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Validation of the Coaguchek® XS INR point-of-care analyser to monitor the INR of patients at Windhoek Central Hospital, Namibia

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Background: The use of point-of-care INR (international normalised ratio) testing is on the rise because of its ability to facilitate quick clinical decisions as it allows for rapid turnaround time of INR results. Ensuring the quality of these tests is crucial when implementing them in new settings.

Objective: This study aimed to assess the sensitivity, specificity, and clinical agreement between the CoaguChek® XS INR meter and the Beckman Coulter ACL 7000 automated coagulometer in outpatients undergoing warfarin therapy.

Methods: A prospective cohort design was employed for this comparison. The analysis included Spearman's correlation, a Bland-Altman plot, and a Cohen's Kappa analysis of paired INR values. Key outcome measures included the percentage sensitivity, specificity, and clinical agreement of the two methods. A p-value < 0.05 was considered statistically significant.

Results: The study involved 89 patients, predominantly female (59.4%), with a mean age of 46 years. Deep vein thrombosis was the most common indication for warfarin therapy (51.9%). The mean difference between INR values determined by the two methods was –0.15 (± 0.27, $N = 89$), and the Spearman rank correlation coefficient was 0.97 ($p < 0.001$, $N = 89$). A clinical agreement of 83.8% ($p < 0.05$) was obtained. The sensitivity was 94.4%, with specificities of 82.5% for subtherapeutic and 100% for supratherapeutic INRs.

Conclusion: The CoaguChek® XS INR meter was proven to be a reliable alternative to the Beckman Coulter ACL 7000 automated coagulometer for monitoring INR results and adjusting warfarin therapy in well-trained patients with stable INR values.

What this study adds: The CoaguChek® XS INR meter was proven to be a reliable alternative to the Beckman Coulter ACL 7000 automated coagulometer for monitoring INR results.

Keywords: CoaguChek® XS INR meter; Beckman Coulter ACL 7000 automated coagulometer; sensitivity; specificity; clinical concordance.

Introduction

Tadesse et al. highlighted that a key factor affecting the quality of anticoagulation control in healthcare facilities is the high patient load.[1] The demand for warfarin therapy is expected to rise because of the increasing prevalence of non-communicable diseases in the Southern African Development Community.[2] To address this issue, it is essential to recruit more qualified healthcare workers for warfarin clinics. In regions such as Namibia, where there is a shortage of qualified healthcare professionals, exploring immediate interventions such as healthcare worker-supervised patient self-management may be necessary. This entails the utilisation of point-of-care (POC) testing for monitoring international normalised ratio (INR).

Point-of-care tests are performed at or near the patient's site of care, eliminating the need to transfer samples to a laboratory for testing. In the field of haematology, various POC tests such as activated clotting time, thromboelastography, platelet function, and D-dimer are available. In particular, the measurement of INR for monitoring warfarin therapy is crucial in this domain.[3] International normalised ratio-POC testing is on the rise because of its ability to provide rapid results, enabling swift clinical decisions.[4] It also offers advantages such as reducing issues related to venipuncture, especially in patients with challenging venous access, and providing convenience for patients in

remote areas.[5,6] This is particularly crucial in Namibia, being a highly rural country where laboratory testing is centralised to district hospitals or higher levels of care. Quality assurance for INR-POC testing is essential to ensure the reliability of results.[6]

The CoaguChek® XS INR meter from Roche Diagnostics has been shown in several studies to provide accurate and precise results comparable to laboratory-based INR determination.[7,8] While positive correlations have been observed between the CoaguChek® XS INR meter and conventional laboratory methods, differences in results were noted at higher INR values. Studies have highlighted the importance of considering factors like serum fibrinogen levels in interpreting results from INR-POC meters.[9] Sensitivity and specificity of INR-POC meters, including the CoaguChek® XS INR meter, are crucial metrics that need to be considered.

