Biosun

The Innovation For Life

COMBINED ARTIFICIAL KIDNEY

Treatment Guidelines

Biosun Medical Technology Co.,Ltd.

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Company Profile

As a key member of the Baihe Medical Group, Biosun Medical focus on research, development, and production of devices and systems for blood treatment and purification based on advanced membrane separation and adsorption technologies. It serves the global market with blood and plasma adsorption products for medical therapy.

Control at every phase of production

Most of our production materials originate either within Biosun Medical itself or the Baihe Medical Group, facilitating close, effective control of our products and processes, and the assurance of product reliability for customers worldwide.

Company Aerial View

State-of-the-art manufacturing processes

To provide products of the highest quality and performance to meet the increasing global demand for these products, Biosun Medical has constantly advanced the process technologies and expanded the production capacities of its plants, and its production is highly automated, from starting materials to finished products.

Strict quality control as a key commitment

Strict quality control is performed at each production stage to ensure high standards and comply with ISO 13485. Biosun Medical is the first Company to obtain the CE Mark in China, as a manufacturer of adsorption medical device. Biosun Medical will continually strive to maintain and improve safety and efficacy, of current and future products.

Product

ISO13485 Certificate

CE Certificate

Three Utility Model Patents

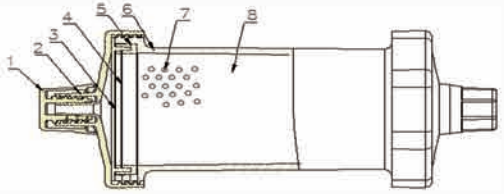
Four Invention Patents

MG Series Disposable Hemoperfusion Cartridge

MG Series Disposable Hemoperfusion Cartridge possesses ability to adsorb middle, large molecular toxins and protein-bound toxins in end stage renal disease (ESRD) patients. Combining with hemodialysis treatment could relieve complication, thus can achieve better life quality.

1. Construction and Feature

MG Series Hemoperfusion Cartridge comprises cap, cover, sealing cushion, mesh, mesh supportor, column, adsorbent and filling solution. Column and cover is made from medical grade polycarbonate, and the adsorbent is medical porous adsorptive resin pocessed by unique technology. The highest blood flow rate is 250 mL/min.



MG Series Hemoperfusion Cartridge Construction Sketch

	Structure	Material
1	cap	polypropylene
2	cover	polycarbonate
3	sealing cushion	silicon rubber
4	mesh	nylon
5	mesh supportor	polypropylene
6	column	polycarbonate
7	adsorbent	polystyrene resin
8	filling solution	sterile water for injection

2. Adsorbed Substance

MG Series Hemoperfusion Cartridge is capable of adsorbing toxins that can not be eliminated by hemodialysis, such as parathyroid hormone, β_2-microglobulin, leptin, oxidative protein products, advanced glycation end products, homocysteine, interleukin-1, interleukin-6 and so on.

3. Intended Use

MG Series Hemoperfusion Cartridge is mainly utilized in treatment of renal failure, chronic kidney disease (CKD), uremia, complication of maintenance hemodialysis (MHD), and the combined hemoperfusion and hemodialysis procedure (HD+HP) could prevent and improve long-term hemodialysis complications such as renal osteopathy, refractory skin pruritus, peripheral neuropathy, cardiovascular disease, refractory hypertension, nephro-encephalopathy, malnutrition etc.

4. Contraindications

No absolute contraindication.
Cautions should be taken for the patients below:
① Patients with severe arrhythmia, acute miocardial infarction, acute brain failure, severe hypertension, hypotension or vitro circulation dysfunction.
② Patients with severe thrombocytopenia, hypocytosis or coagulation dysfunction.

