Original Paper

# Acute Kidney Injury in Critically Ill Pregnant Women: A Retrospective Study on Risk Factors and Outcomes

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**Keywords.** Acute kidney injury (AKI); Pregnancy; Intensive care unit (ICU); Continuous renal replacement therapy (CRRT)

**Introduction.** Despite the significant decline in the incidence of pregnancy-related acute kidney injury (AKI) in recent decades due to advancements in medicine and increased awareness of this disease, it remains an important risk factor for maternal morbidity and mortality. However, as fertilization techniques allow women of advanced age to become pregnant, the incidence of pregnancy- related AKI has increased. Consequently, early identification of and intervention for pregnancy-related AKI are particularly important.
**Methods.** This was a retrospective clinical analysis. Data were collected from pregnant patients who were treated in the ICU of Shengjing Hospital of China Medical University from January 2014 to June 2020; The patients were divided into two groups based on their kidney function status: AKI and non-AKI. Additionally, they were further categorized into recovered and non-recovered groups based on their prognosis. The Wilcoxon rank sum test and the chi- square test were used for multigroup comparisons, while logistic regression analysis was used for the analysis of risk factors. $P < .05$ was considered to indicate a statistically significant difference in all correlation analyses.
**Results.** Among 874 pregnant women in this study, 136 had AKI (15.56%), while 36 developed chronic renal insufficiency (26.47%). Statistically significant associations were shown for shock ($P = .002$), sepsis ($P < .001$), coagulopathies ($P = .001$), liver insufficiency ($P < .001$), postpartum hemorrhage ($P = .016$), intrauterine fetal death ($P = .042$) and mechanical ventilation ($P = .006$) between the AKI- group and the non-AKI group. The development of AKI based on an elevated baseline creatinine level was significantly related to the outcome of renal function ($P < .001$), while a significant difference was shown in the use of continuous renal replacement therapy (CRRT) between the recovery group and the non-recovery group ($P = .023$).
**Conclusion.** We identified the relevant risk factors leading to pregnancy-related AKI and affecting the patients' prognosis. Shock, sepsis, coagulation disorders, liver insufficiency, postpartum hemorrhage, intrauterine fetal death and mechanical ventilation are independent risk factors for pregnancy-related AKI, while an elevated baseline creatine level is a key factor for poor prognosis. Meanwhile, early CRRT can effectively reverse renal outcomes.

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## INTRODUCTION

Acute kidney injury (AKI) is one of the most frequent organ dysfunctions in intensive care unit (ICU) patients.[1] It frequently leads to a significantly longer hospital stay and a worse prognosis.[2] Research has confirmed that approximately 30% of

ICU patients suffer from AKI, and the mortality rate after AKI is as high as 50%.[3] The high morbidity and mortality of AKI in the ICU have aroused widespread concern, and various guidelines have emerged.[4]

Unique physiological changes during pregnancy, significantly increase the burden on the kidneys, leading to pregnancy-related AKI.[5] Pregnancy-related AKI was previously thought to be caused by sepsis following an abortion; however, in the last several decades, the frequency of pregnancy- related AKI has significantly decreased as a result of fewer abortions and better postpartum treatment.[6] For example, the proportion of pregnant women with AKI in India dropped from 15% in the 1980s to 1.5% in the 2010s.[7] However, the incidence of AKI during pregnancy has once again shown an upward trend in recent years.[8] A statistical study in the United States showed that the hospitalization rate caused by pregnancy related AKI increased from 0.04% in 2006 to 0.12% in 2015, while the overall incidence of AKI among hospitalized pregnant women was 0.08%.[8] The reasons for this could include maternal age increases with more complications, pregnancy induced hypertension and obesity.[9] Furthermore, once AKI occurs during pregnancy, catastrophic consequences often occur, with a maternal mortality rate of 30%.[10]

Moreover, the occurrence of AKI is usually related to several factors, including haemorrhage, sepsis, preeclampsia-eclampsia and septic abortion, most of factors are medical histories of other diseases.[11] Therefore, identifying risk factors associated with AKI in pregnant women and performing early intervention are particularly important. Use To the best of our knowledge, for various reasons, pregnant women with AKI have rarely been studied, there is also a lack of relevant studies in China at the same time.

