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Research Article

An Analysis of the Efficacy and Curative Effect of the Intensive Care Unit for Kidney Disease in the Treatment of Critically Ill Patients

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Abstract: ***Objective*：**To observe the therapeutic effect of continuous renal replacement therapy (CRRT) in the kidney intensive care unit (kicu) of our hospital, to explore the opportunity of CRRT treatment, and to observe the efficacy of kicu in the treatment of critical patients. ***Methods:*** 190 critical patients who needed CRRT in ICU and KICU of our hospital were analyzed retrospectively, from January 2017 to December 2019. The above patients were divided into 72 cases of acute renal injury (AKI) and 118 cases of chronic kidney disease (CKD).At the same time, patients with AKI and MODS were divided into two groups according to the creatinine value of 355umol/L. The patients with creatinine value < 355umol/L were in the low creatinine group, and the patients with creatinine value ≥ 355umol/L were in the high creatinine group. The outcome of each index in the two groups was compared after CRRT treatment ***Results:*** CRRT can significantly reduce the white blood cell (WBC) count and procalcitonin (PCT) in patients with AKI and CKD, but there is no significant positive result between the two groups according to the creatinine value of patients with AKI and MODS.In addition to the known function of detoxification and drainage, CRRT can significantly reduce the circulating inflammatory mediators and play an anti-inflammatory and immunomodulatory role. ***Conclusions:*** Creatinine value is a classical index of renal function, but it can not independently evaluate the time of CRRT treatment. It should be combined with age, mechanical ventilation, organ dysfunction, end-stage disease and other comprehensive evaluation. KICU plays an important role in the treatment of critical patients.

Keywords: KICU；CRRT；MODS；AKI；APACHEII

INTRODUCTION

The blood purification center has been quite popular in the tertiary hospitals in China. The method of blood purification has gradually increased the methods of hemofiltration, hemodiafiltration, and plasma replacement from the initial hemodialysis. With the development of blood purification models, long-term treatment models have emerged, such as CRRT, extended daily dialysis (EDD), slow low-effeciency dialysis (SLED), and combined treatment models The combination of CRRT, EDD, SlED combined with plasma exchange, and / or combined blood perfusion, etc., has achieved significant results in the treatment of critically ill patients, especially in critical and hemodynamically unstable Of patients have played an important role in maximizing the treatment of critically ill patients. Many articles have reported that many critical patients have been treated by bedside CRRT or using CRRT in the intensive care unit (ICU). The disadvantage is that whenever there is a critical patient, the medical staff in the blood purification center needs to be transferred, which will have a certain impact on the conventional blood purification treatment. Our hospital established the Kidney Intensive Care Unit (KICU) in 2016, which played an active role in the treatment of critically ill patients, and won time for the first time to rescue patients. The effectiveness of establishing KICU in the treatment of critically ill patients is reported as follows.

MATERIALS AND METHODS

General Information

A retrospective observation of a total of 200 critically ill patients in our hospital from January 2017 to December 2019 in the central ICU and KICU. Among them, 10 patients were extremely critical, and died before the first CRRT was completed. The remaining 190 patients were analyzed and studied, and the 190 patients' APACHEII scores were all greater than 15 points, which met the critical criteria. Among them, there were 125 males and 65 females, aged 63.15 ± 17.03. The above-mentioned patients are all patients with severe systemic inflammatory response syndrome (SIRS) and multiple organ dysfunction syndrome (MODS) who need CRRT treatment for various reasons. The underlying disease that causes SIRS or MODS is pus. 75 cases of toxicemia, 31 cases of cardiogenic shock, 22 cases of hemorrhagic shock, 18 cases of acute respiratory distress syndrome (ARDS, Acute Respiratory Distress Syndrome), 18 cases of acute severe cerebrovascular disease, severe pancreatitis 5 There were 4 cases of severe multiple injuries, 3 cases of severe lupus erythematosus, 3 cases of drug poisoning, 2 cases of diabetic ketoacidosis, 1 case of tsutsugamushi disease, 1 case of hemolytic uremia, and 7 others. Among the above 190 patients, 72 were acute kidney injury patients (AKI) and 118 were chronic kidney disease underlying disease (CKD).

