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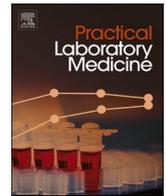
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Point of care creatinine derived eGFR measurement in capillary blood for identifying patients at risk

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A B S T R A C T

Introduction: The aim of the study was to assess the clinical reliability of eGFR values estimated with a creatinine measurement from a point of care (StatSensor®) compared with measured GFR (mGFR) by a gold standard method.

Methods: We prospectively included 113 patients undergoing renal function assessment. We compared eGFR using creatinine from capillary blood or venous blood measured by StatSensor® and measured GFR (mGFR) by Passing Bablok regression. Performance of eGFR was estimated by bias, precision and accuracy.

Results: A total of 113 subjects were included. Median eGFR values were 59 (10–132), 52 (10–123) and 51 (10–131) ml/min/1.73 m² for enzymatic, capillary and venous measurements, respectively. There was no difference between P30 and P10 for the three eGFR values (p = 0.11 and p = 0.1 respectively). StatSensor® eGFR tended to be underestimated compared to mGFR. For CKD stage 4/5 patients, concordance was 79 and 84% for eGFR with capillary creatinine and venous creatinine respectively. For mGFR < 60 ml/min/1.73 m², concordance was 84 and 88% with capillary creatinine and venous creatinine respectively.

Conclusion: The use of a handheld blood creatinine monitoring system with eGFR calculation provides a good estimation of GFR and allow to identify patients at high risk of acute kidney injury.

1. Introduction

Creatinine is the most routinely used endogenous marker to estimate glomerular filtration rate (eGFR) in clinical practice. Creatinine derived eGFR measurements are important for managing patients with chronic kidney disease, for identifying early kidney disease and for classifying chronic kidney disease (CKD). For hospitalised patients, serum creatinine testing is performed in the central laboratory with a turnaround time ranging from one to several hours [1] but in some situations such as critical care setting, patients undergoing computer tomography with iodine contrast medium, or outpatients receiving a nephrotoxic drug a faster creatinine result is necessary. Here point-of-care creatinine tests provide an opportunity for rapid results and the use of these have been reported to help patient management in intensive care units and emergency departments [2,3]. Point of care creatinine methods such as blood gas analysers or mini fluidic analysers used in critical care units require intensive technical maintenance and are often affected by sampling impracticalities [4]. Moreover, point of care creatinine tests could also be used in the ambulatory or primary care setting to identify early stage CKD, and in case of patients with known CKD, for monitoring or self-monitoring their renal function as part of the

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routine management of chronic kidney disease [5].

StatSensor® Creatinine is a handheld point of care device that can be used for monitoring creatinine directly in finger stick capillary blood sample providing a creatinine and eGFR measurement within 30 s. This blood creatinine monitoring system (BCMS) is simple to use and requires no maintenance or calibration. The device has been evaluated in analytical studies [6,7] and in clinical performance studies as a risk assessment tool in radiology [8], traumatic patients [9], and nephrology patients [10]. Currently, Kidney disease improving global outcomes (KDIGO) recommend the use of CKD-EPI for calculating eGFR, but only enzymatic creatinine is specified for use in this formula. The previously published evaluations of StatSensor® Creatinine have compared the creatinine-derived eGFR with eGFR derived from an enzymatic laboratory creatinine measurement compared to iohexol clearance [11].

The aim of the study was to assess the clinical reliability of eGFR values estimated from capillary blood creatinine measurement, compared with measured GFR (mGFR) by a gold standard method: inulin clearance in a large group of patients at different stages of CKD. This also provided an opportunity to compare capillary and venous creatinine/eGFR measurements with laboratory creatinine/eGFR measurements based on our routine laboratory analyser.

2. Materials and methods

2.1. Patients and information

The prospective observational study included adult patients undergoing renal function assessment in a specialized renal unit at the Lyon Sud University Hospital, Lyon between January 2013 and April 2015. The study was approved by the local Institutional Review Board and written informed consent was obtained from each patient. The study intention was to include patients in a stable clinical condition at different stages of CKD. Patients with diseases resulting in a marked alteration of peripheral microcirculatory function such as advanced diabetic microangiopathy or thrombotic microangiopathy were excluded.