## MATERIALS AND METHODS

### Experimental population

This retrospective study collected a total of 926 pregnant women who were admitted to the ICU of Shengjing Hospital affiliated to China Medical University from January 2014 to June 2020, excluding 52 cases who were admitted to the ICU for less than 24 hours. A total of 874 pregnant women were included in the study.

### AKI diagnosis and staging

AKI was diagnosed and staged according to the Kidney Disease: Improving Global Outcomes (KDIGO) guidelines: Stage 1: a serum creatinine (SCr) concentration ≥26.5 μmol / L within 48 hours or ≥1.5 times the baseline concentration within 7 days or a urine output less than 0.5 mL / (kg/h) for 6 hours;[10] Stage 2: a 2.0-2.9 fold increase in the creatinine concentration or a urine output < 0.5 ml/(kg/h) for more than 12 hours; and Stage 3: a more than 3 fold increase in the creatinine concentration, need for renal replacement therapy, a urine output < 0.3 ml (kg/h) for more than 24 hours or anuria lasting more than 12 hours.[12] Because patients may experience changes in AKI staging due to changes in their condition, we have compiled a unified statistics of the highest AKI staging that occurred during hospitalization.

### Clinical data and epidemiological characteristics

The risk factors associated with AKI were analysed, including age, gestational age, parity, hypertension, diabetes, high baseline level of creatinine (higher than 84 μmol/L), caesarean delivery, eclampsia/preeclampsia, hemolytic anemia, elevated liver enzymes and low platelet count (HELLP syndrome), placental abruption, postpartum hemorrhage (24 h blood loss greater than 500 ml), intrauterine fetal death, sepsis (Sequential Organ Failure Assessment (SOFA) score of 2 points or more, according to Sepsis 3.0 standard),[13] coagulopathy (without the application of anticoagulant agents, a PT longer than 15s or/ and an APTT longer than 44.4s), abnormal liver enzymes (an ALT concentration higher than 120u/L or/and an AST concentration higher than 102u/L), shock, and the application of mechanical ventilation (more than 72 h).

The factors affecting renal function and prognosis were analysed; they included: the SOFA score,[14] Acute Physiology and Chronic Health Evaluation II (APACHE II) score,[15] high baseline level of creatinine, continuous renal replacement therapy (CRRT) application, duration of stay in the ICU, AKI stage, and lactic acid level (> 2 mmol/L over 24h).

Patients whose creatinine levels returned to or fall below the baseline levels during the hospital stay, were defined as the "recovered group", and those whose creatinine levels did not return to the

baseline were defined as the "non-recovered group".

The aforementioned risk factors were all present before the onset of AKI. The patients with the most severe SOFA/APACHE II scores within 24h after admission to the ICU were included.[16]

### Data analysis

All the data were analysed by using SPSS 26.0 statistical software (IBM Corporation, USA). The measurement data were presented as (x ± s), and the count data were expressed as specific values and percentages. For multigroup comparisons, the Wilcoxon rank sum test was used for the measurement data, while the chi-square test was used for the count data. Logistic regression analysis was used for the analysis of risk factors. $P < .05$ was considered to indicate a statistically significant difference in all correlation analysis.

## RESULTS

### General conditions

Out of 874 pregnant women in this study, 136 cases (15.56%) were diagnosed with AKI, while 738 cases (84.44%) did not. Among the AKI patients, 33 had stage 1 disease (24.26%), 52 had stage 2 disease (38.24%), and 51 had stage 3 disease (37.5%). At the same time, all AKI patients were divided into recovered and non-recovered groups based on their prognosis, 100 cases (73.53%) in recovered group and 36 cases (26.47%) in non-recovered group.

Clinical data and epidemiological characteristics varied among different groups. Detailed information of AKI and non-AKI groups is shown in Table 1 (Table 1), while statistically related factors of recovered and non-recovered groups are shown in Table 2 (Table 2).

The incidence of various primary diseases varied among the study participants (Figure 1).

### Univariate analysis of AKI risk factors

Hypertension, high levels of baseline creatinine, caesarean delivery, HELLP syndrome, placental abruption, postpartum hemorrhage, intrauterine fetal death, sepsis, coagulopathy, abnormal liver enzymes, shock, and mechanical ventilation differed significantly between the AKI-group and non-AKI group ($P < .05$) (Table 3).