It is important to remain vigilant about the potential for errors in INR results when using POC-INR devices, as highlighted by a case report involving a CoaguChek® S INR meter.[10] In this report, an error in the INR determination by the POC-INR meter led to suboptimal anticoagulation, which consequently resulted in a clot forming on the patient's prosthetic valve. Auto-reactive antibodies associated with antiphospholipid syndrome (APS) have been shown to increase prothrombin (PT) time inaccurately, resulting in a positive supratherapeutic INR bias by POC testing.[11] Hypercoagulable states, such as factor V Leiden and atrial fibrillation, as well as the patient's fibrinogen levels, influence the accuracy of POC testing. It is imperative to note that 10% of patients in the main study were diagnosed with atrial fibrillation and the clinic does not undertake testing of fibrinogen levels.[12] In addition, although correlation studies have been done to assess the clinical accuracy of the CoaguChek® XS INR meter, these comparisons have not been carried out using the Beckman Coulter ACL 7000 automated coagulometer as the comparator. Finally, the CoaguChek® XS INR meter has not been validated in the Namibian setting where some of the factors exist, such as malnutrition, which could affect its accuracy.[13] It has been shown that malnutrition can result in coagulopathies. Thromboelastography is generally preferred in assessing the coagulation status of patients with malnutrition. Thromboelastography is shown to be more accurate than routine laboratory tests. This study, therefore, aimed to determine the sensitivity, specificity, and clinical concordance of the CoaguChek® XS INR meter in comparison to the Beckman Coulter ACL 7000 automated coagulometer of the Namibia Institute of Pathology for monitoring patients on warfarin therapy at the Warfarin Outpatient Clinic of Windhoek Central Hospital.

Methods

Ethical considerations

This research was part of a larger intervention study in which some of the patients had their INR checked using both the CoaguChek® XS INR meter and the Beckman Coulter ACL 7000 automated coagulometer.[12] The intervention study protocol was approved by the Human Research Ethics Committee (HREC) of the University of Namibia (H-G/571/2020). Since the study was carried out among outpatients attending the Warfarin Clinic at a state hospital, permission to conduct the study was sought and obtained from the Ministry of Health and Social Services directorate of research (17/3/3MMT). A prospective cohort study design was used in the intervention study and only data from patients who gave informed written consent were used in the study. Patients were free to withdraw their informed written consent at any point in time during the intervention period without any consequences on their treatment. To ensure anonymity, patients were de-identified by allocating them with study identification numbers.

Validation procedure

Starting from 02 June 2021 to 28 July 2021, the pharmacist carried out POC INR testing using the CoaguChek® XS INR meter on 89 patients who also had their INRs checked by the Namibia Institute of Pathology laboratory. The test strips of the CoaguChek® XS INR meter were costly to procure; this limited the number of patients tested with the CoaguChek® XS INR meter to 89. Convenience sampling was employed as the 89 patients had to have given consent to participate in the main study and visited the clinic from 02 June 2021 to 28 July 2021. Permission was sought from the patients to test their INR using the POC meter. International normalised ratio-POC testing involved setting up the POC meter (by configuring the meter to INR measurement and inserting the INR test strip into the meter), cleaning the surface of the finger with an alcohol swab, pricking the finger, collecting the drop of blood using a sample collector, applying the sample onto the test strips and waiting for the meter to display the INR results. Both the POC meter INR results and Beckman Coulter ACL 7000 automated coagulometer INR results were recorded on the data collection tool.

Research instruments

Two research instruments were used: a data collection tool. CoaguChek® XS INR meter, and the Beckman Coulter ACL 7000 automated coagulometer. The data collection tool was adopted from the information/data collection system used by a free clinic in the United States (Birmingham Free Clinic, Pittsburgh, Pennsylvania). This tool was slightly modified to fit the purpose of this study.[14] Owing to the modifications made, the tool had to be piloted in three patients. It was designed to collect patient demographic information (Demographics of the participants section) and the INR-POC value obtained during the visit. The CoaguChek® XS INR meter (Roche Diagnostics, Basel, Switzerland) was used to obtain the POC-INR values.[15] The CoaguChek® XS INR testing involves three stages: the pre-analytical, analytical, and post-analytical.[15] All of these stages were carried out by one operator; the pharmacist, in the consultation room of the doctors and nurses, generally standardising the procedure. The pre-analytical stage involved obtaining a drop of blood (10 µL to about 35 µL) from a finger prick. The blood sample

was then transferred onto a test strip, which was inserted into the INR meter. The analytical stage followed. The test areas of the test strips contain a PT reagent. Upon application of the blood sample to the test area, the PT reagent is dissolved, resulting in an electrochemical reaction. This reaction measures the thromboplastin-mediated clotting time, which was converted into a plasma PT time upon activation of blood coagulation with human recombinant tissue factor. This PT time, also known as the 'clotting time', was used to calculate the patient's INR value. Finally, the post-analytical stage involved the display of the INR. The pharmacist then assessed the INR value as being subtherapeutic, therapeutic, or supratherapeutic. All POC tests were carried out in the morning hours (08:00–11:30) of each Wednesday (Warfarin Clinic Day). On the other hand, the Beckman Coulter ACL 7000 automated coagulometer (Beckman Coulter, Remington Avenue, Temecula, California) is a centrifugal analyser that assesses the intensity of light dispersion before, during, and after the coagulation of a blood sample.[16] Fibre optic systems are used to transmit a beam of light through the sample at a wavelength of 660 nm.

