Original article

Prognostic value of new-onset anemia as a marker of hemodilution in patients with acute decompensated heart failure and severe renal dysfunction

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A R T I C L E   I N F O

Article history:
Received 22 August 2013
Received in revised form 16 October 2013
Accepted 6 November 2013
Available online 22 December 2013

Keywords:
Heart failure
Renal function
Hemodynamics
Prognosis

A B S T R A C T

Background and purpose: In patients with acute decompensated heart failure (ADHF), the prognostic value of new-onset anemia with regard to renal function has not been investigated.

Methods and subjects: Consecutive 299 ADHF patients (162 men, 62 ± 14 years) were enrolled. Cardiovascular (CV) events composite of CV mortality and rehospitalization occurred in 113 patients (37.8%) during 2 years of follow-up.

Results: Baseline anemia was prevalent (n = 124, 41.5%) and 43 patients (14.4%) had new-onset anemia at 1 month after discharge. Baseline anemia was strongly associated with CV events risk in overall [hazard ratio (HR): 1.79, 95% CI: 1.17–2.74, \(p=0.006\)] and those with preserved renal function [estimated glomerular filtration rate (eGFR) \(\geq 45\) mL/min/1.73 m\(^2\)] (HR: 1.81, 95% CI: 1.05–3.12, \(p=0.031\)). In patients with severe renal dysfunction (eGFR < 45 mL/min/1.73 m\(^2\)), new-onset anemia independently predicted CV events (HR: 2.72, 95% CI: 1.09–6.76, \(p=0.031\)) whereas baseline anemia did not (HR: 1.28, 95% CI: 0.61–2.65, \(p=0.505\)). New-onset anemia was significantly associated with hemodilution, which may reflect inadequate decongestion in ADHF patients.

Conclusions: Baseline anemia was an independent prognostic factor in overall ADHF patients and those with preserved renal function. New-onset anemia as a surrogate for hemodilution better predicted CV events than baseline anemia in ADHF patients with severe renal dysfunction.

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Introduction

Anemia is a common and well-known predictor of poor prognosis in patients with chronic heart failure (HF) [1]. The strong association between the presence of anemia and mortality in chronic HF has been demonstrated in numerous studies [2–5]. New-onset anemia or decrease of hemoglobin level over time was also related to increased long-term mortality and morbidity in stable chronic HF patients [6,7]. In acute decompensated HF (ADHF) patients, however, a few studies have demonstrated that anemia at initial presentation was associated with poor prognosis and the prognostic value of serial assessment of anemia in ADHF has not been intensively investigated [8–10].

Renal dysfunction and hemodilution has been known to be closely interrelated between anemia and adverse outcomes in HF [11–13]. A meta-analysis showed that the effect of anemia on mortality attenuated with increasing serum creatinine level [14]. A recent large HF registry data also showed that baseline anemia was not an independent predictor of all-cause mortality in outpatients with heart failure with severe renal dysfunction [15]. These findings implicate that the prognostic value of baseline anemia might be attenuated when combined with renal dysfunction not only in chronic HF, but also in hospitalized ADHF patients. Instead, serial assessment of anemia reflecting hemodilution due to volume expansion might provide better information on prognosis in ADHF patients with or without severe renal dysfunction [12]. Thus, we aimed to study the prognostic value of baseline anemia and new-onset anemia in ADHF patients according to the presence of severe renal dysfunction.

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http://dx.doi.org/10.1016/j.jjcc.2013.11.007
Materials and methods

Study population

Three-hundred twenty consecutive patients who visited the emergency department (ED) of Severance Cardiovascular Hospital, Seoul, Korea between January 2005 and March 2010 with clinical diagnosis of ADHF were retrospectively investigated in this study, followed up until June 2012. Patients were eligible to be enrolled in this analysis if they were alive at 1 month after hospital discharge. Diagnosis of ADHF was made based on presence of clinical symptoms (dyspnea on exertion, orthopnea, or generalized or pulmonary edema) and left ventricular ejection fraction (LVEF) < 50% measured by two-dimensional trans-thoracic echocardiography. Patients with known hematologic diseases including hematolytic anemia, presence of cancer, pregnancy, acute bleeding events or blood transfusion or iron replacement therapy within 3 months or during hospitalization, and other extracellular fluid-increasing diseases such as liver cirrhosis were excluded from analysis and 299 patients remained in the analysis. This study was approved by the institutional review board of Severance Hospital.

