

Analytical Agreement and Treatment-Decision Concordance between Capillary Point-of-Care and Laboratory INR Testing in Patients Receiving Vitamin K Antagonists: A Prospective Method-Comparison Study

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How to cite this paper: Boka, B.C., Coffie, P., One, J.L., Traore, F., N'goran, Y.N.K., Yapi, M.-C., Andjou, Y.N.E., N'guetta, R. and Sawadogo, D. (2026) Analytical Agreement and Treatment-Decision Concordance between Capillary Point-of-Care and Laboratory INR Testing in Patients Receiving Vitamin K Antagonists: A Prospective Method-Comparison Study. *World Journal of Cardiovascular Diseases*, 16, 763-776. <https://doi.org/10.4236/wjcd.2026.1610070>

Received: August 18, 2026

Accepted: October 18, 2026

Published: October 21, 2026

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Abstract

Background: Vitamin K antagonists remain widely used in sub-Saharan Africa, particularly among patients with mechanical prosthetic valves and rheumatic valvular disease. In many services, INR monitoring still depends on a central laboratory, which can delay treatment decisions. We compared capillary point-of-care and venous laboratory INR measurements and examined whether the two methods led to the same treatment-decision category. **Methods:** This prospective study followed 101 patients receiving vitamin K antagonists over 131 consecutive INR monitoring visits at a tertiary cardiovascular referral centre in West Africa. At each visit, capillary and venous INR measurements were obtained within two minutes of each other. Agreement between the two methods was assessed with repeated-measures Bland-Altman analysis. We also examined whether the two results would lead to the same treatment decision: keeping the dose unchanged, increasing it, or reducing it. **Results:** Two venous results remained right-censored as >6, leaving 129 exact pairs for the primary continuous analysis. The mean capillary-minus-venous bias was +0.09 INR units, with repeated-measures 95% limits of agreement from -0.89 to +1.06. Variability increased at higher INR values. Treatment decisions agreed in 108 of 131 episodes (82.4%); Cohen's kappa was 0.731 (patient-cluster bootstrap 95% CI 0.627 - 0.826). All 23 discordances were minor,

and no episode produced opposite dose directions. **Conclusion:** Overall, capillary point-of-care INR testing gave results that were close to laboratory measurements and led to the same treatment decision in most monitoring episodes. Differences were more noticeable when INR values were high, but none of the discordant results suggested opposite dose adjustments. Taken together, these findings support supervised point-of-care testing as a practical option for routine INR monitoring, especially in areas where access to laboratory services is limited. Reliable quality control remains important, with laboratory confirmation mainly needed for high, unexpected, or borderline results.

Keywords

International Normalized Ratio, Vitamin K Antagonists, Point-of-Care Testing, Capillary Blood, Method Comparison, Anticoagulation

1. Introduction

Vitamin K antagonists (VKAs) remain an important part of anticoagulation care in sub-Saharan Africa, particularly for patients with mechanical prosthetic valves and rheumatic valvular disease [1] [2]. Maintaining stable anticoagulation can be difficult, and studies from the region continue to report suboptimal control [3]-[6]. The therapeutic window is narrow. If anticoagulation is too low, the risk of thromboembolism increases; if it is too high, the risk of bleeding rises. Regular INR monitoring is therefore a key part of safe vitamin K antagonist therapy [7] [8].

At the Abidjan Heart Institute, INR monitoring still relies mainly on laboratory testing. Patients provide a venous blood sample, wait for it to be processed, and receive advice on dose adjustment once the result is available.

Capillary point-of-care (POC) testing offers a shorter pathway because a fingerstick sample can provide an INR result during the same encounter [9] [10]. In other settings, similar systems have also been used for self-testing and self-management in selected patients [11]-[13].

That shorter pathway may be particularly useful where laboratory services are centralised and patients face travel, waiting time, and out-of-pocket costs [14]. Convenience alone, however, is not enough. Two methods can correlate closely while still differing enough to change a treatment decision for an individual patient [15] [16]. Numerical agreement and concordance of the decisions generated by each result therefore need to be considered separately.

We conducted a prospective method-comparison study to assess agreement between capillary POC and venous laboratory INR measurements and to determine how often the two methods led to the same treatment-decision category.

