A comparison of observed versus estimated baseline creatinine for determination of RIFLE class in patients with acute kidney injury

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Abstract

Background. The RIFLE classification scheme for acute kidney injury (AKI) is based on relative changes in serum creatinine (SCr) and on urine output. The SCr criteria, therefore, require a pre-morbid baseline value. When unknown, current recommendations are to estimate a baseline SCr by the MDRD equation. However, the MDRD approach assumes a glomerular filtration rate of ~75 mL/min/1.73 m2. This method has not been validated.

Methods. Data from the Beginning and Ending Supportive Therapy for the Kidney (BEST Kidney) study, a prospective observational study from 54 ICUs in 23 countries of critically ill patients with severe AKI, were analysed. The RIFLE class was determined by using observed (o) pre-morbid and estimated (e) baseline SCr values. Agreement was evaluated by correlation coefficients and Bland–Altman plots. Sensitivity analysis by chronic kidney disease (CKD) status was performed.

Results. Seventy-six percent of patients (n = 1327) had a pre-morbid baseline SCr, and 1314 had complete data for evaluation. Forty-six percent had CKD. The median (IQR) values were 97 µmol/L (79–150) for oSCr and 88 µmol/L (71–97) for eSCr. The oSCr and eSCr determined at ICU admission and at study enrolment showed only a modest correlation (r = 0.49, r = 0.39). At ICU admission and study enrolment, eSCr misclassified 18.8% and 11.7% of patients as having AKI compared with oSCr. Exclusion of CKD patients improved the correlation between oSCr and eSCr at ICU admission and study enrolment (r = 0.90, r = 0.84) resulting in 6.6% and 4.0% being misclassified, respectively.

Conclusions. While limited, estimating baseline SCr by the MDRD equation when pre-morbid SCr is unavailable would appear to perform reasonably well for determining the RIFLE categories only if and when pre-morbid GFR was near normal. However, in patients with suspected CKD, the use of MDRD to estimate baseline SCr overestimates the incidence of AKI and should not likely be used. Improved methods to estimate baseline SCr are needed.

Keywords: acute kidney injury; consensus definition; creatinine; RIFLE criteria; validation

Introduction

In 2004, the Acute Dialysis Quality Initiative (ADQI) Working Group, comprising experts in the fields of nephrology and critical care, developed a consensus definition and classification scheme for acute kidney injury (AKI): the RIFLE criteria [1]. These criteria define AKI into three grades of severity (risk, injury and failure) based on relative changes to serum creatinine (SCr) and urine output, and two clinical outcomes (loss, end-stage kidney disease) [1]. The RIFLE criteria have now been extensively evaluated across a range of clinical settings and been shown to have predictive ability, robustness and clinical relevance [1–10]. This has been an...
imported advancement for both clinical care and research activities in this field [1,11]. Recently, the Acute Kidney Injury Network (AKIN) has proposed modifications to the RIFLE criteria that included a threshold of absolute change in SCR of 0.3 mg/dL to fulfill the criteria for AKI within a 48-h period [12].

To apply the SCR component of the RIFLE or modified AKIN criteria in the diagnosis/classification of AKI, a pre-morbid baseline SCR value must be known. However, not uncommonly, baseline SCR values are either not available or unknown [13]. In these circumstances, the ADQI working group has recommended estimating a baseline SCR value by use of the Modification of Diet in Renal Disease (MDRD) equation [8] assuming a lower limit of normal glomerular filtration rate (GFR) of 75 mL/min/1.73 m² [1,14]. This method has now been performed in numerous clinical studies [2,3,5,13]; however, it has not been validated. In the study by Hoste et al., baseline SCR needed to be calculated for <50% of the cohort, while in those with documented chronic kidney disease (CKD), the SCR at the time of hospital admission was used as a baseline [13].

Accordingly, we interrogated data from the Beginning and Ending Support Therapy (BEST) Kidney study to evaluate and compare the diagnosis and classification of AKI by the RIFLE criteria using observed and estimated baseline SCR values.

Patients and methods

Study protocol

The BEST Kidney study was a prospective, multinational, multicentre observational cohort study of critically ill patients with severe AKI. The study was conducted at 54 centres across 23 countries as previously described [15]. The research ethics board at each participating centre reviewed the study protocol prior to commencement.

