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Analytical and clinical performance of three hand-held point-of-care creatinine analyzers for renal function measurements prior to contrast-enhanced imaging

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ABSTRACT

Background: As iodine-based contrast can cause deterioration of renal function in patients with impaired kidney function, guidelines advise to measure creatinine and calculate estimated glomerular filtration (eGFR) prior to administration. Point-of-care (POC) devices seem an attractive alternative to central laboratory testing but uncertainty regarding analytical and clinical comparability remains.

Methods: This study compared three POC devices, i-STAT (Abbott), StatSensor (Nova) and epoc (Siemens) with a central laboratory method (enzymatic creatinine, Siemens Vista 1500 platform). 120 patients were included and underwent simultaneous finger prick capillary blood analysis on the StatSensor and heparine whole blood analysis on StatSensor, i-STAT and epoc.

Results: All POC devices generated results which showed considerable variability around the creatinine value of the reference standard, with StatSensor having the widest (−1,12–1,11 mg/dL) and epoc the tightest (−0,49–0,49 mg/dL) 95% limits of agreement. I-STAT showed the highest clinical concordance with the reference standard (Kappa: 0,94) and had the smallest average analytical error (6%) for creatinine and eGFR compared to the reference standard, meeting the predefined criteria of 8,87% and 10%, respectively. Epoc only met criteria for eGFR. StatSensor did not meet any of the criteria.

Conclusions: I-STAT and epoc were, analytically and clinically, the most performant POC devices included in this study but showed to be less user-friendly. StatSensor did not meet any of the error criteria, neither for creatinine nor for eGFR measurements, and gave more clinical major classification errors. However, it proved to be more user-friendly compared to the other POC devices.

1. Introduction

Contrast-enhancing agents based on iodine and gadolinium are frequently used in diagnostic imaging but can cause post-contrast acute kidney injury (PC-AKI) or nephrogenic systemic fibrosis (NSF), respectively [1]. Usage of gadolinium-based contrast media with a low risk of NSF, as used in our hospital, allows for administration without prior laboratory testing of renal function [1]. However, for iodine-based contrast, several international guidelines advise creatinine measurement and calculation of the estimated glomerular filtration rate (eGFR) prior to administration in order to stratify and minimize the risk for PC-AKI and fatal complications [1–7]. In a clinical setting where diagnostic imaging is urgent and a patient's kidney function is unknown, the use of point-of-care (POC) devices measuring creatinine and calculating eGFR seems an attractive alternative to standard laboratory testing [8–12]. However, a recent survey regarding strategies for assessing renal function prior to contrast-enhanced imaging revealed significant differences between POC results and central laboratory results and therefore limited clinical utility in everyday practice [13].

This study investigated analytical and clinical comparability of three handheld POC devices with a central laboratory reference standard measuring creatinine and calculating eGFR using the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) formula [14]. Additionally, the study investigated major and minor classification

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errors made by these devices in order to assess their utility in clinical practice.

2. Material and methods

2.1. Patient inclusion

During a 10-week period in May, June and July 2018, 80 consecutive patients (age ≥18 years) undergoing iodine- or gadolinium-enhanced imaging were asked to participate in the current study. Additionally, 25 patients with chronic kidney disease and 15 dialysis patients were included after informed consent in order to cover the entire analytical measuring range of the POC devices. Demographics were collected for each participant including gender, age and race. No POC results were reported to the referring clinicians and medical decision making was based solely on the reference method.

2.2. Ethics

This study was performed in accordance with the Declaration of Helsinki, all relevant national regulations and local hospital policies. The ethical committee of the University of Antwerp and the University Hospital of Antwerp approved this study according to ICH-GCP guidelines (reference 18/08/091). All participants were informed and gave written consent prior to inclusion and sampling.

2.3. Blood sampling

For each participant, a 4 mL heparine (BD Vacutainer® Heparin Tube) tube was collected by an experienced trial nurse following standard phlebotomy procedures. This tube was labelled and sent to the laboratory of clinical biology.