Test Method

In addition to the treatment and rescue of the underlying disease, all patients received continuous blood purification treatment, CRRT method every day or every other day, every 12-24h, blood flow 200-320mL / min; bicarbonate dialysate in HDF (The dialysate flow rate is uniformly set to 500mL / min); the replacement fluid flow rate in HF is 80-120mL / min; the vascular access is a deep vein such as the internal jugular vein or femoral vein.

Condensate

Statistical Analysis

The test data was analyzed by SPSS19.0 statistical software, and the measurement data was expressed as mean ± standard deviation; the comparison between groups was by two independent sample t tests. If the data did not follow the normal distribution, the Mann-Whitney U test was used; the count data was $\chi 2$ test. P <0.05 was considered statistically significant.

RESULTS

Study the effect of creatinine value on the prognosis of CRRT treatment in patients with AKI and MODS

The ROC curve was used to divide patients with AKI and MODS into high creatinine and low creatinine groups. The area under the curve was 0.640, P = 0.001, which was statistically significant. The maximum value of the Youden index corresponds to the creatinine cut-off value of 355umol / L. Therefore, patients with AKI and MODS are divided into two groups.

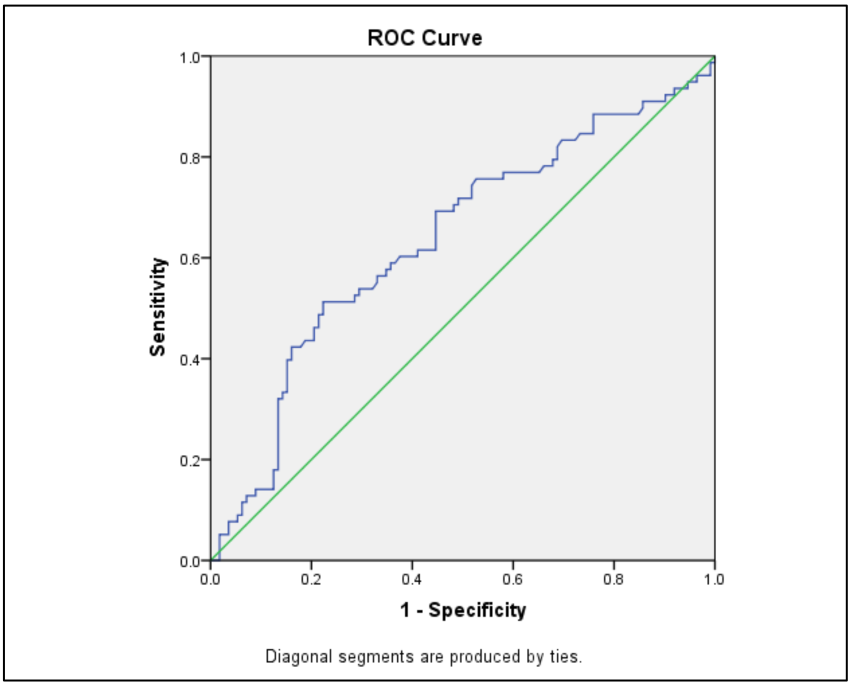

Figure 1- ROC curve of creatinine diagnostic test in patients with AKI and MODS

Table 1. Comparison of the efficacy of patients with MODS and AKI after CRRT treatment

	marked effect	effective	ineffective	total effective rate	p
low creatinine group, n=54	15（27.8%）	7（13.0%）	32（59.2%）	40.8%	0.884
high creatinine group n=18	3 （16.7%）	6（33.3%）	9 （50.0%）	50.0%	