Study population

All patients aged >12 years admitted to a participating ICU with evidence of severe AKI were considered eligible for study inclusion. The operational definition for AKI and study inclusion for the BEST Kidney study was fulfillment of any one of the following criteria: (1) oliguria defined as a urine output <200 mL over 12 h, (2) marked azotaemia defined as a serum urea >30 mmol/L (84 mg/dL) and/or (3) need for acute RRT (renal replacement therapy). Patients with pre-existing end-stage renal disease receiving chronic RRT and those treated with RRT prior to ICU admission or for drug toxicity not associated with AKI were excluded.

Operational definitions

For this secondary analysis, AKI was defined by the RIFLE criteria. We applied the SCR criteria only to determine AKI and RIFLE categories. The study protocol required determination of a pre-hospital observed SCR (oSCR), when available, to represent a steady-state pre-morbid baseline SCR for each patient. The oSCR was then compared with the estimated baseline SCR (eSCR). The prevalence of CKD in the BEST Kidney study, defined as any impairment or abnormality in baseline SCR, was 36.5% (n = 480). However, for the purpose of this secondary analysis, CKD was quantitatively characterized according to the K/DOQI CKD stage. For each patient, baseline estimated glomerular filtration rate (eGFR) was calculated by the MDRD equation. CKD was then defined by K/DOQI CKD Stage III or worse (i.e. eGFR <60 mL/min/1.73 m²). This corresponded to a significantly higher estimated prevalence of CKD in the cohort [46.0% (n = 605)].

Method to estimate baseline SCR

The eSCR values were derived by solving the MDRD equation, with the assumption of a near lower limit of normal GFR of 75 mL/min/1.73 m², as recommended by the ADQI working group using the following equation [14]:

\[
\text{Serum creatinine} = 75/(186 \times (\text{age}^{−0.203}) \times (0.742 \text{ if female} \times 1.21 \text{ if black}))^{−0.887}
\]

Data collection

All data were prospectively collected on standardized data forms. Data variables collected included age, sex, body weight, presence of pre-morbid CKD (any evidence of abnormal SCR or creatinine clearance prior to hospital admission) and type of admission. Measures of kidney function (i.e. SCR, urea, urine output) were documented at hospital and ICU admission, at study enrolment, and at ICU and hospital discharge. Clinical outcomes assessed included hospital survival, renal recovery (i.e. independence from RRT), duration of RRT and length of ICU and hospital stay.

Statistical analysis

Analysis was performed using Stata Release 10 (Stata Corp., College Station, TX, USA). Normally or near normally distributed variables were presented as means and standard deviations (SD) and compared using Student’s t-test or one-way analysis of variance (ANOVA) for repeated measures when appropriate. Non-normally distributed continuous data were presented as medians and inter-quartile ranges (IQR) and compared using the Mann–Whitney U or Kruskal–Wallis test, respectively. Categorical data were compared with Fisher’s Exact Test. Agreement between oSCR and eSCR was evaluated by correlation coefficients and Bland–Altman plots. Sensitivity analysis by CKD status was performed. A P-value <0.05 was considered significant.

Results

During the study period, 1753 critically ill patients developed severe AKI. In total, 75.7% (n = 1327) of the cohort had a pre-morbid baseline SCR available, and of these, 1314 (99%) had complete data for evaluation. The median time from hospital presentation to ICU admission and study enrolment was 2 (0–7) days and 6 (2–14) days, respectively.

Study population

The baseline characteristics of the cohort are summarized in Table 1. The mean (SD) age was 63.6 (15.6) years, 63% were male and 46.0% had pre-existing CKD, defined as an eGFR <60 mL/min/1.73 m². Observed and estimated kidney function at baseline, at ICU admission and at the time of study enrolment is also shown in Table 1.

Use of estimated SCR in the total cohort

At the time of ICU admission, use of eSCR to capture AKI by RIFLE category classified more patients as having AKI but was associated with an 18.8% false positive rate (Table 2 and Figure 1A).

When applied at the time of study enrolment (i.e. patient fulfilled the BEST Kidney study operational definition for AKI), the eSCR had a false positive rate of 11.7% (Table 2 and Figure 1B). Most of this misclassification occurred when patients were wrongly designated as RIFLE category—failure. Alternatively, the use of the eSCR
under-estimated the presence of AKI by 7.3% in those designated RIFLE category—risk (false negative). Overall, the correlation between observed and estimated SCr was modest at best.

Use of estimated SCr excluding CKD patients

After exclusion of CKD patients from the analysis, the correlation between eSCr and oSCr for determining AKI and RIFLE category improved considerably (Table 3). In this subgroup, the rates of misclassification at ICU admission and at the time of study enrolment were only 6.6% and 4.0%, respectively (Figure 2A and B).