At the same time, the trial nurse also performed a finger prick, followed by capillary blood analysis on the ward using the StatSensor (Nova Biomedical, Waltham, USA) device as would be the case in routine practice. A spring-loaded lancet was used to pierce the skin. Capillary blood was collected on the StatSensor creatinine test strip directly from the fingertip, avoiding squeezing or milking of the finger. A quality control was tested weekly to assure performance during the study period. No quality control problems were observed. All blood samples were taken before contrast administration or start of hemodialysis.

2.4. Test methods

The Siemens IDMS calibrated enzymatic creatinine assay performed on heparin plasma on the Dimension Vista 1500 platform (Siemens Healthcare Diagnostics Inc., Newark, USA) was considered the reference standard. The material used for calibration of the creatinine assay was traceable to “Standard Reference Material® 914a” of the National Institute of Standards and Technology (NIST SRM 914[a]). Quality of the reference standard results was assured by performing level 1 (user mean 0,847 mg/dL; fixed analytical CV 5,5%; actual CV 3,1%) and 2 (user mean 1,87 mg/dL; fixed analytical CV 2,2%; actual CV 1,9%) Biorad Multiqual® Chemistry Controls twice a day. No quality control problems were observed during the study period. Besides that, the laboratory participated in the mandatory external quality assessment (EQA) “chemistry” of Sciensano and, additionally, the EQA “general chemistry/therapeutic drugs” of the College of American Pathologists (CAP), with 4 and 3 round per year respectively. No major EQA problems were observed during the last 5 years. The CKD-EPI formula was used to calculate the eGFR [14].

In the laboratory all CE-marked handheld POC devices measuring creatinine and calculating eGFR using the CKD-EPI formula, were available. According to the manufacturers' instructions, heparin whole blood was a validated sample type for all POC devices. Heparinized whole blood samples were first tested on each POC device being the StatSensor (Nova Biomedical, Waltham, USA), the i-STAT (Abbott Laboratories, Princeton, USA) and the epoc Blood Analysis System (Siemens Healthcare Diagnostics Inc., Newark, USA), in an alternating order. Then the heparin tube was centrifuged and plasma was tested using the reference standard. All POC tests use an enzymatic creatinine assay, generating H_2O_2 which is measured amperometrically. A quality control was performed for each POC device at the beginning of the study, ensuring the reagent batch was conform the manufacturers' quality specifications. POC reagents were then stored and used following manufacturers' specifications.

2.5. Definitions and statistics

The European Society of Urogenital Radiology (ESUR) guidelines on contrast media (2018, Version 10) [1] suggests that iodine-based contrast with first pass renal exposure should be avoided in patients having an eGFR < 45 mL/min/1,73 m^2. In our daily practice, a safety margin is applied, preventing the administration of iodine-based contrast in patients with an eGFR < 50 mL/min/1,73 m^2. Iodine-based contrast can be administered with additional hydration in patients having an eGFR between 50 and 59 mL/min/1,73 m^2 and patients having an eGFR ≥60 mL/min./1,73m^2 have no additional requirements prior to administration. In accordance with the ESUR guidelines, metformine intake is stopped prior to contrast administration in patients having an eGFR < 30 mL/min/1,73 m^2. Patients with an eGFR < 60 mL/min/1,73 m^2 are routinely informed of the possible side effects prior to the administration of gadolinium-based contrast.

In order to perform an error analysis for the POC results, major and minor classification errors were defined:

Major error:

- To give iodine-based contrast when iodine-based contrast should be avoided
- Deny iodine-based contrast when there is no contra-indication
- Not stopping metformin before administering iodine-based contrast when it should be stopped
- Administration of iodine-based contrast without hydration when there should be extra hydration
- Administration of iodine-based contrast with hydration when iodine-based contrast should be avoided

Minor error:

- Administration of iodine-based contrast with hydration when hydration was not necessary
- Deny iodine-based contrast when administration with hydration was permitted
- Stopping metformin before administering iodine-based contrast when it should not be stopped