2.2. Creatinine measurement

Creatinine was measured by three techniques: standard laboratory method (creat); a point of care BCMS with capillary blood and a point of care BCMS with venous blood. Laboratory plasma creatinine measurement was performed with an enzymatic method with calibration certified by isotope dilution mass spectrometry using Dimension Vista System (Siemens Healthcare Systems, Saint-Denis, France) laboratory analyser traceable to National Institute of Standards and Technology creatinine Standard Reference Materials 914 (verified with National Institute of Standards and Technology SRM 967). Creatinine and eGFR in capillary and venous whole blood were measured using StatSensor BCMS device (Nova Biomedical, Waltham, USA).

For BCMS measurements a drop of capillary blood was collected from a finger with the first and the last blood samples collected for inulin measurement and laboratory creatinine measurement.

2.3. GFR assessment

The GFR measurement (mGFR) was performed with the inulin clearance reference standard method (INUTEST 25%; Fresenius, Kabi, Austria). The method was performed with a loading dose of 30 mg/kg that was injected in 10 min, with a maintenance dose infusion of a solution of inulin of 40 mg/kg. The urine was collected every 30 min, and we performed blood tests in the middle of each period of urine collection (three to four collection periods of 30 min). Inulin clearance was calculated in each period (UV/P) to obtain the average (where U is urinary inulin, V is urine volume and P is plasmatic inulin). Inulin clearance was normalized to 1.73 m² body surface area determined by the DuBois and DuBois formula [12]. Measurements of plasma and urine polyfructosan concentrations were performed using an enzymatic method [13].

eGFR was calculated using the Chronic Kidney Disease and Epidemiology equation (CKD-EPI_{ASR}) [14] as follow: CKD-EPI = $k_1 \times [PCr/k_2]^{-k_3} \times 0.993^{age}$ with $k_1 = 141, 144, 163, \text{ and } 166$ for white men, white women, black men, and black women, respectively; $k_2 = 0.7$ and 0.9 for women and men, respectively; and $k_3 = 1.209, 1.209, 0.411, \text{ and } 0.329$ for men with PCr >0.9 mg/dl, women with PCr >0.7 mg/dl, men with PCr ≤0.9 mg/dl, and women with PCr ≤0.7 mg/dl, respectively.

We used also the new CKD-EPI equations without race (CKDEPI_{AS}) defined as follow: CKD-EPI = $142 \times [PCr/k]^a \times 0.9939^{age} \times 1.012$ (if female) where $k = 0.7$ (female); 0.9 (male); $a = -0.241$ (female) or -0.302 (male) [15].

2.4. Data analysis

Data was analysed using Graphpad statistical software and SAS version 9.3. Data are presented as means or medians or means, standard deviations and/or 95% CI in function of normality. The performance of the equations was measured by bias, precision, accuracy 30% and 10%. Bias was defined by the difference between eGFR and mGFR (eGFR-mGFR). Precision was assessed as an interquartile range for the differences. Accuracy 30% (P30) and Accuracy 10% (P10) were calculated as the percentage of GFR estimates within 30% and 10% deviation of mGFR.

Bias comparisons were performed using paired Wilcoxon test, and accuracies of eGFR were compared using McNemar's tests. P values < 0.05 were considered significant. Because we measured GFR in an european population, we never use race correction explaining we focused on previous CKDEPI equation to perform Passing-Bablok regression and Bland-Altman plots (used to show the agreement between mGFR and eGFR) [16].

3. Results

3.1. Patients' characteristics

One hundred and thirteen adult patients were enrolled in the study including 56 men and 57 women. The median age was 58 (19–90) years, and mean BMI was 24.2 (15.6–46.8) kg/m². Characteristics of patients are described in Table 1. Patients were distributed across CKD stages with a median mGFR of 52 (14–167) ml/min/1.73 m².