Laboratory measurements

Blood samples were obtained by ante-cubital venipuncture into ethylenediaminetetraacetic acid-treated or plain tubes at the time of admission to the ED and at 1 month after discharge. Hematologic variables such as hemoglobin and hematocrit were measured using the Advia 2120i automated analyzer (Siemens Healthcare Diagnostics, Deerfield, IL, USA). Anemia was defined in accordance with the World Health Organization (WHO) as hemoglobin levels < 13.0 g/dL in men and 12.0 g/dL in women. Baseline anemia was defined as anemia at initial presentation and new-onset anemia was defined as presence of anemia at 1 month after discharge without the evidence of baseline anemia. Serum creatinine level was calibrated to isotope dilution mass spectrometer (IDMS) method according to international standards. Renal function was determined by estimated glomerular filtration rate (eGFR, mL/min/1.73 m²) using Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation [16]. Severe renal dysfunction was defined as eGFR < 45 mL/min/1.73 m². In a prior study about the effect of aggressive decongestion on renal function and prognosis, Testani and his colleagues used pairs of surrogate markers including delta of hematocrit, albumin, and total protein as the evidence of decongestion [17]. We applied this concept to define hemodilution associated with new-onset anemia in heart failure. Hemodilution was defined as 2 ≥ 3 of delta hematocrit, delta total protein, or delta albumin in the lowest tertile. Data on loop diuretics dose before admission, during hospitalization, and at discharge were collected and torasemide doses were converted to dose equivalents to furosemide using conversion value of 4 [18].

Clinical outcomes

Detailed follow-up data of all patients including mortality and hospitalization were retrieved from the electronic medical record system of the hospital. Median follow-up duration after initial admission was 710 days [interquartile range (IQR) 288–1256 days]. The primary endpoint was cardiovascular (CV) events defined as composite of 2-year CV mortality or rehospitalization due to worsening of congestive symptoms by heart failure aggravation, acute coronary syndrome, arrhythmia, or cardiac arrest.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation (SD), median (IQR) and categorical variables as numbers (%). To compare the baseline and follow-up data, we used one-way analysis of variance (ANOVA) with Bonferroni method, Kruskal–Wallis test, t-test, and Wilcoxon rank-sum test for continuous variables and chi-square test for categorical variables as appropriate. Spearman correlation analysis was used to assess the correlation between delta of hemoglobin, hematocrit, total protein, albumin, and eGFR. Comparisons of 2-year CV events among baseline, new-onset, and non-anemia groups were done by Kaplan–Meier survival analyses with log-rank test. Logistic regression analyses were done to determine the independent association of hemodilution with new-onset anemia. The independent prognostic value of baseline anemia and new-onset anemia was assessed using multivariate Cox proportional hazard model incorporating covariates with p < 0.10 on univariate analysis. No covariates violated proportional hazard assumption. All given p-values are two sided and the level of statistical significance was set to 0.05. All statistical analyses were performed using STATA 12.0 (Stata Corp, College Station, TX, USA).

Results

Baseline characteristics of study population

Among a total of 299 patients analyzed in this study, 162 (54%) were men and the mean age was 62.8 ± 14.1 years. Baseline anemia was found in 132 patients (44.1%) and new-onset anemia at 1 month after discharge occurred in 43 patients (14.4%). The majority (83.3%) was normocytic [mean corpuscular volume (MCV) 82–98 fl.] and macrocytic anemia and microcytic anemia were observed in 4.4% and 4.4% of patients, respectively. Baseline characteristics by anemia are presented in Table 1. Compared with patients with new-onset anemia and with no anemia, those who had baseline anemia were more likely to have older age, previous use of higher dose of loop diuretics, lower renal function, and lower serum albumin level. Patients with new-onset anemia were associated with lower renal function, lower baseline hemoglobin level, and lower total doses of discharge diuretics compared to those without anemia. Among anemia groups, MCV did not differ and mean corpuscular hemoglobin (MCH) and mean corpuscular hemoglobin concentration (MCHC) had statistically significant but clinically trivial difference.

