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# Clinical trail report: WLXGX-888TYPE

## WeiLi Plasmapheresis-Artificial Liver Support System

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Virus hepatitis is one of the common contagious diseases with high incidence, which may damage severely people's health. Among various type of hepatitis, severe type is the most dangerous one. With various complications, the severe type of hepatitis has complicated symptoms and dangerous outcome. Routine treatment is poorly effective to control the development of this type of hepatitis, and fatality rate of it is quite high. In order to change the status, we used WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System to exchange plasma of patients with severe hepatitis and got excellent efficacy, especially in management of hyperbilirubinemia and coagulation disorders.

### Subjects and Methods

#### I. General Information

All subjects involved were exclusively the inpatients of our hospital with severe hepatitis. Diagnosis was made according to the criteria amended in the 5<sup>th</sup> National Contagious Disease Conference, Beijing (1995). There were two groups, control group and treatment group.

30 patients in treatment group

- 1) 24 Males and 6 females.
- 2) Averaged age was 48.7, ranged form 20 to 76.
- 3) Among them, 8 patients were suffering from sub-acute hepatitis (2 of hepatitis B, 3 of hepatitis C, 1 of hepatitis E, 1 of drug-induced hepatitis, 1 of combined hepatitis B & E), and the other 22 patients suffering from chronic hepatitis (2 of hepatitis B, 2 of combined hepatitis B, C and E, 1 of combined hepatitis B and E, 1 of combined hepatitis B and C, 1 of combined hepatitis A and B).
- 4) All 30 cases were complicated with obvious symptoms in digestive tract.
- 5) Maximum value of serum total bilirubin was up to 785.0  $\mu\text{mol/L}$  ( $402.7 \pm 167.7 \mu\text{mol/L}$ ).
- 6) Prothrombin time was lengthened  $\geq 11.9 \pm 11.5$  seconds compared with that of reference, and porthrombin activity was  $43.0 \pm 22.0\%$ .
- 7) 10 patients of them were complicated with hepatic encephalopathy, and another 4 of them with hemorrhage in digestive tract.

31 patients in treatment group

- 1) 27 Males and 4 females.
- 2) Averaged age was 48.5, ranged form 29 to 75.
- 3) Among them, 8 patients were suffering from acute and sub-acute hepatitis, and the other 23 patients suffering from chronic hepatitis (22 of hepatitis B, 1 of hepatitis C, 3 of hepatitis E, and 5 of combined hepatitis B and E).

- 4) All 31 cases were complicated with obvious symptoms in digestive tract.
- 5) Maximum value of serum total bilirubin was up to 671.0  $\mu\text{mol/L}$  ( $324.8 \pm 162.5 \mu\text{mol/L}$ ).
- 6) Prothrombin time was lengthened  $\geq 9.5 \pm 11.8$  seconds compared with that of reference, and prothrombin activity was  $44.2 \pm 16.4\%$ .
- 7) 5 patients of them were complicated with hepatic encephalopathy, and another 1 with hemorrhage in digestive tract.

Pre-treatment	tBil	d Bil	PT	PTA (%)
Treatment group	402.7 $\pm$ 166.7	205.97 $\pm$ 95.3	11.8 $\pm$ 11.5	43.0 $\pm$ 22.3
Control group	324.8 $\pm$ 162.5	161.9 $\pm$ 93.9	9.5 $\pm$ 11.8	44.2 $\pm$ 16.4
P value	>0.05	>0.05	>0.05	>0.05

Note:  $P > 0.05$  suggesting no significant difference between two groups.