3.2. Creatinine measurement

Enzymatic and capillary creatinine measurements were available for all 113 patients whereas venous creatinine measurements were available for 111 patients.

Median creatinine values were 1.26 (0.51–4.20), 1.38 (0.64–4.36) and 1.33 (0.55–4.37) mg/dL for enzymatic, capillary and venous measurements, respectively. Median bias, Precision, P10 and P30 are described in Table 2. We found no significant difference between capillary and venous bias, $p = 0.71$. Fig. 1 displays Bland and Altman plot between enzymatic creatinine and capillary creatinine (Fig. 1A) or venous creatinine (Fig. 1B).

Capillary and venous values were measured twice during the GFR measurement, and their variation was 0.06 ± 0.23 (n = 82) and 0.08 ± 0.33 mg/dL (n = 76) respectively without significant difference between both of them.

3.3. GFR performance

Median eGFR values were 59 (10–132), 53 (10–123) and 51 (10–131) ml/min/1.73 m² for enzymatic, capillary and venous measurements, respectively. Bias, Precision, P30, P10 are described in Table 3. Bias between mGFR and eGFR with enzymatic measurements were significantly different from bias between mGFR and eGFR with capillary measurement and between mGFR and eGFR with venous measurements, respectively ($p = 0.0001$). There was no difference between P30 and P10 for the three estimated GFR values ($p = 0.11$ and $p = 0.1$ respectively). When all analysis are done with CKDEPI_AS, precision doesn't change. However, Bias and P30 was higher with CKDEPI_AS.

We focused only on eGFR (CKDEPI_AS) equation for next analysis. Fig. 2A and B displays Bland and Altman plot between mGFR and eGFR with capillary creatinine (Fig. 2A) or mGFR and eGFR with venous creatinine (Fig. 2B). We confirmed a significant difference between mGFR and eGFR (capillary and venous) using Passing-Bablok regression. Compared to mGFR, Passing-Bablok regression obtained with eGFR with capillary measurement was: $eGFR = 0.8579x \text{ mGFR} + 1.98524$, $p = 0.45$ (95% CI: 0.77 to 0.98 and –3.58 to 5.55 for slope and intercept, respectively) Fig. 2C. A correction can be applied to CKDEPI estimation with the POC as follows: CKD EPI CSSCD corrected = $1.16554 * \text{CKD EPI CSSCD} - 2.31388$. Compared to mGFR, Passing-Bablok regression obtained with eGFR and venous measurement was: $eGFR = 0.86111x \text{ mGFR} + 1.02$, $p = 0.44$ (95% CI: 0.76 to 0.97 and –3.2 to 6.5 for slope and intercept, respectively) Fig. 2D. A correction can be applied to CKDEPI estimation with the POC: CKD EPI CSSVD corrected = $1.16129 * \text{CKD EPI CSSVD} - 1.18452$.

3.4. Performance of eGFR (CKD-EPI) with capillary measurement in sub-groups of GFR

Because CKD-EPI with capillary creatinine outperformed CKD-EPI with venous measurement in the studied population, all the following analyses were performed using CKD-EPI equation and capillary creatinine. In a sub-group of patients with $GFR < 60$ ml/min/1.73 m², median mGFR was 38 (34–43) ml/min/1.73 m² and was not different from eGFR with capillary creatinine (34 (31–40) ml/min/1.73 m²). With $GFR > 60$ ml/min/1.73 m², median mGFR was 83 (73–86) ml/min/1.73 m² and was not different from eGFR

Table 1

Patient's demographics. Results are expressed in median (min-max) or n (%).