### Multivariate logistic analysis of AKI risk factors

Multivariate logistic analysis revealed that postpartum hemorrhage, intrauterine fetal death, sepsis, coagulopathy, elevated liver enzymes, shock, and mechanical ventilation were significantly different between the AKI-group and the non-AKI

**Table 1.** Characteristics of the study participants

| Item | All patients | AKI group | non-AKI group |
|---|---|---|---|
| Age (years) | 30.4 ± 5.4 | 31.2 ± 5.8 | 30.3 ± 5.4 |
| Gestational age (weeks) | 33.4 ± 4.6 | 33.5 ± 4.5 | 33.3 ± 4.6 |
| Parity (times)* | 2 | 2 | 2 |
| Hypertension, % | 322 (36.8) | 36 (26.5) | 286 (38.8) |
| Diabetes, % | 130 (14.9) | 14 (10.3) | 116 (15.7) |
| Elevated creatinine levels**, % | 41 (4.7) | 29 (21.3) | 12 (1.6) |
| Caesarean delivery, % | 802 (91.8) | 114 (83.8) | 688 (93.2) |
| Eclampsia/preeclampsia, % | 337 (38.6) | 54 (39.7) | 283 (38.3) |
| HELLP syndrome, % | 82 (9.4) | 32 (23.5) | 50 (6.8) |
| Placental abruption, % | 78 (8.9) | 22 (16.2) | 56 (7.6) |
| Postpartum hemorrhage, % | 143 (16.4) | 41 (30.1) | 102 (13.8) |
| Intrauterine fetal death, % | 160 (18.3) | 60 (44.1) | 100 (13.6) |
| Sepsis, % | 134 (15.3) | 115 (84.6) | 19 (2.6) |
| Coagulopathy, % | 100 (11.4) | 87 (64.0) | 13 (1.8) |
| Elevated liver enzymes, % | 186 (21.3) | 116 (85.3) | 70 (9.5) |
| Shock, % | 123 (14.1) | 96 (70.6) | 27 (3.7) |
| Mechanical ventilation, % | 173 (19.8) | 117 (86.0) | 56 (7.6) |
| Duration of stay in ICU (days) | 4.1 ± 3.5 | 8.3 ± 6.5 | 3.3 ± 1.8 |
| SOFA score | 3.2 ± 2.9 | 8.7 ± 3.2 | 2.2 ± 1.5 |
| APACHE II score | 7.7 ± 6.0 | 18.7 ± 5.6 | 5.7 ± 3.3 |

(n = 874, AKI group = 136, non-AKI group = 738)
*Median of parity
**Elevated creatinine levels than baseline before admission to ICU

**Table 2.** Characteristics of the AKI patients

| Item | AKI patients | recovery group | non-recovery group |
|---|---|---|---|
| Duration of stay in ICU (days) | 8.3 ± 6.5 | 7.5 ± 5.4 | 10.4 ± 8.6 |
| High baseline level of creatinine | 29 (21.3%) | 9 (9%) | 20 (55.6%) |
| AKI stage* | 2 | 2 | 3 |
| Elevated lactic acid level | 92 (67.6%) | 63 (63%) | 29 (80.6%) |
| CRRT | 65 (47.8%) | 35 (35%) | 30 (83.3%) |
| SOFA score | 8.7 ± 3.2 | 7.9 ± 2.6 | 11.0 ± 3.6 |
| APACHE II score | 18.7 ± 5.6 | 17.4 ± 4.9 | 22.5 ± 5.8 |