During median follow-up of 710 days (IQR 288–1256 days), 2-year CV events as a composite of CV mortality and rehospitalization occurred in 113 patients (37.8%) and 30.9% among them (35/113) had CV mortality. Non-CV mortality occurred only in 1 patient (0.66%). When compared with patients without CV events, those who had CV events were more likely to be older and to have lower hemoglobin, hematocrit, eGFR, systolic blood pressure, and sodium level (p < 0.05 in all). Prevalence of baseline anemia was significantly higher in CV events group (56.6% vs. 36.6%, p < 0.001).

Discharge hemoglobin data were available in a subset of 277 patients. Anemia at discharge was present in 166 patients (59.9%) and 115 patients among them (69.3%) had anemia at admission. Among patients without anemia at baseline, development of anemia at discharge occurred in 51 patients (33.3%) and they had higher 2-year CV events rate compared to those without development of anemia (39.2% vs. 24.5%, Log-rank p = 0.025). Among patients with new-onset anemia, 37 (88.1%) had anemia at discharge (p < 0.001).
with severe renal dysfunction (eGFR < 45 mL/min/1.73 m²), how-

significant (ACE, angiotensin-converting enzyme; BP, blood pressure; SD, standard deviation; MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin; MCHC, mean corpuscular hemoglobin concentration; WBC, white blood cell count; BUN, blood urea nitrogen; eGFR, estimated glomerular filtration rate; NT-proBNP, N-terminal pro-brain natriuretic peptide.

Anemia group and non-anemia group showed similar outcomes whereas new-onset anemia were associated with poor prognosis, whereas new-onset anemia (IQR 2.1 to 3.5), delta total protein (<0.1; 0.3 (IQR 0.1 to 0.5)), or delta albumin [<0.0; 0.2 (IQR −0.1 to 0.5)]. In overall ADHF patients, hemodilution was observed in 28% (24.3%) and the prevalence was significantly higher in those with new-onset anemia compared to those with baseline anemia or without anemia (41.6% vs. 24.7% vs. 17.7%, p = 0.016). Compared to those without hemodilution, incidence of 2-year CV events was higher in those with hemodilution with marginal statistical significance (45.9% vs. 33.1%, p = 0.072) while prevalence of severe renal dysfunction was similar between two groups (29.5% vs. 25.8%, p = 0.568).

**Prognostic value of baseline anemia and new-onset anemia for 2-year CV events in ADHF according to presence of renal dysfunction**

In overall ADHF patients, patients with baseline anemia had worse 2-year prognosis than those without anemia (48.4% vs. 26.6%, Log-rank p = 0.001, Fig. 1). In patients with preserved renal function (eGFR ≥ 45 mL/min/1.73 m²), those with baseline anemia were associated with poor prognosis, whereas new-onset anemia group and non-anemia group showed similar outcomes (42.2% vs. 24.2% vs. 26.1%, Log-rank p = 0.009). In ADHF patients with severe renal dysfunction (eGFR < 45 mL/min/1.73 m²), however, those with new-onset anemia had highest CV events rate compared to baseline anemia and non-anemia (80.0% vs. 55.7% vs. 30.7%, Log-rank p = 0.046). To assess the independent prognostic value, baseline anemia and new-onset anemia were entered separately into multivariate Cox-proportional hazard model with other potential predictors and only baseline anemia was independently associated with CV events at 2 years in overall ADHF patients [hazard ratio (HR) 1.79 with 95% confidence interval (CI) 1.18–2.74, p = 0.006, Fig. 2] and in those with preserved renal function (HR 1.81, 95% CI 1.05–3.12, p = 0.031). Similarly, when hemoglobin was entered as a continuous variable, 1 g/dL increase of baseline hemoglobin level was associated with 10% reduction of 2-year CV events risk (HR 0.90, 95% CI 0.82–0.99, p = 0.032) in patients with ADHF. However, the prognostic value of baseline anemia was attenuated in those with severe renal dysfunction (HR 1.28, 95% CI 0.61–2.65, p = 0.505) whereas new-onset anemia independently predicted 2-year CV events in those with severe renal dysfunction (HR 2.72, 95% CI 1.09–6.76, p = 0.031). Interaction between new-onset anemia and severe renal dysfunction was statistically significant (p for interaction = 0.012).