| | Male n = 56 | Female n = 57 | Total n = 113 |
|--|-------------------|-------------------|-------------------|
| Age (years) | 59 (19–88) | 56 (22–90) | 58 (19–90) |
| Weight (kg) | 75.5 (52.0–114.0) | 63.0 (38.0–132.0) | 69.6 (38–132) |
| Taille (cm) | 1.73 (1.58–1.92) | 1.60 (1.44–1.78) | 1.68 (1.44–1.92) |
| BMI range (kg/m ²) | 25.0 (17.4–40.4) | 23.2 (15.6–46.8) | 24.2 (15.6–46.8) |
| mGFR range (mL/min/1.73 m ²) | 51.5 (14.0–167.0) | 52.0 (17.0–122.0) | 52.0 (14.0–167.0) |
| Creat (mg/dL) | 1.34 (0.54–3.23) | 1.03 (0.51–4.20) | 1.26 (0.51–4.20) |
| CKD Stage 1 (%) | 5 (8.9%) | 9 (15.8) | 14 (12.4%) |
| CKD Stage 2 (%) | 18 (32.1) | 16 (28.1) | 34 (30.1%) |
| CKD Stage 3A (%) | 13 (23.2) | 10 (17.5) | 23 (20.4%) |
| CKD Stage 3B (%) | 11 (19.6) | 11 (19.3) | 22 (19.5%) |
| CKD Stages 4/5 (%) | 9 (16.1) | 11 (19.3) | 20 (17.7%) |
| Type 2 Diabetes (%) | 16 (28.6) | 6 (10.5) | 22 (19.5) |
| Hypertension (%) | 29 (51.8) | 26 (45.6) | 55 (48.7) |
| Smokers (%) | 14 (25.0) | 7 (12.3) | 21 (18.6) |

We have 1 missing data for type 2 diabetes, hypertension and smokers for men and women respectively.

Table 2

Creatinine measurement comparison. Bias is expressed as the median of the difference between laboratory creatinine and Statsensor® creatinine measurements (mg/dL) and (CI 95%). Precision refers to the difference between the 25th and 75th percentile, expressed in (mg/dL). Accuracy refers to the percentage of creat estimates that is within 30% and 10% of creat.

| Laboratory creat vs: | Bias | Precision | P30 | P10 |
|---------------------------------|---------------------|-----------|----------------|----------------|
| Median capillary creat (CI 95%) | -0.18 (-1.06- 1.05) | 0.18 | 76 (0.68-0.84) | 26 (0.78-0.34) |
| Median venous creat (CI 95%) | -0.17 (-1.12-1.09) | 0.17 | 71 (0.63-0.80) | 23 (0.15-0.31) |

CI confidence interval.

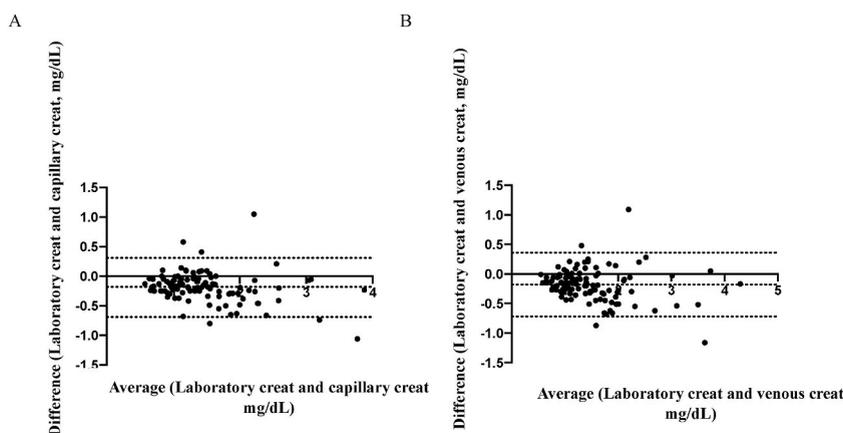


Fig. 1. Bland-Altman chart of enzymatic creatinine and A) capillary creatinine with the POCT B) venous creatinine with the POCT.

