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

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Introduction

Studies on drug-warfarin interactions in human subjects were typically based on

Case reports

lower level of evidence

Studies drawn from healthy volunteers

practical and ethical problems

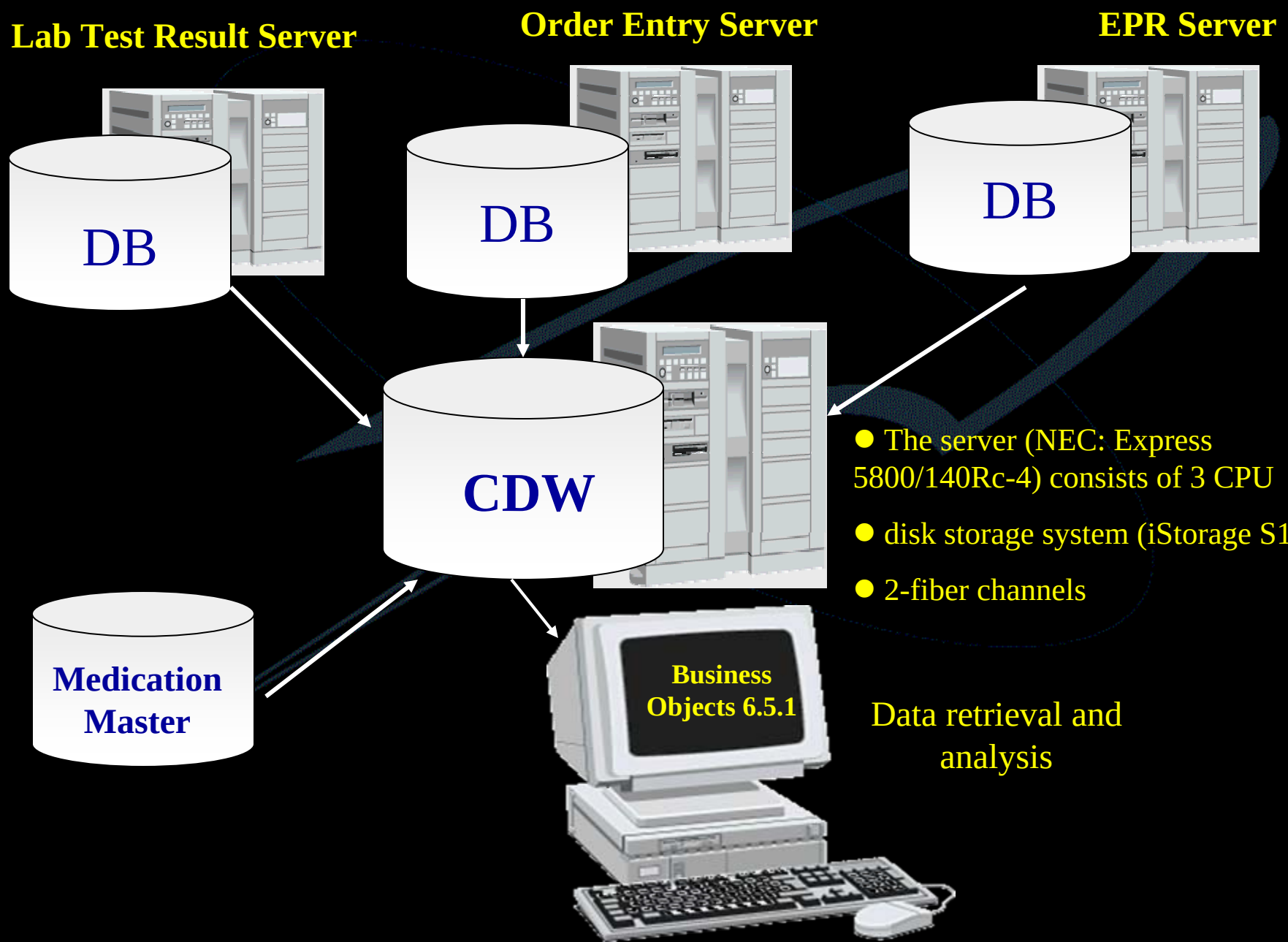
Purpose

- ***To propose a method to apply an institutional clinical data warehouse (CDW) as an alternative approach to assess drug-interactions in a real-world setting***

Materials

Data Source	Clinical Data Warehouse in Osaka University Hospital
Data Retrieval Tool	Business Objects 6.5.1
Data Processing Tool	Microsoft Access 2003
Data Analyses Tool	SPSS 11.0 J for Windows