Table 2. Comparison of outcomes of patients with MODS and AKI after CRRT

			Cr	Hb	WBC	PLT	APTT	ALT	AST	PCT
low creatinine group	**Pre-treatment**	Mean±SD	188.86±87.48	94.32±34.60	34.20±116.03	130.82±111.34	52.40±26.98	275.69±491.02	555.31±1114.7	55.51±123.73
		Median（Q1,Q3）	182.50(115.00,262.00)	88.20(67.40,122.20)	14.48(7.47,21.34)	112.95(39.50,176.40)	47.35(38.70,52.20)	49.50(22.00,318.00)	103.00(36.00,751.00)	11.50(2.40,43.50)
	Post-treatment	Mean±SD	126.29±92.45	84.50±23.10	13.80±11.00	143.37±131.52	50.36±17.47	296.61±714.73	603.55±1549.6	22.20±48.60
		Median（Q1,Q3）	99.50(65.50,152.00)	81.15(65.20,98.00)	10.99(6.69,17.61)	96.55(46.70,211.00)	44.15(38.20,56.90)	31.00(16.00,111.00)	45.50(26.00,266.00)	8.20(1.70,22.40)
	Difference	Mean±SD	-62.57±120.60	-9.82±28.00	-20.40±115.73	12.54±172.05	-2.04±28.19	20.92±788.25	48.23±1789.2	-33.31±113.06
		Median（Q1,Q3）	-73.70(-129.7,14.80)	-2.95(-27.30,8.10)	-2.75(-6.70,2.60)	-2.45(-47.00,73.40)	-1.25(-8.50,4.00)	-3.50(-98.00,27.00)	-17.00(-199.0,30.00)	-2.02(-20.36,0.75)
	P		<0.001	0.013	0.076	0.684	0.497	0.410	0.583	0.004
high creatinine group	**Pre-treatment**	Mean±SD	475.09±85.77	107.64±35.20	15.78±9.02	115.76±95.62	51.83±18.63	212.22±320.95	449.50±698.62	41.78±57.85
		Median（Q1,Q3）	460.00(414.00,506.00)	110.95(74.90,132.90)	14.70(9.51,20.79)	91.50(39.60,165.80)	45.75(38.90,60.20)	39.50(13.00,275.00)	116.50(37.00,571.00)	21.95(1.29,66.15)
	Post-treatment	Mean±SD	158.19±85.14	81.98±22.32	8.88±5.13	161.62±125.91	51.67±35.49	299.72±798.04	1860.7±6097.1	19.41±31.12
		Median（Q1,Q3）	134.35(92.60,247.20)	77.00(65.00,92.00)	8.10(6.05,11.05)	132.55(55.00,235.00)	40.85(39.10,47.10)	19.20(10.00,77.00)	31.50(19.00,111.00)	2.05(0.31,22.70)
	Difference	Mean±SD	-316.9±124.21	-25.66±30.03	-6.89±10.53	45.86±125.52	-0.16±27.99	87.50±799.95	1411.2±5674.3	-22.38±51.34
		Median（Q1,Q3）	-316.6(-391.0,-257.0)	-22.45(-41.50,-7.00)	-3.70(-10.80,-0.74)	16.95(-34.50,118.00)	-2.85(-14.20,2.10)	-4.50(-178.0,17.00)	-18.50(-173.0,19.00)	-7.51(-45.98,-0.19)
	P		<0.001	0.002	0.013	0.140	0.481	0.815	0.332	0.008
P			<0.001	0.050	0.272	0.398	0.528	0.871	0.891	0.455

Table 3: Comparison of APACHE II in MODS patients with AKI

			APACHEII
low creatinine group	**Improved**	Mean±SD	21.05±3.33
		Median（Q1,Q3）	22.00(18.00,24.00)
	Unimproved	Mean±SD	36.31±4.39
		Median（Q1,Q3）	36.00(35.00,39.00)
	Within group	Mean±SD	30.09±8.54
		Median（Q1,Q3）	33.00(22.00,37.00)
			<0.001
high creatinine group	**Improved**	Mean±SD	20.89±3.33
		Median（Q1,Q3）	22.00(17.00,22.00)
	unimproved	Mean±SD	35.78±3.35
		Median（Q1,Q3）	35.00(35.00,37.00)
	Within group	Mean±SD	28.33±8.32
		Median（Q1,Q3）	28.00(32.00,35.00)
			<0.001
			0.399

