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## The efficacy of HA380 hemoperfusion combined with Xuebijing on sepsis patients and its impacts on serum IL-17 and Presepsin levels

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**Abstract: Objective** To observe the clinical value of the HA380 hemoperfusion combined with Xuebijing injection for patients with sepsis, and analyze the effect of this regimen on the serum levels of interleukin (IL) - 17 and soluble leukocyte differentiation antigen 14 subtype (Presepsin) in patients. **Methods** A total of 120 sepsis patients admitted to Cangzhou Central Hospital between December 2021 and June 2023 were enrolled prospectively, and randomly divided into two groups: the Xuebijing group ( $n=60$ ) and the combined group ( $n=60$ ) using a random number table. During the study, 15 cases were excluded due to dropout, resulting in 52 cases in the Xuebijing group and 53 cases in the combined group. The Xuebijing group received intravenous Xuebijing injection, while the combined group received Xuebijing injection combined with HA380 hemoperfusion therapy. The treatment course for both groups lasted one week. The blood indicators and relevant scores of the two groups of patients before treatment and after one week of treatment, as well as the clinical efficacy and adverse reactions after one week of treatment were observed. **Results** After one week of treatment, the total effective rate was significantly higher in the combined group than that in the Xuebijing group (94.34% vs 80.77%,  $\chi^2=4.456$ ,  $P=0.035$ ). Serum levels of IL-17, tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), procalcitonin (PCT), Presepsin, creatinine, urea nitrogen, and arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>), as well as Acute Physiology and Chronic Health Evaluation II (APACHE-II) score and Sequential Organ Failure Assessment (SOFA) score, were significantly reduced in both groups ( $P<0.05$ ), with the combined group showing significantly lower levels than the Xuebijing group ( $P<0.05$ ). Conversely, arterial oxygen saturation (SaO<sub>2</sub>) levels and *pondus hydrogenii* (pH) values were significantly increased in both groups ( $P<0.05$ ), with significantly higher levels in the combined group than in the Xuebijing group ( $P<0.05$ ). The incidence of adverse reactions was significantly lower in the combined group than in the Xuebijing group (5.66% vs 19.23%,  $\chi^2=4.456$ ,  $P=0.035$ ). **Conclusion** The combination of HA380 hemoperfusion and Xuebijing has significant therapeutic effects on sepsis patients, which can improve the prognosis of patients and reduce the levels of serum IL-17 and Presepsin.

**Keywords:** Hemoperfusion; Xuebijing injection; Sepsis; Clinical efficacy; Interleukin-17; Soluble leukocyte differentiation antigen 14 subtype

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Sepsis is a life-threatening disease triggered by infection-induced dysregulated host responses, which further leads to fatal organ dysfunction. Its core pathophysiological mechanism is a vicious cycle formed by immune imbalance and excessive inflammation [1]. Both annual incidence and mortality of sepsis remain at relatively high levels in China, accompanied by heavy medical expenses, making it a major public health challenge [2]. Sepsis presents diverse clinical manifestations, ranging from systemic inflammatory response syndrome to secondary infection or organ failure resulting from immunosuppression [3-4]. Current therapeutic strategies adopt bundled interventions including early anti-infection therapy, fluid resuscitation and organ supportive care, yet monotherapy yields limited efficacy [5]. As a compound traditional Chinese medicine preparation, Xuebijing injection can reduce the levels of pro-inflammatory factors via inhibiting the nuclear factor- $\kappa$ B signaling pathway [6]. On the other hand, HA380 hemoperfusion ameliorates microcirculation disturbance

by adsorbing inflammatory mediators. Nevertheless, clinical evidence supporting the combined application of hemoperfusion and proprietary Chinese medicines remains insufficient [7]. This study aimed to observe the synergistic therapeutic effect of HA380 hemoperfusion combined with Xuebijing injection, so as to explore novel treatment strategies for sepsis.

### 1 Materials and Methods

#### 1.1 General Data

A total of 120 patients diagnosed with sepsis admitted to Cangzhou Central Hospital from December 2021 to June 2023 were prospectively enrolled and randomly divided into Xuebijing group (60 cases) and combined treatment group (60 cases) by random number table method. During the trial, 15 cases were lost to follow-up:

5 cases were transferred to ICU for comprehensive treatment due to aggravated condition; 4 cases voluntarily withdrew owing to economic burden or hospital transfer; 3 cases suffered study-unrelated gastrointestinal hemorrhage during treatment; another 3 cases dropped out due to self-adjusted medication. Ultimately, there were 52 patients in Xuebijing group and 53 patients in combined group. No significant differences were found in baseline clinical data between the two groups ( $P>0.05$ ), as shown in **Table 1**. This study was approved by the Ethics Committee of Cangzhou Central Hospital (Approval No.: 2021-246-02(z)).

