

The pharmacokinetics characteristics of plasma-derived and recombinant FVIII products in Chinese children with severe hemophilia A

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Introduction and Objectives

There are no report of pharmacokinetic (PK) studies comparing plasma derived FVIII (pd-FVIII) against recombinant FVIII (rFVIII) concentrates in Chinese population, To assess the pharmacokinetics plasma-derived FVIII and recombinant FVIII products in Chinese children with severe hemophilia. We compared that the pharmacokinetics (PK) of pd- and rFVIII concentrates in pedatric HA patients.

Methods

A single dose PK (50IU/Kg) comparing pd- and rFVIII concentrates has been performed in pediatric HA patients with more than 50 ED.

A minimum washout period of 72 h washout period before PK determinations.

Blood samples for assay of plasma FVIII: C concentration were collected by enepuncture before dosing and, from the contralateral arm, at 1,9, 24, 48 h after the end of infusion ..

Factor VIII:C was assayed by one-stage clotting method. Blood type and vWF activity and vWF:Ag leves were detected on baseline.

PK analysis has been performed by Non-Compartment Analysis (NCA) on a 4-point decay curve: baseline and 1, 9, 24 and 48 h after the end of infusion , by means of WinNonlinsoftware

Results

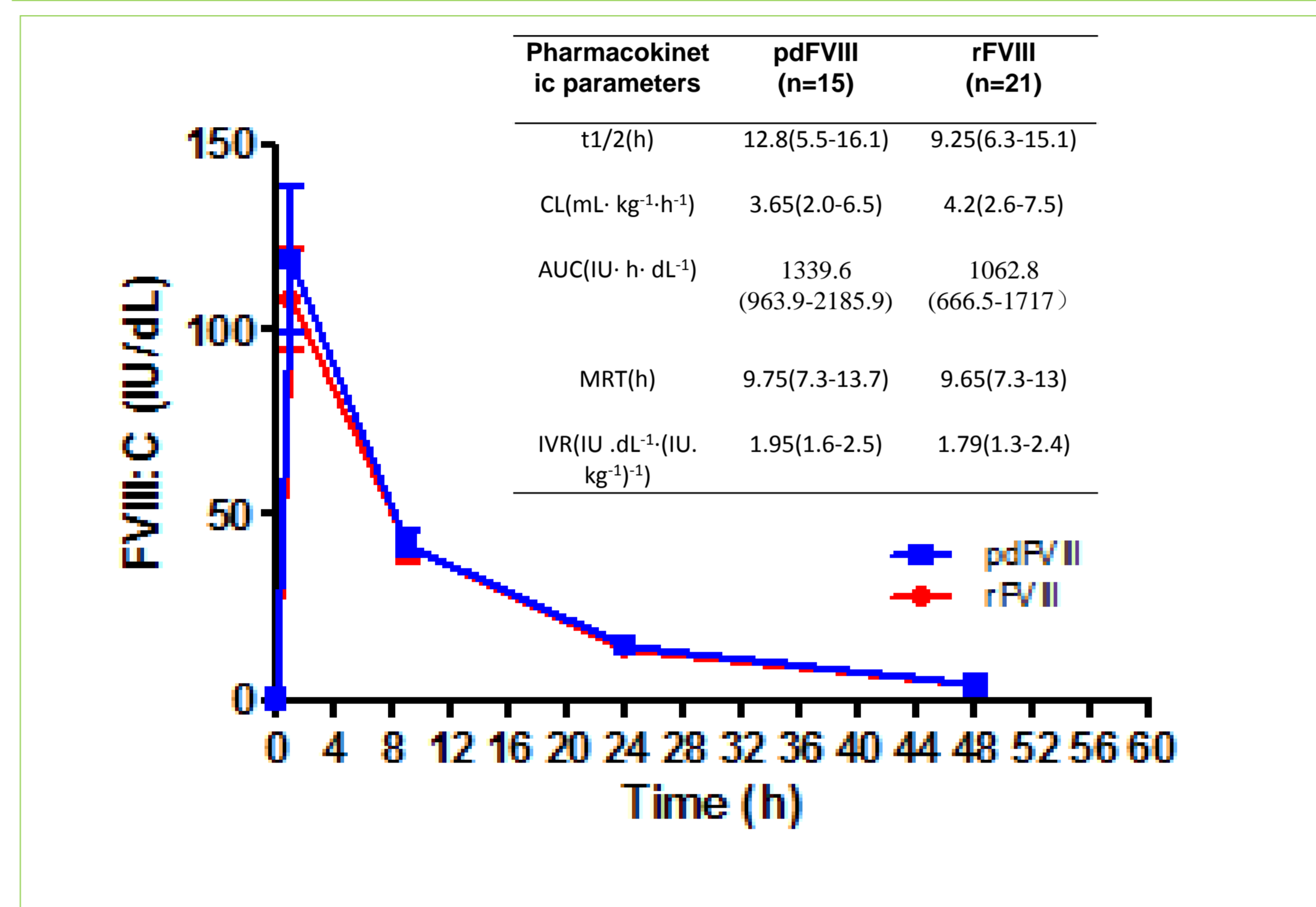


Fig1. Time course of change in mean FVIII level [\pm standard deviation (SD)]. $p>0.05$.