Discussion

We conducted an analysis of a large database of AKI patients to evaluate the validity and compare the performance of using an estimate of baseline SCr, determined by the MDRD equation, with observed baseline SCr for diagnosis and classification of AKI by the RIFLE criteria.

We found that use of eSCr for determining RIFLE category, when applied to the entire cohort, was associated with considerable misclassification of patients and only modest overall correlation with observed values. Specifically, the use of eSCr resulted in false positive rates for AKI of 18.8% at the time of ICU admission and 11.7% at the time of enrolment in the BEST Kidney study. The degree of misclassification worsened with increasing severity grade of RIFLE category. We found that the high rate of misclassification was largely attributable to patients with CKD. When we excluded those with CKD, the rate of misclassification and correlation between eSCr and oSCr for classification of AKI by the RIFLE criteria improved markedly.

The RIFLE classification scheme for AKI represents a fundamentally important step forward for clinical and research activity in critical care nephrology. This classification scheme is analogous to prior consensus definitions applied to other complex syndromes in critical illness such as acute respiratory distress syndrome and sepsis [16,17]. These consensus criteria have led to meaningful research activity and advances for these syndromes, including describing the burden of illness and novel therapeutic strategies [18–20]. The expectation is that broad consensus for a definition of AKI would lead to similar progress.

Nonetheless, the RIFLE criteria (or modified AKIN criteria) are not perfect, have limitations and require prospective validation prior to their integration into epidemiologic studies, randomized trials and/or routine clinical practice. Numerous investigations have now evaluated the RIFLE criteria in >200 000 patients [2–5,10]. From these data, there is general agreement that the RIFLE criteria (or modified AKIN criteria) perform well, are a valid and
Table 2. Details of kidney function stratified by the RIFLE criteria

<table>
<thead>
<tr>
<th>Serum creatinine</th>
<th>Observed (%)</th>
<th>Estimated (%)</th>
<th>Absolute difference (%)</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At ICU admission</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>723 (55.1)</td>
<td>477 (36.3)</td>
<td>246 (18.8)</td>
<td>0.49</td>
</tr>
<tr>
<td>Risk</td>
<td>209 (15.9)</td>
<td>199 (15.2)</td>
<td>10 (0.7)</td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>179 (13.6)</td>
<td>251 (19.1)</td>
<td>−72 (−5.5)</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>202 (15.4)</td>
<td>386 (29.4)</td>
<td>−184 (−14)</td>
<td></td>
</tr>
<tr>
<td>Any AKI</td>
<td>590 (44.9)</td>
<td>836 (63.7)</td>
<td>−246 (−18.8)</td>
<td></td>
</tr>
<tr>
<td><strong>At enrolment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>287 (21.9)</td>
<td>134 (10.2)</td>
<td>153 (11.7)</td>
<td>0.39</td>
</tr>
<tr>
<td>Risk</td>
<td>233 (17.8)</td>
<td>138 (10.5)</td>
<td>95 (7.3)</td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>313 (23.9)</td>
<td>316 (24.1)</td>
<td>−3 (−0.2)</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>479 (36.5)</td>
<td>724 (55.2)</td>
<td>−245 (−18.7)</td>
<td></td>
</tr>
<tr>
<td>Any AKI</td>
<td>1025 (78.1)</td>
<td>1178 (89.8)</td>
<td>−153 (−11.7)</td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Details of kidney function stratified by the RIFLE criteria excluding patients with CKD

<table>
<thead>
<tr>
<th>Serum creatinine</th>
<th>Observed (%)</th>
<th>Estimated (%)</th>
<th>Absolute difference (%)</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>At ICU admission</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>342 (48.3)</td>
<td>389 (54.9)</td>
<td>−47 (−6.6)</td>
<td>0.90</td>
</tr>
<tr>
<td>Risk</td>
<td>112 (15.8)</td>
<td>100 (14.1)</td>
<td>12 (1.7)</td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>107 (15.1)</td>
<td>106 (15.0)</td>
<td>1 (0.1)</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>147 (20.8)</td>
<td>113 (16.0)</td>
<td>34 (4.8)</td>
<td></td>
</tr>
<tr>
<td>Any AKI</td>
<td>366 (51.7)</td>
<td>319 (45.1)</td>
<td>47 (6.6)</td>
<td></td>
</tr>
<tr>
<td><strong>At enrolment</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>85 (12.0)</td>
<td>113 (16.0)</td>
<td>−28 (−4.0)</td>
<td>0.84</td>
</tr>
<tr>
<td>Risk</td>
<td>80 (11.3)</td>
<td>98 (13.9)</td>
<td>−18 (−2.6)</td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>164 (23.2)</td>
<td>192 (27.2)</td>
<td>−28 (−4.0)</td>
<td></td>
</tr>
<tr>
<td>Failure</td>
<td>378 (53.5)</td>
<td>304 (43)</td>
<td>74 (10.5)</td>
<td></td>
</tr>
<tr>
<td>Any AKI</td>
<td>622 (88.0)</td>
<td>594 (84.0)</td>
<td>28 (4.0)</td>
<td></td>
</tr>
</tbody>
</table>