Methods - Outline of the CDW in Osaka University Hospital



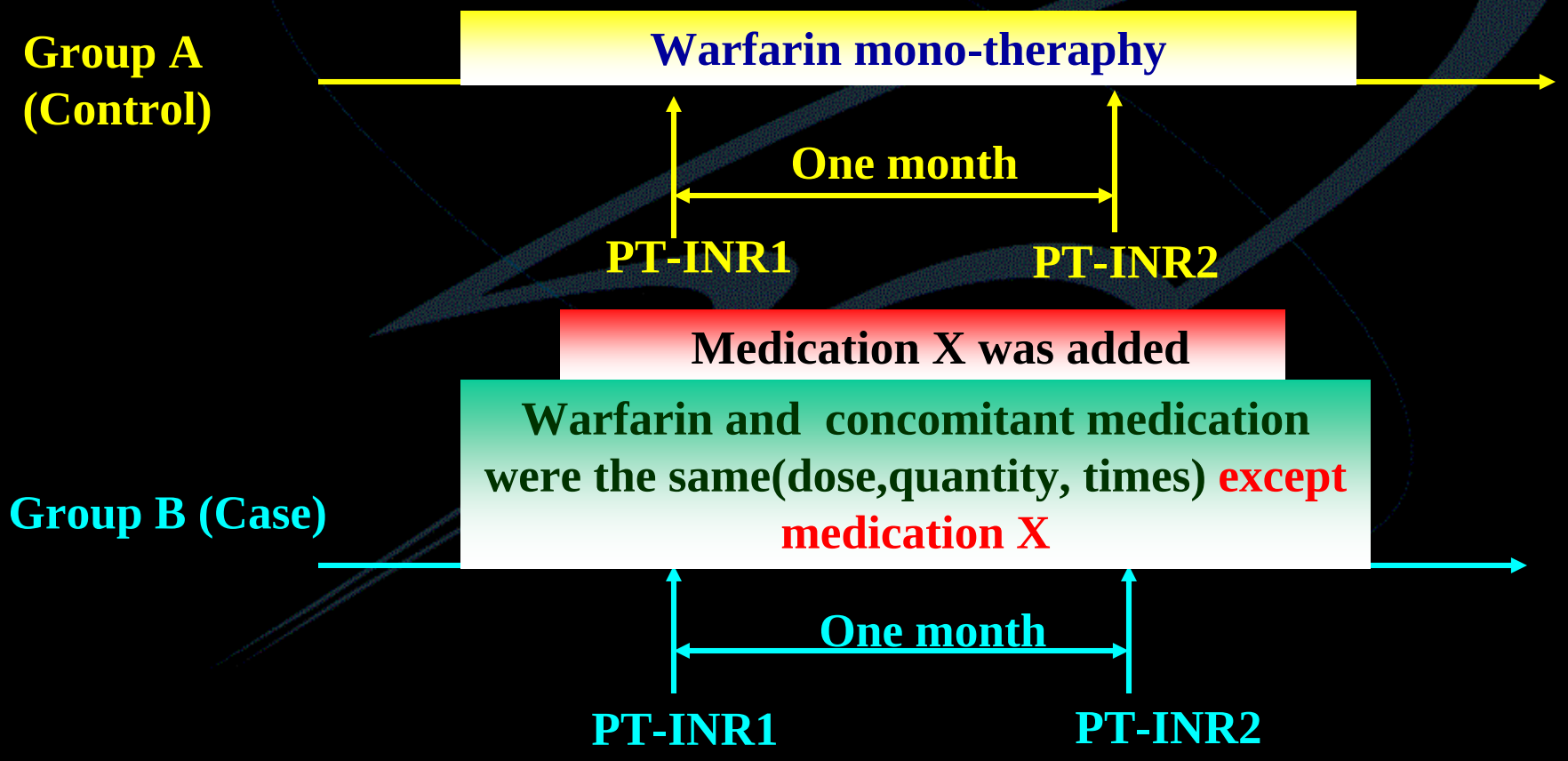
- The server (NEC: Express 5800/140Rc-4) consists of 3 CPU
- disk storage system (iStorage S100)
- 2-fiber channels

Data retrieval and analysis

Methods - Referred Data Sources,Tables, and Core Data Elements

Source of Data	CDW Tables	Core Data Elements
Lab test reporting system →	◆ Laboratory test results	PatientNo, OrderNo, PatientAge, Sex, CollectDate, TestitemCode, TestitemName, Result
Order Entry System →	◆ Prescriptions	PatientNo, OrderNo, PatientAge, Sex, StartDate, EndDate, MedicationCode, MedicationName, Quantity,Unit, Times, PrescribDays
Medication Master →	◆ Medication Master	MedicationCode, MedicationName, CatalogName