(n = 136, recovered group = 100, non-recovered group = 36)
*Median of AKI stage

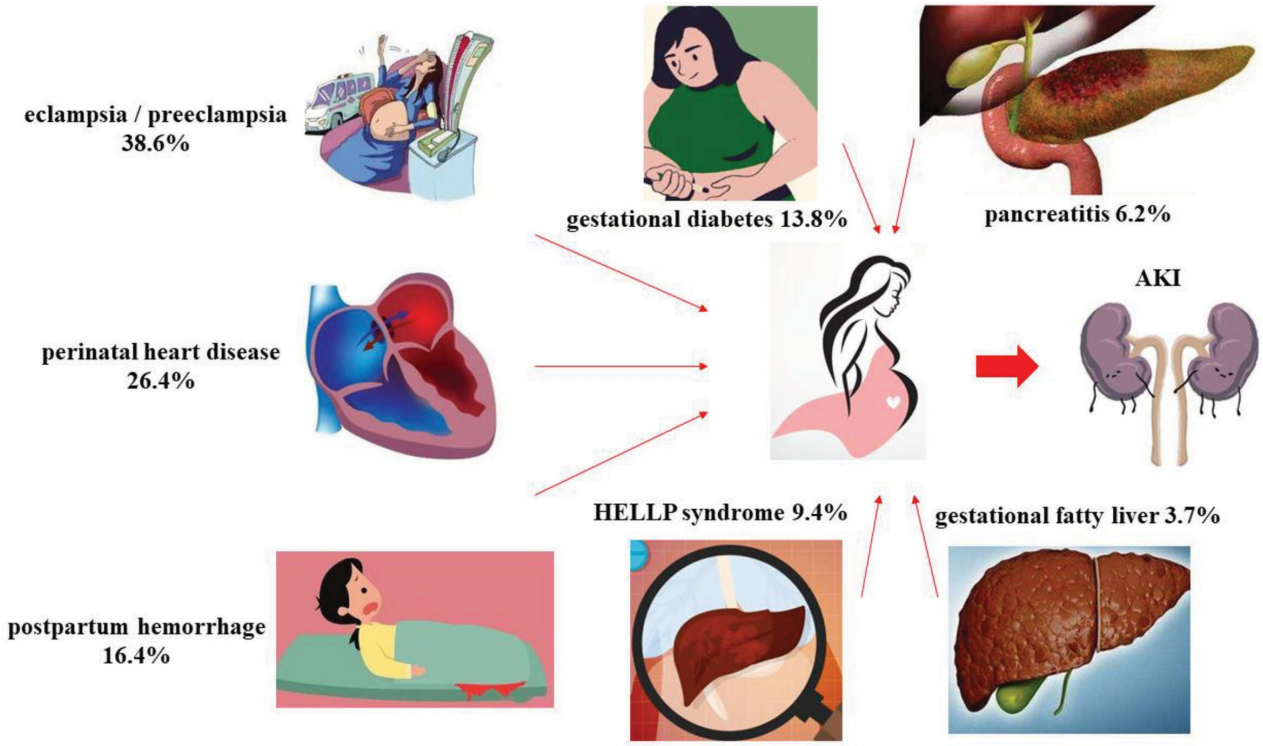


**Figure 1.** Incidence rate of primary diseases (n = 874)

group ($P < .05$) (Table 4).

### Recovery of renal function, prognosis and intervention

In the AKI-group, 36 patients (26.47%) ultimately had a poor prognosis (Figure 2).

A statistical analysis of the relevant factors was conducted between recovered group and non-recovered group. The results revealed significant differences in elevated baseline creatinine levels, AKI stage, CRRT, and SOFA and APACHE II scores ($P < .05$) (Table 5).

Multivariate logistic analysis revealed that the administration of CRRT and elevated baseline creatinine levels were significantly different between the recovered group and non-recovered group ($P < .05$) (Table 6).

## DISCUSSION

The overall incidence of AKI among patients admitted to the ICU is 10-33%, but for critically ill pregnant women, this incidence increases to 61%.[17] With improvements in the understanding of AKI, the incidence of pregnancy-relate AKI in the ICU has decreased. However, a Brazilian study showed that the overall incidence of AKI in ICU patients was 27.8%.[18] Moreover, special physiological conditions during pregnancy exacerbate the kidney burden of pregnant women. In the first trimester of pregnancy, there is a 50% increase in

