Accuracy and Clinical Utility of a Portable Coagulometer in an Emergency Setting

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Background: *There are limited data concerning accuracy of portable coagulometer in emergency setting.*
Objective: *To evaluate the accuracy of the CoaguChek® XS international normalized ratio (INR) monitor compared to the standard laboratory method in emergency department.*
Material and Method: *Emergency room patients who required coagulation test were recruited. Parallel INR measurements between portable coagulometer and standard laboratory were performed.*
Results: *Fifty-five patients with a mean age of 59.1 ± 15.7 years (20-87) were included. Men constituted 56.4%. Indications for testing were as follows: acute stroke 72.7%; abnormal bleeding 7.3%; taking anticoagulant 7.3%; and others 12.7%. Mean time ± SD used from blood drawn to INR result report was 65.02 ± 24.5 minutes for standard laboratory and 1 minute for portable coagulometer. Mean difference of INR result from portable coagulometer and standard laboratory was 0.02 ± 0.13 and an excellence correlation between INR (r = 0.969) was demonstrated. There was no significant difference between the INR value from the two methods (p = 0.34).*
Conclusion: *The use of portable coagulometer (CoaguChek® XS) in emergency setting was accurate and required less time. Acute ischemic stroke patients are likely to benefit from a timely clinical decision making for thrombolysis medication.*

Keywords: *International normalized ratio (INR), Portable coagulometer, Point of care testing, Thrombolysis, Acute stroke*

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Portable coagulometer is a small portable unit made of two components: the meter and the cartridge or strip. The device is capable of measuring international normalized ratio (INR) on a drop of whole blood[1]. Measuring the INR with point of care (POC) devices has several advantages over measurements in the laboratory. Many studies[2-12] demonstrate a high accuracy of portable monitor for INR determination. However, insufficient data are available concerning its use in emergency settings.

Taking stroke as an example, acquiring a timely blood result can determine patients' outcome. According to the National Institute of Neurological Disorders and Stroke (NINDS) study[13] and the European Cooperative Acute Stroke Study III (ECASS III)[14], treatment with intravenous tissue plasminogen activator (t-PA) within 4.5 hours improved 3-month outcomes in acute ischemic stroke. However, treatment benefits reduce over time. One of the challenges in acute stroke treatment is to minimize any delay in getting mandatory neuro-imaging and laboratory results including the INR. The use of portable coagulometer or POC devices may help physicians to get an accurate result and eventually to a timely thrombolysis decision-making.

The objective of this study was to assess the accuracy of portable coagulometer in measuring INR in an emergency setting.

Material and Method

Eligible patients who were more than 18 years of age and required an emergency coagulation blood

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test were recruited from an emergency room, Department of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand. Parallel INR measurements from capillary blood were performed using portable coagulometer (CoaguChek® XS; Roche) and venous blood was drawn for an INR testing by a standard laboratory-based system. Demographic data, diagnosis, coagulation test indication(s), type of medical personnel who use the device, blood drawn to blood result time, and INR value from both techniques were recorded. Medical personnel who used the device were trained prior to the beginning of the study. An instructive manual was prepared and placed with the device. This study was approved by the Research Ethics Committee of Siriraj Hospital, Mahidol University.

Statistical Analysis

Sample size calculation was based on testing the correlation between INR values from laboratory and portable coagulometer. Previous study[2] showed an excellent positive correlation coefficient of 0.968. Using a 2-sided type I error of 0.05, 85% power, a sample of 44 subjects were required to test the null hypothesis (H_0) of $r_0 = 0.90$ against the alternative hypothesis (H_1) of $r_1 = 0.96$.

Data were analyzed using the statistical package for the social sciences (SPSS) version 17.0 and presented as mean, standard deviation (SD) and percentage, where appropriate. A paired t-test was used to compare the INR values between the 2 methods. Confidence intervals (CI) were calculated at the 95% level. A Bland-Altman plot was performed to assess the magnitude of disagreement between the two INR results. P-value of less than 0.05 was considered statistical significance.

Results

In all, 55 patients were included in this study with a mean age of 59.1 $\pm$ 15.7 years (20-87 years). Men constituted 56.4%. Indications to perform INR blood tests were tabulated in Table 1: acute stroke and transient ischemic attack (TIA) 72.7%; abnormal bleeding 7.3%; currently taking anticoagulant 7.3%; and others 12.7%. Mean time used from blood drawn to INR result report was 65.02 $\pm$ 24.5 minutes for standard laboratory and 1 minute for portable coagulometer. Types of medical personnel who use the device were: neurology and emergency room residents 50.0%; nurses 41.67%; and emergency medicine staff 8.33%.