Fig. 2. (A) Bland–Altman plot of actual versus estimated baseline serum creatinine at ICU admission excluding patients with CKD. X-axis, average of actual and measured baseline creatinine; Y-axis, difference between actual and measured baseline creatinine. (B) Bland–Altman plot of actual versus estimated baseline serum creatinine at study enrolment excluding patients with CKD. X-axis, average of actual and measured baseline creatinine; Y-axis, difference between actual and measured baseline creatinine.

A robust tool and have clinical relevance for correlation with patient-centred outcomes [4,11]. However, a potentially problematic issue with the RIFLE criteria (or modified AKIN criteria) is whether the criteria can apply an estimate of baseline kidney function (i.e. SCr) when such a value is either not available or unknown [2,3,15]. This scenario is not unusual [13]. Prior studies have used SCr at the time of hospital presentation as proxy for baseline SCr. However, this SCr value may be modified by the acute illness prompting hospitalization, is unlikely
to be representative of true baseline steady state, and may lead to misclassification [21]. While actual baseline kidney function, when unknown, cannot truly be estimated, current recommendations are to calculate an estimate of baseline SCr by the MDRD equation to enable the classification of AKI. This premise operates on the assumption that the MDRD equation can act as a reasonable surrogate for baseline SCr in most clinical circumstances; however, this may not be true. The observed misclassification in our study would suggest that ideally, a prior known or documented SCr value should be used to diagnose and classify the severity of AKI by the RIFLE criteria whenever possible. Yet, our data would also suggest that this method may be a practical and reasonably valid approach only in circumstances where the pre-morbid kidney function was likely to be near normal or there was no objective evidence to indicate underlying CKD (i.e. risk factors, urine studies, diagnostic imaging). If, on the other hand, the MDRD equation is applied to CKD patients or in populations where a high prevalence of CKD is suspected, this method may greatly overestimate the occurrence and/or severity of AKI. Failing to appreciate this limitation and misclassifying patients as having (or not having) a diagnosis of AKI may translate into significant differences in the therapeutic and prognostic approach to patient care. Fortunately, most patients with a prior diagnosis of CKD are likely to have a SCr value available in their medical record.

We recognize that there are limitations to our study that warrant discussion. First, this was a secondary interrogation of the BEST Kidney study data, and in general, patients enrolled in this study were all critically ill and had severe AKI not diagnosed by the RIFLE criteria. Second, for the purposes of this specific analysis, patients were classified as having AKI on the basis of the RIFLE–SCr criteria only and not based on urine output, serum urea or having received RRT. Accordingly, the described occurrence of AKI in this analysis does not reflect true occurrence of AKI in the BEST Kidney study (as all patients had severe AKI in order to be enrolled). We recognize that use of the SCr criteria to classify AKI modified the occurrence of AKI. However, our intent in this analysis was to specifically examine the SCr criteria only and compare the performance of observed and estimated baseline SCr to determine the RIFLE class at various time points. Finally, we did not specifically evaluate the proposed modified AKIN criteria for AKI, as both criteria essentially operate on the assumption of calculating a baseline SCr by the MDRD equation when an observed value is unavailable.

In summary, whenever possible, prior documented SCr values likely to be representative of baseline SCr should be used when applying the RIFLE criteria. However, when unavailable, estimating the baseline SCr by the MDRD equation represents a reasonable mechanism for diagnosing/classifying AKI in critically ill patients with severe AKI only if and when pre-morbid GFR is near normal. For patients with known or suspected CKD, the MDRD method will overestimate the incidence of AKI and should not likely be used in these circumstances. However, better methods to estimate baseline creatinine would be welcome. Future refinements to the RIFLE criteria that incorporate provisions for discrimination of kidney ‘injury’ from changes to or loss of kidney ‘function’, perhaps by use of novel biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL), kidney injury molecule-1 (KIM-1) and interleukin-18 (IL-18), could potentially circumvent this issue.

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Conflict of interest statement. None declared.

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