Data analysis

Statistical analyses were conducted using IBM Statistical Package for Social Sciences for Windows version 29.0 (Statistical Package for Social Sciences Inc, Chicago, Illinois, United States), with statistical significance set at $p \leq 0.05$. The sensitivity and specificity of the CoaguChek® XS INR meter were evaluated by comparing paired INR results from the POC device and the Beckman Coulter ACL 7000 automated coagulometer in each patient. This comparison involved Spearman's correlation analysis, a Bland-Altman plot, and a Cohen's Kappa analysis of the paired INR values. Spearman's coefficient interpretation was based on a scale ranging from very weak to very strong.[17] Proportional bias between the two methods was assessed through simple linear regression before constructing Bland-Altman plots. Clinical concordance, sensitivity, and specificity were determined from the Cohen's Kappa analysis, with interpretation based on the level of agreement.[18]

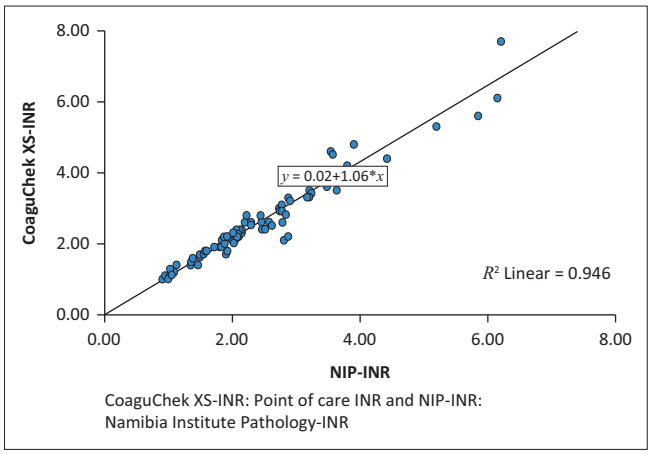
Results

Demographics of the participants

Of the 89 patients for whom INR values determined by two methods were available, 55 (61.8%) were women and 34 (38.2%) were men. Their median age was 42 years and 50% of the participants were aged between 18 and 66 years. The top three most frequent clinical indications for warfarin use were: deep vein thrombosis ($n = 45$, 50.6%), double valve replacement (mitral and aortic) ($n = 18$, 20.2%), and atrial fibrillation ($n = 9$, 10.1%).

Correlation analysis

International normalised ratio results from the CoaguChek® XS meter were positively and highly correlated to the Beckman Coulter ACL 7000 automated coagulometer results (r_s: 0.97, $p < 0.001$, $N = 89$) (Figure 1).



INR, international normalised ratio.

FIGURE 1: Scatter plot graph showing the correlation between the international normalised ratio values obtained by the CoaguChek® XS international normalised ratio meter and Beckman Coulter ACL 7000 automated coagulometer, June 2021–July 2022, Namibia.

