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An evaluation of a coagulation system (Xprecia Stride) for utilisation in anticoagulation management

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ABSTRACT

Aim To evaluate the reliability and performance of the Xprecia Stride coagulometer under the conditions in which it is most likely to be used.

Methods The performance of the Xprecia Stride coagulometer was compared with a local laboratory and the CoaguChek systems routinely used for international normalised ratio (INR) estimation within one primary and one secondary care based anticoagulation clinic in Birmingham. Anticoagulation clinic personnel were trained to use the Xprecia Stride. Patients attending the clinics were eligible if aged ≥18 years and had received warfarin for at least 3 months. Consenting participants provided capillary blood samples for parallel testing on the Xprecia Stride and CoaguChek systems. At the secondary care clinic, a venous blood sample was also collected for laboratory INR estimation. INR results were compared using linear regression analysis and Bland–Altman plots.

Results A total of 102 laboratory and 205 parallel coagulometer INR tests were performed. Linear regression revealed strong correlation between the Xprecia Stride and the laboratory (r=0.83) and between the Xprecia Stride and CoaguChek systems (r=0.92). Within the therapeutic range, agreement between the systems was very good with 87% of the Xprecia Stride and laboratory INR results and 93% of the Xprecia Stride and CoaguChek INR results being within 0.5 INR units of each other.

Conclusion INRs tested using the Xprecia Stride system showed good agreement with the laboratory and CoaguChek systems. Findings indicate that in the hands of the intended users the Xprecia Stride is accurate, reliable and acceptable for use in a routine clinical setting.

INTRODUCTION

Community management of anticoagulation has increased owing to expanding indications for warfarin therapy, particularly non-rheumatic atrial fibrillation,[1] and the introduction of reliable point-of-care (POC) devices for international normalised ratio (INR) estimation.[2–6] POC devices are defined as portable coagulometers designed for use in close proximity to the patient—that is, at the bedside or in the clinic, and are ideal for use outside the laboratory within the community. Previous primary care based studies comparing INR estimation using POC testing systems appropriate for primary care with regional reference laboratories have shown consistent results between the systems.[7] Portable coagulometers have also been evaluated widely for use in patient self-monitoring of warfarin therapy.[8–12]

The 2008 Centre for Evidence-based Purchasing (CEP) guidelines recommend a number of technical, operational and economic considerations for POC devices monitoring oral anticoagulation, and the British Committee for Standards in Haematology (BCSH) guidelines for POC testing also provide recommendations for management, training, equipment selection and safety.[13 14] The CEP guidelines provide a framework for the management of POC testing services and the guidance applies to both hospital and community services. The guidelines state that POC devices should have received a successful independent performance evaluation and that they should generate results that are comparable to those of the local laboratory. An accredited external quality assessment (EQA) programme and internal quality control (IQC) system must also be in place. The guidelines also state that anyone outside the laboratory setting undertaking POC testing should have training and annual competency assessment. The BCSH guidelines recommend an evaluation under the conditions most likely to be encountered in normal everyday use—that is, within the community and under less highly controlled conditions than seen in the laboratory.

The Xprecia Stride system is a new to market, Conformité Européenne (CE) marked, point-of-care coagulometer intended for use by healthcare professionals for the monitoring of warfarin therapy. It is a hand-held analyser using a single-use test strip and electrochemical technology to measure the prothrombin time in capillary blood samples. Although independent Medicines and Healthcare products Regulatory Agency evaluation is no longer available, the manufacturers of the Xprecia Stride were keen to seek independent evaluation and expert review (table 1). The purpose of this study was therefore to evaluate the reliability and performance of the Xprecia Stride under the conditions in which the coagulometer is most likely be used. The primary objective was to determine the level of agreement of the INR results obtained using the Xprecia Stride with INR results obtained from a local laboratory system and a POC system routinely used in a primary and secondary care based anticoagulation clinic.