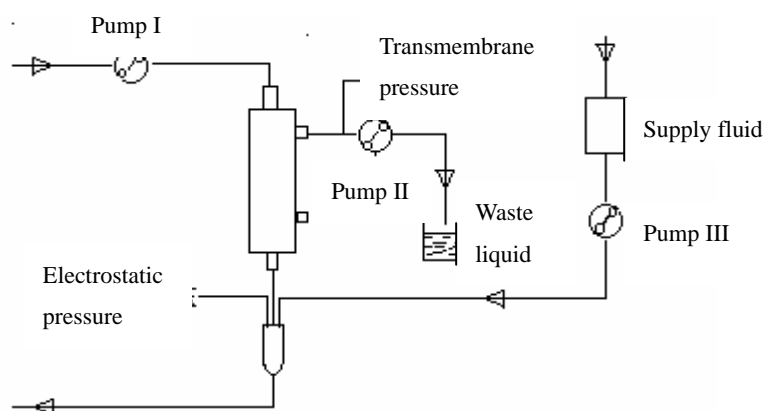
## II. Methods

### (I) Theory basis of therapy

Liver is an important organ in the body that play critical role in detoxification. When hepatic dysfunction occurs, it fails to eliminate toxins, which resulting into accumulation of many metabolic wastes in the body. Severe complications will consequently induced to threaten the health, even the life of patients. Among these toxic metabolites, molecules with medium and small molecular weight account for the main proportion, for instance, bilirubin, aromatic amino acid, and so on. Membrane of plasmapheresis in primary separation has pores with diameter of 0.4 – 0.6 $\mu\text{m}$ . It could keep all visual components in the blood side and let all toxic materials and pathogens go with plasma, thus eliminate effectively those toxic metabolites in the body. Through 3 pumps in WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System (Beijing WeiLi Inc), it could meet the requirements of related functions, including extracorporeal circulation, separating wasted plasma, supplying various exchanging fluids as needed, maintaining equilibrium of blood circulation. Thus blood purification could be fulfilled. Also there is a stable and efficient system carrying out safety monitoring to make sure the artificial liver supporting system work properly according to clinical requirements.

### (II) Operation methods

Routine examinations were undertaken on patients in both groups. As soon as diagnosis was determined, patients were treated in routine ways. To the treatment group, plasma exchange was added and Primary Membrane Plasma Separating Methods was adopted. Plasmapheresis instrument was WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System manufactured by Beijing WeiLi Inc. (Refer to the flow chart as below)



1. Connect blood path tubes with primary plasma separator, and then install it to the panel of plasma exchanger. Switch on heating plate, pre-fill with normal saline and saline with heparin. Eliminate bubbles remaining in the plasma separator completely. Extracorporeal circulation requires systemically heparinization of patients. Dosage of heparin should be adjusted according to coagulation status of patients. Generally speaking, the first dose was 0.5 – 1.0 mg/kg, and additional 5-10 mg heparin should be complemented for each 1000ml of plasma separated.
2. To preventing spontaneous hemorrhage, protamine should be used after treatment to neutralize excess heparin in the body. Its dosage would be 2/3 of that of heparin, or adjusted according to measured result of prothrombin time.
3. Flow rate of blood was set as 100 – 150ml/min, rate of plasma separation may be around 30ml/min, and rate of supplying exchanging fluid should also be 30 ml/min (to balance with that of separation). Special caution should be paid to pre-heat the exchanging fluid at 37°C around.
4. As to the exchanging fluid that being supplied, fresh or frozen plasma would be preferred. Amount of exchanging fluid was recommended 1000ml, no more than 2000ml, for every supplement. Small amount for every time was necessary. Frequency of exchange was 2-3 times every week.
5. To prevent adverse events such as allergic reaction, dexamethasone 5-10mg or phenergan 25 mg (i.v. or i.m.) may be administrated as routine before supplement of plasma.
6. After 1 – 3 treatments some laboratory index should be examined repeatedly, which included total bilirubin, direct reacting bilirubin, prothrombin time and porthrombin activity. Meanwhile, clinical symptoms such as conscious state, status of stained yellow, and symptoms in digestive tract should be monitored in order to adjust the treatment.

## Results

The 30 patients in this trail were totally treated 137 case / episode (averaged  $4.57 \pm 2.49$  treatments for each patient).

Among them, 2 cases were treated once, 5 cases were treated 5 times, 4 cases treated 3 times, 7 cases treated 4 times, 3 cases treated 5 times, 2 cases treated 6 times, 2 cases treated 7 times, 2 cases treated 8 times, 2 cases treated 9 times, and 1 cases treated 10 times.

Totally there were 240000ml plasma being exchanged, averaged 1752 ml per case per treatment.

### I. Clinical symptoms

Symptoms in digestive tracts were improved less or more in 30 patients after plasma exchange. Appetite of them was taking a favorable turn and nausea and vomiting were markedly ameliorated also by the treatment. Among them symptoms in digestive tract of 18 patients disappeared completely after plasma exchange, and jaundice in 23 patients had gone away significantly. Additionally, 8 patients regained consciousness.