Bland-Altman plots and Passing-Bablok regressions were generated for each POC device using MedCalc® version 17.5.5 (MedCalc, Ostend, Belgium). The analytical error percentage compared to the reference standard (=100 × ([POC device] – [reference standard])/[reference standard]) was calculated for each POC device in each patient. In addition, average analytical error percentage and a 95% confidence interval (95%CI) was calculated for each POC device following CLSI procedures [15]. Criteria used to check analytical error percentage were derived from the ‘Desirable Specifications for Allowable Total Error (ATE)’ database [16] for creatinine (ATE = 8,87%) and from the Laboratory Working Group of the National Kidney Disease Education Program (NKDEP) [17] for eGFR (ATE = 10%). Although the 10% ATE for eGFR is actually a performance specification for creatinine, it has yet been used in several articles as an acceptable total error for eGFR [18–20]. Categorical agreement of POC devices with the reference

standard was calculated using the unweighted Kappa statistic. Finally, error analysis using predefined minor and major classification errors was performed for each POC device.

3. Results

3.1. Demographics study population

A total of 120 Caucasian patients were included comprising 61 males and 59 females. Age ranged from 18 to 88 years old with a median age of 64 years. In two patients (2%) a measuring error occurred and no finger prick result was generated by the StatSensor device. Three (3%) other patients were excluded due to milking of the finger while performing finger prick analysis giving gross underestimation of the capillary creatinine value and subsequently a major overestimation of the eGFR compared to the plasma reference standard values. These five patients were excluded for all calculations using capillary blood StatSensor values. The prevalence of decreased renal function (eGFR < 60 mL/min/1,73 m^2) in the current study population at the diagnostic imaging wards was 15%, which is somewhat lower then percentages reported in other studies [8,10,11].

3.2. Bland-Altman and Passing-Bablok analysis

Table 1 shows an overview of Passing-Bablok and Bland-Altman analysis of creatinine values quantified by the three POC devices. According to the Bland-Altman analysis only i-STAT demonstrated a small but statistically significant negative average bias compared to the reference standard. From the lower and upper limits of agreement it is clear that all the POC devices can over- and underestimate the true value of the reference standard with StatSensor having the widest limits of agreement. Passing Bablok regression reveals that all devices have a proportional and/or constant error compared to the reference standard, except for StatSensor performed on capillary blood. Bland-Altman scatterplots and Passing-Bablok regression curves for creatinine are shown in Fig. 1. Fig. 2 shows Bland-Altman scatterplots and Passing-Bablok regression curves for eGFR.

3.3. Kappa statistics and error analysis

Table 2 shows categorical agreement and error analysis of the POC devices. For identifying patients who can or should not receive iodine-based contrast i-STAT was the most concordant and StatSensor was the least concordant device compared to the reference standard. The same was true for identifying patients in who metformin should have been stopped prior to contrast administration. I-STAT made the least major and minor errors, whereas StatSensor showed the most major errors.

3.4. Checking allowable analytical error for creatinine and eGFR

In Table 3 the analytical error between the POC devices and the central laboratory reference standard is calculated for creatinine and eGFR. I-STAT had an average analytical error of 6% for creatinine and eGFR compared to the reference standard and was the only device that did not exceed the ATE criteria of 8,87% and 10%, respectively. Epoc did not meet the criteria for creatinine (10%) but did meet criteria for eGFR (8%). StatSensor did not meet any of the criteria, neither for creatinine nor for eGFR, and this for both heparine whole blood and finger prick analysis.

4. Discussion

As many guidelines recommend assessing the kidney function based on risk stratification and/or measurement of eGFR prior to contrast-enhanced imaging [1,5,6], some hospitals consider measuring creatinine using a POC device. The i-STAT and StatSensor are the most

Table 1
Analytical comparison of creatinine measurements of POC devices with central laboratory reference standard using Bland-Altman and Passing Bablok analysis.