**Association of hemodilution surrogates with renal function and anemia in ADHF**

To investigate the role of hemodilution on varying prognostic value of anemia by severe renal dysfunction in ADHF patients, the complete pairs of follow-up hematocrit, albumin, and total protein data as a surrogate for hemodilution were analyzed in the subset of 251 patients with available data. Hemodilution was defined as ≥ 3 of lowest tertile in delta hematocrit (<−1.0; median 1.1 (IQR −2.1 to 3.5)), delta total protein [<0.1; 0.3 (IQR −0.1 to 0.5)], or delta albumin [<0.0; 0.2 (IQR −0.1 to 0.5)]. In overall ADHF patients, hemodilution was observed in 33% (24.3%) and the prevalence was significantly higher in those with new-onset anemia compared to those with baseline anemia or without anemia (41.6% vs. 24.7% vs. 17.7%, p = 0.016). Compared to those without hemodilution, incidence of 2-year CV events was higher in those with hemodilution with marginal statistical significance (45.9% vs. 33.1%, p = 0.072) while prevalence of severe renal dysfunction was similar between two groups (29.5% vs. 25.8%, p = 0.568).

**Predictors of anemia in ADHF patients by severe renal dysfunction**

Compared to patients with preserved renal function (N = 215, eGFR ≥ 45 mL/min/1.73 m²), patients with severe renal dysfunction (N = 84, eGFR < 45 mL/min/1.73 m²) had lower baseline hemoglobin level (11.4 vs. 13.1 g/dL, p < 0.001) and higher prevalence of baseline anemia (72.6% vs. 33.0%, p < 0.001). Among 167 patients without baseline anemia, patients with severe renal dysfunction (N = 23) had higher prevalence of new-onset anemia (43.5% vs. 22.9%, p = 0.036) and had a tendency to show lower decrease in hemoglobin level (−0.8 vs. −0.3, p = 0.099) compared to the preserved renal function group (N = 144). In multivariate logistic
analyses, old age, impaired renal function, and low body mass index (BMI), and higher doses of previous loop diuretics were significantly associated with presence of baseline anemia. Hemodilution, low baseline hemoglobin, ischemic etiology, and lower doses of loop diuretics at discharge were the independent predictors of new-onset anemia (Table 2). When hemodilution was entered into multivariate logistic model for new-onset anemia, presence of hemodilution was significantly associated with about 3-fold higher risk of new-onset anemia [odds ratio (OR) 3.53, 95% CI 1.32–9.43, \( p = 0.012 \)]. Delta of each surrogate in lowest tertile was also significantly associated with new-onset anemia except total protein with marginal significance (hematocrit, OR 10.95, 95% CI 4.20–28.52, \( p < 0.001 \); albumin, OR 2.90, 95% CI 1.12–7.47, \( p = 0.027 \); total protein, OR 2.09, 95% CI 0.96–4.58, \( p = 0.063 \)).

### Discussion

The principal findings of this study are as follows: (1) baseline anemia was prevalent and was associated with poor prognosis in overall ADHF patients and in a subgroup with preserved renal function; (2) in patients with severe renal dysfunction, however, baseline anemia was not an independent predictor of CV events whereas presence of new-onset anemia was significantly associated with 2.7-fold increased CV events risk after adjustment for other potential confounders; and (3) hemodilution was an independent predictor of new-onset anemia in ADHF patients.