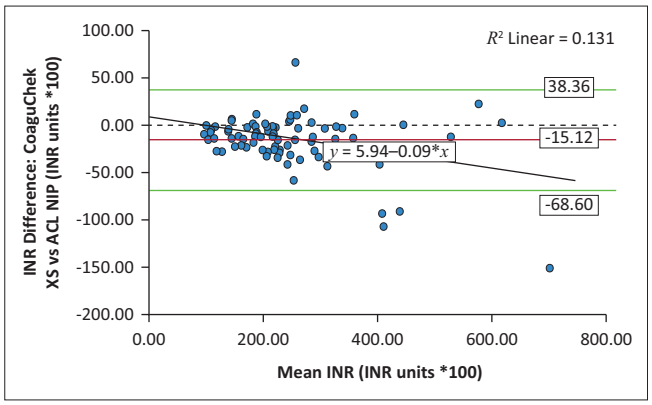
The Bland-Altman plot

The Bland-Altman plot, inclusive of outliers, showed that the mean INR difference between the CoaguChek® XS INR meter and the Beckman Coulter ACL 7000 automated coagulometer was –0.15 (± 0.27, $N = 89$) (Figure 2). The limits of agreement were between –0.68 and 0.38, a range in which 95% of the differences fell in the paired INR values between the two methods. Five INR differences fell outside the aforementioned limits of agreement. The first INR difference outside the limits of agreement had a mean INR of about 2.5. A negative trend was evident as shown by the regression line ($y = 5.94 – (0.09 * X)$). The Bland-Altman plot essentially showed that the difference in the paired INR values between the two methods increased with the increase in mean paired INR values, meaning that the higher the INR the more likely it was to be a discrepancy.

Cohen's Kappa analysis

The agreement of INR measurements between the CoaguChek® XS and Beckman Coulter ACL 7000 automated coagulometer was further assessed based on three categories, i.e. subtherapeutic, therapeutic, and supratherapeutic, using Cohen's Kappa analysis. The results showed a statistically significant and high clinical agreement between CoaguChek® XS INR and Beckman Coulter ACL 7000 automated coagulometer of 83.8%, $p < 0.05$.

In comparison to the Beckman Coulter ACL 7000 automated coagulometer, the sensitivity of the CoaguChek® XS INR meter in detecting therapeutic INRs accurately was assessed to be 94.4%. The POC device had a specificity of 82.5% in detecting subtherapeutic INR values correctly and 100% for detecting supratherapeutic INR values correctly (Table 1).



Note: The line that corresponds to an INR difference (Y-axis) of 0.00 is the line of equality, the red line shows the mean difference, the green line below the red line is the lower limit of agreement LL = mean difference – (1.96 × standard deviation), and the green line above the red line shows the upper limit of agreement UL = mean difference + (1.96 × standard deviation).
INR, international normalised ratio.

FIGURE 2: Bland-Altman Plot (Tukey mean difference) illustrating the difference in the CoaguChek® XS and Beckman Coulter ACL 7000 automated coagulometer values within the limits of agreement, June 2021–July 2022, Namibia.

TABLE 1: Sensitivity (%) and specificity (%) of the CoaguChek® XS international normalised ratio meter, June 2021–July 2022, Namibia.

Sensitivity and specificity results		Beckman Coulter ACL 7000 automated coagulometer INR class		
		Subtherapeutic	Therapeutic	Supratherapeutic
CoaguChek® XS INR Class	Subtherapeutic	82.5	0.0	0
	Therapeutic	17.4	94.4	0
	Supratherapeutic	0.0	5.6	100

INR, international normalised ratio.

Discussion

In anticoagulation services, patient education, along with the safe use of POC devices for INR monitoring and warfarin therapy adjustments, is crucial for introducing patient self-management and potentially reducing the workload on healthcare workers. The accuracy and precision of POC devices in measuring INR values must be assessed. This study showed a very high positive correlation ($r = 0.973$, $p < 0.001$) between the Roche CoaguChek® XS INR meter and the ACL INR analyser of the Namibia Institute of Pathology, highlighting its potential role in expanding access to anticoagulation services in Namibia.

Comparing these results with previous studies, our findings align with the high correlation reported by Kalçlk et al. between Roche's CoaguChek® XS INR meter and the laboratory method (STAGO STAR).[7] However, differences in INR values between the CoaguChek® XS INR meter and STAGO STAR analyser increased with higher mean INR values, consistent with findings from other studies.[7,19] Notably, our study found a mean difference of 0.15 units, below the 0.5 cut-off reported in the literature.[4]

The Bland-Altman plot in our study showed a narrower limit of agreement compared to that reported by Moore et al., with 95% of the differences falling within these limits.[4] While differences in INR values tend to increase with higher mean INR values, our study observed a lower mean INR value of 2.5 compared to the 3.6 and 4.5 reported in the literature.[8,20] This discrepancy may be influenced by factors such as the fibrinogen and haemoglobin status of patients, some of the factors known to affect the sensitivity and precision of POC devices in clinical settings.[21]