METHODS

The evaluation was conducted over a period of 10 weeks during February and April 2016 in one primary care and one secondary care based anticoagulation clinic in Birmingham. The anticoagulation clinic personnel were all experienced in the use of POC devices for INR estimation. Eight clinic personnel were involved in the evaluation at the

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Table 1 Description of the Xprecia stride system

Feature	
Specimen collection	Test strip
Quantity of blood	6 µL
Detection principle	Electrochemical detection of thrombin activity
Measurement time	<1.6 min (depending on INR level)
Measurement range	0.8–8.0
Haematocrit (%)	25–50
Type of blood	Capillary blood
Thromboplastin	Human recombinant, Dade Innovin
Electrical power supply	Disposable alkaline batteries/rechargeable nickel batteries
Memory store	640 Test results, 300 liquid controls and 300 error messages
IQC	Control kit comprising 2 levels of IQC supplied by manufacturer
EQA programmes	Currently WEQAS. UKNEQAS will introduce an EQA programme 1 April 2017
Calibration	Batch-specific barcode on strip phial

EQA, external quality assessment; IQC, internal quality control; INR, international normalised ratio; UKNEQAS, United Kingdom National External Quality Assessment Service; WEQAS, Wales External Quality Assessment Scheme.

secondary care site and two at the primary care site. All clinic personnel received training in the evaluation protocol from members of the research team. Training in the use of the Xprecia Stride was provided by the POC product manager, Siemens Healthcare Ltd, who also supplied the clinics with two Xprecia Stride testing systems, test strips (batch number 400570) and IQC materials (batch number 509010). Training reflected that usually given to intended users. Personnel from Siemens Healthcare Ltd were not involved in the conduct of the evaluation. Patients attending the anticoagulation clinics were eligible to participate if aged ≥18 years and they had been receiving warfarin for at least 3 months. Patients were ineligible if they were housebound or pregnant. Patients registered at the primary care anticoagulation clinic received an invitation letter and participant information sheet through the post. Patients registered with the secondary care clinic were provided with a participant information sheet and invitation to participate when they attended their clinic. Eligibility was confirmed by a member of the research team and eligible patients provided written informed consent to participate. In the primary care setting, participants consented to collection of two samples of capillary blood using one finger stick. In the secondary care setting, participants consented to collection of two samples of capillary blood using one finger stick and a venous blood sample.

To meet the minimum requirements of verification of system accuracy, the protocol aimed to collect 100 samples at each site to obtain a spread of INR values throughout (ie, 1.5–4.0) and above the therapeutic range (ie, >4.1). It was not possible to obtain 100 samples at the primary care site owing to a lower than expected attendance at the clinic. To enable collection of 200 capillary samples, recruitment at the secondary care site continued until 100 venous and 200 capillary samples with INR results >1.5 had been collected.

POC testing procedure

Capillary samples were obtained using the single-use lancing device routinely used in the clinic (Accu-Chek Safe-T-Pro Plus, Roche, Mannheim, Germany). POC testing was undertaken in parallel on the Xprecia Stride system and the routinely used POC system using one finger stick and two drops of capillary blood. The capillary blood sample was applied to the two POC devices within 15 s of the finger stick being undertaken. The order of the application of the capillary blood to the two machines was varied to ensure an equal distribution of samples across the two machines throughout the evaluation period. The order of blood application was dictated by the INR case report forms administered to the clinic personnel by the research team. If either device failed to display an INR result, the finger stick procedure was repeated using a different finger/site if the patient was agreeable. The procedure was limited to two attempts so as not to overburden the patient. A third finger stick to obtain an INR reading on the routinely used POC device was allowed if necessary. Ethical approval was obtained from the West Midlands Black Country research ethics committee Ref 15/WM/0382. Warfarin dose and recall for INR monitoring was based on the INR result obtained on the routinely used POC system.

The POC device used within the primary care anticoagulation clinic was the CoaguChek XS Plus (Roche, Mannheim, Germany), the secondary care clinic used the CoaguChek XS Pro (Roche, Mannheim, Germany). The CoaguChek XS Pro has the additional ability to scan bar-coded patient identification numbers and to connect a data management system through a handheld base unit. These CoaguChek systems are otherwise similar, using the same test materials (CoaguChek XS prothrombin time (PT) test, Roche) and principle of clot detection. Equivalence between INR results determined using these two systems has been previously demonstrated.[15] Four batches of the CoaguChek XS PT test strips were used at the secondary care site (batch numbers 294-030-11, 206-631-11, 206-632-12 and 206-465-12) and three batches at the primary care site (batch numbers 294-030-11, 203-359-11 and 205-138-11).