Table 4: Comparison of outcomes of CKD patients with MODS after CRRT

			Cr	Hb	WBC	PLT	APTT	ALT	AST	PCT
Improved	**Pre-treatment**	Mean±SD	656.83±300.14	83.47±25.65	11.58±5.60	198.12±136.59	44.29±12.98	48.08±96.72	74.13±161.08	24.68±74.91
		Median（Q1,Q3）	633.00(413.00,790.00)	85.00(64.90,103.00)	10.96(7.27,14.96)	173.70(123.40,245.30)	40.70(37.30,46.60)	12.00(8.00,32.00)	20.00(13.00,46.00)	3.80(1.23,23.94)
	Post-treatment	Mean±SD	449.10±215.79	86.28±18.89	8.51±2.88	201.73±82.75	39.60±3.81	18.24±24.14	29.38±32.65	3.67±6.18
		Median（Q1,Q3）	432.00(318.00,573.00)	83.00(72.30,104.00)	8.17(6.04,10.62)	188.40(132.90,245.00)	38.50(37.30,41.70)	10.00(5.00,19.00)	19.00(16.00,32.00)	1.29(0.79,3.76)
	Difference	Mean±SD	-207.7±286.50	2.81±23.40	-3.06±6.10	3.61±162.40	-4.69±12.91	-29.84±99.82	-44.75±165.91	-21.02±75.50
		Median（Q1,Q3）	-155.9(-380.0,-49.00)	-1.00(-10.00,16.40)	-1.93(-6.28,0.67)	10.00(-43.00,72.00)	-0.10(-5.60,2.30)	-2.00(-12.00,2.00)	-2.00(-14.00,5.00)	-2.02(-11.49,0.56)
	P		<0.001	0.414	0.003	0.560	1.000	0.011	0.542	0.019
Unimproved	**Pre-treatment**	Mean±SD	478.20±320.48	81.13±24.37	15.84±10.22	175.79±110.67	149.42±846.49	120.07±377.33	247.66±853.51	29.03±58.37
		Median（Q1,Q3）	358.00(258.00,612.00)	75.00(63.00,98.00)	12.74(9.09,20.97)	141.40(97.10,268.00)	44.50(38.40,51.30)	16.00(8.00,40.00)	26.00(16.00,91.00)	10.70(2.27,24.22)
	Post-treatment	Mean±SD	253.66±164.76	72.19±18.64	21.37±41.16	97.76±79.89	157.26±845.51	339.27±660.18	958.61±2221.2	34.04±66.26
		Median（Q1,Q3）	206.00(119.00,376.00)	70.00(60.00,84.30)	14.03(9.93,20.40)	78.10(46.70,124.70)	53.70(44.50,68.34)	25.00(10.00,134.00)	86.00(29.00,257.00)	11.74(5.21,36.42)
	Difference	Mean±SD	-224.5±292.87	-8.94±25.59	5.53±41.56	-78.03±96.12	7.84±21.96	219.20±661.76	710.94±2239.9	5.01±83.30
		Median（Q1,Q3）	-160.0(-380.0,-36.00)	-7.00(-19.90,6.50)	2.52(-6.33,7.43)	-56.00(-128.9,-9.60)	5.70(-2.10,19.20)	1.00(-8.00,113.00)	30.00(-2.00,207.00)	0.92(-5.79,17.66)
	P		<0.001	0.096	0.154	<0.001	<0.001	0.396	<0.001	0.403
p			0.985	0.025	0.003	<0.001	<0.001	0.006	<0.001	0.001

Comparison of the efficacy of patients with MODS and AKI after CRRT treatment

A total of 72 patients with AKI were divided into two groups according to the creatinine 355umol / L as a boundary. The creatinine value <355umol / L was the low creatinine group, and the creatinine value ≥355umol / L was the high creatinine group. Among them, 54 cases were in the low creatinine group and 18 cases were in the high creatinine group. The two groups were divided into the final efficacy according to marked effect, effective and ineffective. The total effective rate of the low creatinine group was 40.8%, and the total effective rate of the high creatinine group was 50.0%. There was no significant statistical significance between the two groups.