2. Materials and Methods

2.1. Study Design and Setting

This prospective method-comparison study was conducted in the biology labora-

tory of the Abidjan Heart Institute, a tertiary cardiovascular referral centre in Côte d'Ivoire, from June to August 2026. Reporting followed the Guidelines for Reporting Reliability and Agreement Studies (GRRAS) [17].

2.2. Participants and Recruitment

Patients of all ages receiving long-term VKA therapy and attending the laboratory for scheduled INR monitoring were eligible. Patients were enrolled consecutively as they came for routine INR monitoring, and each eligible monitoring episode was included until the available capillary test strips ran out. No sample-size calculation was performed in advance, since recruitment was mainly limited by the cost and availability of the strips. Each monitoring episode was analysed as a separate observation.

The dataset first included 132 entries. One was a summary line rather than a patient visit, so it was excluded, leaving 131 paired monitoring episodes for analysis.

Patient-level linkage identified 101 unique patients: 78 contributed one visit, 16 contributed two visits, and seven contributed three visits. **Figure 1** summarises the study and analysis populations.

2.3. INR Measurement

For each monitoring episode, venous blood was collected first, followed immediately by capillary testing; the two measurements were obtained less than two minutes apart so that both reflected essentially the same clinical state. Citrated venous blood was analysed on a Sysmex CS-2500 automated coagulation analyser using a chronometric method with Dade® Innovin® thromboplastin reagent (Siemens Healthineers). Calibration was performed according to the laboratory's routine procedure using a Siemens calibrator. Internal quality control was performed daily at two levels using Dade® Ci-Trol® Level 1 and Dade® Ci-Trol® Level 2 control materials (Siemens Healthineers). The lot-specific ISI used during the study could not be retrieved from the archived laboratory records. Under the laboratory's routine reporting procedure, INR values above 6 were systematically reported as ">6"; this was treated as a reporting threshold and not assumed to represent the intrinsic analytical limit of the analyser/reagent combination. Capillary INR was measured with the CoaguChek® XS Pro device (Roche Diagnostics) using a 10 - 15 µL fingerstick whole-blood sample. The manufacturer-stated INR measuring range for the CoaguChek XS Pro system is 0.8 - 8.0. A single trained operator performed all capillary measurements. The device's integrated internal quality-control function was used; no external liquid control solution was used during the study. Laboratory personnel performing the venous INR assay were not informed of the capillary result.