**Tab.1** Comparison of general data between two groups

Group	n	Gender (case)		Age (years, $\bar{x}\pm s$ )	BMI ( $\text{kg}/\text{m}^2$ , $\bar{x}\pm s$ )
		Male	Female		
Xuebijing group	52	34	18	51.84±6.70	23.51±4.29
Combined group	53	33	20	51.77±6.52	23.67±4.35
$\chi^2/t$ value			0.111	0.054	0.19
P value			0.739	0.957	0.85

### 1.2 Inclusion and Exclusion Criteria

**Inclusion criteria:** (1) Conforming to the clinical diagnostic criteria for sepsis [8]; (2) Free of cognitive and communication disorders and capable of cooperating with treatment; (3) Complete medical records and good treatment compliance; (4) Patients or their family members fully informed and signed informed consent forms voluntarily.

**Exclusion criteria:** (1) Allergy to Xuebijing injection used in this study; (2) Received glucocorticoid therapy within the latest 3 months; (3) Complicated with immunodeficiency diseases; (4) Combined with severe infectious diseases.

**Elimination criteria:** (1) Terminated treatment for any reason during the intervention period; (2) Participated in other concurrent clinical trials.

### 1.3 Treatment Protocols

All patients received conventional treatments including empirical anti-infection therapy, nutritional support and ventilator-assisted ventilation. On the basis of conventional therapy, patients in Xuebijing group were given Xuebijing injection (National Medicine Approval No. Z20040033, Tianjin Hongri Pharmaceutical Co., Ltd., specification: 10 mL per ampoule). A total of 100 mL Xuebijing injection was diluted with 100 mL 0.9% sodium chloride solution for intravenous infusion, administered once every 6 hours for consecutive 7 days. Patients in combined group received identical Xuebijing treatment plus HA380 hemoperfusion (Jafro Biomedical Co., Ltd.). A double-lumen femoral venous catheter was placed to establish vascular access. The catheter was flushed with

0.9% normal saline, with blood flow velocity maintained at 150–200 mL/min and single treatment duration of 2.0–2.5 hours, once daily for continuous 7 days.

### 1.4 Observation Indicators

(1) **Clinical efficacy:** Markedly effective: clinical symptoms resolved and laboratory indicators returned to normal range; Effective: clinical symptoms relieved and laboratory indicators tended to normalize; Ineffective: no improvement or even deterioration of symptoms and laboratory parameters. Total effective rate = (Markedly effective cases + Effective cases) / Total cases × 100%.

(2) **Inflammatory factors:** Fasting venous blood (10 mL) was collected at baseline (T0) and after 1-week treatment (T1) for serum separation. Serum samples were partially detected immediately and the rest stored in refrigerator for standby use. Enzyme-linked immunosorbent assay (ELISA) was adopted to detect serum levels of interleukin-17 (IL-17), tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), procalcitonin (PCT) and soluble leukocyte differentiation antigen 14 subtype (Presepsin).

(3) **Renal function indexes:** The reserved serum specimens at T0 and T1 were used to detect serum creatinine (SCr) and blood urea nitrogen (BUN) levels via fully automatic biochemical analyzer (Shanghai Kehua Bio-engineering Co., Ltd.).

(4) **Severity scoring systems:** Acute Physiology and Chronic Health Evaluation II (APACHE II) score [9] and Sequential Organ Failure Assessment (SOFA) score [10] were adopted to evaluate disease severity at T0 and T1. The total score of APACHE II ranges from 0 to 71, with higher scores indicating higher mortality risk; the total SOFA score ranges from 0 to 24, and higher scores represent poorer prognosis.

(5) **Arterial blood gas parameters:** Arterial partial pressure of carbon dioxide ( $\text{PaCO}_2$ ), arterial oxygen saturation ( $\text{SaO}_2$ ) and blood pH value were determined by blood gas analyzer (Radiometer Medical ApS) at T0 and T1.

(6) **Adverse reactions:** The incidence of adverse events was recorded and compared between the two groups during treatment.

### 1.5 Statistical Analysis

SPSS 25.0 statistical software was used for data analysis. Normally distributed measurement data including inflammatory factors, renal function indexes, clinical scores and blood gas parameters were expressed as  $\bar{x}\pm s$ . Paired-samples *t*-test was used for intra-group comparison and independent-samples *t*-test for inter-group comparison. Enumeration data such as clinical efficacy and adverse reactions were presented as case (%), and chi-square test was applied for inter-group comparison. A P value <0.05 was defined as statistically significant difference.

2 Results

2.1 Clinical Efficacy

After one-week intervention, the total clinical effective rate was 94.34% in combined group, which was significantly higher than 80.77% in Xuebijing group ( $P<0.05$ ), see Table 2.

2.2 Levels of Inflammatory Factors

No significant inter-group differences were observed in serum IL-17, TNF- $\alpha$ , PCT and Presepsin levels at T0 ( $P>0.05$ ). Compared with baseline values, all above inflammatory biomarkers were obviously decreased in both groups at T1 ( $P<0.05$ ), and the levels in combined group were remarkably lower than those in Xuebijing group ( $P<0.05$ ), see Table 3.

2.3 Serum Creatinine and Blood Urea Nitrogen

There was no statistical difference in SCr and BUN levels between the two groups before treatment ( $P>0.05$ ). Both renal function indicators were markedly decreased after treatment in two groups ( $P<0.05$ ), with lower levels detected in combined group ( $P<0.05$ ), see Table 4.

