



## Original Article

# Do we need a simplified model to predict outcomes in patients hospitalized with Acute Decompensated Heart Failure? Results from The Role of Sodium in Heart Failure Outcomes Prediction ('SHOUT-PREDICTION') study



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## ABSTRACT

**Context:** Hyponatremia is associated with high in-hospital mortality in patients with acute decompensated Heart Failure (ADHF) and is one of the components in various risk scores in heart failure (HF). However, some risk scores predict outcomes in these patients without using hyponatremia as its component.

**Aim:** The study was aimed to evaluate the relationship between serum sodium levels at admission and clinical outcomes during the in-hospital course and three months' follow-up, in patients admitted in the intensive cardiac care unit (ICCU) with ADHF.

**Methods and material:** This was a single-center prospective, observational study in which 130 consecutive patients admitted with ADHF were observed for clinical characteristics and blood investigation at admission and their clinical outcomes during the in-hospital course and follow-up of 3 months.

**Results:** Hyponatremia and systolic blood pressure (SBP) both were found to be the independent predictor of in-hospital mortality. The SXS score (calculated as a product of SBP and serum sodium, divided by 1000) as a new prediction variable was significantly associated with in-hospital mortality and was compared with the Get with the guideline HF (GWTG-HF) score and ADHF national registry (ADHERE) score. The SXS score showed the best overall accuracy in predicting in-hospital mortality [area under the curve (AUC) = 0.899] as compared to the ADHERE (AUC = 0.780) and the GWTG (AUC = 0.815).

**Conclusions:** A score derived from the product of serum sodium and SBP (SXS score) had a significant association with in-hospital mortality, and better predictive value as compared to GWTG and ADHERE risk score in these patients.

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## 1. Introduction

Acute decompensated Heart failure (ADHF) is mostly defined as a clinical syndrome characterized by worsening signs or symptoms of heart failure (HF) requiring unscheduled hospital visits or medical care.<sup>1</sup> Despite its significant contribution to the increasing health burden with high in-hospital mortality (3%–8.7%), post-discharge mortality (8%–31%), and re-hospitalization (6%–38.1%), risk stratification scores are less commonly used in these patients.<sup>1–3</sup> In the presence of multiple risk prediction models for

HF, precisely predicting the risk in patients with ADHF becomes difficult.<sup>4,5</sup> Moreover, the complexity associated with these models results in their limited use. Another disadvantage is that the variables used in these scores are not consistently same. GWTG-HF score incorporates 7 variables, while ADHERE risk score uses only 3 variables to predict the risk. Moreover, serum sodium is used in GWTG-HF score but not in the ADHERE risk score.<sup>6,7</sup> Hyponatremia i.e. serum sodium (SNa)  $\leq 135$  mEq/L, is associated with around 20% of patients admitted with ADHF and has shown to predict poor outcomes in patients with worsening HF.<sup>1,8–13</sup> Although the majority of the risk scores for HF involve hyponatremia as one of the components, still, some HF-risk scores do not use SNa levels in their model.<sup>(6,7)</sup> The role of sodium in HF outcomes prediction ('SHOUT-PREDICTION') study was done to assess the importance of SNa in

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patients admitted in the intensive cardiac care unit (ICCU) with ADHF.

## 2. Methods

### 2.1. Study design and setting

This prospective observational study was conducted from March 2015 to October 2015 in a tertiary care teaching hospital from central India after obtaining ethical approval from the Institutional Ethics Committee.

### 2.2. Participants

Subjects satisfying inclusion and exclusion criteria were recruited in the study after obtaining written-informed-consent. The study included 130 consecutive patients admitted to the Intensive cardiac care unit (ICCU) with ADHF. The diagnosis of ADHF was based on the Boston criteria and only those patients classified as “definite” HF were included in the study.<sup>14</sup> Patients with sepsis, stenotic valvular heart disease, rheumatic heart disease, acute exacerbation of chronic obstructive pulmonary disease (COPD), acute coronary syndrome, and with recent (<3 months) history of myocardial infarction, or surgical procedure or any percutaneous procedure including angioplasty, stenting, or intra-cardiac device implantation in past 6 months were excluded from the study. After admission, patients were evaluated with a detailed history and clinical examination. Blood samples for SNa, renal function test, and complete blood count were taken at the time of admission. Patients were evaluated for in-hospital outcomes including length of stay, mortality, arrhythmia, myocardial infarction, and cerebrovascular event till discharge or death and then at 1 month, 2 months, and 3 months follow up post-discharge for assessing re-hospitalization rates, cardiovascular event, and mortality.

