Abstract

Introduction
The risk of venous thromboembolism (VTE) with oral contraceptives (OCs) is well documented. Recently, questions have been raised about an increased risk of VTE of 4th generation OCs (containing drospirenone) compared to 2nd generation OCs containing levonorgestrel. Objectives

This IMEDS Evaluation pilot used a distributed network of FDA Sentinel data partners to examine the rate of VTE in new users of 2nd and 4th generation OCs using the standardised data analytics capabilities of the IMEDS Evaluation pilot.

Methods

The analytic cohort consisted of women aged 15-44 who were new OC users in 2nd or 4th generation. Patients with VTE risk factors were excluded. Dispensings were defined by National Drug Code in publications. VTE was defined by ICD9 codes 415.1 or 453.x, occurring in the inpatient or emergency department setting. Nine Sentinel data partners participated. Publicly available Sentinel modular programs were used. Feasibility data were reviewed to inform use of the more complex modular analytics. Consistent with typical FDA use of these programs, the analysis did not include any direct comparison or statistical testing; rather, the results include rates of VTE stratified by age, sex, and year.

Results

As shown in table 1, between 1st January 2008 and April 30, 2015 there were 350,572 new users of 4th generation OCs and 31,736,363 new users of 2nd generation OCs. There were 158 new VTE events for 4th generation OCs, and 121 for 2nd generation OCs. The rate of VTE events per 10,000 person-years was 8.56 for 4th generation and 6.58 for 2nd generation OCs (interquartile range from 5.89 to 13.13 and 7.94 to 12.81 respectively). There were a total of 158 new treatment episodes with VTE events for 4th generation OCs, and 121 for 2nd generation OCs. The rates of new episodes with VTE events per 10,000 person-years were 8.56 for 4th generation and 6.58 for 2nd generation OCs (details of variations across the data partners are shown in table 1 and figure 2). Rates were slightly higher for both when exclusions were limited to 90 days (5.96 and 7.94 respectively).

Conclusion

This rapid analysis approach shows rates of VTE were greater for 4th generation than 2nd generation OCs in line with the literature. Limited variation was seen across data partners, although some partners had few events. Limitations include lack of controlling confound, no direct comparisons or matching, and VTE defined solely by diagnosis code. The pilot shows the potential of the large distributed data network in exploring safety issues and the value in leveraging Sentinel data and analytics.

Acknowledgement

We thank the participating data partners Group Health, Harvard Pilgrim, HealthPartners, HealthPartners, Humana, Marshfield, Meyers Primary Care, Optum and Vanderbilt for their contributions, expertise and data that contributed to this study to disclose.

References


Table 1. Oral Contraceptives (OCs) and VTE across participating data partners from the IMEDS between January 1, 2008 and April 30, 2015, by Oral Contraceptive Exposure and OC User Type

Table 2. Summary Statistics Across Participating Data Partners of MSDD

Results (Cont.)

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References