2.4 Disease Severity Scores

Baseline APACHE II and SOFA scores were comparable between groups ( $P>0.05$ ). Both scores were significantly reduced after treatment in two arms ( $P<0.05$ ), and the reduction degree was more prominent in combined group ( $P<0.05$ ), see Table 5.

2.5 Arterial Blood Gas Indicators

All blood gas parameters showed no significant difference at T0 ( $P>0.05$ ). After intervention, PaCO<sub>2</sub> was obviously declined while SaO<sub>2</sub> and pH value were distinctly elevated in both groups ( $P<0.05$ ). The combined group presented lower PaCO<sub>2</sub>, higher SaO<sub>2</sub> and higher pH value relative to Xuebijing group ( $P<0.05$ ), see Table 6.

2.6 Incidence of Adverse Reactions

The total incidence of adverse reactions was 5.66% in combined group, which was significantly lower than 19.23% in Xuebijing group ( $P<0.05$ ), see Table 7.

Tab.2 Comparison of clinical efficacy between two groups (case)

Group	n	Markedly effective	Effective	Ineffective	Total effective rate (%)
Xuebijing group	52	20	22	10	80.77
Combined group	53	27	23	3	94.34
$\chi^2$ value					4.456
P value					0.035

Tab.3 Comparison of levels of inflammatory factors between two groups ( $\bar{x}\pm s$ )

Group	n	IL-17 (pg/mL)		TNF- $\alpha$ (pg/mL)		PCT (ng/mL)		Presepsin (pg/mL)	
		T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>
Xuebijing group	52	78.82 $\pm$ 8.72	67.47 $\pm$ 6.91*	68.84 $\pm$ 8.67	55.84 $\pm$ 6.89*	13.77 $\pm$ 2.21	11.26 $\pm$ 2.25*	857.35 $\pm$ 129.83	447.71 $\pm$ 72.30*
Combined group	53	78.69 $\pm$ 8.53	52.60 $\pm$ 5.73*	68.39 $\pm$ 8.78	37.35 $\pm$ 4.54*	13.85 $\pm$ 2.34	9.43 $\pm$ 1.83*	836.74 $\pm$ 105.96	367.34 $\pm$ 64.98*
t value		0.077	12.013	0.264	16.267	0.18	4.576	0.892	5.993
P value		0.939	<0.001	0.792	<0.001	0.857	<0.001	0.375	<0.001

\*Note: Compared with T<sub>0</sub> in the same group,  $P<0.05$ .

Tab.4 Comparison of Scr and BUN between two groups ( $\bar{x}\pm s$ )

Group	n	SCr ( $\mu$ mol/L)		BUN (mmol/L)	
		T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>
Xuebijing group	52	264.68 $\pm$ 26.35	226.46 $\pm$ 22.90*	29.94 $\pm$ 4.34	22.75 $\pm$ 3.86*
Combined group	53	262.55 $\pm$ 26.47	196.69 $\pm$ 21.06*	29.86 $\pm$ 4.38	17.34 $\pm$ 3.17*
t value		0.413	6.936	0.094	7.855
P value		0.68	<0.001	0.925	<0.001

\*Note: Compared with T<sub>0</sub> in the same group,  $P<0.05$ .

Tab.5 Comparison of related scores between two groups (point,  $\bar{x}\pm s$ )

Group	n	APACHE II score		SOFA score	
		T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>
Xuebijing group	52	24.68 $\pm$ 6.46	16.46 $\pm$ 5.02*	20.05 $\pm$ 2.54	17.86 $\pm$ 1.79*
Combined group	53	24.55 $\pm$ 6.58	12.69 $\pm$ 4.17*	20.23 $\pm$ 2.29	13.24 $\pm$ 1.46*
t value		0.102	4.189	0.382	14.505
P value		0.919	<0.001	0.704	<0.001

\*Note: Compared with T<sub>0</sub> in the same group,  $P<0.05$ .

Tab.6 Comparison of arterial blood gas indicators between two groups ( $\bar{x}\pm s$ )

Group	n	PaCO <sub>2</sub> (mmHg)		SaO <sub>2</sub> (%)		pH value	
		T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>	T <sub>0</sub>	T <sub>1</sub>
Xuebijing group	52	52.89±5.47	45.67±5.12*	83.26±8.75	89.07±9.54*	7.05±0.25	7.16±0.14*
Combined group	53	52.76±5.54	39.80±4.21*	83.44±8.40	95.46±9.79*	7.03±0.28	7.30±0.12*
t value		0.121	6.422	0.108	3.387	0.386	5.505
P value		0.904	<0.001	0.915	0.001	0.7	<0.001

\*Note: Compared with T<sub>0</sub> in the same group,  $P<0.05$ .