2.4. Treatment-Decision Classification

For each episode, the patient's therapeutic INR interval had already been

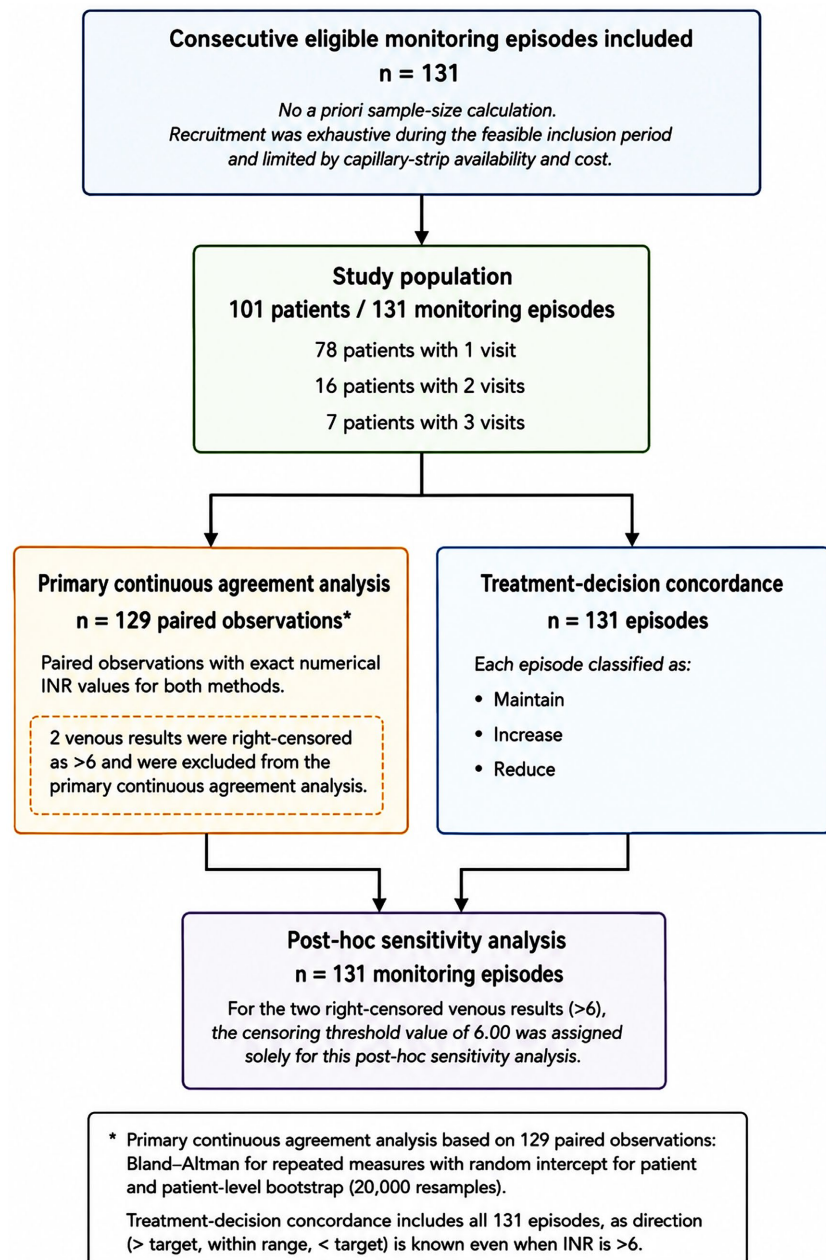


Figure 1. Study flow and analysis populations. The primary continuous agreement analysis used 129 exact numerical pairs because two venous INR results remained right-censored as >6. All 131 episodes contributed to treatment-decision concordance. The value 6.00 was assigned to the two censored results only in the post-hoc sensitivity analysis.

documented in the medical record before the paired venous and capillary measurements were obtained. This pre-existing interval was applied independently to both measurements using a prespecified directional rule. A value below the lower boundary indicated a dose increase; a value within the interval, including either boundary, indicated dose maintenance; and a value above the upper boundary indicated a dose reduction. For the final analysis, treatment categories were recalculated directly from the recorded therapeutic interval. These were algorithm-de-

rived analytical categories rather than observed clinician decisions, so no discretionary treatment-category assessor was used. Across the 131 monitoring episodes, the documented therapeutic intervals were 2.0 - 3.0 in 63 episodes, 2.5 - 3.5 in 55, 3.0 - 4.5 in 10, and 2.0 - 4.0, 3.0 - 4.0, and 3.5 - 4.5 in one episode each.

2.5. Data Management and Patient Linkage

Before analysis, the merged source file was reconciled with the available study records. One confirmed capillary INR transcription error was corrected from the source record, and exact high-range capillary values were restored where they could be recovered. Each correction was retained in an audit trail. Hospital record numbers were normalised to link repeated visits deterministically; direct identifiers were then removed and replaced by sequential study identifiers.

2.6. Statistical Analysis

The primary continuous agreement analysis used paired numerical INR values. Five venous values that had previously been treated as censored were recovered as exact measurements from the merged source file. Two venous observations remained right-censored as >6 . Because an exact pairwise difference cannot be calculated from a right-censored value, these two observations were excluded from the primary continuous analysis, leaving 129 exact pairs. They remained in the treatment-decision analysis because both were clearly above their documented therapeutic ranges. In a post-hoc sensitivity analysis only, the censoring threshold of 6.00 was assigned to these two observations so that all 131 episodes could be analysed numerically.