### II. Laboratory examinations:

Comparison of examinations in treatment group pre- and post-treatment.

Treatment Group	tBil	dBil	PT	PTA (%)
Pre-treatment	402.7±166.7	206.0±95.3	11.8±11.5	43±22
Post-treatment	201.1±202.6	82.3±100.1	9.8±11.7	63.4±22.4
P value	<0.01	<0.01	<0.01	<0.01

P<0.01, suggesting that plasma exchange could decrease tBil, dBil, PT and PTA significantly.

Comparison of laboratory bio-chemical index between treatment group and control group

Groups	tBil		dBil	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Control	324.8±162.5	296.0±162.5	161.9±93.9	144.6±93.9
Treatment	402.7±166.7	201.1±202.6	206.0±95.3	92.3±100.1
P value	>0.05	<0.01	>0.05	<0.01

Comments: 1) Before treatment there was no statistical difference between control group and treatment group (P<0.05).

2) Both P values for parameters tBil and dBil between pre- and post-treatment were less than 0.01, which suggesting that plasma exchange was markedly better than traditional treatment on tBil and dBil.

	PT		P1 value	PTA (%)		P2 value
	Pre-treatment	Post-treatment		Pre-treatment	Post-treatment	
Control group	9.9±11.5	9.8±11.5	>0.05	44.2±16.4	49.0±22.3	>0.05
Treatment group	11.9±11.5	4.7±4.6	<0.01	43.0±22.3	63.4±22.4	<0.01

Comments: 1) Before treatment there was no statistical difference between control group and treatment group (P<0.05).

2) Both PT and PTA in the treatment group were markedly improved by the treatment, and the differences of which were statistically significant (P<0.01).

3) There was no significant difference in PT and PTA of the control group between pre- and post-treatment (P>0.05).

Comparison of common clinical symptoms between the control group and the treatment group.

Symptoms Groups	Conscious state		Symptoms in digestive tract		Status of stained yellow	
	Observed cases	Cases with effective response	Observed cases	Cases with effective response	Observed cases	Cases with effective response
Treatment group	10	8	30	18	30	23
Control group	5	1	31	6	31	12
X <sup>2</sup>	5.18		10		8.30	
P	<0.01		<0.01		<0.01	

In comparisons of clinical symptoms (conscious state, symptoms in digestive tract, and status of stained yellow) between pre- and post-treatment, all p values gained were less than 0.01, that is, there was statistically significant difference between pre- and post-treatment in these observations. It could be concluded that plasma exchange was effective to relieving symptoms mentioned above.

Among 30 patients in this trail:

- 1) The maximum reduction was from 785.0µmol/L before treatment down to 44.2µmol/L after treatment. And averaged reduction was form 402.7µmol/L before treatment down to 201.1µmol/L after treatment.
- 2) There was an obvious improvement in prothrombin time (PT), from averaged 11.8 seconds

before treatment down to averaged 9.0 second after treatment. And porthrombin activity (PTA) was increased markedly up to averaged 63.4%.

### **Discussion**

As an important organ of human body, liver has many biosynthetic processions occurring in it. Besides, it also assumes the critical function of detoxification, which could not be replaced by any other organs. While in patients with severe hepatitis, failure of liver function will lead to serious metabolic disturbance and consequently result into accumulation of various waste metabolites. Traditional treatments are mainly relying on drugs. Take account of the status of liver, it may have no ability to deal with this additional burden any more. Plasmapheresis (plasma exchange) is a new method developing quickly in recent years to purify blood. Considering the properties of molecular weight of those metabolites accumulating in the body of patients with severe hepatitis, primary membrane separation is adopted to separate various metabolic toxins and pathogenic substances dissolved in plasma and eliminate these wastes along with discarded plasma. At the same time, equal amount of fresh or frozen plasma is supplemented to fill up those necessary materials lost during treatment or being insufficient. Thus body fluid could maintain equilibrium and metabolic disturbance will be corrected. Along with reduction of liver's burden, regeneration of liver cells and recovery of liver function may be possible.

In our trail 30 patients were treated totally 137 case / episode by plasma exchange. Serum total bilirubin of them was reduced from averaged 402.7 $\mu$ mol/L before treatment down to 201.1 $\mu$ mol/L after treatment, and it recovered approximately to normal level along with further treatment, among them 8 patients (26.7%) with acute and sub-acute hepatitis and 22 patients (73.3%) with chronic hepatitis. Additionally, duration of disease was shortened markedly.