Comparison of outcomes of patients with MODS and AKI after CRRT treatment

Comparing the hemoglobin (Hb), white blood cell (WBC), platelet (PlT) counts, activated partial thromboplastin time (APTT), alanine aminotransferase (ALT), aspartate before and after CRRT treatment in patients with MODS and AKI The results of transaminase (AST), procalcitonin (PCT) and other indicators found that after CRRT treatment, the Hb count, WBC count, and PCT in both groups decreased significantly and were statistically significant (P <0.05). However, no significant differences were found between the two groups in the above indicators. Comparing the APACHEII scores of the improved and non-improved patients in the two groups, it was found that the APACHEII scores of the improved patients were significantly lower than that of the non-improved group, the difference was statistically significant (P <0.05), and there was no significant difference between the two groups.

Comparison of outcomes of patients with CKD and MODS after CRRT treatment

CKD patients combined with MODS, because of their original degree of kidney damage,can not be simply grouped by creatinine value, we divided them into "improved group" and "unimproved group" according to the efficacy, including 9 cases in the improved group, not improved group 9 cases. Compare the outcomes of creatinine (Cr), Hb, WBC, PLT, APTT, ALT, AST, PCT and other indicators after CRRT treatment. It was found that the creatinine value of both groups decreased significantly after treatment (P <0.05), and the WBC, PLT, and ALT of the improved group decreased significantly (P <0.05). The PLT of the unimproved group decreased significantly (P <0.05), and the APTT was significantly extended (P <0.05), AST increased significantly (P <0.05). There were statistical differences between the two groups except creatinine value.

DISCUSSIONS

Since the establishment of the Kidney Disease Intensive Care Unit (KICU) in 2016, our center not only undertook the critical care work of the undergraduate department, including the nephrology ward and the blood purification center, but also actively participated in the critical care of the center's ICU.In addition, they have participated in the management of perioperative period of some critically ill patients, and all have achieved good results. The Kidney Intensive Care Unit (KICU) has transformed from a single department function to a bridge of communication and collaboration between multiple departments, playing an indispensable and important role in the treatment of critically ill patients.

The Kidney Disease Intensive Care Unit (KICU) of our center has been established for more than five years. During the five years, we actively explored and gradually moved on the right track. Regardless of the scope of treatment, treatment timing, treatment mode, treatment effect and other aspects, there has been considerable progress. Although multiple treatment modes have been proven to have a clear effect in the treatment of critically ill patients, CRRT treatment because of its high solute clearance rate and hemodynamic stability, can effectively remove a large number of inflammatory mediators, (while providing sufficient solution supplement Drugs and parenteral nutrients) and the characteristics of maintaining fluid balance in the body (Daxi, J. 2004; Chen, Y. *et al.*, 2003; & Chen canbing, S. (2019) are still regarded as the basis of all treatments.This article retrospectively studied 190 patients who needed CRRT in critically ill patients admitted to the central ICU and KICU from January 2017 to December 2019, and 1268 CRRT treatments were performed. Share with you the experience of CRRT treatment in our center, and try to explore the timing of CRRT treatment.

INDICATIONS FOR CRRT TREATMENT

(1) Acute kidney injury (AKI)

Simple mild to moderate AKI does not necessarily require CRRT treatment, but when AKI is secondary to postoperative and serious systemic diseases, even MODS, CRRT treatment should be appropriately released. Especially when AKI patients have severe volumetric load problems, acid-base balance disorders, and electrolyte imbalance, CRRT treatment should be started urgently.