Venous testing procedure

At the secondary care site a 4 mL venous blood sample was taken immediately after the POC measurements in a siliconised glass citrated anticoagulated sample bottle (containing 0.109 molar citrate, Vacutainer system). Tubes were inverted to ensure adequate mixing and kept at room temperature until being transported to the hospital laboratory. The laboratory system used was the ACL TOP 700, which uses the RecombiPlasTin reagent and routinely undergoes INR calibration for each new batch of reagent. The mean normal PT used for the laboratory INR calculation was derived from measurement of PT in 20 healthy, non-anticoagulated patients. A programme of daily internal quality assurance using commercial and local plasmas is used. The laboratory is Clinical Pathology Accreditation registered and regularly participates in UKNEQAS (UK National External Quality Assurance Service). The laboratory performs well within the UKNEQAS blood coagulation EQA scheme achieving results which are within consensus. INR measurement was undertaken within 6 hours of sample collection.

Internal quality control

IQC procedures were performed on each of the POC systems at the start of each clinic. Materials for the procedures were supplied by the manufacturers with one level of IQC being performed on the CoaguChek systems and two levels of IQC being performed on the Xprecia Stride system in accordance with the instructions for use.

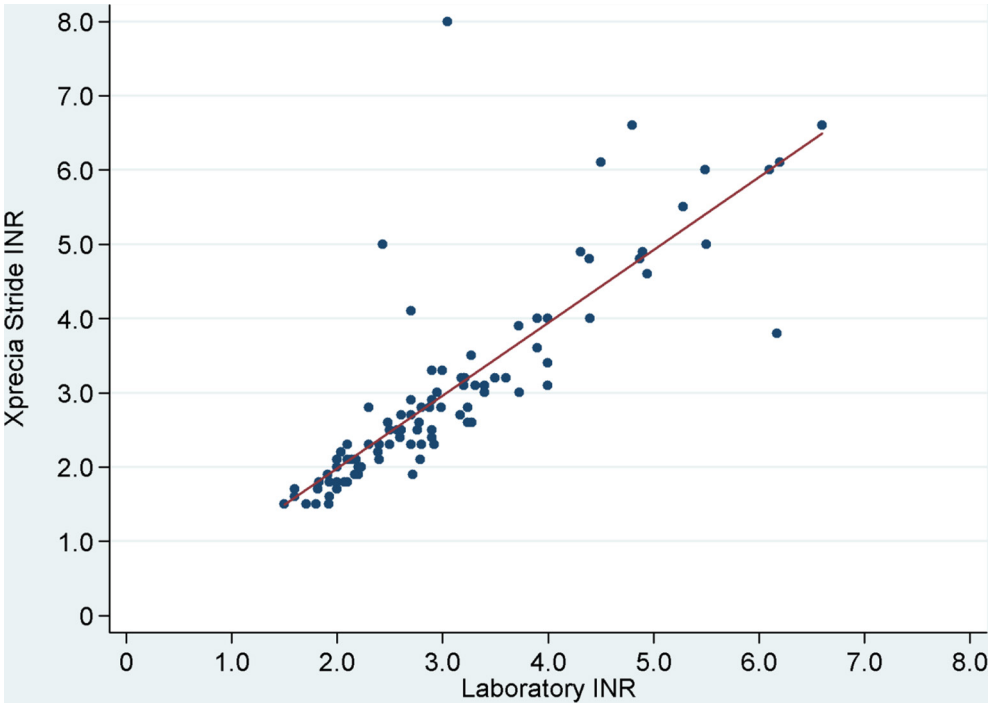

Figure 1 Scatterplot of international normalised ratio (INR) measured by Xprecia Stride versus a laboratory in a secondary care setting (including outliers).

Data collection

Clinic personnel recorded the INR results obtained in parallel, strip batch numbers and details of error messages or repeated attempts on the INR case report form. All IQC results were recorded on the IQC case report forms. Technical problems encountered outside of the INR testing were also recorded.

Analysis

Scatterplots and linear regression analysis were used to visually explore and assess the strength of the linear association between the INR measurements recorded by different methods. Agreement between the different methods was then formally assessed via Bland–Altman plots. The difference in INR was plotted against the mean INR along with the corresponding limits of agreement (mean±1.96 SD). The 95% CIs of these limits were also displayed. The predefined clinically acceptable limits of agreement were ±0.5 INR units. The percentage of samples with bias that occurred outside these limits is reported with corresponding 95% CIs. INR measurements were also classified into those 'in range' (ie, INR 2–4) and those 'out of range'. To assess the impact of setting, the rate of disagreement in classification of the INR (ie, in range vs out of range) between the Xprecia Stride and CoaguChek systems used within the primary and secondary care settings was compared using binomial exact tests.