Among the 101 patients, 23 had more than one INR monitoring visit. The primary agreement analysis therefore used a linear mixed-effects Bland-Altman model for the paired difference $d_{ij} = \text{capillary INR} - \text{venous INR}$, with a fixed intercept representing the overall mean bias and a patient-specific random intercept representing between-patient variation. The model estimated between-patient and within-patient residual variance components, and the repeated-measures 95% limits of agreement were calculated as the estimated mean bias ± 1.96 times the square root of the sum of these two variance components [18]-[20]. Patient-cluster bootstrap resampling was performed by sampling patients with replacement and retaining all monitoring episodes contributed by each selected patient. Twenty thousand bootstrap replicates were used to obtain cluster-aware confidence intervals for the bias, the limits of agreement, and Cohen's kappa. Analyses were performed in Python 3.13 using statsmodels 0.14.6 for the mixed-effects model and SciPy 1.17.0 for ancillary statistical calculations; the patient-cluster bootstrap and concordance calculations were implemented in custom Python code.

Pearson's correlation coefficient was reported only as a descriptive measure of linear association and not as evidence of interchangeability.

Possible proportional bias was examined by regressing the paired difference on

the pairwise mean, while heteroscedasticity was assessed from the association between the absolute difference and mean INR. Because the differences between the two methods became more variable as INR increased, we added a post-hoc Bland-Altman analysis based on log ratios as a sensitivity check. No therapeutic-boundary proximity margin had been prespecified, so we did not introduce an arbitrary threshold around the therapeutic limits. Instead, heteroscedasticity was explored descriptively in post-hoc strata defined by the mean of the paired INR measurements: <2.0, 2.0 - 3.0, 3.01 - 4.0, and >4.0. Within each stratum, the mean difference and conventional 95% limits of agreement (mean difference $\pm$ 1.96 SD) were calculated as descriptive subgroup summaries; the repeated-measures model remained the primary agreement analysis. Treatment decisions were compared across all 131 monitoring episodes using the proportion of matching decisions and Cohen's kappa [21] [22]. A disagreement was considered major only when the two methods suggested opposite dose changes—an increase with one and a reduction with the other. All remaining disagreements were classified as minor. Linear- and quadratic-weighted kappa values were also calculated as sensitivity analyses. Because no clinically acceptable difference or agreement margin had been defined in advance, the observed limits were interpreted descriptively rather than as evidence of complete interchangeability.

2.7. Ethical Considerations

The protocol was submitted to the competent national ethics committee before recruitment began. Before the first participant was enrolled, the investigators received oral notification that the protocol had received a favourable opinion. Recruitment and paired study sampling began only after that notification, with the informed-consent procedures specified in the protocol already in place. Formal written authorization was subsequently issued on 8 July 2026 (reference 00137/26/MSHPCMU/CNESVS-km). No participant was enrolled or underwent paired study sampling before the oral favourable opinion had been communicated and consent procedures were in place. Informed consent was obtained from adult participants. For participants younger than 18 years, consent was obtained from the parent accompanying the minor.

2.8. AI-Assisted Manuscript Preparation

During manuscript preparation, OpenAI ChatGPT (accessed August 2026) was used to assist with English-language editing, organization of the text, and reference checking. It was not used for participant recruitment, data collection, or statistical analysis. The authors reviewed and revised all AI-assisted content and remain responsible for the final manuscript.

3. Results

3.1. Study Population

The analysis included 131 monitoring episodes from 101 patients. Seventy-eight

patients contributed one episode, 16 contributed two, and seven contributed three. At the episode level, mean age was 46.8 years (SD 17.2; range 8 - 84); 13 episodes (9.9%) involved participants younger than 18 years, and 85 (64.9%) involved women. Acenocoumarol was used in 100 episodes (76.3%), and a mechanical prosthetic valve was the indication for VKA therapy in 72 (55.0%) (**Table 1**).

Table 1. Characteristics of the analysed monitoring episodes.

Characteristic	Value
Monitoring episodes analysed, n	131
Unique patients, n	101
Age, mean (SD), years; range*	46.8 (17.2); 8 - 84
Episodes involving patients < 18 years, n (%)*	13 (9.9%)
Episodes involving women, n (%)*	85 (64.9%)
Acenocoumarol-treated episodes, n (%)	100 (76.3%)
Mechanical prosthetic valve as indication, n (%)	72 (55.0%)
Patients with >1 monitoring episode, n/N (%)	23/101 (22.8%)

*Age and sex are summarised at the monitoring-episode level because some patients contributed more than one visit. Percentages for episode-level characteristics use 131 monitoring episodes as the denominator; the final row uses the 101 unique patients. Patient-level clustering was incorporated into the repeated-measures analyses.