### 2.3. Variables

The primary outcome was in-hospital mortality due to cardiac causes and the secondary outcome was the length of stay in the hospital and hospitalization for HF after discharge during a 3-month follow-up.

### 2.4. Data sources

Data was collected and recorded in a case report sheet designed at the time of initiation of the study. Outcomes during the in-hospital course were confirmed through medical records. Post-discharge follow-up was done in the outpatient clinic of the hospital at 1 month, 2 months, and 3 months after discharge. Any event occurring in between the follow-up visit related to a worsening of symptoms requiring hospitalization or death was confirmed telephonically or at the next visit.

### 2.5. Statistical methods

The characteristics of the patients at baseline and their outcomes during the in-hospital course and 3-month follow-up were summarized as mean with standard deviation (SD) for continuous variables and as percentages for categorical variables. The comparison was done with the use of student *t*-tests for continuous variables and chi-square tests or fisher's test for categorical variables. Multivariate logistic regression analysis was done to assess independent predictors of mortality and other outcomes. Simple linear regression analysis, Pearson correlation, and analysis of

variance (ANOVA) were used to find the relation between the length of stay (continuous variable) and various predictors including SNa, systolic blood pressure (SBP), serum urea, serum creatinine, left ventricular ejection fraction (LVEF) and risk predicting scores. Receiver operating characteristic (ROC) curves were generated to estimate the accuracy of the new prediction model (product of SNa and SBP divided by 1000) in predicting in-hospital mortality. The area under the curve (AUC) was calculated for new prediction scores as well as for Get-with the guideline HF (GWTG-HF) and ADHF national registry (ADHERE) score for comparison. A two-sided *p*-value of <0.05 was considered statistically significant. All analyses were performed using SPSS 20.0 (IBM Corp, Armonk, NY, USA).

## 3. Results

### 3.1. Baseline characteristics

A total of 130 patients were enrolled in the study. Based on laboratory investigations done at the time of admission, 57 (43.8%) patients had SNa  $\leq 135$  mEq/L while 15 (11.5%) patients had SNa  $\leq 125$  mEq/L. Risk prediction was done with the GWTG-HF score and ADHERE score. The mean GWTG score was  $43.14 \pm 8.3$  with 101 patients having a score  $\leq 50$ . Based on the ADHERE risk score 72 patients were at low risk while remaining at intermediate risk. Baseline characteristics and laboratory parameters of patients are summarized in [Table 1](#).

### 3.2. Outcomes

#### 3.2.1. In-hospital mortality

Out of 130 patients, 114 were discharged however 16 patients had in-hospital death and all were due to cardiac causes preceded by cardiogenic shock. Characteristics of the patients who died during the in-hospital course were compared with survivors ([Table 2](#)). Amongst various parameters, SBP and SNa were significantly associated with in-hospital mortality ( $p < 0.001$  for both). On multivariate logistic regression analysis, both SBP [Odds Ratio (OR) = 1.052, 95% Confidence interval (CI) = 1.019–1.085] and SNa [OR = 1.11, 95% CI = 1.016–1.213] were found to independently predict the risk of in-hospital mortality.

**3.2.1.1. SXS score: new prediction tool.** Based on the above findings a new prediction model consisting of a product of SNa and SBP, divided by 1000 (SXS score) was produced. The lower value of the SXS score was expected to predict poor outcomes. The SXS score, GWTG score and ADHERE score were calculated for each patient and were compared with each other.

Using the SXS score, 75 patients were identified at lower risk (SXS score more than 15) and 55 patients at higher risk, out of which in-hospital death was 1 and 15 respectively. While the in-hospital death was 6 out of 101 patients predicted to have a low risk by GWTG score (Score  $\leq 50$ ) and 1 out of 72 patients identified at low risk by the ADHERE risk score. The ROC was generated and AUC was calculated which showed better accuracy of the SXS score (AUC = 0.899) as compared to the GWTG score (AUC = 0.815) and ADHERE risk score (AUC = 0.780) in predicting the risk of in-hospital mortality in these patients ([Fig. 1](#)).