(2) Chronic kidney disease with multiple organ dysfunction (CKD)

When severe complications such as uremic encephalopathy and uremic pericarditis occur in patients with chronic kidney disease, CRRT treatment should be started in time.

Indications for CRRT treatment

With the continuous deepening of CRRT treatment research, the mechanism of action of CRRT has been to simply remove toxins, expel excess water, and expand to remove inflammatory mediators, block inflammation storms, and immune regulation. At the same time, due to the effective removal of toxins and excess water, the body's oxygenation level is increased, tissue edema is reduced, especially lung edema and cerebral edema, and important organ perfusion is increased, so as to achieve the role of organ support and maintenance. So far, the application of CRRT treatment has been expanded from simple kidney diseases to include sepsis, refractory heart failure, liver failure, acute severe pancreatitis, severe pneumonia, acute severe cerebrovascular disease, diabetic ketoacidosis, and crush Syndrome, hemolytic uremic syndrome, refractory severe autoimmune system disease, acute poisoning and other diseases (Zhengting, H., & Yunfeng, X. 2018; Jiantao, P., & Jiahua, C. 2003; & Berger, B. *et al.*, 2014). During the treatment of this new coronary pneumonia outbreak, several literatures reported that CRRT played a role in the treatment of critically ill patients (Gao, ya., & Shu zhen, S. 2020).

The timing and effect of CRRT treatment

An early article reported that there were no significant differences in patient outcomes and mortality when grouping patients with MODS and comparing them with or without CRRT. A large number of clinical trials have since reported that this non-significant difference may be related to the time when CRRT intervention was started too late (Kai, K., & Rongli, Y. 2014; & Juan, Z. *et al.*, 2018). Kang Kai (Kai, K. 2015) observed 118 patients with infectious AKI in his study. The study found that for patients with advanced AKI, CRRT treatment as early as possible can reduce mortality and improve recovery.

However, there is no unified standard for the timing of starting CRRT treatment. Earlier Ronco (Ronco, C. *et al.*, 2014) pointed out in a report comparing the doses of three CVVHs and the timing of starting treatment that those with a low BUN level at the beginning of CRRT had a high survival rate and the opposite had a high mortality rate. However, a large number of experiments have since proved that the use of serum urea nitrogen as a standard for renal replacement therapy has no guiding significance for the prognosis of patients (Qingzhi, D. *et al.*, 2018; & Xinbo, H., & Hongwei, Z. 2018).

Although a variety of laboratory indicators have been found to be biomarkers for the timing of CRRT treatment, creatinine and urea nitrogen are still the most common indicators of renal function monitoring due to the low clinical penetration rate. Considering the original varying degrees of renal insufficiency in CKD patients, this article selected 72 patients with AKI to study the timing of CRRT treatment. This article attempts to select creatinine as a reference standard for the timing of starting CRRT treatment. The cut-off value of creatinineis 355umol / L using ROC curve (see Figure 1 for details), and AKI patients are divided into two groups according to this, one group is the low creatinine group , That is, creatinine <355 umol / L (n = 54), one group is the high creatinine group, that is, creatinine ≥355umol / L (n = 18). Compare the overall efficacy and hemoglobin (Hb) of the two groups of patients before and after CRRT treatment, WBC, platelet (PlT), activated partial thromboplastin time (APTT), alanine aminotransferase (ALT), aspartate aminotransferase (AST), procalcitonin (PCT) and other specific indicators.

It can be seen from Table 1 that the overall efficacy of the patients is divided into three groups: marked, effective, and ineffective. The total effective rate of the low creatinine group is 40.8%, and the total effective rate of the high creatinine group is 50%.