3.2. Analytical Agreement

The primary continuous agreement analysis included 129 exact paired measurements from all 101 patients; two venous observations remained right-censored as >6. Capillary and venous INR values were closely associated (Pearson $r = 0.934$, $p < 0.001$; **Figure 2**), although correlation was not used to judge interchangeability.

The repeated-measures Bland-Altman model estimated a mean capillary-minus-venous bias of +0.087 INR units, with 95% limits of agreement from -0.887 to +1.061 (**Figure 3**). The estimated between-patient variance of the paired differences was 0.00895 and the within-patient residual variance was 0.23796. Patient-cluster bootstrap 95% confidence intervals were -0.004 to +0.170 for the mean bias, -1.288 to -0.559 for the lower limit, and +0.760 to +1.358 for the upper limit. Five of the 129 exact differences (3.9%) fell outside the model-based limits.

The difference between methods increased modestly with the pairwise mean (slope 0.066 INR units per one-unit increase in mean INR; $p = 0.046$), while absolute dispersion rose more clearly as INR increased (Spearman $\rho = 0.512$; $p < 0.001$). On the log-ratio scale, the geometric mean capillary/venous ratio was 1.030, with 95% ratio limits of agreement from 0.773 to 1.373. Residual heteroscedasticity was reduced (Spearman $p = 0.052$).

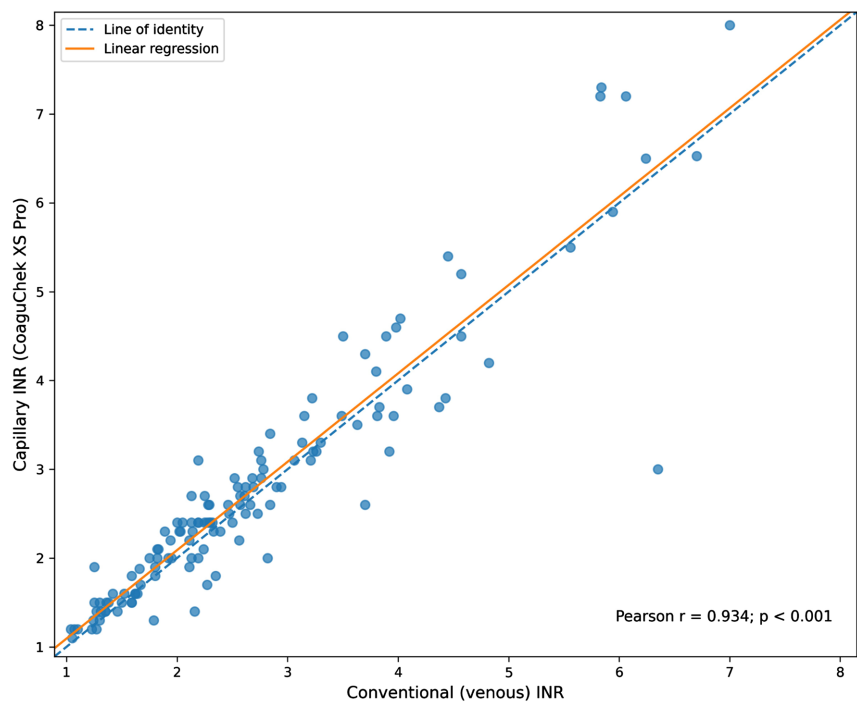


Figure 2. Capillary versus venous INR measurements for the 129 episodes with exact paired numerical results. The dashed line is the line of identity and the solid line is the descriptive linear regression. Pearson $r = 0.934$, $p < 0.001$. Two venous results retained as >6 were excluded from the primary continuous analysis.