#### 3.2.2. Other outcomes

The other outcomes including the length of stay in the hospital, re-hospitalization for HF, and post-discharge deaths are summarized in [Tables 3](#) and [4](#).

**Table 1**  
Baseline characteristics of patients.

Characteristic	n (%) or mean $\pm$ SD
Age (years)	58.13 $\pm$ 13.734
Male	81 (62.3%)
Comorbidities	
Hypertension	88 (67.7%)
DM	26 (20%)
CAD	117 (90%)
COPD	44 (33.8%)
Dyslipidemia	41 (31.5%)
History of CVA	5 (3.8%)
LVEF (%)	38.65 $\pm$ 11.47
Laboratory Parameters	
S. Sodium (m)	135.3 $\pm$ 7.3
Hyponatremia (Serum Na $\leq$ 135mEq/L)	57 (43.8%)
Severe Hyponatremia (Serum Na $\leq$ 125mEq/L)	15 (11.5%)
S. Potassium	4.38 $\pm$ 0.47
S. Urea (mg/dl)	44.95 $\pm$ 11.658
S. Creatinine (mg/dl)	1.36 $\pm$ 0.35
Hemoglobin (g/dl)	12.09 $\pm$ 0.18
GWTC-HF SCORE	43.14 $\pm$ 8.3
0-33 (Grade 1)	13 (10%)
34-50 (Grade 2)	88 (67.7%)
51-57 (Grade 3)	23 (17.7%)
58-61 (Grade 4)	6 (4.6%)
ADHERE risk score	
Low risk	72 (55.4%)
Intermediate Risk	58 (44.6%)
High Risk	0
Product of Serum Sodium and SBP divided by thousand (SXS Score)	17.135 $\pm$ 4.5
SXS Score	
>25 (Grade 1)	4 (3.1%)
20–24.9 (Grade 2)	39 (30%)
15–19.9 (Grade 3)	32 (24.6%)
10–14.9 (Grade 4)	51 (39.2%)
<10 (Grade 5)	4 (3.1%)

Abbreviations:- ADHERE: Acute decompensated heart failure national registry, CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, DM:Diabetes mellitus, GWTC-HF: Get with the guideline heart failure score, LVEF: Left ventricular Ejection Fraction, SNa: Sodium, SBP: Systolic Blood Pressure, SD: Standard deviation, SXS Score: Product of Serum Sodium and SBP divided by thousand.

**Table 2**  
Parameter comparison of patients of Acute Decompensated Heart Failure (ADHF) with different outcomes.

Parameters	Non-Survivors vs Survivor			Re-hospitalization vs No Re-hospitalization		
	n (%) or mean $\pm$ SD		p-value	n (%) or mean $\pm$ SD		p-value
Patients(n)	16	114	–	21	93	–
Age (years)	58.5 $\pm$ 11.8	58.0 $\pm$ 018	0.894	61 $\pm$ 12.3	57.4 $\pm$ 14.3	0.291
Male	10 (62.5%)	71 (62.3%)	0.986	15	56	0.338
Female	6	43	0.986	6	37	0.338
Comorbidities						
Hypertension (n)	10 (62.5%)	78 (68.42%)	0.635	11	67	0.08
DM (n)	5	21	0.313	4	17	1.000
COPD (n)	3	41	0.173	9	32	0.466
CAD (n)	16	101	0.154	19	82	0.764
LVEF (%)	37.19 $\pm$ 13.9	38.86 $\pm$ 11.151	0.587	35.48 $\pm$ 11.5	39.62 $\pm$ 10.99	0.124
SBP (mmHg)	91.25 $\pm$ 26.80	131.12 $\pm$ 29.002	<b>0.000*</b>	122.67 $\pm$ 25.2	133.0 $\pm$ 29.58	0.14
S. Urea (mg/dl)	49.7 $\pm$ 11.2	44.2 $\pm$ 11.6	0.078	47.48 $\pm$ 11.026	43.55 $\pm$ 11.674	0.162
S. Creatinine (mg/dl)	1.52 $\pm$ 0.37	1.34 $\pm$ 0.34	0.050	1.5 $\pm$ 0.35	1.3 $\pm$ 0.33	<b>0.015*</b>
Hemoglobin (g/dl)	11.6 $\pm$ 2.09	12.4 $\pm$ 2.11	0.252	12.67 $\pm$ 2.0	12.06 $\pm$ 2.1	0.193
S. Sodium (mEq/L)	128.7 $\pm$ 8.5	136.2 $\pm$ 6.7	<b>0.000*</b>	132.97 $\pm$ 7.28	137.0 $\pm$ 6.3	<b>0.012*</b>
Hyponatremia (S.Na<135mEq/L)	11	46	<b>0.032*</b>	11	35	0.213
Severe Hyponatremia (S.Na<125mEq/L)	7	8	<b>0.000*</b>	5	3	<b>0.005*</b>
GWTC-HF score	51.25 $\pm$ 6.39	42.0 $\pm$ 7.9	<b>0.000*</b>	45.24 $\pm$ 7.07	41.27 $\pm$ 7.9	<b>0.037*</b>
ADHERE score			<b>0.000*</b>			
Low risk	1	71		10	61	0.125
Intermediate risk	15	43		11	32	
High risk	0	0	–	0	0	–
SXS score	11.72 $\pm$ 3.24	17.89 $\pm$ 4.13	<b>0.000*</b>	16346.8 $\pm$ 3599	18244.9 $\pm$ 4189.4	0.057