RESULTS

Samples

Overall 205 blood samples were collected, 83 in primary care and 122 in the secondary care setting. A total of 102 venous blood samples were collected for laboratory INR estimation and 205 capillary blood tests were used in parallel for INR estimation on the Xprecia Stride and CoaguChek systems. INR results determined by the CoaguChek ranged from 1.3 to 6.5. INR results obtained on the Xprecia Stride ranged from 1.3 to >8.0. Laboratory-determined INRs ranged from 1.5 to 6.6.

INR comparison

Xprecia Stride versus the laboratory system

Regression analysis yielded an intercept of 0.03 units (95% CI −0.39 to 0.45, p=0.89) and a slope of 0.98 (95% CI 0.85 to 1.11, p<0.001). The correlation (r) between the Stride and laboratory INR testing systems was 0.83 (p<0.001) with R^2 of 69% (figure 1). These figures were obtained from the linear regression and include the outliers. Outliers were identified by visual inspection of the scattergrams. After removal of outliers the correlation (r) between the Stride and laboratory INR testing system was 0.97 with an R^2 of 94%.

The Bland–Altman difference plots of the Xprecia Stride and laboratory data showed a mean difference (average bias) of −0.035 units with 95% limits of agreement between −1.46 to 1.40 and the percentage of samples outside ±0.5 bias (within the INR range 1.5 to 4.0) 12.8% (11/86, 95% CI 6.6% to 21.7%) (figure 2). After removal of 6 outliers (four with laboratory results outside the therapeutic range—ie, <1.5 and >4.0), the mean bias was −0.14 units with 95% limits of agreement between −0.69 and 0.41 and the percentage of samples outside ±0.5 bias (within the INR range 1.5 to 4.0) 10.7% (9/84, 95% CI 5.0% to 19.4%).

Xprecia Stride versus the CoaguChek POC systems

Regression analysis yielded an intercept of units −0.20 (95% CI −0.38 to −0.02, p=0.028) and a slope of 1.04 (95% CI 0.98 to 1.10, p<0.001) (figure 3). The correlation between the Stride and CoaguChek INR testing systems was 0.92 with R^2 of 85%. After removal of outliers the correlation (r) between the Stride and the CoaguChek systems was 0.94 with R^2 of 89%.

The Bland–Altman difference plots for the Xprecia Stride and CoaguChek systems showed a mean difference (average bias) of −0.09 units with 95% limits of agreement between −0.95 and 0.77 and 6.6% (12/183, 95% CI 3.4% to 11.2%) of samples outside ±0.5 bias within the INR range 1.5 to 4.0 (figure 4). After removal of two outliers (one with a CoaguChek result

