

Original Articles

Comparison of Automated and Semi-Automated Determination for Prothrombin Time

Viroj Wiwanitkit

Department of Laboratory Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok 10330

Objective: To compare automated and semi-automated determination for clotting assay. **Study Design:** Descriptive study. **Setting:** Faculty of Medicine, Chulalongkorn University. **Methods:** In each day of July 1999, determination for PT was performed using control pooled plasma reagent. All assay tests were determined by two methods-using automated and semi-automated machine. Average values for PT in one month were calculated, compared then analyzed. **Results:** The average values by automated method were 12.25 ± 0.48 seconds for PT. The average values by semi-automated method were 12.33 ± 0.58 seconds for PT. It revealed that there was no significant between PT values determined by both methods. **Conclusion:** The clotting assay results from automated and semi-automated methods are not significant different. Recommendation for using of semi-automated method to perform clotting assay tests in small setting is set.

Key Words : ● Prothrombin time ● Automate ● Clotting assay

Thai J Hematol Transf Med 1999;9:279-82.

Laboratory investigation is an important tool in diagnosis and follow-up of patient with bleeding disorder. A number of coagulation tests as primary hemostasis and secondary hemostasis tests are available. Prothrombin time (PT) and activated partial thromboplastin time

(APTT) are the two common tests as clotting assay in medical practice.¹

In the present day, there are two common methods to perform clotting assay, automated and semi-automated methods. Automated method makes use of automated hematology machine to directly perform clotting assay.² Considering semi-automated method, medical technologist has to perform the test by the analyzer.

Received December 22, 1999. Accepted January 20, 2000.
Requests for reprints should be addressed to Dr. Viroj Wiwanitkit M.D, Department of Laboratory Medicine, Faculty of Medicine, Chulalongkorn University, Bangkok 10330

Due to the fact that interpretation of clotting assay results must base on the references and quality of the tests so much, therefore, in this study, a comparison between the two methods was performed. Results from this study can be useful data for the physicians in interpretation of laboratory results and in selection of the laboratory tests.

Materials and Methods

This study was carried out in Division of Laboratory Medicine, King Chulalongkorn Memorial Hospital during July 1999. In each day, determination for PT was performed using control pooled plasma reagent - Prothrombin SL, Dade Behring for PT and Thromorel, Dade Behring for APTT. All assay tests were determined by two methods - using automated Fibrintimer A, Dade Behring and semi - automated Option,² bioMerieux. Average values for PT in one month were calculated. Descriptive statistical analysis was performed where it

was appropriate. Comparison was performed using two-tailed paired T-test. Correlation coefficients were also performed to assess significant differences in determination of PT and APTT by automated and semi-automated methods. p value equaled to 0.05 was accepted as significant level.

Results

The average values by automated method were 12.25 ± 0.48 seconds for PT. The average values by semi-automated method were 12.33 ± 0.58 seconds for PT. It revealed that there was no significant between values determined by both methods (p value = 0.637). Comparing determination by automated to semi-automated methods gave correlation coefficient = -0.34 for PT (Figure 1).

Discussion

PT and APTT are the common coagulation screening tests widely used in medicine. To

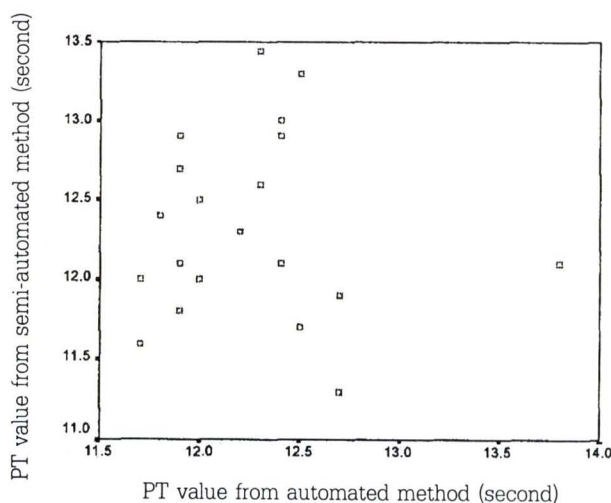


Figure 1 PT value from automated and semi-automated methods.

perform the clotting assay, a number of steps can result in abnormal result.³ In pre-analytical process, proper blood collection technique and proper anticoagulant used must be considered. In analytical process, good quality control must be considered. In post-analytical process, validation of laboratory results before reporting is necessary.