Tab.7 Comparison of incidence of adverse reactions between two groups (case)

Group	n	Nausea and vomiting	Hypotension	Thrombocytopenia	Allergic reaction	Total incidence (%)
Xuebijing group	52	3	3	2	2	19.23
Combined group	53	1	1	0	1	5.66
$\chi^2$ value						4.456
P value						0.035

### 3 Discussion

Sepsis originates from excessive host responses to pathogenic infection [1]. When pathogens including bacteria, viruses and fungi invade the human body, the immune system initiates defensive reactions. In some cases, overactivated immune responses trigger massive release of inflammatory mediators and induce systemic inflammatory storm, resulting in irreversible organ damage, which is the core pathogenic feature of sepsis [1-2]. Sepsis progresses rapidly, and delayed intervention will lead to disease deterioration and even death [11]. Therefore, early identification and timely standardized treatment are critical to improve clinical cure rate. The main active ingredients of Xuebijing injection include safflower, red peony root, chuanxiong rhizome, salvia miltiorrhiza and angelica sinensis, which exert effects of activating blood circulation, removing blood stasis and detoxification in traditional Chinese medicine theory [12-13]. Xuebijing can effectively inhibit the release of inflammatory mediators and relieve inflammatory responses in septic patients [14-16], bind and neutralize endotoxin to reduce systemic toxic injury, improve sepsis-related microcirculatory disturbance, increase tissue blood perfusion, optimize tissue oxygen supply and nutritional metabolism, and further protect vital organ functions [17-18]. Additionally, it can rectify immune disorder, restore functional activity of immune cells and enhance host anti-infection and inflammatory regulatory capacity [19]. The basic principle of hemoperfusion is to extracorporeally drain patient blood, remove harmful substances such as inflammatory mediators via specific adsorbents, and reinfuse purified blood back into circulation to achieve blood purification [20-22]. The core component of HA380 hemoperfusion cartridge adopted in this study is HA380 resin adsorption column, which can efficiently adsorb circulating inflammatory mediators to mitigate systemic inflammation and protect organs, and eliminate endotoxin to alleviate endotoxemia [23]. Furthermore, HA380 hemoperfusion can modulate immune cell function, restore

immune homeostasis and host anti-pathogen ability. It also suppresses coagulation system activation by clearing inflammatory mediators and endotoxin, prevents microthrombosis formation, improves tissue perfusion, maintains vascular endothelial barrier integrity, and alleviates tissue edema and organic injury.

This study confirmed that combined therapy achieved superior total effective rate compared with single Xuebijing treatment, indicating synergistic symptom-improving effects between HA380 hemoperfusion and Xuebijing injection. Anti-inflammation is the core of sepsis management [24]. Significant reductions of IL-17, TNF- $\alpha$  and PCT were observed in both groups, with more satisfactory anti-inflammatory outcomes in combined group. The underlying mechanism may be that Xuebijing inhibits endogenous inflammatory mediator synthesis and release, while hemoperfusion directly eliminates residual circulating inflammatory factors. Accumulated studies have verified that elevated Presepsin level is closely correlated with sepsis severity, which can be applied in clinical diagnosis and disease severity assessment [25]. Increased SCr suggests renal parenchymal injury, and elevated BUN indicates renal insufficiency or abnormal protein metabolism; sepsis is prone to induce multiple organ failure [26-27]. The remarkable declines of Presepsin, SCr, BUN, APACHE II and SOFA scores after treatment proved that this combined regimen could effectively alleviate liver and renal injury in septic patients. Respiratory and circulatory function are vital indicators reflecting sepsis severity [6,28]. The decreased PaCO<sub>2</sub> and increased SaO<sub>2</sub> and pH value after treatment demonstrated that combined intervention could optimize blood oxygen supply and restore acid-base balance in vivo. Meanwhile, lower adverse reaction rate in combined group verified its superior clinical safety profile.

In conclusion, HA380 hemoperfusion combined with Xuebijing injection possesses remarkable clinical efficacy in sepsis treatment, which can effectively ameliorate systemic inflammatory state, improve respiratory and circulatory function, relieve renal impairment and ensure favorable safety. This combined therapeutic regimen provides a reliable reference for clinical sepsis intervention.

Further researches are required to clarify its exact molecular mechanisms, optimize clinical administration protocols and enrich therapeutic options for sepsis.