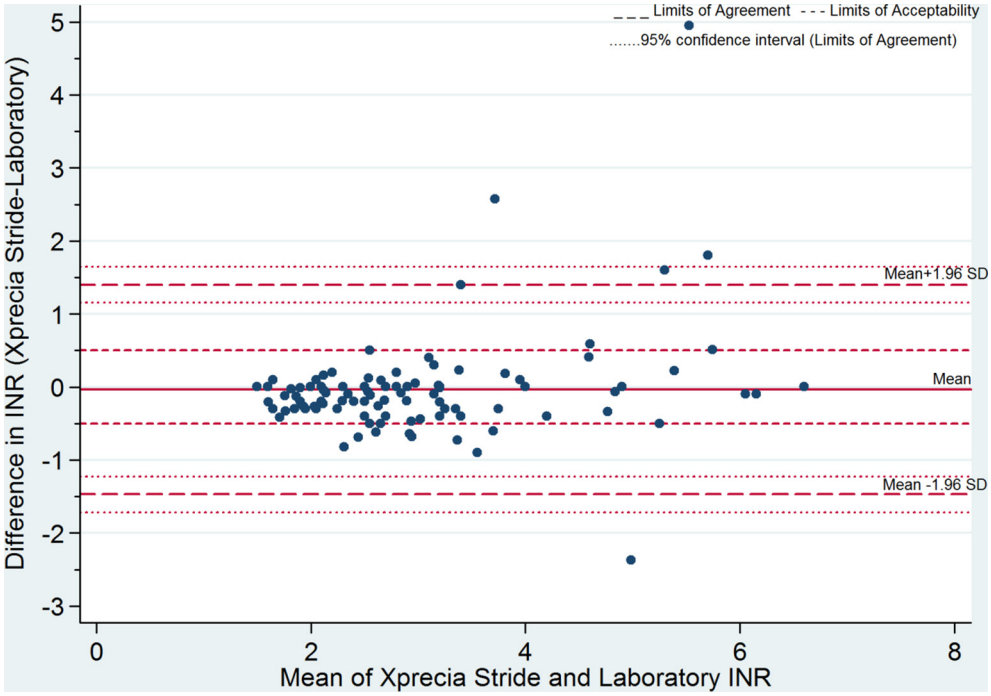

Figure 2 Bland–Altman plot of difference in international normalised ratio (INR; Xprecia Stride minus Laboratory measurement) against the mean of the two measurements (including outliers).

outside of the therapeutic range—ie, <1.5 and >4.0), the mean bias was −0.12 units with 95% limits of agreement between −0.81 to 0.57 and a percentage of samples outside ±0.5 bias within the INR range 1.5 to 4.0 of 6.0% (11/182, 95% CI 3.1% to 10.6%).

Impact of setting

INR measurements were classified into those 'in range' (INR 2–4) and those 'out of range' (<2 and >4) (table 2). No significant difference was observed in the rate of disagreement in INR classification between the Stride and CoaguChek systems used within the primary care setting compared with the secondary care setting (10.8% vs 12.3%, difference =1.5% (95% CI −8.0% to 10.9%, p=0.78).

Internal quality control

The IQC results for all three methods were within the allowable limits. The one-level IQC for the CoaguChek took less time

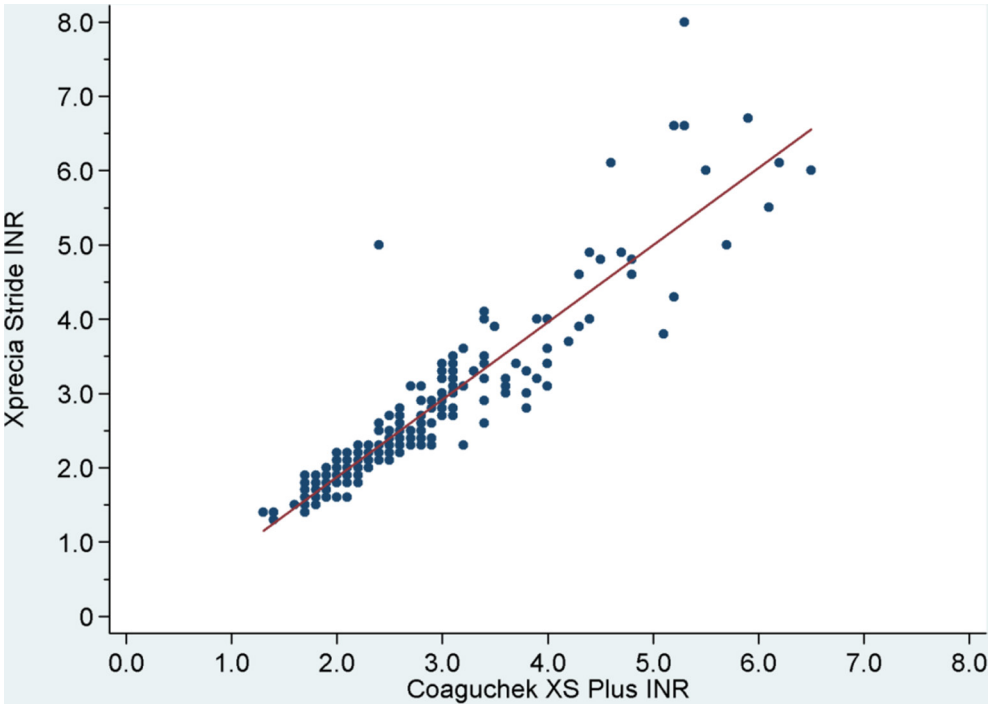

Figure 3 Scatterplot of international normalised ratio (INR) measured by Xprecia Stride versus CoaguChek in primary and secondary care settings (including outliers).

