Original article
COMPARISON OF PT/INR RESULTS BETWEEN AUTOMATIC SELF-MONITORING COAGULATION ANALYZER DEVICE AND LABORATORY METHOD IN PATIENTS ON ORAL ANTICOAGULATION
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ABSTRACT

Background—Warfarin and Acitrom are commonly used oral anticoagulants in preoperative and postoperative period in patients with cardiovascular diseases which needs frequent dose modification depending on INR values in specialized biochemistry laboratories. Nowadays newer self-monitoring devices are available to assess the INR values. Objective—To compare the INR values obtained by self-monitoring coagulometer with the standard laboratory method. Methods—Total 200 patients underwent INR estimation by both conventional laboratory method and self-monitoring coagulometer. Correlation between the methods was analyzed by pearson correlation coefficient and Bland–Altman analysis was used to assess mean difference. Results—The mean INR values by standard laboratory test was 2.72±1.25 and 2.92±1.35 by self-monitoring coagulometer. There was a strong correlation between both the methods and mean difference was 0.2±0.1. Conclusion—There was good consistency between INR values by both methods showing rapid and reliable analysis by self-monitoring coagulometers.

Introduction

Diseases of the heart valves constitute a major cause of cardiovascular morbidity and mortality worldwide with an enormous burden on healthcare resources. Rheumatic heart disease (RHD) continues to be the dominant form of heart valve disease in developing nations.1

The mean age of patients with valvular diseases in India are young and over 98% of them receive mechanical cardiac valves.

After mechanical cardiac valve replacement surgery patients require lifelong anticoagulation therapy. Vitamin K antagonists (VKAs), such as warfarin, have been the drugs of choice for oral anticoagulation for a long time.

The anticoagulant effect of VKAs can be monitored by the prothrombin time or the international normalized ratio (INR). Limited therapeutic index of warfarin requires regular INR testing to adjust the dose of anticoagulation and prevent complications of both higher and lower levels.

Conventional methods of INR testing require patients to visit a professional medical institution, which is time consuming costly, and many patients fail to follow up on regular basis.

In recent years, several portable coagulometers using capillary blood for INR analysis have been developed. These instruments, known as point of care (POC), have eliminated the need for whole blood collection and plasma separation by centrifugation and, thus, facilitate easy fast and accurate monitoring of VKAs therapy.

Although they were originally developed for home use, POC monitors have become very useful in hospital and outpatient clinics due to the practicality and speed in obtaining results. However, there are limited studies in the literature regarding the consistency of their results with standard laboratory methods. The purpose of this study is to analyze the safety accuracy and cost effectiveness of INR testing by portable coagulometers as compared to conventional testing in patients of mechanical heart valve replacement surgeries.

Material and Methods

The study was conducted in department of CTVS and dept. of Biochemistry of G B Pant institute of postgraduate medical education and research, Delhi.

Inclusion Criteria

· Patients receiving oral warfarin or Acenocoumarin therapy after mechanical valve replacement surgery
· Patients without coagulopathy disorder
· Patients having good compliance

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Exclusion criteria

- Patients with coagulopathy disorder
- Non compliant patients
- Patients on warfarin or acenocoumarin therapy without cardiac valve replacement

Methods

To examine the coagulation functions of these patients, conventional lab testing methods and self testing methods are used in parallel to check and record the INR values of the patients.

Standard Laboratory Procedure

Blood samples were collected by a clean puncture of an antecubital vein in the blood collection room. Peripheral venous blood of about 3 cm³ was collected by laboratory staffs, and added into a blood collection tube containing 3.8% buffered sodium citrate. Then, the tubes were transferred to the laboratory where they were centrifuged at 2500 g for 20 minutes at room temperature. The plasma obtained after centrifugation were analyzed with a STAGO STA-R (Diagnostica Stago, France) automatic coagulometer using STA-R Hepato Quick kit (Diagnostica Stago, SAS) with an ISI value of 0.91.

Point-of-Care Procedure

The CoaguChek XS (Roche Diagnostics, Basel, Switzerland) system consists of a small and portable coagulometer and disposable test strips. It measures the INR in whole blood obtained by finger prick, using recombinant human thromboplastin, and has an international sensitivity index (ISI) value of 1.0. All measurements were performed simultaneously in the blood collection room when venous blood samples were taken for standard laboratory tests. About 0.01 cm³ blood at the end of capillary of finger was collected from all patients by the same physician and added into corresponding area on the dry reaction test strip and tested with a portable CoaguChek XS coagulometer.