**Conflict of Interest:** None

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· 脓毒症专题·论著·

# HA380血液灌流联合血必净治疗脓毒症患者的疗效及对血清IL-17和Presepsin水平的影响

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**摘要:** 目的 观察HA380血液灌流联合血必净注射液用于脓毒症患者的临床价值,分析其对患者血清白细胞介素(IL)-17、可溶性白细胞分化抗原14亚型(Presepsin)水平的作用。方法 前瞻性选取沧州市中心医院2021年12月至2023年6月收治的120例脓毒症患者为研究对象,采用随机数字表法分为血必净组和联合组,各60例。研究过程中共脱落15例,最终血必净组纳入52例,联合组53例。血必净组给予血必净注射液治疗,联合组给予血必净注射液联合HA-380树脂血液灌流器治疗。两组疗程均为1周。观察两组患者治疗前和治疗1周的血液指标、相关评分以及治疗1周的临床疗效和不良反应情况。结果 治疗1周后,联合组患者总有效率显著高于血必净组(94.34% vs 80.77%,  $\chi^2=4.456$ ,  $P=0.035$ );两组患者血清IL-17、肿瘤坏死因子- $\alpha$ (TNF- $\alpha$ )、降钙素原(PCT)、Presepsin、血清肌酐、血尿素氮、动脉血二氧化碳分压(PaCO<sub>2</sub>)水平和急性生理学与慢性健康状况评分系统II(APACHE-II)评分、序贯器官衰竭评估(SOFA)评分显著降低( $P<0.05$ ),且联合组显著低于血必净组( $P<0.05$ );两组患者动脉血氧饱和度(SaO<sub>2</sub>)、酸碱度(pH值)显著升高( $P<0.05$ ),且联合组显著高于血必净组( $P<0.05$ )。联合组患者不良反应总发生率显著低于血必净组(5.66% vs 19.23%,  $\chi^2=4.456$ ,  $P=0.035$ )。结论 HA380血液灌流联合血必净治疗脓毒症患者的疗效显著,可改善患者预后,降低患者血清IL-17和Presepsin水平。

**关键词:** 血液灌流; 血必净注射液; 脓毒症; 临床疗效; 白细胞介素-17; 可溶性白细胞分化抗原14亚型

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## The efficacy of HA380 hemoperfusion combined with *Xuebijing* on sepsis patients and its impacts on serum IL-17 and Presepsin levels

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**Abstract: Objective** To observe the clinical value of the HA380 hemoperfusion combined with *Xuebijing* injection for patients with sepsis, and analyze the effect of this regimen on the serum levels of interleukin (IL)-17 and soluble leukocyte differentiation antigen 14 subtype (Presepsin) in patients. **Methods** A total of 120 sepsis patients admitted to Cangzhou Central Hospital between December 2021 and June 2023 were enrolled prospectively, and randomly divided into two groups: the *Xuebijing* group ( $n=60$ ) and the combined group ( $n=60$ ) using a random number table. During the study, 15 cases were excluded due to dropout, resulting in 52 cases in the *Xuebijing* group and 53 cases in the combined group. The *Xuebijing* group received intravenous *Xuebijing* injection, while the combined group received *Xuebijing* injection combined with HA380 hemoperfusion therapy. The treatment course for both groups lasted one week. The blood indicators and relevant scores of the two groups of patients before treatment and after one week of treatment, as well as the clinical efficacy and adverse reactions after one week of treatment were observed. **Results** After one week of treatment, the total effective rate was significantly higher in the combined group than that in the *Xuebijing* group

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(94.34% vs 80.77%,  $\chi^2=4.456, P=0.035$ ). Serum levels of IL-17, tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), procalcitonin (PCT), Presepsin, serum creatinine, blood urea nitrogen, and arterial partial pressure of carbon dioxide (PaCO<sub>2</sub>), as well as Acute Physiology and Chronic Health Evaluation II (APACHE-II) score and Sequential Organ Failure Assessment (SOFA) score, were significantly reduced in both groups ( $P<0.05$ ), with the combined group showing significantly lower levels than the Xuebijing group ( $P<0.05$ ). Conversely, arterial oxygen saturation (SaO<sub>2</sub>) levels and *pondus hydrogenii* (pH) values were significantly increased in both groups ( $P<0.05$ ), with significantly higher levels in the combined group than in the Xuebijing group ( $P<0.05$ ). The incidence of adverse reactions was significantly lower in the combined group than in the Xuebijing group (5.66% vs 19.23%,  $\chi^2=4.456, P=0.035$ ). **Conclusion** The combination of HA380 hemoperfusion and Xuebijing has significant therapeutic effects on sepsis patients, which can improve the prognosis of patients and reduce the levels of serum IL-17 and Presepsin.

**Keywords:** Hemoperfusion; Xuebijing injection; Sepsis; Clinical efficacy; Interleukin-17; Soluble leukocyte differentiation antigen 14 subtype

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脓毒症是一种危及生命的疾病,由感染引发宿主反应失调,进而导致危及生命的器官功能障碍,核心病理生理过程为免疫失衡与过度炎症形成的恶性循环<sup>[1]</sup>。我国脓毒症年发病率和死亡率均处于较高水平,且治疗费用高昂,成为公共卫生的重要难题<sup>[2]</sup>。脓毒症临床表现多样,可能表现为全身炎症反应综合征,也可能因免疫抑制继发感染或器官衰竭<sup>[3-4]</sup>。当前治疗策略采用“集束化”方法,涵盖早期抗感染、液体复苏及器官支持,但单一疗法效果有限<sup>[5]</sup>。血必净注射液作为一种中药复方制剂,能通过抑制核因子- $\kappa$ B信号通路降低促炎因子水平<sup>[6]</sup>。另一方面,HA380血液灌流通过吸附炎症介质改善微循环,然而,其与中成药联合使用的疗效证据尚不充分<sup>[7]</sup>。本研究旨在观察HA380血液灌流与血必净的联合效应,探讨脓毒症治疗的新策略。