Method	Sample type	Median (range) mg/dL	Interquartile range mg/dL	r	Bland-Altman			Passing Bablok	
					Mean bias (mg/dL) [95%CI]	Lower 95% LoA [95%CI]	Upper 95% LoA [95%CI]	Constant error [95%CI]	Proportional error [95%CI]
Reference standard	P	0,98 (0,50–10,20)	1,11	–	–	–	–	–	–
i-STAT	HWB	1,05 (0,50–9,40)	1,10	0,99	−0,09 [−0,14–0,04]	−0,61 [−0.69 to −0,53]	0,42 [0,35 − 0,51]	0,04 [0,01–0,07]	0,94 [0,92–0,96]
epoc	HWB	1,03 (0,36–9,51)	1,22	0,98	0,007[−0,04–0,05]	−0,49 [−0,56–0,40]	0,49 [0,42–0,57]	−0,06 [−0,10–0,02]	1,06 [1,03 − 1,09]
StatSensor	CB[a]	0,98 (0,49–7,94)	1,14	0,93	−0,003 [−0,11–0,10]	−1,12 [−1,30–0,94]	1,11 [0,93–1,29]	0,05 [−0,0002–0,11]	1,03 [0,97–1,07]
	HWB	1,00 (0,52–9,26)	1,25	0,91	0,05 [−0,03–0,12]	−0,75 [−0,87–0,62]	0,84 [0,72–0,97]	0,08 [0,009–0,14]	0,98 [0,93–1,04]

[a] In two patients a measuring error occurred and no finger prick result was generated; three patients were excluded for milking of the finger while performing finger prick analysis. CB: capillary blood; HWB: heparin whole blood; LoA: Limit of Agreement.

