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The Application of a Clinical Data Warehouse to the Assessment of Drug-Warfarin Interactions

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Abstract and objective

Studies on drug-warfarin interactions in human subjects were typically based on single case reports or extrapolated in healthy volunteers. In this study, we proposed a method to apply an institutional clinical data warehouse (CDW) to address this issue in a real-world setting. A case-control study was conducted by using the CDW in Osaka University Hospital from 2000/01/01/-2005/12/31. We randomly selected the steady-state outpatients who were under warfarin mono-therapy as Group A and those who were on the pre-existing warfarin therapy but with only the added medication X as Group B. The difference between the PT-INR values on one-month interval in Group A and those before and after taking medication X for one month in Group B was compared. The warfarin-Allopurinol interaction was illustrated as one example. We identified 25 cases in Group A and 15 cases in Group B respectively. The difference of the PT-INR values on one-month interval between the two groups was not significant (P=0.394,Mann-Whitney test), indicating that no warfarin-Allopurinol interaction was present. This method can be used as an alternative approach to assess drug-warfarin interactions.

Keywords:

clinical data warehouse, Warfarin, drug interaction, PT-INR

Introduction

Warfarin is an effective and commonly used oral anticoagulant agent for the treatment and prevention of thromboembolism in a variety of conditions. The risk of major complication- hemorrhage may be increased when concomitant drug therapy is required. Previous studies on drug-warfarin interactions in human subjects were based on single case reports or extrapolated in healthy volunteers. Clinicians need to balance the therapeutic benefits with the bleeding risk through monitoring patient's PT-INR values during warfarin therapy. In this study, we proposed a method to apply an institutional clinical data warehouse (CDW) in a real-world setting to reduce certain practical and ethical problems faced by studies drawn from healthy volunteers and aimed to provide an alternative approach to assess drug-warfarin interactions.

Methods

The CDW in Osaka University Hospital was built in 1995 as a subject-oriented database. The outpatient's prescription data and PT-INR results were picked up from 2000/1/1/-2005/12/31 through Business Objects 6.5.1. Data were processed via Microsoft Access 2003 and statistic analyses were performed via SPSS 11.0 Japanese Version for Windows. A case-control study was conducted. The steady-state outpatients who took warfarin consecutively for at least one month were considered as the eligible study subjects. We randomly selected those who were under warfarin mono-therapy as Group A and those who were on the pre-existing warfarin therapy but with only the added medication X as Group B. Then we compared the difference between the PT-INR values with one-month interval in Group A and those before and after taking medication X for one month in Group B. The warfarin-Allopurinol interaction was demonstrated as one example.

Results

For the chosen example, we identified 25 cases in Group A and 15 cases in Group B respectively. The difference of the PT-INR values on one-month interval between the two groups was not statistically significant (P=0.394, Mann-Whitney test), indicating that no warfarin-Allopurinol interaction was present.

Mann-Whitney test

	GROUP	N	Average Rank	Rank Sum
PTINR1	B	15	23.13	347.00
	A	25	18.92	473.00
	Sum	40		
PTINR2	B	15	24.87	373.00
	A	25	17.88	447.00
	Sum	40		
DIFFEREN	B	15	22.53	338.00
	A	25	19.28	482.00
	Sum	40		

	PTINR1	PTINR2	DIFFEREN
Mann-Whitney U test	148.000	122.000	157.000
Wilcoxon W test	473.000	447.000	482.000
Z	-1.104	-1.830	-.852
P (two-tailed)	.269	.067	.394

Figure 1

Conclusion

This method can be used as an alternative approach to assess drug-warfarin interactions.