Table 2 Comparison of international normalised ratio (INR) measurements

Primary care setting				
	Coaguchek			
Xprecia Stride	**<2**	**2–4**	**>4**	**Total**
<2	11	8	0	19
2–4	0	60	1	61
>4	0	0	3	3
Total	11	68	4	83
Secondary care setting				
	Coaguchek			
Xprecia Stride	**<2**	**2–4**	**>4**	**Total**
<2	19	9	0	28
2–4	1	73	3	77
>4	0	2	15	17
Total	20	84	18	122
	Laboratory			
Xprecia Stride	**<2**	**2–4**	**>4**	**Total**
<2	11	7	0	18
2–4	0	66	2	68
>4	0	3	13	16
Total	11	76	15	102

to prepare than the two-level IQC for the Xprecia Stride (the reconstituted control solution for the CoaguChek being ready for use 1 min after the addition of the diluent vs 5 min for the Stride). Time to perform one IQC test on either system was similar (CoaguChek, one-level IQC 4–5 min vs Stride, two level IQC 8–10 min).

Technical difficulties

No mechanical problems were encountered with the POC devices during the evaluation. Error messages due to application of an inadequate capillary sample were seen on the POC systems in 8 of 208 (3.8%) occasions. The Stride displayed this error message on four of the eight (50%) occasions and the CoaguChek displayed this error message on four of the eight occasions (associated error rate for each system 1.9%).

DISCUSSION

In this study the performance of the Xprecia Stride system used within both a primary and secondary care setting by intended users was compared with a laboratory method and two CoaguChek POC systems for INR estimation. Linear regression revealed strong correlation between the Stride and the laboratory (r=0.83) and between the Stride and the CoaguChek systems (r=0.92). It is recognised that this correlation measures only the straight line of linear association between the two measurements and does not provide a meaningful measure of agreement. Bland–Altman was therefore used to investigate the mean differences in INR between the Stride, laboratory and CoaguChek testing systems.

Bland–Altman plots showed good agreement within the therapeutic range between 1.5 and 4.0, with the Stride performing on average 0.03 INR units lower than the laboratory and 0.09 INR units lower than the CoaguChek. Although perfect agreement between the systems was not observed within the INR range 1.5 to 4.0, the overall variance in INR results was within acceptable limits, with an analytical bias of more than 0.5 INR units being evident in fewer than 13% of samples. The overall agreement between the systems was therefore good with 87% (75/86) of the INR results from the Stride being within 0.5 INR units of the results obtained by the laboratory. Furthermore, despite the use of different batches of strips, CoaguChek systems and other user-dependent variables within and between the anticoagulation clinics, 93% (171/183) of the Stride and CoaguChek INRs were within 0.5 INR units of each other. These results compare favourably with figures of 76%, 83%, 85% and 88% reported in previous studies comparing POC-determined INR with laboratory-determined INR.[16–19]

Findings suggest that the Stride system has a tendency to slightly overestimate the INR when measurements are above the therapeutic range (>4.0) and underestimate the INR when it is within or below the therapeutic range. Similar findings, however, are well documented in other studies comparing INRs determined using POC systems with laboratory methods.[20–22] Thus the performance of any POC system for INR estimation above the therapeutic range when compared with another system has to be viewed in the context of the inherent inaccuracies of INR measurements. Furthermore, this finding is unlikely to be of clinical importance as management of high INRs should be clinically guided.[23] The accuracy of the Stride is acceptable for use in everyday clinical practice. Use of the two-level IQC, however, is recommended to assess day-to-day consistency and ensure proper functioning of the system and test strips.

Although no technical difficulties were reported during the evaluation, error messages indicating failed measurements were observed on both the Stride and CoaguChek systems, leading to repeat testing. The overall rate of failed tests due to application of an inadequate sample observed during the evaluation was <4% and probably due to the per protocol requirement for parallel testing with application of one drop of capillary blood from one finger stick to two POC systems. Thus these errors are less likely to occur when using the Stride in routine clinical practice where only one drop of capillary blood is required for INR estimation. The frequency and associated cost of repeat testing in routine clinical practice is therefore likely to be minimal.

This evaluation has a number of strengths. The study was performed under real–life conditions by intended users in a primary and secondary care setting and included comparison of INR results with an established hospital laboratory method. Furthermore, the analysis employed linear regression to examine the relationship between the INR results obtained via the different systems and Bland–Altman plots to assess the mean differences in INR and agreement over the therapeutic range.