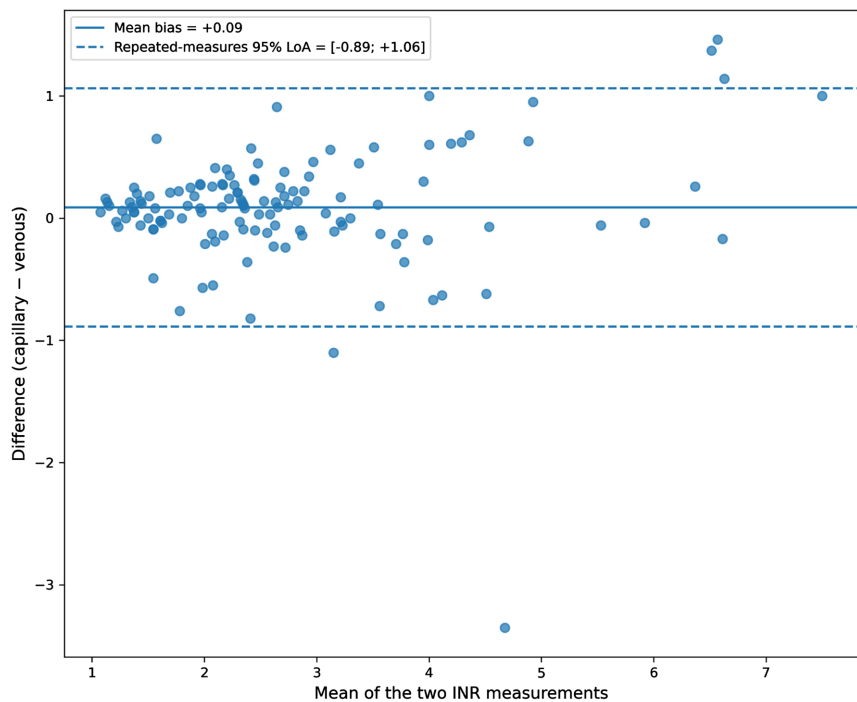


Figure 3. Repeated-measures Bland-Altman agreement for 129 exact pairs from 101 patients. The solid line shows the estimated mean bias (+0.09 INR units); dashed lines show the repeated-measures 95% limits of agreement (−0.89 to +1.06). Two venous observations retained as >6 were excluded from the primary continuous analysis.

Post-hoc descriptive strata showed widening dispersion: mean INR < 2.0 (n = 40), bias +0.05 with 95% limits of agreement -0.41 to +0.50; INR 2.0 - 3.0 (n = 51), +0.10 with limits -0.46 to +0.66; INR 3.01 - 4.0 (n = 20), +0.04 with limits -0.89 to +0.97; and INR > 4.0 (n = 18), +0.17 with limits -2.00 to +2.34. These subgroup analyses were post hoc and descriptive.

The post-hoc sensitivity analysis assigned a value of 6.00 to the two right-censored venous observations and therefore included all 131 episodes. The mean bias was +0.115 INR units, with repeated-measures 95% limits of agreement from -0.957 to +1.186. Because the original laboratory results were reported as >6 rather than as exact values, these estimates were considered secondary.

3.3. Treatment-Decision Concordance

The two methods produced the same algorithm-derived treatment category in 108 of 131 episodes (82.4%). Cohen's kappa was 0.731, with a patient-cluster bootstrap 95% confidence interval of 0.627 to 0.826 based on 20,000 resamples. The remaining 23 episodes (17.6%) were discordant, but all were adjacent-category disagreements. No episode had one method indicating a dose increase while the other indicated a dose reduction. Linear- and quadratic-weighted kappa values were 0.792 and 0.856, respectively (**Figure 4**).

		Capillary POC decision		
		Maintain	Increase	Reduce
Laboratory decision	Maintain	36	4	5
	Increase	11	45	0
	Reduce	3	0	27

Figure 4. Treatment-decision concordance between capillary and laboratory INR for all 131 monitoring episodes. Rows show the laboratory decision and columns the capillary POC decision. Diagonal cells represent concordant decisions (108 episodes). Overall agreement was 82.4%; Cohen's kappa was 0.731 (patient-cluster bootstrap 95% CI 0.627 - 0.826). All 23 discordances were minor, with no opposite dose directions.

4. Discussion

In this prospective comparison, capillary INR was close to the laboratory value on average, but individual differences were sometimes much larger than the mean

bias suggests. Across the 129 paired measurements, capillary and venous INR values were close overall, with a mean difference of +0.09 INR units. Differences were wider for some individual measurements, with limits of agreement from -0.89 to +1.06. Despite this variation, both methods led to the same treatment decision in 82.4% of monitoring episodes. These findings support the use of supervised capillary INR testing in routine care, particularly where laboratory access is limited, with laboratory confirmation kept available when a result is high, borderline, or otherwise uncertain.