Table 3

eGFR performance. Bias is expressed as the median of the difference between eGFR and mGFR (mL/min/1.73 m²) (CI 95%). Precision refers to the difference between the 25th and 75th percentile, expressed in mL/min/1.73 m². Accuracy refers to the percentage of GFR estimates that is within 10% and 30% of mGFR.

| Laboratory creat vs: | Bias | Precision | P30 | P10 |
|--|--------------------|-----------|------------|------------|
| Median eGFR (CKDEPI_AS) (Laboratory creatinine) (CI 95%) | -4 (-6; -2) | -13 | 80 (73-88) | 19 (12-27) |
| Median eGFR (CKDEPI_AS) (Capillary creatinine) (CI 95%) | 5 (3; 7) | 20 | 79 (72-87) | 20 (13-28) |
| Median eGFR (CKDEPI_AS) (venous creatinine) (CI 95%) | 5 (3; 7) | 19 | 70 (61-78) | 30 (21-39) |
| Median eGFR (CKDEPI_AS) (Laboratory creatinine) (CI 95%) | 0.42 (-1.6; -3.34) | 18 | 65 (56-74) | 20 (13-28) |
| Median eGFR (CKDEPI_AS) (Capillary creatinine) (CI 95%) | -9.4 (-11.1;-6.2) | 19 | 56 (47-66) | 19 (12-27) |
| Median eGFR (CKDEPI_AS) (venous creatinine) (CI 95%) | -8.6 (-11.3;-5.9) | 15 | 80 (73-88) | 19 (16-2) |

eGFR estimation glomerular filtration rate. (CKDEPI_AS) = original CKDEPI. (CKDEPI_AS) = CKDEPI without race. CI confidence interval.

with capillary creatinine (67 (63-76) mL/min/1.73 m²). There was no systematic or proportional difference between the two methods for patients with a GFR ≥ 60 mL/min/1.73 m²; we did not reject the linearity hypothesis, $p = 0.65$ (Fig. 3A). There seems to be a significant difference between the 2 methods for patients with a GFR < 60 mL/min/1.73 m² (Fig. 3B), so we can apply a correction: CKD EPI CSSCD corrected = 0.74723 * CKD EPI CSSCD + 9.79915.

3.5. Ability of eGFR results to correctly classify patients (< 30 ml/min/1.73 m², < 60 ml/min/1.73 m², > 90 ml/min/1.73 m²) (Table 4)

Concordance between mGFR and eGFR (CKDEPI_AS) are described in Table 4. For stage 4/5, 79%, 84% and 74% of eGFR estimated with capillary, venous and laboratory creatinine respectively concurred with mGFR level with no significant difference. For mGFR < 60 mL/min/1.73m², concordance between eGFR estimated with laboratory creatinine (100%) was significantly higher than with eGFR estimated with capillary (84%) or venous creatinine (88%), $p = 0.03$ and $p = 0.01$. For mGFR > 90 mL/min/1.73 m², eGFR (CKDEPI_AS) estimated with laboratory creatinine (100%) was also significantly higher than eGFR with capillary creatinine (57%) and venous creatinine (50%), $p = 0.02$ and $p = 0.008$ respectively. We found no significant difference in concordance between eGFR (CKDEPI_AS) with capillary creatinine and mGFR with venous creatinine. We showed no difference in concordance for CKD stage when GFR was estimated with CKD-EPI_AS.

4. Discussion

Our study confirms that Statsensor® device can be used for creatinine and GFR screening when enzymatic creatinine is not