**Table 3.** Univariate analysis of AKI risk factors

| Item | All patients | AKI group | Non-AKI group | $\chi^2$/Z | *P* |
|---|---|---|---|---|---|
| Age& | 30.4 ± 5.4 | 31.2 ± 5.8 | 30.3 ± 5.4 | -1.779 | .075 |
| Gestational age& | 33.4 ± 4.6 | 33.5 ± 4.5 | 33.3 ± 4.6 | -0.145 | .885 |
| Parity& | 2 | 2 | 2 | -1.141 | .254 |
| Hypertension* | 322 (36.8%) | 36 (26.5%) | 286 (38.8%) | 7.446 | .006 |
| Diabetes* | 130 (14.9%) | 14 (10.3%) | 116 (15.7%) | 2.668 | .102 |
| High baseline level of creatinine* | 41 (4.7%) | 29 (21.3%) | 12 (1.6%) | 99.655 | < .001 |
| Caesarean delivery* | 802 (91.8%) | 114 (83.8%) | 688 (93.2%) | 13.427 | < .001 |
| Eclampsia/preeclampsia* | 337 (38.6%) | 54 (39.7%) | 283 (38.3%) | 0.09 | .765 |
| HELLP syndrome* | 82 (9.4%) | 32 (23.5%) | 50 (6.8%) | 37.916 | < .001 |
| Placental abruption* | 78 (8.9%) | 22 (16.2%) | 56 (7.6%) | 10.421 | .001 |
| Postpartum hemorrhage* | 143 (16.4%) | 41 (30.1%) | 102 (13.8%) | 22.367 | < .001 |
| Intrauterine fetal death* | 160 (18.3%) | 60 (44.1%) | 100 (13.6%) | 71.748 | < .001 |
| Sepsis* | 134 (15.3%) | 115 (84.6%) | 19 (2.6%) | 594.609 | < .001 |
| Coagulopathy* | 100 (11.4%) | 87 (64.0%) | 13 (1.8%) | 438.605 | < .001 |
| Abnormal liver enzymes* | 186 (21.3%) | 116 (85.3%) | 70 (9.5%) | 393.955 | < .001 |
| Shock* | 123 (14.1%) | 96 (70.6%) | 27 (3.7%) | 425.402 | < .001 |
| Mechanical ventilation* | 173 (19.8%) | 117 (86.0%) | 56 (7.6%) | 445.074 | < .001 |

(n = 874, AKI group = 136, non-AKI group = 738)
*P* < .05 Chi-square test (*)
*P* < .05 Wilcoxon rank sum test (&)

**Table 4.** Multivariate analysis of AKI risk factors

| Item | β | $S_\beta$ | Wald | *P* |
|---|---|---|---|---|
| Hypertension | -0.679 | 1.331 | 0.261 | .610 |
| High baseline level of creatinine | -4.087 | 4.666 | 0.767 | .381 |
| Caesarean delivery | 0.844 | 1.396 | 0.366 | .545 |
| HELLP syndrome | 0.432 | 1.468 | 0.087 | .768 |
| Placental abruption | -0.735 | 1.379 | 0.284 | .594 |
| Postpartum hemorrhage | 3.939 | 1.631 | 5.833 | .016 |
| Intrauterine fetal death | 2.759 | 1.360 | 4.115 | .042 |
| Sepsis | -7.861 | 1.719 | 20.907 | < .001 |
| Coagulopathy | -5.885 | 1.693 | 12.076 | .001 |
| Elevated liver enzymes | -5.909 | 1.610 | 13.479 | < .001 |
| Shock | -5.047 | 1.606 | 9.876 | .002 |
| Mechanical ventilation | -3.764 | 1.366 | 7.595 | .006 |

(n = 874, AKI group = 136, non-AKI group = 738)
*P* < .05 Multivariate logistic analysis