Plasma exchange is effective therapy of artificial liver supporting system. During treatment, special properties for each individual patient should be considered when deciding the kind of exchange fluids, amount of exchange, and rate of exchange. Take into account that exchange fluid used is mainly heterogeneous and always originated from several donators, allergic reaction is difficult to avoid. Therefore, adrenocortical hormones or antihistamine drugs should be administrated beforehand to make sure successful plasma exchange.

In conclusion, through 3 pumps in WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System (Beijing WeiLi Inc.), it could meet the requirements of related functions, including extracorporeal circulation, separating wasted plasma, supplying various exchanging fluids as needed, maintaining equilibrium of blood circulation. Thus blood purification could be fulfilled. Also there is a stable and efficient system carrying out safety monitoring to make sure the artificial liver supporting system work properly according to clinical requirements. This system is applicable to patients with various type of hepatitis, especially to those with severe hepatitis and hyperbilirubinemia. Excellent efficacy will be gained by the system, which routine treatment could not fulfill at all.

### **Reference**

Dalian 6th People's Hospital

# Clinical efficacy observation: WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System

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## Summary

**Key words:**

### General Information and Methods

#### I. General Information

All subjects involved were exclusively the inpatients of our hospital with severe hepatitis. Diagnosis was made according to the criteria amended in the 5<sup>th</sup> National Contagious Disease Conference, Beijing (1995). There were two groups, control group and treatment group.

	Treatment group	Control group
Number of patients	32	31
Male / Female	22 / 10	27 / 4
Age (years)	19-83, averaged 46.8	29-75, averaged 48.5
Number of patients with acute and sub-acute hepatitis	9	8
Number of patients with chronic hepatitis	23	23
Number of patients with obvious symptoms in digestive tract	32	31
Serum total bilirubin ( $\mu\text{mol/L}$ )	397.0 $\pm$ 124.2	392.8 $\pm$ 156.4
Serum direct reacting bilirubin	182.6 $\pm$ 101.2	190.1 $\pm$ 98.1
Prolonged value of prothrombin time	10.3 $\pm$ 9.5	11.2 $\pm$ 10.1
Prothrombin activity (%)	39.3 $\pm$ 21.6	40.7 $\pm$ 21.1

#### Comparison of biochemical parameters before treatment between treatment group and control group.

Pre-treatment	tBil	d Bil	PT	PTA (%)
Treatment group	397.0 $\pm$ 124.2	182.6 $\pm$ 101.2	10.3 $\pm$ 9.5	39.3 $\pm$ 20.1
Control group	392.8 $\pm$ 156.4	190.1 $\pm$ 98.1	9.5 $\pm$ 12.0	41.1 $\pm$ 15.0
P value	>0.05	>0.05	>0.05	>0.05

\* all P values were >0.05, suggesting no significant difference between two groups.

#### II. Methods

### **(I) Instrument**

WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System, plasma separator with membrane pore with diameter of 0.4 – 0.6 $\mu$ m, supplied by Beijing WeiLi New Century Science & Tech Dev. Co., Ltd.

### **(II) Basic theory**

Artificial liver supporting system is an important method to treat severe hepatitis, especially for those with liver failure. When liver function is damaged seriously, it would be impossible to play its critical role in detoxification and biosynthesis. The system may eliminate large amount of toxic materials accumulated in human body, especially those with medium or small molecular weight, such toxins and bilirubin. At the same time the artificial liver supporting system would supplement exogenous coagulation factors. Therefore it could be used to deal with hyperbilirubinemia and would improve actually those symptoms related to insufficient coagulation function.

The system separated toxic substances dissolved in plasma by its plasma separator whose membrane pore with diameter of 0.4-0.6 $\mu$ m. At the same time it could complement exogenous plasma to maintain body fluid in equilibrium. Extracorporeal circulation comprised of 3 pumps and related tube systems. Refer to Figure 1.

### **(III) Operating procedure**

As soon as diagnosis was determined, patients of both groups were treated in routine ways. For the treatment group, WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System was added and simple plasma exchange was adopted.