PT is the test for extrinsic pathway and APTT is the test for intrinsic pathway screening. These two tests are combined altogether as secondary hemostasis coagulation check up. Therefore, investigation for patient with delayed and pressure-resisted bleeding must make use of these two combined tests.^{4,5}

In this study, a comparison between automated and semi-automated methods for determination of clotting assay was performed. It revealed that there was no significant difference between both methods. Therefore, whatever methods used in determination of clotting assay, it seems to have no effect in the interpretation of the laboratory results on the general references.⁶

Concerning to previous study^{7,8}, the automated method for determination assay can be the candidate for conventional manual clotting assay technique. But considering details, the instrument cost of automated hematology machine is very high and it seems not to cost-effective in small setting.⁹ From this study, it seems that semi-automated machine which is smaller and cheaper than automated machine can be a good alternative candidate one for

clotting assay tests.

But the important fact that should be concerned is that most spurious clotting assay results result from poor collection technique^{4,5}, therefore, good collection technique should be stated. All physicians should realize that not only laboratory but also data from physical examination and history taking must be combined in diagnosis of patient with bleeding problems.

References

1. Eisenberg JM, Clarke JR, Sussman SA. Prothrombin and partial thromboplastin times as preoperative screening tests. *Arch Surg* 1982;117:48-51.
2. Becker U. Automated prothrombin - time test with use of a chromogenic peptide substrate and a centrifugal analyzer. *Clin Chem* 1984;30:524-8.
3. Wiwanitkit V. Abnormal laboratory results as presentation in screening test. *Chula Med J* 1998;42:1059-67.
4. Suchman AL, Mushlin AI. How well does the activated partial thromboplastin time predict post-operative hemorrhage? *JAMA* 1986;256:750-3.
5. Lind SE. The bleeding time does not predict surgical bleeding. *Blood* 1991;77:2547-52.
6. Heil W, Koberstein R, Zawta B. Reference Ranges for Adult and Children Pre-Analytical Considerations. 1st ed. Germany: Boehringer, 1998.
7. Tripodi A, Mannucci PM. Clinical evaluation of a fully automated chromogenic method for prothrombin time compared with a conventional coagulation method. *Clin Chem* 1984;30:1392-5.
8. Duncan A, Bowie EJ, Owen CA Jr, Fass DN. A clinical evaluation of automated chromogenic tests as substitutes for conventional prothrombin time and activated partial thromboplastin time tests. *Clin Chem* 1985;31:853-5.
9. อภิสิทธิ์ ฤทธิธรรมการโชติกุล. เศรษฐศาสตร์การบริหารงานห้องปฏิบัติการ. วารสารเทคนิคการแพทย์เชียงใหม่ 2540;30:S108-10.

การศึกษาเปรียบเทียบการหาค่า Prothrombin Time ด้วยวิธีอัตโนมัติและกึ่งอัตโนมัติ

วิโรจน์ ไววนิชกิจ

ภาควิชาเวชศาสตร์ชันสูตร คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย กรุงเทพมหานคร 10330

วัตถุประสงค์: เพื่อเปรียบเทียบการหาค่าของ prothrombin time ด้วยวิธีอัตโนมัติและกึ่งอัตโนมัติ **รูปแบบ:** การศึกษาเชิงพรรณนา **สถานที่ทำการศึกษา:** คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย **วิธีการ:** ได้ดำเนินการในช่วงเดือนกรกฎาคม พุทธศักราช 2542 โดยได้หาค่า PT โดยใช้ control pooled plasma reagent สำหรับแต่ละวันแล้วนำมาหาค่า โดยได้ทำการทดสอบแต่ละตัวอย่างด้วยวิธีอัตโนมัติและกึ่งอัตโนมัติ นำค่าเฉลี่ยที่ได้มาเปรียบเทียบและวิเคราะห์ **ผลการศึกษา:** จากการศึกษาได้ค่าเฉลี่ยเท่ากับ 12.25 ± 0.48 วินาทีสำหรับ PT ทั้งนี้ไม่พบความแตกต่างอย่างมีนัยสำคัญระหว่างวิธีการตรวจทั้งสองวิธี **บทสรุป:** จากการศึกษาพบว่าไม่มีความแตกต่างอย่างมีนัยสำคัญระหว่างวิธีการตรวจทั้งสองวิธี ทั้งนี้ได้อภิปรายข้อแนะนำในการใช้การตรวจด้วยวิธีกึ่งอัตโนมัติสำหรับห้องปฏิบัติการขนาดเล็ก

Key Words : ● Prothrombin time ● Automate ● Clotting assay

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต 2542;9:279-82.