## 1 资料与方法

**1.1 一般资料** 前瞻性选取沧州市中心医院2021年12月至2023年6月收治的120例脓毒症患者为研究对象,采用随机数字表法将患者分为血必净组(60例)和联合组(60例)。研究过程中共脱落15例,其中5例因病情恶化需转入重症监护病房进行综合治疗,退出本研究;4例因个人原因(经济负担、转院)主动要求中止参与;3例因治疗过程中出现非研究相关的消化道出血;3例因自行调整用药退出研究。最终血必净组剩余52例,联合组剩余53例。两组患者一般资料差异无统计学意义( $P>0.05$ ),见表1。研究经沧州市中心医院伦理委员会审核批准[2021-246-02(z)]。

**1.2 纳入与排除标准** 纳入标准:(1)符合脓毒症临床诊断标准<sup>[8]</sup>;(2)无认知与表达障碍,可配合完成治疗;(3)病历资料齐全,依从性良好;(4)患者或

表1 两组一般资料比较

Tab.1 Comparison of general data between two groups

组别	例数	性别(例)		年龄 (岁, $\bar{x}\pm s$ )	身体质量指数 (kg/m <sup>2</sup> , $\bar{x}\pm s$ )
		男	女		
血必净组	52	34	18	51.84 $\pm$ 6.70	23.51 $\pm$ 4.29
联合组	53	33	20	51.77 $\pm$ 6.52	23.67 $\pm$ 4.35
$\chi^2$ 值		0.111		0.054	0.190
P值		0.739		0.957	0.850

家属知情,自愿入组,并签署同意书。排除标准:(1)对本研究使用药物(血必净)过敏;(2)近3个月接受过激素类药物治疗;(3)合并免疫缺陷;(4)合并严重传染性疾病。脱落标准:(1)治疗过程因任何原因中止治疗;(2)同时参与其他研究。

**1.3 治疗方法** 所有患者给予常规抗感染、营养支持和呼吸机辅助治疗。血必净组在常规治疗基础上给予血必净注射液(国药准字Z20040033,天津红日药业,10 mL)治疗。100 mL血必净注射液加入100 mL 0.9%氯化钠注射液中,行静脉滴注,每6 h给药1次,连续治疗1周。联合组患者在血必净组治疗基础上,采用HA380血液灌流器(健帆生物科技)治疗,在股静脉置入双腔导管,建立血管通路,使用0.9%氯化钠溶液冲洗导管,维持血流量为150~200 mL/min,持续时间2~2.5 h,每天治疗1次,连续治疗1周。

**1.4 观察指标** (1)临床疗效:临床症状消退,实验室指标恢复正常水平判定为显效;临床症状改善,实验室指标靠近正常水平判定为有效;临床症状与实验室指标无改善甚至加重判定为无效。总有效率=(显效+有效)/总例数 $\times$ 100%。(2)炎性因子水平:治疗前(T<sub>0</sub>)和治疗1周后(T<sub>1</sub>),取患者空腹静脉血10 mL,离心得到血清。取部分血清(剩余放冰箱备用),采用酶联免疫吸附法(enzyme-linked immunosorbent assay,

ELISA)测定患者血清白细胞介素(interleukin, IL)-17、肿瘤坏死因子- $\alpha$ (tumor necrosis factor- $\alpha$ , TNF- $\alpha$ )、降钙素原(procalcitonin, PCT)、可溶性白细胞分化抗原14亚型(soluble leukocyte differentiation antigen 14 subtype, Presepsin)水平。(3) 血清肌酐(serum creatinine, SCr)和血尿素氮(blood urea nitrogen, BUN)水平:取备用血清( $T_0$ 、 $T_1$ 时),采用全自动生化分析仪(上海科华实验系统有限公司)检测患者SCr和BUN水平。(4) 相关评分: $T_0$ 、 $T_1$ 时刻,采用急性生理学与慢性健康状况评分系统II(Acute Physiology and Chronic Health Evaluation II, APACHE II)<sup>[9]</sup>评分和序贯器官衰竭评估(Sequential Organ Failure Assessment, SOFA)<sup>[10]</sup>评分对患者治疗情况进行辅助评估。APACHE II总分0~71分,分数越高表明患者死亡风险越高。SOFA总分0~24分,分数越高表明预后越差。(5) 动脉血气指标: $T_0$ 、 $T_1$ 时刻,采用血气分析仪(雷度米特医疗设备有限公司)测定患者动脉血二氧化碳分压(partial pressure of arterial carbon dioxide, PaCO<sub>2</sub>)、动脉血氧饱和度(arterial oxygen saturation, SaO<sub>2</sub>)及酸碱度(pondus hydrogenii, pH)。(6) 不良反应情况:治疗过程中,观察两组患者不良反应发生情况。

1.5 统计学方法 数据分析使用SPSS 25.0软件。计量资料(炎症因子水平、血清肌酐、尿素氮水平、相关评分、血气指标)符合正态分布,以 $\bar{x}\pm s$ 的形式描述,组内和组间比较分别行配对、独立样本 $t$ 检验;计数资料(临床疗效、不良反应情况)以例(%)表示,比较使用 $\chi^2$ 检验。 $P<0.05$ 为差异有统计学意义。