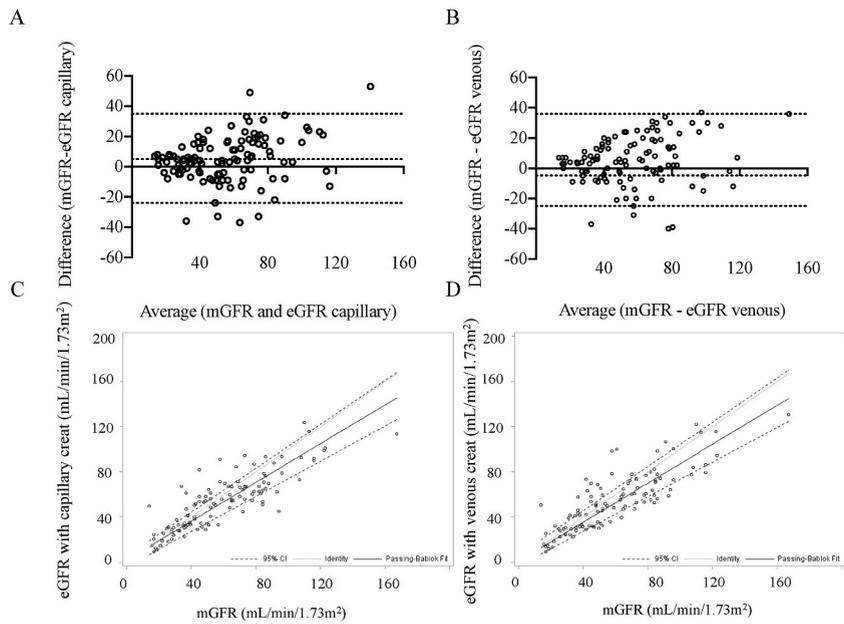


Fig. 2. Bland-Altman chart of the eGFR (mL/min/1.73 m²) obtained between mGFR and A) eGFR estimated by CKD-EPI and enzymatic creatinine, B) eGFR estimated by CKD-EPI and capillary creatinine with the POCT and C) Passing Bablock correlation fit between mGFR and eGFR with capillary creatinine D) Passing Bablock correlation fit between mGFR and eGFR with venous creatinine.

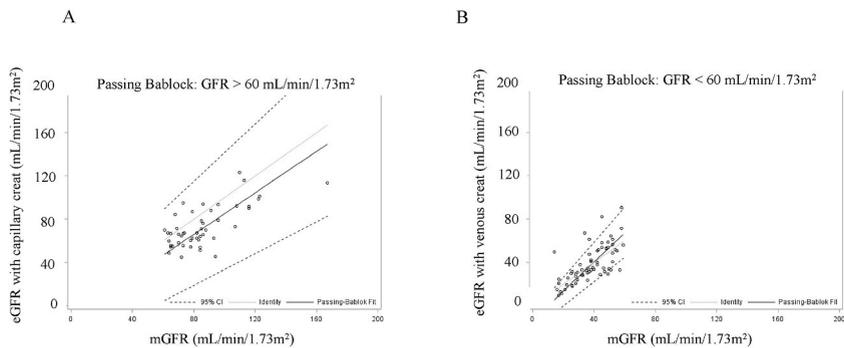


Fig. 3. Passing Bablock correlation for mGFR < 60 mL/min/1.73 m². A) Passing Bablock correlation fit between mGFR and eGFR with capillary creatinine B) Passing Bablock correlation fit between mGFR and eGFR with venous creatinine.

Table 4

Concordance around CKD stages compared to mGFR.

| Stage | eGFR (CKDEPI_ASR) (creat_capillary) | eGFR (CKDEPI_ASR) (creat_venous) | eGFR (CKDEPI_ASR) (creat_laboratory) | eGFR (CKDEPI_ASR) (creat_capillary) | eGFR (CKDEPI_ASR) (creat_venous) | eGFR (CKDEPI_ASR) (creat_laboratory) |
|--------------------|--|-------------------------------------|---|--|-------------------------------------|---|
| mGFR <30 n = 19 | 15 (79%) | 16 (84%) | 14 (74%) | 18 (95%)* | 18 (95%)* | 16 (84%) |
| mGFR <60 n = 63 | 53 (84%) * | 56 (88%) * | 63 (100%) | 60 (95%) | 57 (90%) | 55 (97%) |
| mGFR <90 n = 97 | 94 (97%) | 94 (97%) | 89 (91%) | 81 (83%) | 79 (81%) | 80 (82%) |
| mGFR >90 n = 14 | 8 (57%) * | 7 (50%) * | 14 (100%) | 8 (57%) * | 7 (50%) * | 14 (100%) |

*p < 0.05 vs eGFR calculated with laboratory creatinine.

eGFR estimation glomerular filtration rate. (CKDEPI_ASR) = original CKDEPI. (CKDEPI_AS) = CKDEPI without race.

immediately available. We showed good agreement and reproducibility along the time for creatinine measurement. We also reported a good concordance between mGFR and eGFR allowing to identify patients at risk of acute kidney injury.