Moreover, Gardiner et al. explained that out-of-range INRs from POC devices were mostly because of the use and preparation of INR testing rather than faulty instruments or test strips.[20] Perry et al. shared a similar view, emphasising the need for adequate formal training on the use of POC devices.[3] The current study did not test the fibrinogen status of patients, and haemoglobin testing is not carried out routinely at the clinic. However, some of these explanations could apply to our study since the pharmacist who conducted the CoaguChek® INR testing did not receive formal training on the use of the device. The relative inaccuracy of POC devices in measuring INR at higher mean INR values led authors like Sharma et al. to recommend that laboratory INR testing should be conducted in patients with an INR result of >4.0 from the POC device.[22]

It is important to note that almost 100% of the POC results matched with the overall assessment of INR control: subtherapeutic, therapeutic, and supratherapeutic. The Cohen's Kappa analysis between Roche's CoaguChek® XS INR meter and Beckman Coulter ACL 7000 automated coagulometer yielded a Kappa value of 0.838 ($p < 0.001$). The Kappa analysis is used to assess clinical concordance between two methods based on a grading system (k value of <0.4, poor; 0.4–0.75, fair to good; >0.75, excellent).[18] Our analysis found an excellent clinical concordance between the two methods. Furthermore, the analysis showed that the CoaguChek® XS INR meter had a sensitivity of 94.4% in detecting therapeutic INR values correctly. It also revealed a specificity of 82.5% (subtherapeutic) and 100% (supratherapeutic) in detecting non-therapeutic INR values correctly. Although most studies do not report on the sensitivity and specificity of POC devices, Weyrauch et al. similarly reported a sensitivity of 91.7% and specificity of 99.2%.[23]

This study confirmed that the CoaguChek® XS INR meters are safe for use in patients attending our warfarin clinic. Their major drawback is that, without reimbursement, they can be costly for health systems.[20] However, staff costs should also be considered. Routine use of INR-POC testing could allow for more efficient clinic visits and reduce telephone follow-ups by clinic staff; other studies have found reduced turnaround times from 6 to 1 h using INR-POC monitoring.[24] In addition to possibly reducing workload, POC testing offers various benefits in managing patients on warfarin therapy. These advantages include faster availability of INR results and the ability to make prompt clinical decisions. Although this study did not assess these benefits because of the need to wait for laboratory results from Namibia Institute of Pathology for warfarin adjustments, it did demonstrate excellent clinical agreement between Roche's CoaguChek® XS INR meter results and Beckman Coulter ACL 7000 automated coagulometer INR results. With proper training

for patients and healthcare workers, POC testing can be implemented safely at the Warfarin Outpatient Clinic of Windhoek Central Hospital. With reimbursement, the use of POC devices can be expanded to include supervised patient self-management of warfarin therapy.

Limitations

A limitation of the study was that the INR results using the CoaguChek® XS INR meter could not be obtained in all patients because it was too costly to procure the test strips for all patients in the intervention study. This was the sole determinant of the sample size, with no power determinations carried out. Second, the test was carried out by an early-career pharmacist who had no formal training on the CoaguChek® XS INR meter.

Conclusion

In conclusion, the CoaguChek® XS INR meter is a safe alternative to Beckman Coulter ACL 7000 automated coagulometer for monitoring INR results and adjusting warfarin therapy in well-trained patients within the tested range. Therefore, we recommend that Roche's CoaguChek® XS INR monitoring can be carried out safely among outpatients in Namibia.

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Competing interest

The authors, Moses M. Thikukutu, Lauren J. Jonkman, Bonifasius S. Singu, Mubita Mwangana, and Roger K. Verbeeck, declare that they have no financial or personal relationships that may have influenced them inappropriately in writing this article.

CRediT authorship contribution

Moses M. Thikukutu: Conceptualisation, Formal Analysis, Investigation, Methodology, Project administration, Visualisation, Writing – original draft. Lauren J. Jonkman: Conceptualisation, Methodology, Supervision, Writing – review & editing. Bonifasius S. Singu: Conceptualisation, Methodology, Supervision, Writing – review & editing. Mubita Mwangana: Conceptualisation, Formal, analysis, Methodology, Supervision, Writing – review & editing. Roger K. Verbeeck: Conceptualisation, Formal analysis, Methodology, Supervision, Writing – review & editing. All authors reviewed the article, contributed to the discussion of results, approved the final version for submission and publication, and take responsibility for the integrity of its findings.

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Data availability

The data that support the findings of this study are not available openly because of sensitivity and confidentiality and are available from the corresponding author, Moses M. Thikukutu, upon reasonable request.

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