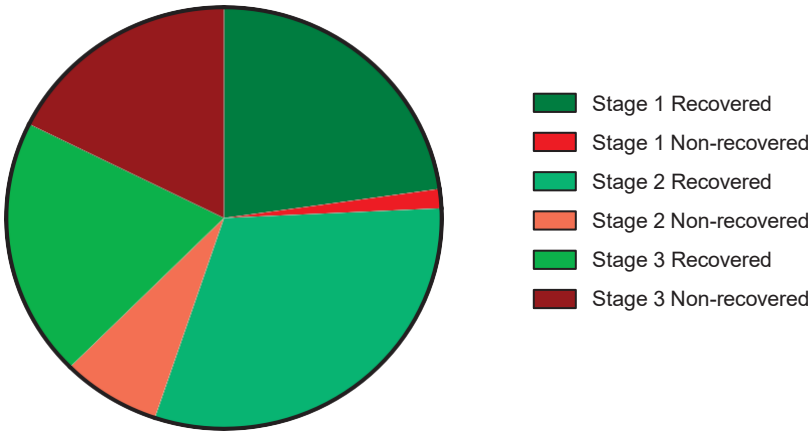


**Figure 2.** The recovery of renal function at different stage (n = 136)

**Table 5.** Univariate analysis of recovery risk factors

| Item | AKI patients | recovery group | non-recovery group | $\chi^2$/Z | *P* |
|---|---|---|---|---|---|
| Duration of stay in ICU& | 8.3 ± 6.5 | 7.5 ± 5.4 | 10.4 ± 8.6 | -1.553 | .120 |
| High baseline level of creatinine* | 29 (21.3%) | 9 (9%) | 20 (55.6%) | 34.198 | < .001 |
| AKI stage& | 2 | 2 | 3 | -4.356 | < .001 |
| Elevated lactic acid level* | 92 (67.6%) | 63 (63%) | 29 (80.6%) | 3.728 | .054 |
| CRRT* | 65 (47.8%) | 35 (35%) | 30 (83.3%) | 24.784 | < .001 |
| SOFA score& | 8.7 ± 3.2 | 7.9 ± 2.6 | 11.0 ± 3.6 | -4.335 | < .001 |
| APACHE II score& | 18.7 ± 5.6 | 17.4 ± 4.9 | 22.5 ± 5.8 | -4.324 | < .001 |

(n = 136, recovered group = 100, non-recovered group = 36)
*P* < .05 Chi-square test (*)
*P* < .05 Wilcoxon rank sum test (&)

**Table 6.** Multivariate analysis of recovery risk factors

| Item | β | $S_\beta$ | Wald | *P* |
|---|---|---|---|---|
| High baseline level of creatinine | 2.705 | 0.612 | 19.569 | < .001 |
| AKI stage | -0.538 | 0.465 | 1.340 | .247 |
| CRRT | 1.601 | 0.704 | 5.171 | .023 |
| SOFA score | -0.079 | 0.151 | 0.269 | .604 |
| APACHE II score | -0.072 | 0.085 | 0.720 | .396 |

(n = 136, recovered group = 100, non-recovered group = 36)
*P* < .05 Multivariate logistic analysis

the glomerular filtration rate (GFR) compared with pre-pregnancy. The physiological changes begin in the first month of pregnancy and continue until the postpartum period.[19] Studies have shown that pregnancy increases the incidence of AKI by 51%,[20] which may be related to an increased maternal age at conception, an increased BMI, diseases such as hypertension and diabetes, and polyembryony caused by assisted reproductive technology.[21]

Our study showed that 15.56% of the pregnant women experienced AKI, and of those with AKI, 26.47% had an adverse prognosis. Studies in China[22] have shown that the incidence of pregnancy-relate AKI is 2.09% and the maternal mortality rate is 2.9%. A meta-analysis showed that 2.4% of patients with pregnancy-relate AKI eventually developed chronic kidney disease (CKD).[10] Considering that this study included only pregnant women who were admitted to the ICU, there are certain limitations based on region and population.

The current study showed that compared with that of primiparas, the risk of AKI was not greater in multiparas. Studies have shown that the incidence of AKI is greater in the third trimester of pregnancy.[23] However, we did not reach similar conclusions in this study. In addition, we believe that the occurrence of AKI is not influenced by age or gestational age.

Hypertension and diabetes mellitus are often considered to be closely associated with impaired kidney function.[8,24] However, we did not reach the same conclusion, which might be due to the limitation of small sample size.

The pathogenesis of pregnancy-related AKI is relatively complex. Taber-Hight *et al.* showed that the common causes of pregnancy-related AKI were hyperemesis gravidarum, septic abortion, preeclampsia/eclampsia, urinary tract infection/ acute pyelonephritis, HELLP syndrome, thrombotic thrombocytopenic purpura (TTP)/hemolytic uremic syndrome (HUS), and acute fatty liver disease of pregnancy.[9] The main causes of AKI in this study were eclampsia / preeclampsia (38.6%), perinatal heart disease (26.4%), postpartum hemorrhage (16.4%), gestational diabetes (13.8%), HELLP syndrome (9.4%), pancreatitis (6.2%), and fatty liver of pregnancy (3.7%), which are consistent with the findings of studies conducted abroad.[25]

On the other hand, other conditions such as postpartum hemorrhage (PPH) and intrauterine fetal death could also be risk factors for AKI. As the leading cause of maternal mortality, PPH can directly cause maternal death without effective treatment.[26] Our study confirmed that PPH had a statistically significant effect on the occurrence of AKI. Intrauterine fetal death can seriously

threaten the safety of pregnant women if it is not properly managed.[27] Our study showed that there was a relationship between intrauterine fetal death and the occurrence of AKI, which might be due to the death of the fetus resulting in a series of complications such as disseminated intravascular coagulation (DIC).