1. Firstly venous puncture was operated and needle was indwelled in central vein. After routine sterilization, it was ready to be connected with extracorporeal circulation system.
2. Connect blood path tubes with plasma separator, and then install it to the panel of WeiLi Plasmapheresis-Artificial Liver Support System (refer Figure 1). Switch on heating plate, pre-fill with normal saline and saline with heparin. Eliminate bubbles remaining in the plasma separator completely. Extracorporeal circulation requires systemically heparinization of patients. Dosage of heparin should be adjusted according to coagulation status of patient

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***Note: please see the same graph in Page 2  
for the operation procedure.***

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3. Connect catheter to needle indwelling in central vein, switch on pump 1, pump 2, and pump 3. Circle was closed and plasma exchange was starting then.
4. Protamine should be used after treatment to neutralize excess heparin in the body. Its dosage would be 2/3 of that of heparin
5. Flow rate of blood was set as 100 – 150ml/min, rate of plasma separation may be

around 30ml/min. As to the exchanging fluid that being supplied, fresh or frozen plasma would be preferred. And the rate of supplying fluid should be balance to that of separation. Amount of exchanging fluid was generally recommended 1000ml for every supplement. Frequency of exchange was 2-3 times every week.

**Caution:**

- 1) To prevent adverse events such as allergic reaction, dexamethasone 5-10mg or phenergan 25 mg (i.v. or i.m.) may be administrated as routine before supplement of plasma.
- 2) After every time of treatment some laboratory index should be examined repeatedly, which included total bilirubin, direct reacting bilirubin, prothrombin time and porthrombin activity. Meanwhile, clinical symptoms such as conscious state, status of stained yellow, and symptoms in digestive tract should be monitored in order to adjust the treatment.

**Results**

The 32 patients in this trail were totally treated 151 case / episode (averaged  $5.03 \pm 2.16$  treatments for each patient).

Times of treatment	1	2	3	4	5	6	7	8	9	10
Number of patients	2	5	4	8	5	2	2	2	2	1

Totally there were 279000ml plasma being exchanged, averaged 1848 ml per case per treatment.

Symptoms in digestive tracts were improved less or more in 32 patients after treated by WeiLi Plasmapheresis-Artificial Liver Support System. Appetite of them was taking a favorable turn and nausea and vomiting were gradually ameliorated also by the treatment. Among them symptoms in digestive tract of 19 patients disappeared completely after plasma exchange, and jaundice in 29 patients had gone away significantly. Additionally, 8 patients regained consciousness. Comparison with those of the control group was listed in Table 1:

Table 1: Comparison of clinical symptoms between the control group and the treatment group.

	Symptoms in digestive tract		Jaundice		Conscious state	
	Observed cases	Cases with effective response	Observed cases	Cases with effective response	Observed cases	Cases with effective response
Treatment group	32	19	32	27	12	10
Control group	31	5	31	13	6	1
p	<0.01		<0.01		<0.01	

In comparisons of clinical symptoms including conscious state, symptoms in digestive tract, and jaundice between pre- and post-treatment, all p values gained were less than 0.01, that is, there was statistically significant difference between pre- and post-treatment in these observations. It could be concluded that plasma exchange was more effective to relieving symptoms mentioned above than routine therapy.

Table 2. Comparison of tBil, dBil, PT and PTA in treatment group pre- and post-treatment.

	TBil	dBil	PT	PTA (%)
Pre-treatment	397.0±124.2	182.6±101.2	10.3±9.5	39.3±20.1
Post-treatment	197.6±150.6	87.7±68.5	4.5±3.8	76.2±20.3
P value	<0.01	<0.01	<0.01	<0.01

All P values were <0.01, that is, there were statistically significant differences between them, which suggesting that plasma exchange could significantly decrease tBil, dBil, and improve PT and PTA.

Table 3. Comparison of tBil, dBil between treatment group and control group

Groups	tBil		dBil	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Control	397.0±124.2	197.6±131.5	182.6±101.2	92.3±60.7
Treatment	392.8±156.4	371.6±180.2	190.1±98.1	144.6±93.9
P value	>0.05	<0.01	>0.05	<0.01

- 1) Before treatment there was no statistical difference between control group and treatment group (P<0.05). Two groups were comparable.
- 2) Compared with the data of pre-treatment, both tBil and dBil after treatment were significant different (P<0.01), which suggesting that plasma exchange was markedly better in decreasing tBil and dBil than traditional treatment.