Abbreviations: ADHERE: Acute decompensated heart failure national registry, CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, DM:Diabetes mellitus, GWTC-HF: Get with the guideline heart failure score, LVEF: Left ventricular Ejection Fraction, SNa: Sodium, SBP: Systolic Blood Pressure, SD: Standard deviation, SXS Score: Product of Serum Sodium and SBP divided by thousand.

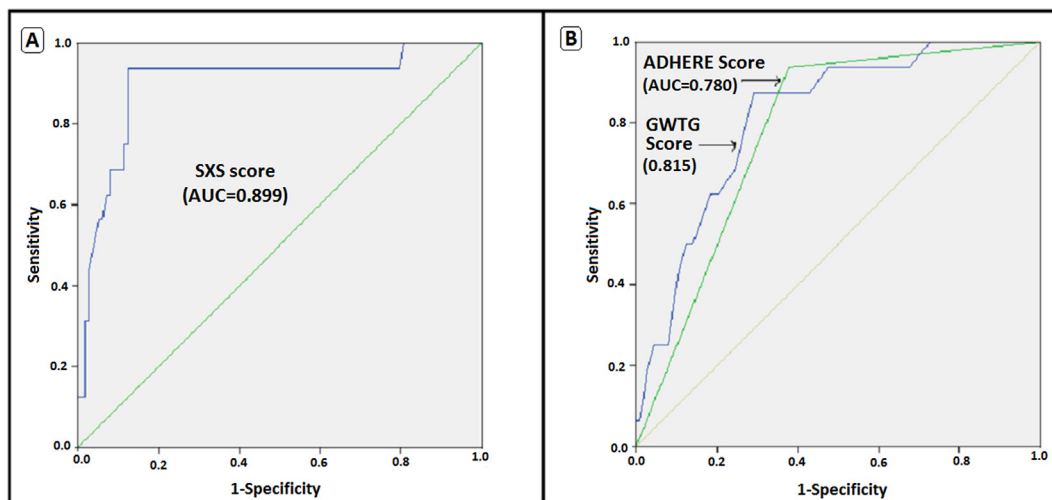


Fig. 1. Receiver operating characteristic (ROC) curve showing the comparison of SXS score (panel A) with GWTG-HF Score and ADHERE Score (Panel B).

Table 3

Independent predictors of outcomes in patients with ADHF using multivariate logistic regression analysis.

Variable	In-hospital mortality			Re-hospitalization		
	Odds Ratio	95% Confidence interval	p-value	Odds Ratio	95% Confidence interval	p-value
SBP	1.052	1.019–1.085	<b>0.002*</b>	—	—	—
S. Sodium	1.110	1.016–1.213	<b>0.021*</b>	1.076	0.994–1.164	0.071
S. Creatinine	—	—	—	0.541	0.185–1.578	0.260

Abbreviations: CI: Confidence interval, SBP: Systolic Blood Pressure.