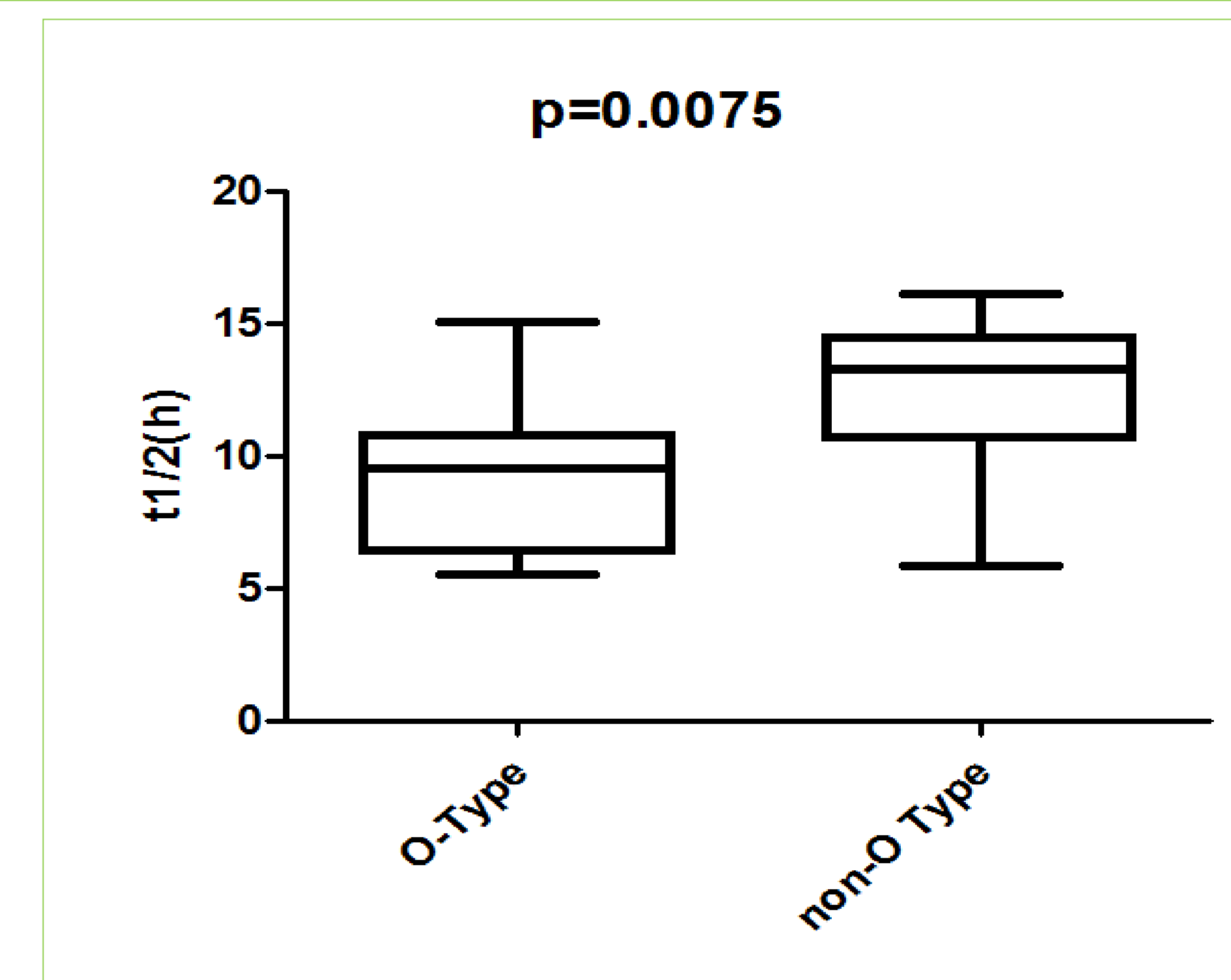


Fig2. FVIII half-life between type O and non-O blood groups.

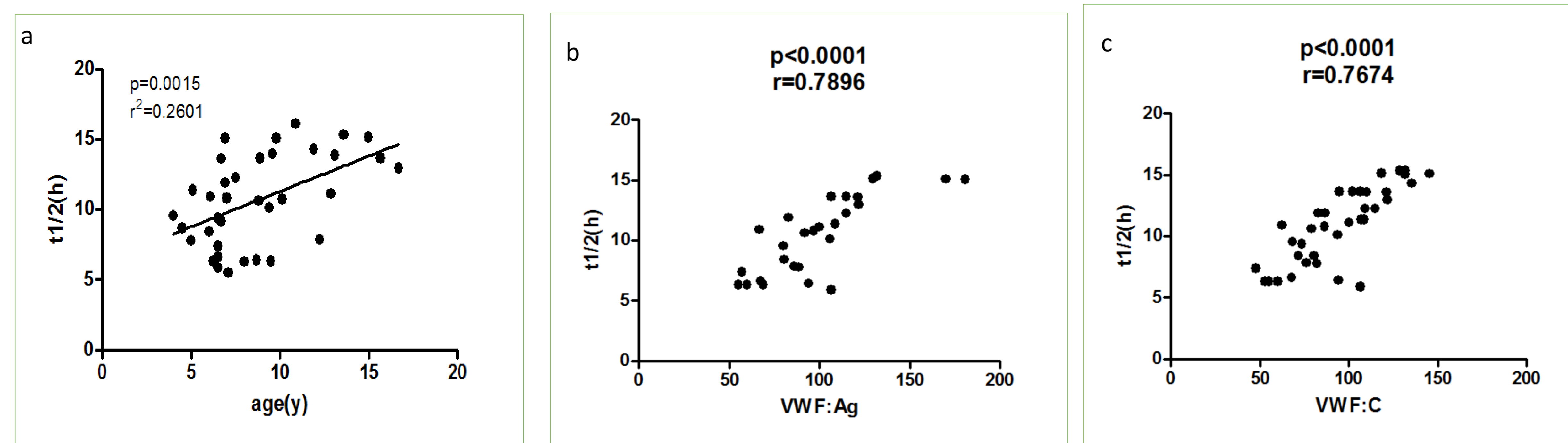


Fig3 Scatter plots of association between FVIII half-life, age, VWF:Ag and activity . (a) Age and FVIII half-life ;(b) VWF antigen levels and FVIII half-life. (c) Association between VWF activity levels and FVIII half-life..

Conclusions

- There are similar pharmacokinetics values between plasma-derived and recombinant FVIII products in Chinese children with severe hemophilia A ..
- Patients with blood group O had shorter FVIII half-life compared to patients with non-O blood group.
- Age was significantly associated with FVIII half-life.
- Besides age, also VWF antigen and activity levels were associated with FVIII half-life.

Acknowledge

This work was supported in part by grants from Hemophilia Management System Project (No.IHECC2014HEM04), Novo Nordisk Haemophilia Research Fund in China, Beijing Municipal Administration of Hospitals Clinical medicine Development of special funding support (code ZY201404).

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