Methods - Study Design Diagram



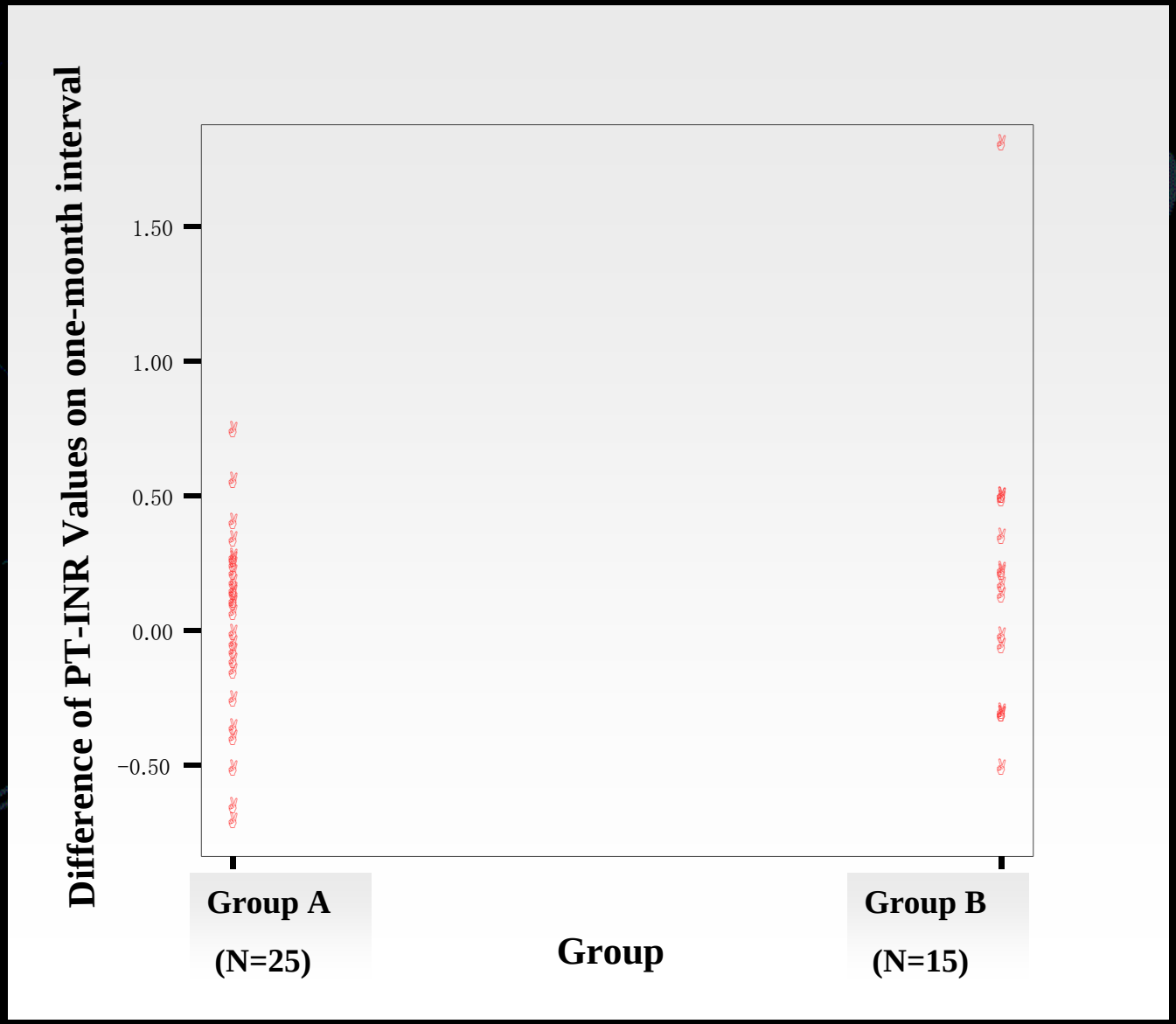
Results

Studied example: Warfarin-Allopurinol Interaction

Case -Group B: 15cases

Control- Group A: 25cases

Results


Difference of PT-INR Values on one-month interval
1.50
1.00
0.50
0.00
−0.50
Group A
(N=25)
Group
Group B
(N=15)

Results

Mann-Whitney test-Warfarin-Allopurinol Interaction

	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

Conclusions

- No warfarin-Allopurinol interaction presents in this investigation.
- This method can be used as an alternative approach to assess drug-warfarin interactions.

Reference

Anne M. Holbrook, Jennifer A. Pereira, Renee Labiris et al., Systematic Overview of Warfarin and Its Drug and Food Interactions. *Arch Intern Med. 2005;165:1095-1106*

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