Study Protocol

A total of 200 patients with median age who visited the CTVS OPD of G.B. Pant hospital were enrolled in this study who were previously operated (Valve replacement surgery) and were taking warfarin/acitrom therapy and were in regular follow up.

Patients underwent INR testing by both conventional method as well as coaguchek device. Values obtained by both these methods were compared considering the conventional laboratory testing as standard of care. By comparing the values off all patients the accuracy of self monitoring device is compared to the standard method. Cost per test is also calculated for both the methods of testing and cost effectiveness is compared. Turnaround time was calculated for both the methods and was also compared.

RESULTS

The INR value of all 200 patients were collected for analysis. Table 1 shows the list of indications for oral anticoagulation therapy. The INR values tested by standard laboratory procedure ranged from 0.8 to 11.7 with mean 2.72 and standard deviation (SD) 1.25. The INR self-tested by patient by CoaguCheck XS system ranged from 0.9 to 12.3 with mean 2.92 and SD 1.35. The mean INR difference between the 2 methods was 0.20 ±0.10. In Bland-Altman analysis, the INR values by CoaguCheck XS system exhibited bias of -0.024 with a standard error of 0.316. Pearson correlation coefficient (r) obtained by comparing INR levels of these two methods was 0.948 (p value <0.001 and 95% confidence interval 0.901-0.997). The agreement of INR measurements between CoaguChek XS and STA-R was further analyzed according to INR categories as Subgroup INR< 2, Subgroup INR 2-3.5, Subgroup INR>3.5. Pearson correlation coefficients (r) obtained at subgroups INR < 2.0, INR 2.0-3.5, and INR > 3.5 ranges were 0.901 (95% CI:0.871-0.980, P <.001), 0.945 (95% CI:0.870-0.991, P <.001), and 0.916 (95% CI: 0.832-0.982, P < .001), respectively. The mean differences in the INR measurements in subgroups were 0.31 ± 0.43 ± 0.34, and 0.55 ± 0.49, respectively. The overall differences of INR values by 0.5 between the two methods were 20% with 17.3% cases in subgroup INR< 2, 21.1% cases in subgroup INR 2.0-3.5 and 32.3% cases in subgroup INR>3.5.

Table 1 List of indications for oral anticoagulation therapy

<table>
<thead>
<tr>
<th>Disease</th>
<th>No. of patients</th>
<th>percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prosthetic valve replacement</td>
<td>146</td>
<td>73%</td>
</tr>
<tr>
<td>Prothrombin induced thrombosis</td>
<td>29</td>
<td>14.5%</td>
</tr>
<tr>
<td>Deep vein thrombosis</td>
<td>14</td>
<td>7%</td>
</tr>
<tr>
<td>Propranolol in atrial fibrillation</td>
<td>11</td>
<td>5.5%</td>
</tr>
<tr>
<td>Total</td>
<td>200</td>
<td></td>
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</tbody>
</table>

Table 2- Summary of Accuracy Analysis Between the 2 Methods

<table>
<thead>
<tr>
<th>SUBGROUP</th>
<th>STATO-R</th>
<th>CoaguCheck</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR&lt;2</td>
<td>2.72±1.25</td>
<td>2.92±1.35</td>
</tr>
<tr>
<td>INR 2-3.5</td>
<td>2.33±0.34</td>
<td>2.32±0.39</td>
</tr>
<tr>
<td>INR&gt;3.5</td>
<td>2.82±0.82</td>
<td>2.98±0.98</td>
</tr>
</tbody>
</table>

Table 3: Performance Criteria Results

<table>
<thead>
<tr>
<th>Criteria</th>
<th>STATO-R</th>
<th>CoaguChek XS</th>
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identification and prevention haemorrhagic or thromboembolic complications of non-compliant anticoagulation therapy. The self-monitoring devices have potential widespread utility among the patients taking anticoagulation as an alternative to conventional laboratory methods though further large scale multicenter randomized studies are required.

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References


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