Scatter plots of INR from portable coagulometer versus those from standard laboratory showed no difference (Fig. 1). Difference in INR between portable coagulometer and standard laboratory varied from -0.54 to 0.51 with the mean of 0.02 (SD 0.13) which was not significant different from zero ($p = 0.34$, 95% CI of -0.02, 0.05). An excellence correlation between INR ($r = 0.969$) results from portable coagulometer and standard laboratory were demonstrated.

Bland-Altman plot (Fig. 2) was performed and showed some disagreement between the two INR results when INR was more than 1.5.

Discussion

This study showed that the use of portable coagulometer for INR determination in an emergency setting was accurate and required much less time (1 minute) when compared to the standard laboratory

Table 1. Indications to perform INR blood test

	Number (%)
Acute stroke and transient ischemic attack	40 (72.7)
Acute ischemic stroke	23
Thrombolysis treatment with t-PA	6
Not eligible for thrombolysis treatment	17
Transient ischemic attack	4
Acute hemorrhagic stroke	13
Abnormal bleeding	4 (7.3)
Suspected coagulopathy in patients currently taking anticoagulant	7 (7.3)
Others	7 (12.7)
Preoperative or pre-procedural analysis	3
Sepsis	3
Anemia of unknown cause	1

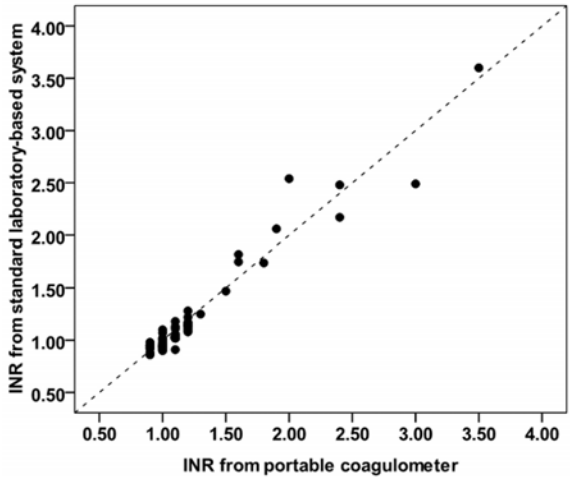

Fig. 1 Scatter plot of INR from portable coagulometer and standard laboratory.

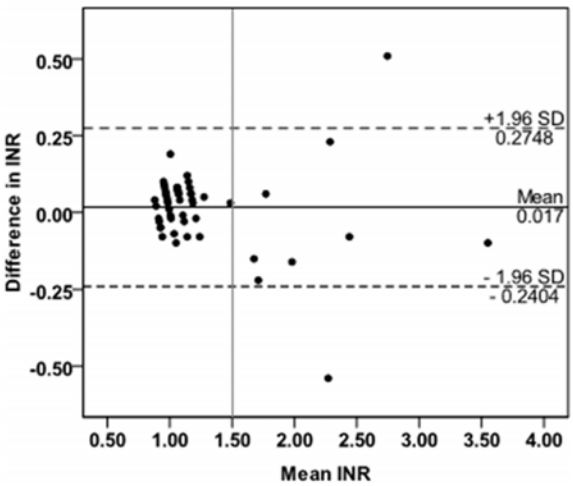

Fig. 2 Bland-Altman difference plot; the different INR values compared to the mean INR from the INR measurements between portable coagulometer and standard laboratory-based system are plotted.

technique (65 minutes).

Previous studies demonstrated similar results. Study by Poomlek V et al[2] performed in 39 consecutive ambulatory patients receiving long-term anticoagulant treatment showed that portable coagulometer provided comparable INR results with standard laboratory method. Another study by Green TL et al[11] conducted in 150 patients composed of 51 healthy volunteers, 48 anticoagulated inpatients and 51 acute stroke patients in an emergency department. The authors concluded that when being used by trained health care personnel in an emergency department, the portable coagulometer produced reliable results comparable to standard laboratory values. Rizos T et al[12] studied 113 patients in an emergency department who were known to use or suspected of using oral anticoagulant and 48 acute ischemic stroke patients who were eligible for thrombolysis. They demonstrated a highly significant correlation between portable coagulometer and central laboratory INR values (r = 0.98 and 0.97 in both groups of patient, respectively). The authors proposed that INR measurement by the portable coagulometer may hasten the initiation of thrombolysis in acute ischemic stroke patients.

This study was the first study of the use of portable coagulometer in an emergency department in Asia regardless history of using oral anticoagulant.

