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Data-driven drug safety signal detection methods in pharmacovigilance using electronic primary care records: A population based study

Zhou, Shang-Ming[1*], Muhammad, Rahman[1], Lyons, Ronan[1], and Brophy, Sinead[1]

[1]Swansea University

Objectives

Though an effective drug to treat heart failure and heart rhythm abnormalities, digoxin has side effects, such as confusion. Adverse drug events (ADEs) are major public health issues, but signal detection of ADEs is challenging for healthcare professionals. The objectives of this study is to evaluate if data-driven techniques can be used to detect ADEs, specifically examine the best method to detect the known event of confusion in patients prescribed digoxin from electronic primary care records and generate evidence for unknown ADEs.

Approach

In this study, we analysed 195,454 patients from a general practitioner (GP) database Wales, UK held in the SAIL (Secured Anonymised Information Linkage) databank with 51,920 patients prescribed digoxin and the rest acted as controls. All diagnostic events within 1 year after taking digoxin were considered. We used different data-driven analytic techniques - the proportional reporting ratio (PRR), the reporting odds ratio (ROR), the information component (IC), and the Yule's Q (YULE) to detect signal of a statistical association between digoxin and associated adverse events.

Results

The YULE detected the highest number of 544 signals, the IC the lowest number of 117 signals, and they commonly identified 83 same signals. All ROR based signals were included in the YULE based signals. It detected that 8.09 people per 10,000 who took digoxin suffered from the side effect of confusion including acute confusional state of cerebrovascular origin and others. All 4 methods can detect the confusion event with the values of IC =5.35 (standard deviation =0.312), PRR=1407.2 (95% confidence interval=[993.72, 1992.71]), ROR== 2813.39 (95% confidence interval=[1692.443, 4676.776]), and YULE=0.99 (95% confidence interval=[0.9992892, , 0.9992895]) respectively. Also some unknown signals, such as "carcinoma in situ of rectum", were identified by the 4 methods. One common signal detected which was not clearly mentioned in clinical guideline is "digoxin poisoning" with the values of IC =1.87 (standard deviation =0.0946), PRR=214.71 (95% confidence interval=[68.75, 670.56]), ROR=215.67(95% confidence interval=[69.05, 673.63]), and YULE=0.99 (95% confidence interval=[0.9907,0.9908]) respectively. This finding is consistent with the previous study that digoxin can sometimes have toxic effects, particularly at high blood concentrations, because it normally takes a long time to be broken down by the body.

Conclusion

Data-driven analytic methods are a valuable aid to signal detection of ADEs from large electronic health records for drug safety monitoring. This study finds the methods can detect known ADE and so could potentially be used to detect unknown ADE.

*Corresponding Author:
Email Address: s.zhou@swansea.ac.uk (S. Zhou)

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