Table 4

Predictors of length of stay in hospital (as a continuous variable) by using simple regression analysis.

Parameters (Independent variables)	Pearson Correlation <sup>a</sup>	R square	p-value <sup>b</sup> (ANOVA)	95% Confidence Interval
Serum Sodium (mEq/L)	−0.026	0.001	0.783	−0.039 to 0.029
SBP (mmHg)	−0.330	0.109	<b>0.000<sup>b</sup></b>	−0.021 to −0.006
Serum creatinine	−0.066	0.004	0.487	−0.899 to 0.431
Serum Urea	−0.070	0.005	0.462	−0.027 to 0.012
LVEF (%)	−0.092	0.008	0.332	−0.030 to 0.010
SXS score (mmHg.mEq/l)	−0.318	0.101	<b>0.001<sup>b</sup></b>	−0.147 to −0.042
GWTG-HF Score	−0.155	0.024	0.101	−0.005 to 0.052

Abbreviations: - GWTG: Get with the guideline, SXS: Product of systolic blood pressure and serum sodium divided by 1000, SBP: Systolic Blood pressure.

<sup>a</sup> Calculated by using Length of stay in hospital (in days) as the dependent variable.

<sup>b</sup> Calculated by using ANOVA as test of significance.

#### 4. Discussion

The ‘SHOUT Prediction’ study analyzed data from patients with ADHF admitted to ICU and provides insight into the role of prediction models and other variables in analyzing the outcomes. In the present study, the GWTG and the ADHERE registry model were used to predict in-hospital mortality and their higher scores were found to have a significant association with in-hospital mortality. As compared to various trials and registries with in-hospital mortality ranging from 3% to 8.7%, the present study had higher in-hospital mortality of 12.3%.<sup>6–11</sup> The Re-hospitalization rate (18.4%) at 3 months’ follow-up was similar to other large registries.<sup>10–12</sup> Predicting the risk and outcomes in patients with HF has largely been difficult.<sup>3,13</sup> Various studies have proposed risk prediction models for HF and studied their role in predicting outcomes namely mortality, re-hospitalization or death, and re-hospitalization alone.<sup>13</sup> However, the complexity of these models and questionable accuracy has led to their limited use.<sup>3,13</sup>

Risk prediction with GWTG score involves SNa apart from other variables such as S.B.P, blood urea nitrogen, age, heart rate, race,

and history of COPD to predict the in-hospital mortality in patients with HF.<sup>13</sup> Whereas ADHERE risk score does not involve SNa and uses only 2 variables (BUN and SBP) if BUN is < 43 mg/dl and 3 variables (additionally involving S.Cr) if BUN is ≥ 43 mg/dl.<sup>6,7</sup> Previously the validity of these risk-scores has been tested in a single-center retrospective study evaluating 6203 consecutive hospitalizations for HF in which 57% and 20% hospitalizations were identified at low risk by ADHERE risk score and GWTG-HF score respectively and these patients had significantly lower mortality as compared to those identified at high risk ( $p < 0.0001$ ).<sup>15</sup> In the present study, out of 101 (77.6%) patients predicted to have low mortality by GWTG (predicted mortality 1–5%) and 72 (55.3%) by ADHERE score (predicted mortality 2.1–2.3%), mortality occurred in 7 (5.3%) and 1 (0.76%) respectively. A study by Lyle et al assessing the predictive value of GWTG-HF scores in patients admitted in intensive cardiac care unit found a higher GWTG-HF score in non-survivor (47.7) as compared to the survivor (40.2), however, the overall mean GWTG-HF score was lower as compared to present study.<sup>16</sup>

Although various models are available, the majority of them are complex.<sup>17–20</sup> A systematic review by Ouwerkerk et al evaluating the predictive ability of various such models in patients with HF identified more than 100 models and found that 249 different variables were used and the prediction of mortality in patients with HF was moderately successful.<sup>18</sup> A systematic review and analysis by the Rahimi et al identified, 64 main models and found that more than 10 different variables including SBP and SNa consistently predicted the HF outcomes.<sup>19</sup> A study by the Lagu et al comparing seven risk prediction models including GWTG-HF and ADHERE risk score in 13,163 patients with ADHF, found similar discrimination ability of these two scores with the area under the curve (AUC) in ROC of 0.69 and 0.68 respectively.<sup>21</sup> In the present study GWTG-HF scores and ADHERE scores had AUC in ROC of 0.815 and 0.780 respectively, which indicates the better discriminative ability of these two scores in this study population.