Our results showed that the accuracy of this device was retained although there were many types of patients and healthcare personnel who use the device. However, from Bland-Altman difference plot (Fig. 2), there is a trend of decrement in agreement when an INR value was high, especially in INR more than 1.5. This finding was also found in previous studies[2,3,6,11,12,15]. Therefore, we recommend performing a confirmatory test using standard laboratory result when an INR from portable coagulometer is more than 1.5.

The cost of INR testing by portable coagulometer was approximately 3 times higher than standard laboratory. However, in situation that requires a timely decision making, such as thrombolysis decision making in acute stroke, the benefit outweighs the cost.

Study limitations include: 1) a small sample size especially those with an INR > 2, 2) the lack of data concerning how an INR result from portable coagulometer would impact physicians' decision-making in regards to patients' management and 3) inability to report activated partial thromboplastin time (APTT). However, this was a pilot study testing an accuracy of INR results from portable coagulometer in an emergency situation. Patients with acute ischemic stroke who do not require APTT testing may benefit from this device in thrombolysis decision making. Because of the limitations, future study concerning an impact of this device on physicians' thrombolysis decision making in acute stroke is needed.

Conclusion

An INR result from portable coagulometer in emergency setting was accurate and required less time when compared to the standard laboratory-based

system. Patients may receive benefits from a timely clinical decision making in emergency situation including in thrombolysis decision making in acute stroke.

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Potential conflicts of interest

None.

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ความแม่นยำ และประโยชน์ทางคลินิกของการใช้อุปกรณ์ตรวจค่าการแข็งตัวของเลือดชนิดพกพาในผู้ป่วยห้องฉุกเฉิน

ชัชวาล รัตนบรรณกิจ, ยงชัย นิละนนท์, จุฬาลักษณ์ โกมลตรี, นาราพร ประยูรวิวัฒน์, นิพนธ์ พวงวรินทร์

ภูมิหลัง: *การศึกษาเกี่ยวกับความแม่นยำของอุปกรณ์ตรวจค่าการแข็งตัวของเลือดชนิดพกพาในผู้ป่วย ณ ห้องฉุกเฉินยังมีจำนวนน้อย*

วัตถุประสงค์: *เพื่อวิเคราะห์ถึงความแม่นยำของการตรวจหาค่า International normalized ratio (INR) ในผู้ป่วยห้องฉุกเฉิน โดยใช้อุปกรณ์ CoaguChek® XS เทียบกับการตรวจตามวิธีมาตรฐานทางห้องปฏิบัติการ*

วัสดุและวิธีการ: *ผู้ป่วยในห้องฉุกเฉิน ที่จำเป็นต้องได้รับการเจาะเลือดตรวจค่าการแข็งตัวของเลือดได้รับการเจาะเลือดตรวจหาค่า INR โดยใช้อุปกรณ์ตรวจค่าการแข็งตัวของเลือดชนิดพกพา ร่วมกับส่งตรวจทางห้องปฏิบัติการ*

ผลการศึกษา: *มีผู้ป่วยรวม 55 คน อายุเฉลี่ย 59.1 ± 15.7 ปี (20-87) เป็นเพศชายร้อยละ 56.4 ข้อบ่งชี้ในการตรวจเลือดได้แก่ โรคหลอดเลือดสมองร้อยละ 72.7, ภาวะเลือดออกผิดปกติร้อยละ 7.3, ผู้ป่วยกินยาป้องกันการแข็งตัวของเลือดอยู่ร้อยละ 7.3 และอื่นๆ ร้อยละ 12.7 ระยะเวลาเฉลี่ยตั้งแต่เจาะเลือดจนถึงเวลาที่รายงานผลจากห้องปฏิบัติการเท่ากับ 65.02 ± 24.5 นาที และจากอุปกรณ์ตรวจค่าการแข็งตัวของเลือดชนิดพกพาเท่ากับ 1 นาที ผล INR จากการตรวจทั้ง 2 วิธีมีค่าความแตกต่างเฉลี่ยเท่ากับ 0.02 ± 0.13 และค่าสหสัมพันธ์สูง (r = 0.969) ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติในสำหรับค่า INR จากทั้ง 2 วิธี (p = 0.34)*

สรุป: *การใช้อุปกรณ์ตรวจค่าการแข็งตัวของเลือดชนิดพกพา (CoaguChek® XS) ณ ห้องฉุกเฉิน มีความแม่นยำดีและใช้เวลาในการตรวจน้อยกว่าเมื่อเทียบกับการตรวจตามวิธีมาตรฐานทางห้องปฏิบัติการ ในผู้ป่วยโรคหลอดเลือดสมองตีบหรืออุดตันเฉียบพลันน่าจะได้ประโยชน์ในการตัดสินใจให้ยาละลายลิ่มเลือดเร็วขึ้น*