Critically ill pregnant women often have severe infection or sepsis, abnormal blood coagulation or DIC, liver dysfunction, shock, respiratory failure, and multi-organ failure, which can cause AKI. Studies have shown that sepsis account for almost 33% to 59% of AKI cases in ICU patients,[5] and pregnant women with sepsis-related AKI have a worse prognosis.[23] The study findings indicated a substantial correlation between severe infection or sepsis, abnormal blood coagulation or DIC, liver dysfunction, shock, and respiratory failure and the occurrence of AKI. These characteristics were identified as independent risk factors for AKI.

Studies have also shown that patients with CKD are more likely to develop AKI,[28] and the level of basal renal function also affects the prognosis.[29] Recent studies have confirmed that patients with AKI have a higher likelihood of developing CKD.[30] Research have demonstrated that individuals with Acute Kidney Injury (AKI) who have prompt recovery without any subsequent relapses exhibit a greater likelihood of surviving.[31] Early recovery helps to prevent progression to CKD.[32] In recent years, additional studies have supported this theory.[33] In our study, pregnant women with higher creatinine levels than baseline levels also had a worse prognosis.

Lactate is an important indicator for assessing the conditions of patients in the ICU.[34] High baseline lactate levels were found to be an independent risk factor for the occurrence of contrast-induced acute kidney injury (CI-AKI) and an independent predictor of poor prognosis.[35] Related studies have confirmed that patients with stage 2 and stage 3 AKI have a significantly greater probability of complications and recurrence.[36] However, we failed to reach the same conclusion in this study, which might be related to the small sample size.

The SOFA and APACHE II scores are important for evaluating disease in the ICU.[14] In this study, an increase in these two scores had no statistically significant effect on the prognosis of patients with AKI. This may be attributed to subjective bias in the scoring process.

Overall, early identification and intervention are beneficial in improving the prognosis of patients with AKI.[37] This study indicated that CRRT could effectively improve kidney function and the prognosis of patients with AKI, so early application of CRRT is beneficial for pregnant women with pregnancy-relate AKI. However, there is still controversy over the timing, dosage, and complications of CRRT treatment for AKI patients, and further relevant research needed to be conducted.[38,39]

## LIMITATIONS

The study limitations are numerous. First, this was a single-center study, so there is population and regional bias. Moreover, the Study participants were all in the late stage of pregnancy. Finally, several other AKI-related factors, such as drug use, were not addressed in this study.

## CONCLUSION

This study showed that AKI is a common comorbidity in critically ill pregnant women and might lead to an adverse prognosis. Postpartum hemorrhage, intrauterine fetal death, sepsis, coagulopathy, abnormal liver enzymes, shock and the application of mechanical ventilation were found to be independent risk factors for the development of AKI in pregnant patients. An elevated baseline creatinine level could have a significant negative effect on the prognosis of pregnant women with AKI, while CRRT could effectively improve it.

Conslusion Adequate precautions and early intervention should be provided for pregnant women with the aforementioned risk factors to effectively reduce the incidence of AKI.

## ABBREVIATIONS

AKI: acute kidney injury
ICU: intensive care unit
CRRT: continuous renal replacement therapy
KDIGO: Kidney Disease Improving Global Outcomes
Scr: serum creatinine
SOFA: sequential organ failure assessment
APACHE II: Acute Physiology and Chronic Health Evaluation II
PPH: postpartum hemorrhage
DIC: disseminated intravascular coagulation

CKD: chronic kidney disease
Hellp syndrome: hemolyticanemia elevated liver function and low platelet count syndrome
GFR: glomerular filtration rate
TTP: thrombotic thrombocytopenic purpura
HUS: hemolytic uremic syndrome
AMI: acute myocardial infarction
PCI: percutaneous coronary intervention
CI-AKI: contrast-induced acute kidney injury

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## DATA AVAILABILITY STATEMENT

The authors confirm that the data supporting the findings of this study are available within the supplementary materials.

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## CONFLICTS OF INTEREST

Authors declare no Conflicts of Interest.

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