### Table 2

<table>
<thead>
<tr>
<th>Variables</th>
<th>Univariate</th>
<th>Multivariate</th>
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<tbody>
<tr>
<td></td>
<td>Odds ratio (95% CI)</td>
<td>Odds ratio (95% CI)</td>
</tr>
<tr>
<td></td>
<td>( p )-Value</td>
<td>( p )-Value</td>
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<tr>
<td><strong>Predictors for baseline anemia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (+1 year)</td>
<td>1.03 (1.01–1.05)</td>
<td>1.02 (1.00–1.04)</td>
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<tr>
<td>( \text{BMI} ) (+1 kg/m(^2))</td>
<td>0.92 (0.87–0.97)</td>
<td>0.93 (0.87–0.99)</td>
</tr>
<tr>
<td>Low eGFR (&lt;45 mL/min/1.73 m(^2))</td>
<td>5.37 (3.08–9.39)</td>
<td>4.19 (2.34–7.52)</td>
</tr>
<tr>
<td>Loop diuretics at admission (+20 mg/day)</td>
<td>1.25 (1.06–1.47)</td>
<td>1.19 (1.00–1.43)</td>
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| **Predictors for new-onset anemia** |                                |                                |
| Hemodilution          | 3.27 (1.42–7.48)               | 3.53 (1.32–9.43)               |
| Baseline hemoglobin (+1 g/dL) | 0.75 (0.57–0.98)            | 0.58 (0.41–0.84)               |
| Ischemic etiology     | 4.36 (2.07–9.20)               | 4.23 (1.74–10.29)              |
| Loop diuretics at discharge (+20 mg/day) | 0.69 (0.49–0.97) | 0.75 (0.50–1.12)               |

\( p \)-Value: \( <0.001 \), \( 0.001 \), \( 0.039 \), \( 0.001 \), \( 0.035 \), \( 0.012 \), \( 0.004 \), \( 0.001 \), \( 0.169 \).

CI, confidence interval; BMI, body mass index, eGFR, estimated glomerular filtration rate.

**Fig. 1.** Kaplan–Meier survival curve for 2-year cardiovascular events according to baseline anemia, new-onset anemia, and no anemia in acute decompensated heart failure (ADHF). (A) Overall, (B) with preserved renal function, and (C) with severe renal dysfunction. CV, cardiovascular; eGFR, estimated glomerular filtration rate.

**Fig. 2.** Multivariate-adjusted hazard ratio for 2-year cardiovascular events in patients with acute decompensated heart failure grouped by presence of severe renal dysfunction and anemia status at 1 month after discharge. HR, hazard ratio; CI, confidence interval; eGFR, estimated glomerular filtration rate.
Previous studies showed that the prevalence of anemia was relatively high in patients with ADHF (30–68%) and the prevalence of anemia in our data (44%) was within the range of previous reports [1,8,12]. The strong association between baseline anemia and poor prognosis in HF patients has been demonstrated in numerous studies [2–4,19,20]. In our study, we found independent association between baseline anemia and CV events at 2 years in overall patients and those with preserved renal function, which was consistent with previous studies. Linear decrease of CV events risk per baseline hemoglobin increase as a continuous variable was also similar to previous reports [21]. The predictive value of baseline anemia, however, was attenuated in ADHF patients with severe renal dysfunction. A large out-patient clinic based registry study showed that baseline anemia was not an independent predictor of all-cause mortality in patients with advanced HF or severe renal dysfunction, supporting our findings [15]. In a meta-analysis, Groeneveld et al. suggested that the effect of anemia on mortality declined with higher serum creatinine levels, which may imply that impaired renal function plays a greater role than anemia itself in association with poor prognosis in ADHF with impaired renal function [14].