A large number of parallel measurements (n=183) within the INR range 1.5 to 4.0 were undertaken on the Stride and CoaguChek, providing a precise estimation of accuracy. The estimation of accuracy of the Stride within the INR range 1.5 to 4.0 compared with the laboratory is, however, limited by a smaller number of samples (n=86) and as indicated by the wider confidence intervals around the estimates, is less precise.

Test strip batch-to-batch variation comparison was not within the scope of this study. Thus the findings of this evaluation are limited by the use of one batch of test strips. Furthermore, patients with conditions known to interfere with POC INR estimation, such as antiphospholipid syndrome, anaemia and polycythaemia, were not excluded from the evaluation. It is possible that samples from these patient groups were included and are responsible for the analytical bias of more than 1.4 INR units (ie, above the upper limit of agreement) evident in the comparison of the Stride- and laboratory-determined INRs before the removal of the outlying INR results.

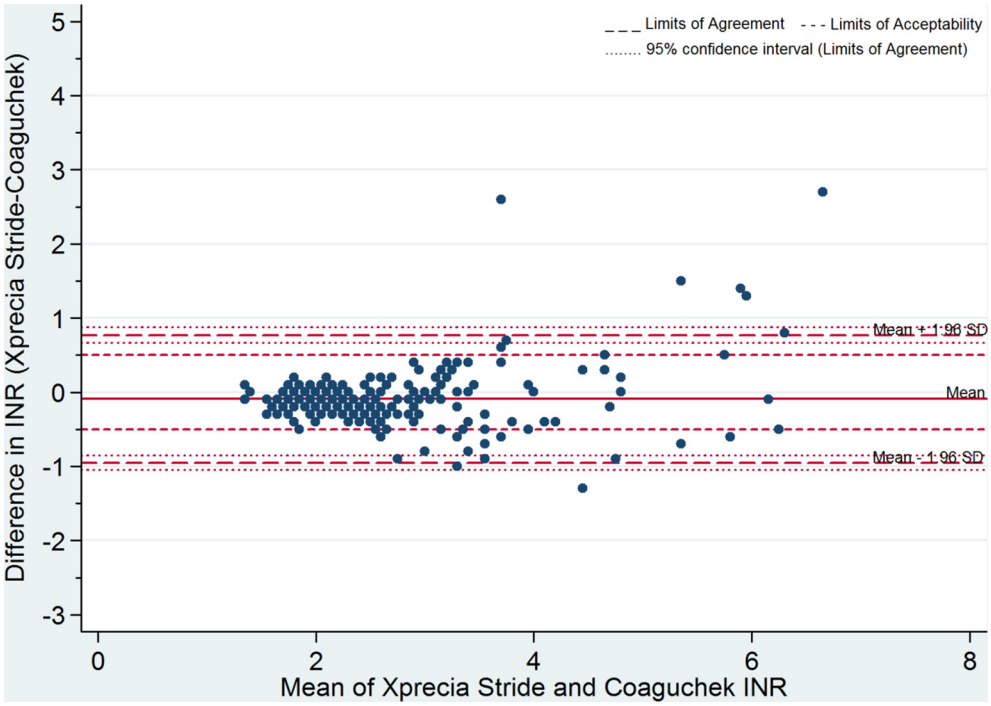

Figure 4 Bland–Altman plot of the difference in international normalised ratio (INR; Xprecia Stride minus Coaguchek measurement) against the mean of the two measurements (including outliers).

CONCLUSION

INRs tested using the Xprecia Stride system showed good agreement with the laboratory and CoaguChek systems for patients with INR results within the therapeutic range up to an INR of 4.0. Findings suggest that the Xprecia Stride system is accurate, reliable and acceptable for INR estimation in everyday clinical practice in a primary and secondary care setting as long as correct procedures are followed.

Take home messages

- The Xprecia Stride system is a new to market, point-of-care (POC) coagulometer intended for use by healthcare professionals.
- The British Committee for Standards in Haematology (BCSH) guidelines for POC testing recommend an evaluation under the conditions most likely to be encountered in normal everyday practice.
- Within both a primary and secondary care setting, the overall agreement between the INRs determined by the Xprecia Stride, CoaguChek systems and the laboratory method was within acceptable limits.
- In the hands of the intended users the Xprecia Stride is appropriate for use in everyday clinical practice.

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Competing interests None declared.

Ethics approval Ethical approval was obtained from the West Midlands Black Country research ethics committee Ref 15/WM/0382.

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