May 2018 BHIVA published recommendations on the use of Dolutegravir (DTG) in women of reproductive age. This followed the preliminary unscheduled analysis of an on-going birth surveillance study in Botswana which showed increased signal for neural tube defects in infants of women conceiving on DTG. This audit looked at the clinic’s actions and the resulting outcomes from these recommendations.

Method

Clinical records of all women under 55 who were prescribed DTG at the time of the position statement were reviewed. A total of 82 records from three clinic sites were analysed.

Results

At baseline 82 women were on DTG, 74 of whom were under age 50 at the time of statement release. 76% (56/74) had documented contraception or pregnancy status: 37% (28/74) were on contraception at last clinic visit or postmenopausal, 7% (5/74) TTC, 5% (4/74) not on contraception, 5% (4/74) pregnant, and 20% (15/74) had reported not being sexually active. Baseline contraceptive status of women on DTG is shown in Fig. 1.

Contact for discussion was needed in 95% (70/74) and was successful in 76% (53/70) women. Of 27 women TTC or without documented contraception method at last visit, 89% (24/27) were successfully contacted, by telephone, letter and/or face to face conversation. All pregnant women were beyond 1st trimester and remained on DTG.

Following discussion, 46% (11/24) women reported either TTC or not using any contraception. In addition to the initial 9 from the baseline investigation, a further 2 were found to be TTC. 9 of these 11 elected to switch treatment, either because they were TTC or planned to conceive in the near future. Switches were to: Raltegravir(5) Atazanavir(2) Efavirenz(1) Darunavir(1). Reasons for non-first line switches were patient preference, resistance or intolerance. Current contraceptive method was updated for 9 of the 24 women. A further 5 women started contraception (one patient elected to switch treatment but also started contraception). Recommendation of 5mg folic acid was documented in one case.

Patients not using contraception and at present remaining on DTG:

Patient 1: Was not using contraception and did not want to start contraception. Patient chose not to switch following a detailed discussion of the risks.
Patient 2: This patient had complex resistance and intolerance and had decided to use contraception until the outcome of discussion in a virtual clinic.

Aims and Objectives

To evaluate local performance against the following recommendations at three clinic sites:

• Women on DTG up to 50 years old should have a documented contraception method
• Women trying to conceive (TTC) on anti-retroviral therapy (ART) should be prescribed folic acid 5mg
• All women at risk of pregnancy on DTG should be contacted for discussion, if TTC an appropriate alternative regimen should be prescribed, or discussion documented regarding contraception.
• Pregnant women taking DTG in first trimester should be advised to switch.

Conclusions

• Patients were contacted appropriately in the majority of cases and the outcomes of discussion were documented as per the BHIVA recommendations.
• Most women on DTG planning pregnancy elected to switch, and switches were onto suitable agents taking into account the circumstances and wishes of the patient.
• As per guidelines, no pregnant women beyond first trimester were switched off DTG.
• Our documentation of baseline contraception status needs improvement, as does our prescription of 5mg folic acid to women who are trying to conceive whilst on ART.

We recommend from this audit that we should routinely discuss contraception and plans for future conception to optimise treatment and ensure appropriate clinical advice is given. This audit has given an insight into how we can respond quickly to post-marketing surveillance trials which is likely to be of use in the future.

References

BHIVA statement on Potential Safety Signal in Infants Born to Women Conceiving on Dolutegravir (on behalf of the BHIVA HIV in Pregnancy Guidelines Committee) 22nd May 2018. Available at: https://www.bhiva.org/BHIVA-statement-on-Dolutegravir/BHIVA-statement-on-Dolutegravir-22nd-May-2018