In our study, new-onset anemia was a strong and independent predictor of 2-year CV events risk in ADHF patients with severe renal dysfunction. In large observational and clinical trial studies, new-onset anemia was associated with long-term mortality and morbidity in stable ambulatory HF patients in out-patients settings [6,7]. Maintaining high hemoglobin level, however, was associated with greater reduction in left ventricular mass index and wall thickness in HF patients with CKD not on dialysis [22]. Hemodilution has been suggested as a potential underlying mechanism for onset of anemia in HF and poor prognosis [12,23,24]. Androne et al. reported that the prevalence of hemodilution measured by I131-tagged albumin was high as 46% among advanced HF patients with anemia and those with hemodilution had worse prognosis than those with true anemia [12]. Among HF patients, hemodilution was more common in those with lower than preserved ejection fraction [25]. Hemodilution was significantly associated with development of low hemoglobin level when hemodilution defined as percentage of plasma volume was entered into multivariate regression model with other potential confounders for anemia in HF patients [24]. We observed high prevalence of hemodilution in ADHF patients with new-onset anemia and hemodilution was a potent independent predictor of new-onset anemia in our study, which supports previous findings. Previous studies demonstrated that hemoconcentration was significantly associated with aggressive fluid removal, transient renal function deterioration, and substantial improvement in survival, implicating the importance of aggressive decongestion during hospital admission [17,23].

In line with previous findings, development of anemia at discharge was significantly associated with poor prognosis and new-onset anemia at 1 month after discharge in this study. Considering the difficulties in achieving optimal decongestion such as diuretic resistance in patients with ADHF, it is reasonable to hypothesize that hemodilution significantly accounts for onset of anemia and for association with adverse outcomes in ADHF patients with severe renal dysfunction [26]. Taken together, our findings suggest that new-onset anemia, a potential indicator of hemodilution leading to poor prognosis, might provide better prognostic performance than baseline anemia in ADHF patients with severe renal dysfunction, although further studies are needed to understand the mechanism clearly.

Our study is limited by its retrospective observational design conducted in a single center. We cannot rule out the possibilities of residual confounding factors and biases, although extensive statistical adjustments were done. Patients with in-hospital mortality during first admission or CV events within 1 month after discharge were not eligible to be enrolled in our study, suggesting that our study might not be free from selection bias, although it was inevitable due to study design and similar methods were used in previous studies [7,10]. Arbitrary follow-up duration of 1 month after discharge was used to define new-onset anemia based on short-term follow-up period within 1 month according to similar previous studies [10,17,27]. Iron profile such as total iron binding capacity, serum ferritin level, and serum vitamin B12 level were not available in our data, even though we excluded the patients with acute bleeding events, on transfusion, or on iron replacement therapy and the majority of our patients had MCV and MCHC within normal range. Hemodilution was defined using surrogate markers such as the pair of hematocrit, albumin, and total protein in a subset of our patients. Given the significant association between new-onset anemia and the presence of 2 ≥ 3 of delta hematocrit, delta total protein, or delta albumin in the highest tertile, these surrogates were considered to provide good evidence of hemodilution, although no direct measurement for plasma volume was available in our study [17,23,28]. Further studies using direct measurement of volume status are needed to validate this concept. In our study, we observed that stratification by severe renal dysfunction had significant interaction on the association among baseline anemia, new-onset anemia, and CV events, leading to ambiguous effect of new-onset anemia on prognostication of CV events in those with preserved renal function, although there was no statistical significance. Previous studies with long-term follow-up on anemia in HF suggested that anemia in HF could be resolved with better control of fluid status and reversible concomitant conditions and this transient anemia was associated with similar outcomes compared with no anemia [6,7]. Considering the short length of follow-up time and definition of new-onset anemia in our study setting, it is conceivable that those with new-onset anemia and preserved renal function might have a higher chance of recovery from transient anemic status due to remaining kidney function compared to those with severe renal dysfunction, although it is hypothesis-generating. Long-term follow-up studies on anemia status, co-morbidities, fluid status, and responses to standard therapies are needed.

In conclusion, our study suggests that baseline anemia independently predicts 2-year CV events risk in overall ADHF patients and in a subgroup with preserved renal function but not in those with severe renal dysfunction. New-onset anemia reflecting hemodilution at 1 month after discharge may provide better prognostic information for CV events than baseline anemia in ADHF patients with severe renal dysfunction. Repeated measurement of hemoglobin, a simple low-cost strategy already available in most clinics, might have important implications on risk stratification of ADHF patients with respect to presence of severe renal dysfunction.

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