Blood creatinine/eGFR testing provides an opportunity for instant assessment of patient kidney function prior to treatment with a nephrotoxic procedure or drug therapy. This allows for an immediate decision to be made about any modification to the procedure or treatment in order to reduce the risk of acute kidney injury (AKI) in the CKD patients. In this situation practice guidelines are generally aimed at identifying as patients at risk of AKI patients with an eGFR <45 mL/min/1.73 m² or an eGFR <60 mL/min/1.73 m² depending on patient condition and how contrast media is received [17,18]. Identifying patients with CKD stages 3b, 4 and 5 has been shown to reduce the risk of a nephrotoxic event after treatment such as reduce the risk of contrast-induced acute kidney injury. The use of POCT creatinine in a radiology setting has also been reported to be cost effective in improving clinical operations [19].

First, we studied the agreement between laboratory creatinine and creatinine measurement with Statsensor®. The laboratory creatinine was measured by enzymatic method with calibration certified by Isotope Dilution Mass Spectrometry (IDMS) using Siemens Healthcare Systems, providing a reference value to compare to creatinine measurements with Statsensor®. Moreover, we compared two different blood specimens for creatinine measurement with statsensor®: capillary blood derived from finger puncture and venous blood. These 2 ways of blood collection stick to the clinical reality where blood can be taken from the catheter inserted for the iodine injection or can be taken by a finger puncture similarly to what happens for glycaemia monitoring in diabetic patients, being the latter a very straightforward way to assess kidney function before contrast driven imaging. Both methods provide good creatinine measurements since bias are low with a trend towards the overestimation. Bland and Altman plot showed good agreement between creatinine measurements and a trend to increase overestimation when creatinine increases. In addition, we performed two consecutive blood samplings (both capillary and venous) during the 4 h inuline clearance period and we found a low variation either with capillary or venous blood, showing good reproducibility of the BCMS method.

The CKD-EPI based equation is now established for calculating eGFR based on patient serum creatinine measurements explaining why we chose to use this formula to estimate GFR with creatinine measured from StatSensor® device. In this present study, median bias between mGFR and eGFR using CKD-EPI formula and laboratory enzymatic creatinine was similar to previous published paper [20]. Median Bias with CKD-EPI formula using creatinine from StatSensor® device were higher and acceptable for a GFR screening. The StatSensor® device tends to underestimate GFR explaining why around 90% of patients are correctly classify with a GFR <30 mL/min/1.73 m² and more than 80% for GFR <60 mL/min. In our study capillary and venous blood eGFR assessment showed good concordance and allow to identify patients with eGFR <60 mL/min/1.73m². The trend for lower StatSensor® eGFR results will improve the sensitivity for identifying at risk patients of AKI. This will increase the likelihood of falsely identifying patients with Stage 3/4/5 CKD but the status of these patients will be clarified with follow-up laboratory testing.

Only one previous study compared eGFR and a measured GFR by plasma clearance with iohexol [11]. In the present study, we confirmed previous results using another reference method to measure GFR, a urinary clearance with inuline.

Recently a new CKDEPI equation has been published to remove race in the equations. Because we studied an European population, we did not use the race correction initially for estimating eGFR. In our experience, the new CKD-EPI is less accurate for European population than the previous one, explaining why we showed results with CKDEPI_AS and CKDEPI_AS.

Our study has some limitations. First of all, it was a single centre study with a small number of patients. However almost 60% of patients had a GFR <60 mL/min/1.73 m. Secondly, as mentioned in a previous study [11], the subjects undergoing GFR measurement in our study were not randomly selected but they underwent GFR measurement because we suspected a difficulty of GFR estimation as suspicion of muscle wasting.

5. Conclusions

The use of a handheld blood creatinine monitoring system with eGFR calculation provides a good estimation of GFR as compared with a gold standard method for GFR determination. Creatinine measurement and GFR estimation provide good results either with capillary blood or with venous blood and can be thus easily used in clinical practice to screen patients.

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Declaration of competing interest

Nothing to declare.

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