It can be seen from Table 2 that after CRRT treatment, the two groups of patients have a significant decrease in white blood cells (WBC) and procalcitonin (PCT), and have statistical significance. WBC and PCT are commonly used as clinical inflammatory indicators, especially PCT as an independent predictor of sepsis (JUANJUAN, Z. *et al.*, 2018). The decline of these two indicators once again confirms that CRRT treatment can effectively reduce the inflammatory factors in the circulation, and by reducing Inflammatory factors in the circulation further block the cascade of inflammation, reduce the inflammatory response of organs, and avoid the spread of inflammation from a single organ to multiple organs (Juan, Z. *et al.*, 2018; & Lianghong, Y. *et al.*, 2010). However, the comparison between the groups is not statistically significant, indicating that the immunomodulatory mechanism of CRRT treatment can play a good role in different creatinine groups, and is not directly related to the level of creatinine.

At the same time, the red blood cell counts of the two groups of patients have decreased to varying degrees before and after treatment. It is considered to be mainly related to the consumption of the disease itself, and it does not exclude that certain red blood cell depletion may occur during CRRT treatment (Li, M. *et al.*, 2016).

So far, using creatinine as the cut-off point does not seem to yield a more meaningful positive result. The reason may be attributed to the fact that although creatinine is the most common clinical evaluation of renal function, its prediction of renal function is often lagging behind. However, when creatinine is significantly increased, the damage to renal function has often exceeded 30% -40% (Minghai, H. 2012), so it is undesirable to use creatinine as an index to start CRRT treatment. In terms of renal function monitoring, new biomarkers such as neutrophil gelatinase-associated lipocalin (NGAL), IL-18, kidney injury factor 1 (kidneyinjurymolecule-1, KIM-1) and cyst Cystatin C (cystatinC, CysC) performs well. It is possible to detect changes in glomerular filtration rate (GFR) more promptly than creatinine (Xuan, P. *et al.*, 2019; & kejing, Y. 2017). However, because it is not common in clinical development, the center believes that it is undesirable to evaluate CRRT based on creatinine value, but it is also undesirable to completely discard creatinine value. Creatinine and urea nitrogen, as traditional biomarkers, still have an irreplaceable role in evaluating kidney function.

Our center believes that the timing of starting CRRT treatment, based on the importance of creatinine value, should also consider the patient's age, mechanical ventilation, organ dysfunction, end-stage disease, etc., comprehensive consideration (Qianlin, T., & Qiao, M. 2018; & Mario, P. *et al.*, 2017). As a commonly used prognostic evaluation scale for critically ill patients, the APACHEII score can reflect the patient's comprehensive condition to a certain extent. The higher the APACHEII score, the worse the prognosis and the higher the mortality. As expected, the APACHEII score of the improvement group between the two groups was significantly lower than that of the non-improvement group, which means that the patient's overall situation has a better guiding significance for CRRT initiation time (Hong, Y. 2017).

For patients with CKD, because they originally had varying degrees of kidney damage, creatinine values could not be simply grouped. We will temporarily divide them into "improved group" and "unimproved group". Comparing the two sets of data, no matter what the final outcome of the patient is, after the CRRT treatment, the uremic toxin index will be significantly reduced, and the ability of CRRT to clear the poison is undoubted. Specifically comparing the indicators of the "improvement group", we found that in addition to the significant decline in WBC and PCT, ALT also declined significantly. The reasons for the decline in WBC and PCT are roughly the same as the reasons for the decline in infection indicators in patients with AKI, which are related to the removal of inflammatory mediators in the circulation by CRRT. This also proves once again that the immunomodulatory effects of CRRT treatment are true in both AKI and CKD patients. existing. At the same time, ALT, as an indicator of acute liver injury, also has a significant decrease. We consider that CRRT treatment can effectively remove protein-bound toxins and water-soluble toxins and correct the acid-base and electrolyte disorders. It may also be because CRRT treatment can reduce body capacity. Load, relieve liver congestion.

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In summary, as the most common treatment method in KICU, CRRT treatment is important. At present, with the deepening of the research on the treatment mechanism of CRRT, the application scope of CRRT treatment is becoming wider and wider, especially for the clearance of inflammatory mediators, which has attracted more and more attention. It plays a role that cannot be ignored in treatment. However, due to the short observation time and insufficient sample size in this trial, more samples are needed to further enrich the evidence.

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