Comparison of a Portable Device and Standard Laboratory Measured INR in the University Malaya Medical Centre

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Abstract

Introduction: Warfarin is widely prescribed for various indications in a large number of patients. Anticoagulation therapy with warfarin is monitored by a prothrombin time (PT) assay which requires venipuncture and extensive laboratory resources for specimen handling and analysis. The portable capillary whole blood coagulation monitor is an alternative to laboratory venipuncture. Many interventional studies have shown that portable devices have many advantages over the standard laboratory venous plasma international normalized ratio (INR) measurement. The purpose of this study was to evaluate the accuracy and clinical correlation of the CoaguChek®XS portable device compared with standard laboratory methods for prothrombin time determination in the University Malaya Medical Centre.

Methods: Patients were recruited from the INR clinic in April and May 2006. This is a prospective open comparison study. Consented patients had their Capillary PT measured with the portable coagulation monitor CoaguChek®XS. The result was compared with the usual laboratory measured citrated venous plasma INR.

Results: A total of 65 patients were recruited. The indications for warfarin therapy were mainly cardiac causes (75 %) with the remaining 25 percent of them due to thrombotic events. Only 30 patients (46 %) achieved the therapeutic range whereas 31 patients (48 %) had an INR lower than the expected range and four patients (6 %) had an INR higher than the therapeutic range. We found a correlation coefficient of 0.967 between capillary and venous INR values among the 65 patients.

Conclusion: The new INR test with CoaguChek®XS was found to be reliable and to correlate with our laboratory INR measurement.

Keywords: Warfarin, INR, Portable Device, Correlation.
makes it relatively easier to use. Moreover, it has a potential capacity for home monitoring.

The purpose of this study was to compare the accuracy as well as correlate the INRs obtained by this device with the laboratory measured INR.

**Methods**

This is a prospective open comparison study. Patients were recruited from the INR clinic in April and May 2006. Informed consent was obtained from all patients. The result from the portable capillary monitor was compared with the usual laboratory measured citrated venous plasma INR. The therapeutic range for INR is between 2 to 3 for patients with pulmonary embolism, deep vein thrombosis and atrial fibrillation. It is between 2.5 to 3.5 for patients with prosthetic valves. The data was analyzed with SPSS for the correlation and other parameters.

**Results**

A total of 65 patients were recruited. There were 29 males (45%) and 36 females (55%). The indication for warfarin therapy was mainly cardiac causes which consisted of 49 patients (75%) (Figure 1). The indications for cardiac causes included prosthetic valve replacement and atrial fibrillation. The remaining 16 patients (25%) were for the treatment of deep vein thrombosis or pulmonary embolism. Only 30 patients (46%) achieved the expected therapeutic range whereas 31 patients (48%) had INR lower than the expected range and four patients (6%) had INR higher than the expected range (Figure 2). We found a correlation coefficient of 0.967 (Table 1 and Figure 3) between capillary and venous INR values among these patients. The individual differences between venous INR and capillary INR were 0 in 17 cases, 0.1 in 22 cases, 0.2 in 12 cases, 0.3 in five cases, 0.4 in three cases and 0.5 or more in five cases. The difference of the mean between venous and capillary INR was not statistically significant (p = 0.935)

**Discussion**

Warfarin currently is still the mainstay of treatment in deep vein thrombosis and pulmonary embolism. It is also widely prescribed as a prophylactic anticoagulant drug in various medical problems. Many studies had proven its efficacy in reducing a thromboembolic event in procoagulant states such as atrial fibrillation(1).

Although warfarin is effective in treating and preventing thrombosis, frequent monitoring is mandatory due to its unpredictable level and narrow therapeutic range. Tight INR control is important to ensure that the therapeutic range is achieved, and secondly, to reduce any bleeding complication from overdosage. This study showed that only 48% of patients achieved the expected therapeutic range. 46% of them were below the therapeutic dose and the other 6% had high INR levels which exposes them to the risk of hemorrhage.

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**Correlation is significant at the 0.01 level (2-tailed)**

**Table 1. Correlations between venous and capillary INR**
To ensure patients benefit from warfarin therapy without an excess risk of bleeding, more frequent monitoring and dose adjustment is mandatory. The oral anticoagulation monitoring study group (2001)(2) have shown that frequent blood tests are required. 92% of the patients who had their INR monitored every three days achieved the target range. Of those who had INR checked weekly, 77-85% achieved the target range. Only 50-60% achieved the target range among patients who had their blood test done monthly. It would appear that close monitoring of the INR does affect the quality of care. Unfortunately, this is not possible due to the heavy workload and limited resources in our local centre.

The portable capillary whole blood coagulation monitor is an alternative to laboratory venipuncture which provides an INR result within minutes. This device is able to shorten the waiting time in the INR clinic and in turn the INR can be monitored more closely. This device also has eliminated the technical errors that might occur in conventional INR testing when handling and processing the blood such as under filling or overfilling tubes containing
anticoagulant, temperature and storage time and the effect of centrifugation on anticoagulant. On the other hand, inappropriate technique in operating this portable device and obtaining blood such as squeezing a finger to obtain enough blood may cause the INR result to be inaccurate. Therefore, training of staff in handling the device and obtaining blood is essential to minimal the possible technical error.

CoaguChek® XS is one of the devices available on the market for portable INR measurement. Various studies have validated its accuracy (3-4). The aim of this study was to determine the accuracy and the correlation of the INR measured by CoaguChek® XS to our laboratory measured INR. The results showed that the correlation was 0.967. The difference of the mean between venous and capillary INR was not statistically significant (p = 0.935). The individual differences between venous INR and capillary INR were 0 in 17 cases, 0.1 in 22 cases, 0.2 in 12 cases, 0.3 in five cases, 0.4 in three cases and 0.5 or more in five cases. One interesting observation is that the differences between these two measurements are larger when the INR reading is high. This is not unexpected because conventional INR measuring is most accurate between readings of 1.5 to 4.5. This is due to the fact that WHO calibration model only using plasma from patients within this interval. Therefore, the assigned International Sensitivity Index value that enables the conversion of PT to INR is valid only for this range. As a result, INR at higher value should be interpreted with caution in both methods.

In conclusion, the portable capillary coagulation monitor (CoaguChek® XS) is reliable and correlates well with our laboratory method in measuring INR. However, at higher INR readings the result might not be so reliable. The study is consistent with findings from other studies. Using the portable capillary coagulation monitor enables us to give more efficient service and frequent INR monitoring which will then lead to more patients achieving the target range.

However, the cost of CoaguChek® XS is about RM 9.00 per test and the laboratory INR test is RM 6.20. Therefore an economical study should be conducted to compare the capillary coagulation monitor and laboratory method of checking INR in order for this new test to be made widely available in clinical practice.

References