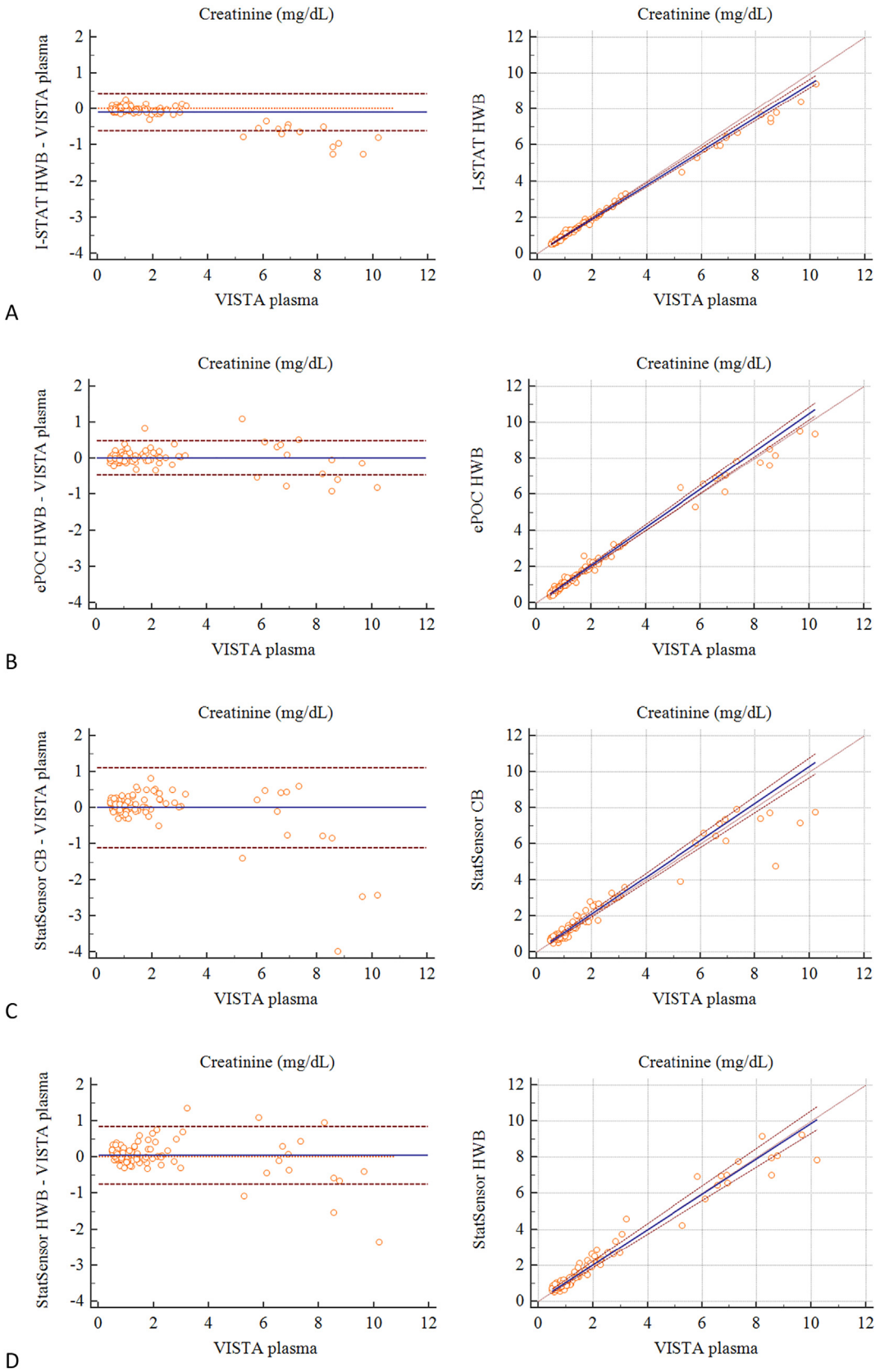

Fig. 1. Bland-Altman plots and Passing Bablok regression for creatinine comparing POC devices.
(A) i-STAT HWB, (B) epoc HWB, (C) StatSensor CP and (D) StatSensor HWB, with the central laboratory reference standard. HWB: heparin whole blood; CB: capillary blood.