## 2 结果

2.1 临床疗效 治疗1周后,联合组患者总有效率(94.34%)显著高于血必净组(80.77%)( $P<0.05$ )。见表2。

2.2 炎症因子水平  $T_0$ 时,两组患者IL-17、TNF- $\alpha$ 、PCT、Presepsin水平差异无统计学意义( $P>0.05$ );与 $T_0$ 时比较, $T_1$ 时两组患者IL-17、TNF- $\alpha$ 、PCT、Presepsin水平显著降低( $P<0.05$ ),且联合组显著低于血必净组( $P<0.05$ )。见表3。

2.3 SCr、BUN水平  $T_0$ 时,两组患者SCr、BUN水平差异无统计学意义( $P>0.05$ );与 $T_0$ 时比较, $T_1$ 时两组患者SCr、BUN水平显著降低( $P<0.05$ ),联合组显著低于血必净组( $P<0.05$ )。见表4。

2.4 相关评分  $T_0$ 时,两组患者APACHE II、SOFA评分差异无统计学意义( $P>0.05$ );与 $T_0$ 时比较, $T_1$ 时两组患者APACHE II、SOFA评分显著降低( $P<0.05$ ),且组间比较差异有统计学意义( $P<0.05$ )。见表5。

表2 两组临床疗效比较 (例)

Tab.2 Comparison of clinical efficacy between two groups (case)

组别	例数	显效	有效	无效	总有效率(%)
血必净组	52	20	22	10	80.77
联合组	53	27	23	3	94.34
$\chi^2$ 值					4.456
$P$ 值					0.035

表3 两组炎症因子水平比较 ( $\bar{x}\pm s$ )

Tab.3 Comparison of levels of inflammatory factors between two groups ( $\bar{x}\pm s$ )

组别	例数	IL-17(pg/mL)		TNF- $\alpha$ (pg/mL)		PCT(ng/mL)		Presepsin(pg/mL)	
		$T_0$	$T_1$	$T_0$	$T_1$	$T_0$	$T_1$	$T_0$	$T_1$
血必净组	52	78.82 $\pm$ 8.72	67.47 $\pm$ 6.91*	68.84 $\pm$ 8.67	55.84 $\pm$ 6.89*	13.77 $\pm$ 2.21	11.26 $\pm$ 2.25*	857.35 $\pm$ 129.83	447.71 $\pm$ 72.30*
联合组	53	78.69 $\pm$ 8.53	52.60 $\pm$ 5.73*	68.39 $\pm$ 8.78	37.35 $\pm$ 4.54*	13.85 $\pm$ 2.34	9.43 $\pm$ 1.83*	836.74 $\pm$ 105.96	367.34 $\pm$ 64.98*
$t$ 值		0.077	12.013	0.264	16.267	0.180	4.576	0.892	5.993
$P$ 值		0.939	<0.001	0.792	<0.001	0.857	<0.001	0.375	<0.001

注:与同组 $T_0$ 时刻比较,\* $P<0.05$ 。

表4 两组SCr和BUN水平比较 ( $\bar{x}\pm s$ )

Tab.4 Comparison of SCr and BUN between two groups ( $\bar{x}\pm s$ )

组别	例数	SCr( $\mu$ mol/L)		BUN(mmol/L)	
		$T_0$	$T_1$	$T_0$	$T_1$
血必净组	52	264.68 $\pm$ 26.35	226.46 $\pm$ 22.90*	29.94 $\pm$ 4.34	22.75 $\pm$ 3.86*
联合组	53	262.55 $\pm$ 26.47	196.69 $\pm$ 21.06*	29.86 $\pm$ 4.38	17.34 $\pm$ 3.17*
$t$ 值		0.413	6.936	0.094	7.855
$P$ 值		0.680	<0.001	0.925	<0.001

注:与同组 $T_0$ 时刻比较,\* $P<0.05$ 。

表5 两组相关评分比较 (分,  $\bar{x}\pm s$ )

Tab.5 Comparison of related scores between two groups (point,  $\bar{x}\pm s$ )

组别	例数	APACHE II		SOFA	
		$T_0$	$T_1$	$T_0$	$T_1$
血必净组	52	24.68 $\pm$ 6.46	16.46 $\pm$ 5.02*	20.05 $\pm$ 2.54	17.86 $\pm$ 1.79*
联合组	53	24.55 $\pm$ 6.58	12.69 $\pm$ 4.17*	20.23 $\pm$ 2.29	13.24 $\pm$ 1.46*
$t$ 值		0.102	4.189	0.382	14.505
$P$ 值		0.919	<0.001	0.704	<0.001

注:与同组 $T_0$ 时刻比较,\* $P<0.05$ 。

2.5 动脉血气指标  $T_0$ 时,两组患者血气相关指标差异无统计学意义( $P>0.05$ );与 $T_0$ 时比较, $T_1$ 时两组患者 $PaCO_2$ 显著降低( $P<0.05$ ), $SaO_2$ 、pH值显著升高( $P<0.05$ ),且联合组 $PaCO_2$ 低于血必净组, $SaO_2$ 、pH值