Previous evaluations of the CoaguChek family have generally reported close association with laboratory INR and little average systematic bias [15] [23]-[27]. Our findings are in the same direction, but they also illustrate why the mean bias alone is not sufficient. A small average difference can coexist with clinically meaningful variation from one patient to another. Here, the overall limits of agreement covered almost two INR units, and the bootstrap intervals around those limits were themselves broad. The post-hoc INR-stratified analysis further showed that dispersion widened substantially above an INR of 4. This becomes particularly relevant near a therapeutic boundary, where a relatively small difference may change the treatment category.

The disagreement between methods also became less predictable as INR increased. Both the relation between paired difference and mean INR and the rise in absolute dispersion at higher values point to greater uncertainty toward the upper end of the range. Log transformation reduced this pattern but did not remove it completely. The two venous results reported only as >6 further show a practical difficulty at high INR values: once one method is censored at a threshold, the exact numerical difference between methods can no longer be calculated.

The treatment-decision analysis places this analytical variation in a more clinically interpretable context. In 108 episodes, both measurements led to the same directional category. The 23 discordant episodes involved neighbouring categories only, and none indicated opposite directions of dose adjustment. This finding supports the clinical consistency of capillary INR testing for treatment guidance, while recognizing that the study focused on decision concordance rather than on clinical outcomes such as bleeding or thromboembolism.

For anticoagulation services in West Africa, the benefit of capillary testing is not limited to the INR measurement itself. Getting a result during the same visit could reduce dependence on a central laboratory and make dose adjustment possible without unnecessary delay.

Studies from other settings have shown that POC systems can also support self-testing and self-management in selected patients [11]-[13] [28]. Our study did not evaluate that model, since all capillary measurements were performed by a trained operator. The findings therefore apply most directly to supervised POC testing within an organised anticoagulation service.

5. Clinical Implications

If capillary INR testing is used routinely, the process needs to remain simple but

well controlled. Staff should be trained, quality checks should be regular, and dose-adjustment rules should be clear. Laboratory confirmation would still be useful when INR values are high, close to the edge of the therapeutic range, or likely to lead to an important change in treatment. With these safeguards in place, point-of-care testing could make INR monitoring easier to access, especially where laboratory services are distant or difficult to reach, while preserving laboratory testing for situations where confirmation is needed.

6. Strengths and Limitations

The study has some limitations. It was conducted in a single referral centre, and the findings therefore reflect the experience of that setting; confirmation in other centres would be useful. No formal sample-size calculation was performed, and recruitment ended when the available capillary test strips had been used. Two venous INR results were reported only as >6 , which meant that exact pairwise differences could not be calculated for these observations in the main agreement analysis. We also observed greater variability between the two methods at higher INR values. Finally, no clinically acceptable agreement margin was defined in advance, and the study did not examine outcomes such as time in therapeutic range, bleeding, thromboembolism, turnaround time, or patient costs.

7. Conclusion

Capillary point-of-care INR testing produced results that were generally close to venous laboratory values, and both methods led to the same treatment category in most monitoring episodes. Differences were more noticeable at higher INR values, so a little more caution is warranted in that range. In settings where laboratory testing is difficult to access, supervised capillary INR testing could help bring follow-up closer to patients. This approach would still require reliable quality control and access to laboratory confirmation when results are high or close to therapeutic thresholds.

Data Availability Statement

The study dataset can be obtained from the corresponding author upon reasonable request, with appropriate safeguards for confidentiality and data protection.

Author Contributions

Boka B.C. designed the study, supervised data collection, performed the statistical analysis, and drafted the manuscript. Coffie P. contributed to data collection and interpretation. Andjou Y.N.E. contributed to data collection. Sawadogo D. supervised the work and revised the manuscript. One J.L., Traore F., N'goran Y.N.K., Yapi M.C., and N'guetta R. contributed to data interpretation and critically revised the manuscript. All authors read and approved the final manuscript.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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