A simple risk score (SXS score) consisting of only two variables was derived and evaluated in the present study because both S.B.P and SNa had an independent association with in-hospital mortality in the present study. Therefore, this new score (the product of both SBP and SNa divided by 1000) was tested for its accuracy in predicting in-hospital mortality and compared to GWTG-HF and ADHERE risk score and it was found that SXS score had a significant association with in-hospital mortality. Moreover, the AUC in ROC was 0.899 for the SXS score, which was better than GWTG-HF and ADHERE score tested for predicting in-hospital mortality in this study. Out of 75 (57.7%), patients identified to have SXS score > 15 (low risk), in-hospital mortality occurred in only 1 patient, hospital stays longer than 7 days seen in 13 patients, and over 3 months' follow-up, re-hospitalization occurred in 11 patients only. The SXS score also showed a significant correlation for predicting length of stay in the hospital ( $R = 0.101$ ,  $p = 0.001$ ). Unlike other prediction models, the SXS score is a simple score based on two variables namely SBP and SNa which have been previously proposed as strong predictors of outcomes in patients with worsening HF. Moreover, hyponatremia was found to be associated with low SBP and higher creatinine levels in some large HF registries.<sup>22</sup> Hyponatremia ( $\text{SNa} \leq 135 \text{mEq/L}$ ) in the present study was found to be significantly associated with in-hospital mortality ( $p = 0.032$ ) but not with the length of stay and re-hospitalization (over 3 months follow up). However,  $\text{SNa} < 125 \text{mEq/L}$  showed a significant association with a higher re-hospitalization rate ( $p = 0.005$ ) during 3 months follow up post-discharge.

Hyponatremia in HF is not uncommon and has prognostic implications that have been shown in previous studies but with varying data mainly because of differences in the study population and the cut-off values used to label hyponatremia.<sup>23,24</sup> In the present study cut-off value of  $135 \text{mEq/L}$  was used to differentiate patients with hyponatremia from those with normal SNa levels in the blood and found hyponatremia in 43.8% of patients. Hyponatremia in these patients was mainly attributable to HF (dilutional) rather than depletion because most of the patients presented in volume overload state. Hyponatremia in patients with HF is an indicator of worst outcomes but as a single risk prediction variable, it may not precisely predict HF outcomes in the heterogeneous population. Therefore, there is a need to develop a simple tool such as the SXS score which can be widely used by the physicians to estimate the risk in the HF population that can guide them in deciding follow-up visits and to convey projected outcomes to the patients and their relatives.<sup>17–21,25</sup>

## 5. Limitations

This study had small sample size. With recently introduced drugs as HF therapy including angiotensin receptor neprilysin

inhibitor and gliflozins, the prognosis is likely to be affected. Thus a well designed study on recent HF population with a larger sample size can better reveal the prognostic efficacy of these HF risk scores.

## 6. Conclusion

Hyponatremia ( $\text{SNa} \leq 135 \text{mEq/L}$ ) was found to have a significant association with in-hospital mortality in patients hospitalized with ADHF. Severe hyponatremia ( $\text{SNa} \leq 125 \text{mEq/L}$ ) had a significant association with re-hospitalization during 3 months follow up. Lower SNa and SBP had an independent association with in-hospital mortality on multivariate analysis. SXS score derived from their product was found to have better predictive value as compared to the GWTG and the ADHERE risk score.

## Key messages

### What is already known?

1. Serum sodium levels at admission in patients with decompensated heart failure predicts outcomes.
2. Several risk prediction models triaging high risk patients with heart failure are cumbersome and not widely used.

### What this study adds:

1. Score derived from the product of serum sodium and systolic blood pressure (SXS score) can predict outcomes in patients with ADHF

## Declaration of competing interest

The Authors have no conflict of interest.

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