高于血必净组( $P<0.05$ )。见表6。

2.6 不良反应发生情况 治疗期间,联合组患者不良反应总发生率(5.66%)显著低于血必净组(19.23%) ( $P<0.05$ )。见表7。

表6 两组动脉血气指标比较 ( $\bar{x}\pm s$ )  
Tab.6 Comparison of arterial blood gas indicators between two groups ( $\bar{x}\pm s$ )

组别	例数	$PaCO_2$ (mmHg)		$SaO_2$ (%)		pH值	
		$T_0$	$T_1$	$T_0$	$T_1$	$T_0$	$T_1$
血必净组	52	52.89±5.47	45.67±5.12*	83.26±8.75	89.07±9.54*	7.05±0.25	7.16±0.14*
联合组	53	52.76±5.54	39.80±4.21*	83.44±8.40	95.46±9.79*	7.03±0.28	7.30±0.12*
t值		0.121	6.422	0.108	3.387	0.386	5.505
P值		0.904	<0.001	0.915	0.001	0.700	<0.001

注:与同组 $T_0$ 时刻比较,\* $P<0.05$ 。

表7 两组不良反应发生情况比较 (例)

Tab.7 Comparison of incidence of adverse reactions between two groups (case)

组别	例数	恶心呕吐	低血压	血小板降低	过敏反应	总发生率 (%)
血必净组	52	3	3	2	2	19.23
联合组	53	1	1	0	1	5.66
$\chi^2$ 值						4.456
P值						0.035

### 3 讨论

脓毒症源于机体对感染的过度反应<sup>[1]</sup>。细菌、病毒或真菌等病原体入侵人体后,免疫系统启动防御机制,但部分情况下防御机制过度活跃,释放大量炎症物质会引发全身性“炎症风暴”,损害器官功能,这种过度免疫反应是脓毒症的核心特征<sup>[1-2]</sup>。脓毒症发展迅速,不及时治疗会导致疾病恶化甚至危及生命<sup>[11]</sup>。因此,早期识别和及时治疗是提高治愈率的关键。

血必净注射液的主要成分包括红花、赤芍、川芎、丹参、当归等,该药方中中药活性成分具有活血、化瘀、解毒的功效<sup>[12-13]</sup>。血必净可显著抑制脓毒症患者炎症介质的释放以减轻炎症<sup>[14-16]</sup>,且可有效结合并中和内毒素,减少机体损害;同时,它能改善脓毒症伴随的微循环障碍,增加血流量以改善组织氧供与营养,保护器官功能<sup>[17-18]</sup>。还可调节脓毒症患者的免疫紊乱,恢复免疫细胞功能,增强机体抗病及调节炎症的能力<sup>[19]</sup>。血液灌注治疗的基本原理是将患者血液引出体外,经特定吸附剂吸附炎症介质等有害物质后回输,以实现血液净化<sup>[20-22]</sup>。本研究采用的HA380血液灌流器,核心组件为HA380树脂吸附柱,其可高效吸附血液中的炎症介质以减轻炎症、保护器

官,还能吸附内毒素,从而减轻内毒素血症<sup>[23]</sup>。此外,HA380血液灌流可调节免疫细胞功能、促进免疫平衡以恢复机体抗感染能力,且能通过清除炎症介质与内毒素,抑制凝血系统激活,预防微血栓形成,改善组织灌注,同时维护血管屏障功能,减轻组织水肿与器官损伤。

本研究显示,联合组总有效率显著高于血必净组,提示HA380血液灌流联合血必净治疗脓毒症疗效显著,二者或具有协同改善患者症状的作用。抗炎是脓毒症治疗的关键<sup>[24]</sup>,两组IL-17、TNF- $\alpha$ 、PCT水平均显著降低,且联合组更低,表明联合治疗抗炎效果优于单用血必净,推测血必净可抑制炎症介质释放,而灌流能直接过滤血液中残留的炎症介质。相关研究指出,脓毒症患者Presepsin水平显著升高,其可用于临床诊断与病情评估<sup>[25]</sup>。SCr升高提示肾功能受损,BUN升高可能指示肾功能不全或蛋白质代谢异常,且脓毒症可致多器官衰竭<sup>[26-27]</sup>。本研究中,治疗后两组Presepsin、SCr、BUN水平及APACHE II、SOFA评分均显著降低,证实该治疗方案可改善脓毒症患者肝肾损伤。呼吸循环状况是脓毒症病情严重程度的重要衡量指标<sup>[6,28]</sup>,治疗后两组 $PaCO_2$ 显著降低, $SaO_2$ 、pH值显著升高,且组间差异有统计学意义,表明联合治疗可提升患者血氧供应、促进酸碱平衡恢复。此外,联合组不良反应总发生率显著低于血必净组,提示联合治疗具有更好的安全性。

综上所述,HA380血液灌流器联合血必净治疗脓毒症患者的疗效显著,可改善患者炎症水平、呼吸循环、肾脏受损程度,且具有一定安全性。该治疗方式可为临床治疗脓毒症提供参考,后续研究可深入探讨其作用机制,优化治疗方案,为脓毒症临床治疗提供更多选择。

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