Table 4. Comparison of PT, PTA between treatment group and control group

	PT		P1 value	PTA (%)		P2 value
	Pre-treatment	Post-treatment		Pre-treatment	Post-treatment	
Control group	10.3±9.5	4.7±4.6	<0.01	39.3±20.1	76.2±20.3	<0.01
Treatment group	9.5±12.0	9.5±12.0	>0.05	41.1±15.0	50.0±23.1	>0.05

- Comments: 1) Before treatment there was no statistical difference between control group and treatment group (P>0.05).
- 2) Both PT and PTA in the treatment group were markedly improved by the treatment, and the differences of which were statistically significant (P<0.01), which suggesting that plasma exchange was significantly effective on improvement of coagulation function.
- 3) There was no significant difference in PT and PTA of the control group between pre- and post-treatment (P>0.05), which suggesting that routine therapy had no effects on improvement of coagulation function..

### Discussion

Liver is one of the most important organs that play a critical role in detoxification, metabolism, biosynthesis, and secretion. Severe hepatitis responds poorly to routine therapies and will quickly result into failure of liver function. A large amount of metabolic wastes will accumulate in the body with insufficient hepatic function, and disturbance of metabolism may lead to disturbance of multiple organs, even to failure of their functions. Thus severe hepatitis is one common severe disease in clinical practice and may reduce high mortality.

We used WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System (Beijing WeiLi New Century Science & Tech Dev. Co., Ltd.) to treat 32 patients with severe hepatitis, and totally

151 case / episode were managed. Our study showed that: WeiLi Plasmapheresis-Artificial Liver Support System showed more significant effects in improving symptoms including those in the digestive tract, jaundice, and conscious state compared with routine therapy (see Table 1); This system decreased serum total bilirubin and direct reacting bilirubin markedly (see Table 2), and serum total bilirubin of patients was reduced from 397.0 $\mu$ mol/L before treatment down to 197.6 $\mu$ mol/L after treatment, directly reacting bilirubin reduced from 182.6 $\mu$ mol/L down to 87.7 $\mu$ mol/L. Also the effects of the system were much better than those of traditional medical therapy (see Table 3); As to coagulation function of patients (see Table 3), the artificial liver supporting system could restore significantly the prolonged prothrombin time, whose increase value decreased from averaged 10.3 seconds pre-treatment down to averaged 4.7 second post-treatment. At the same time, prothrombin activity improved from averaged 50.0% pre-treatment to 72.6% post-treatment.

Through 3 pumps in WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System (Beijing WeiLi Inc.), it could implement extracorporeal circulation required in blood purification, and thus separate and discard toxic materials out of plasma by the plasma separator. At the same time, the system could complement exogenous plasma to maintain equilibrium of body fluid. Also there were monitoring systems to pressure, bubble, and macro-injection system, blood (plasma) heat-retaining system, and automatic alarming system as well. All these will guarantee a safe, stable, efficient, and easily operated treatment system meeting the requirements of clinical practice.

Take into account that exogenous plasma was used, in order to prevent allergic reaction adrenocortical hormones or antihistamine drugs should be administered beforehand to make sure successful plasma exchange. To fulfill successful treatment, special properties for each individual patient should be considered when deciding amount of exchange and rate of exchange.

Artificial liver supporting system is an important management to deal with severe hepatitis. Through blood purification the system exchange and process the plasma of patients, and supplement all kinds of coagulation factors. After treatment it could relieve symptoms, decrease hyperbilirubinemia, and improve coagulation function. As a transient alternate of liver, artificial liver supporting system may play important functions, including metabolism, detoxification, and synthesis. Thus the system will share the burden of liver and allow possible re-generation of liver cells and recovery of liver function. The necessary support it provided to patients with severe liver diseases may help them survive through danger situation and gain precious timing for further clinical management (such as liver transplant).

### **Conclusion**

WLXGX-888 WeiLi Plasmapheresis-Artificial Liver Support System could improve effectively clinical symptoms including poor appetite, nausea and vomiting, jaundice, and coma. It may decrease hyperbilirubinemia, and improve coagulation function, which is much better than routine therapies. The system is safe, stable, and easily operated, and it is worthy to be recommended for extensive application in clinical practice.

### **Reference**