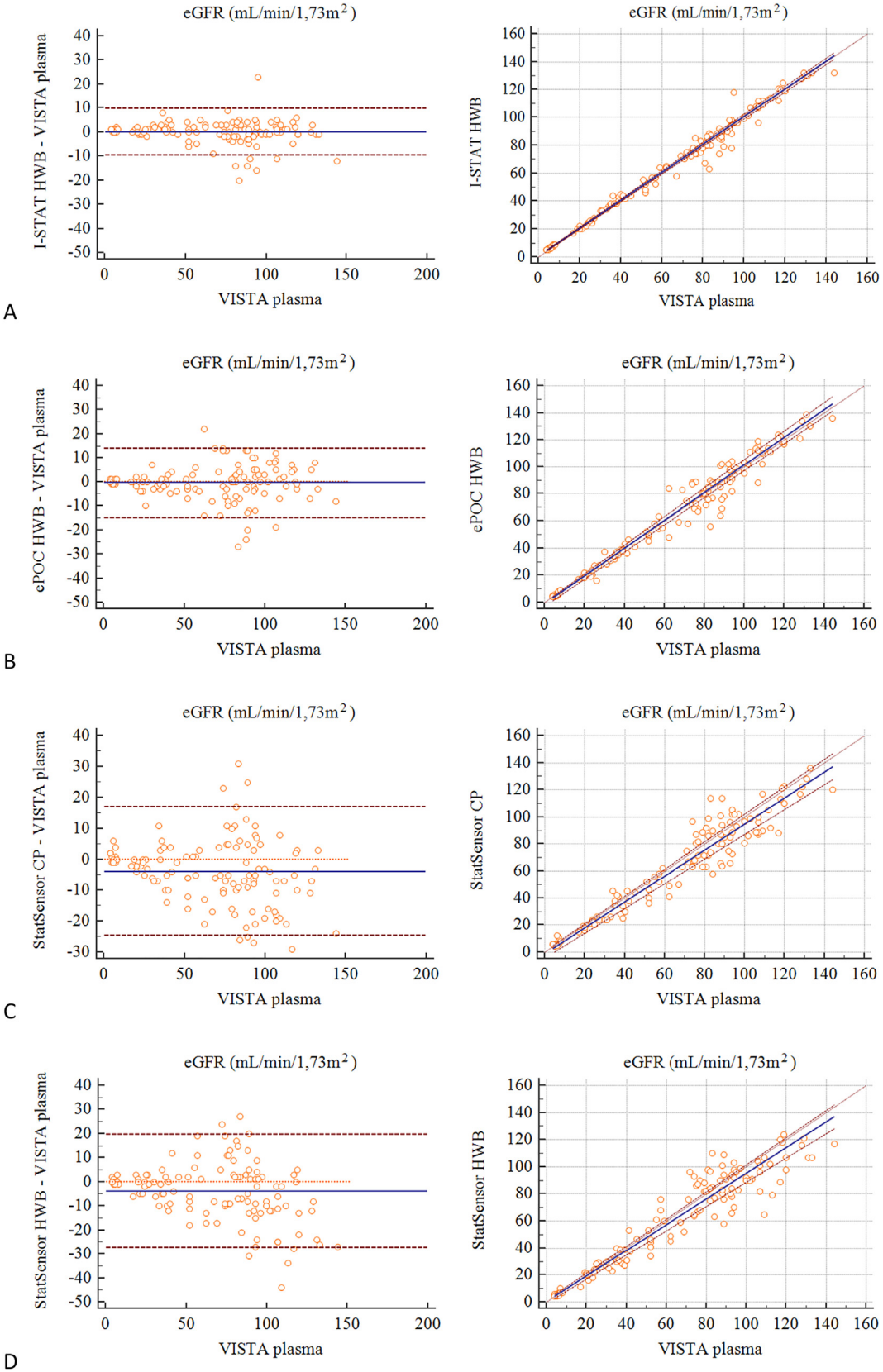

Fig. 2. Bland-Altman plots and Passing Bablok regression for eGFR comparing POC devices (A) i-STAT HWB, (B) epoc HWB, (C) StatSensor CP and (D) StatSensor HWB, with the central laboratory reference standard. HWB: heparin whole blood; CB: capillary blood.

Table 2
Clinical agreement of eGFR with central laboratory reference standard and error classification analysis of POC devices.

	Predefined eGFR cut-offs mL/min/1,73 m^2	StatSensor CB[a]	StatSensor HWB	i-STAT HWB	epoc HWB
		Categorical agreement, Kappa [95%CI]			
Administration of iodine-based contrast	≥ 60; 50–59; < 50	0,87 [0,78–0,96]	0,78 [0,67–0,89]	0,94 [0,88–1,00]	0,88 [0,79–0,96]
Alert for gadolinium-based contrast	≥ 60; < 60	0,91 [0,83–0,99]	0,85 [0,75–0,94]	0,97 [0,92–1,00]	0,91 [0,84–0,99]
Stop metformin for iodine-based contrast	≥ 30; < 30	0,87 [0,75–0,98]	0,90 [0,81–0,99]	1,00	0,98 [0,93–1,00]
		Number of classification errors (%)			
Major error		2 (2%)	8 (7%)	1 (1%)	2 (2%)
	iodine-based contrast would have been denied when there was no contraindication	2	3	–	1
	iodine-based contrast would have been administered without hydration when there should be extra hydration	–	4	–	–
	iodine-based contrast would have been administered with hydration when iodine-based contrast was contraindicated	–	1	–	–
	iodine-based contrast would have been administered without hydration when there should be extra hydration	–	–	1	1
Minor error		6 (5%)	6 (5%)	3 (2%)	6 (5%)
No error		107 (93%)	106 (88%)	116 (97%)	112 (93%)

[a] In two patients a measuring error occurred and no finger prick result was generated; three patients were excluded for milking of the finger while performing finger prick analysis. CB: capillary blood; HWB: heparin whole blood.

studied handheld POC devices in literature dealing with contrast-enhanced imaging [8,10,11]. For epoc such studies are not performed yet. Besides the handheld devices there are also benchtop analyzers like the ABL800 FLEX who were evaluated in literature but were not included in this study as only handheld devices were considered [8,9,12].

The current study statistically compared all handheld POC creatinine/eGFR analyzers, available on the Belgian market using clearly defined criteria for analytical error compared to the reference standard and clear definitions of potential classification errors. Patients were prospectively included on wards that would use the POC device in a real life setting. Additionally, patients known with kidney failure were included to cover the analytical measuring range of the devices.

Comparison of heparin whole blood analysis indicated i-STAT as the best performing POC device, meeting ATE criteria for both creatinine and eGFR, showing the highest categorical agreement and the least major errors. StatSensor showed the highest major error rate and failed to meet ATE criteria for creatinine and eGFR. Epoc had the second highest categorical agreement and major error rate. The device met ATE criteria for eGFR but not for creatinine. As decisions are made based on eGFR in the ESUR guidelines both i-STAT and epoc can be used with an acceptable analytical error compared to the reference standard. These findings are in line with other studies concluding that i-STAT is appropriate for use in the context of contrast-enhanced imaging, whereas StatSensor did not meet the ATE criteria [8,17]. This study also investigated the epoc device and considered it appropriate if eGFR cut-off values are used in hospital guidelines regarding contrast-enhanced imaging.Although the trial nurses were well trained, gross underestimation of finger prick creatinine occurred in 3 patients (3%) using the StatSensor. Nurses did not recall squeezing or milking the finger. However, these finger prick results were excluded from further analysis because heparin whole blood analysis of these patients gave results close to the reference standard. This issue may suggest that for any POC device finger prick capillary blood may not be the most robust sample type for measuring creatinine. Dilution of capillary blood by squeezing or milking the finger can occur, even when nurses are thoroughly trained and samples are taken in a non-emergency setting. The fact that dilution of capillary blood occurred in 3% of the cases indicates an unacceptable risk for administration of contrast media based on POC creatinine and eGFR measurement. Frequent training and monitoring of good finger prick blood sampling practices remains of the utmost importance but POC devices measuring creatinine in capillary blood should be more robust for potential dilution of capillary blood or should at least give a warning (based on hematocrit) for potential dilution of the capillary sample.

In terms of user-friendliness StatSensor was far-out the most easy to use POC device as finger prick capillary blood samples can be applied directly from the fingertip to the biosensor test strip within 30 s. If one would sample capillary blood for epoc or i-STAT analysis, blood should first be transferred into a heparinized capillary tube and then put into a test cartridge, measuring creatinine within 3 min. Due to a problem with the battery, there was a measuring error during the capillary blood analysis by StatSensor in two patients (2%). After replacement of the battery, no more problems were observed. In another study a measuring error occurred in 1% of the patients using StatSensor [8].

This study was limited to the statistical comparison of POC creatinine devices with a reference standard, being an IDMS calibrated enzymatic creatinine assay. Because this reference method is not the actual gold standard, the obtained ATE's are calculated in relation to the reference method with its own imprecision. Therefore, these results should be interpreted with caution when extrapolated to laboratories using another assay type or calibration standard as reference standard. To restrain costs, not all aspects of analytical performance (repeatability, interference, limit of detection, limit of quantification) were evaluated. In addition, the influence of capillary dilution was only studied for the StatSensor and not for the i-STAT and epoc device. This could be the subject of future studies regarding performance of POC

Table 3
Calculation of analytical error between POC devices and central laboratory reference standard for creatinine and eGFR.

	StatSensor CB[a]	StatSensor HWB	i-STAT HWB	epoc HWB
	eGFR			
Patients where analytical error exceeds 10%	58/115 (50%)	68/120 (57%)	20/120 (17%)	38/120 (32%)
Average analytical error [95%CI]	13% [11–14]	14% [12–16]	6% [4–7]	8% [7–10]
	Creatinine			
Patients where analytical error exceeds 8,87%	72/115 (63%)	77/120 (64%)	26/120 (22%)	48/120 (40%)
Average analytical error [95%CI]	15% [12–17]	16% [14–17]	6% [5–7]	10% [8–11]

[a] In two patients a measuring error occurred and no finger prick result was generated; three patients were excluded for milking of the finger while performing finger prick analysis. CB: capillary blood; HWB: heparin whole blood.

devices measuring creatinine by a finger prick.

5. Conclusions

Regarding analysis of heparin whole blood, i-STAT and epoc seemed trustworthy POC devices for measuring eGFR, but were less user-friendly then StatSensor. I-STAT also had an acceptable analytical error compared to the reference standard when measuring creatinine. StatSensor finger prick capillary blood and heparine whole blood analysis did not meet ATE criteria for creatinine or eGFR measurements and gave more major classification errors but was more user-friendly for finger prick analysis compared to the other POC devices. POC creatinine devices could be used as a screening tool for assessment of renal function prior to contrast-enhanced imaging, when using heparin whole blood as sample type. For patients in whom the POC results indicate that iodine-based contrast should be avoided or additional hydratation is recommended, a follow-up creatinine analysis in the central laboratory is advised. Besides that, this study suggests that finger prick capillary blood may not be the most robust sample type for measuring a delicate analyte like creatinine.

Declarations of Competing Interests

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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