5. Other Information

Available Specification

MG150 *(adsorbent volumn 150mL)*
MG250 *(adsorbent volumn 250mL)*
MG350 *(adsorbent volumn 350mL)*

Shelf Life 2 Years

MG Series Disposable Hemoperfusion Cartridge

DO NOT REUSE SEE INSTRUCTIONS FOR USE STERILE STERILIZED USING STEAM

MG Series Hemoperfuion Cartridge Advantages

CE Mark approval – *CE Mark approval meets safety and efficacy label claims as dictated by the European Union Medical Devices Directive.*

Proven, efficient uremic toxins removal – *Robust and broad toxins removal demonstrated in ESRD.*

No new infrastructure is needed – *Works with standard hospital dialysis equipment and does not need dialysate or replacement fluid.*

Easy to use – *Minimal learning curve, uncomplicated set up, and high ease of use.*

Hemocompatible – *Polymer beads can directly contact blood without material negative effects.*

Massive capacity – *A single cartridge has more than 5 European football fields of surface area to bind uremic toxins.*

Long shelf life – *No biologic components (e.g. antibodies or cells) means excellent storage at room temperature.*

Biocompatibility – *The modified polymer beads have passed all of the standard battery of biocompatibility tests required by the International Organization for Standardization guidelines (ISO 10993).*

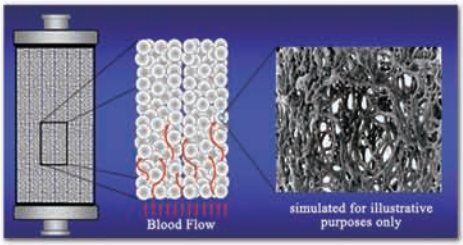
Sterilization – *The devices are steam-sterilized. Priming volumn could be reduced to minimum level for saving time and cost.*

High-quality manufacturing – *MG cartridge manufactures and packages its own polymer bead cartridges under ISO 13485:2003 Full Quality Systems certification.*

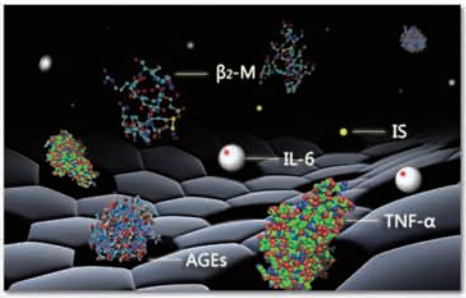
Adsorption Mechanism for Hemoperfusion

Hemoperfusion is an extracorporeal form of treatment as the blood is pumped through a device outside the patient's body. As the blood passes through the cartridge, the toxic molecules are adsorbed by adsorbent.

Hemoperfusion devices containing adsorbents have been used to remove uremic toxins (such as creatinine, middle-size particles) , drugs, poisons, immunopathogenic agents, endotoxin, low density lipoprotein, bilirubin, β_2-microglobulin and so on. The most commonly available adsorbent are porous resin, various forms of activated charcoal and immunosorbent.



MG Series Hemoperfusion Cartridge's relatively specific adsorption to middle and large molecular and protein-bound uremic toxins depends on adsorbent pore capture, the ability to sieve decided by structure, Van der Waals force and hydrogen bond.



Adsorption Sketch of MG Series Hemoperfusion Cartridge

Combined Artificial Kidney

ESRD results from chronic nephropathy of all sorts of reason. Due to significant decrease in glomerular filtration function, large, middle and small molecular uremic toxins accumulate in patient, which brings about various symptoms related to long-term dialysis. Hemodialysis is a major treatment for renal failure at present. Conventional hemodialysis aims to eliminate small soluble-water toxins such as urea, creatinine while middle-size uremic toxin of molecular weight between 500 to 5000 dalton can hardly be removed.

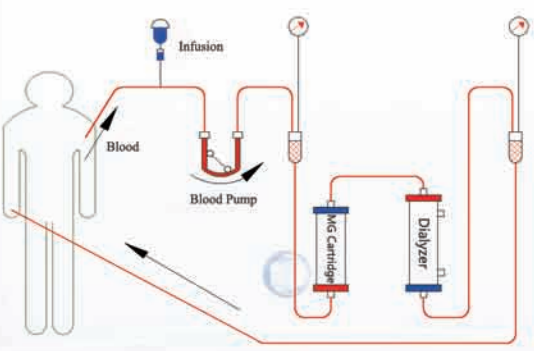
As prolonging of dialysis, middle-size, large-size molecular and protein-bound toxins accumulating in patients may induce maintenance dialysis complication such as renal osteopathy, refractory skin pruritus, peripheral neuropathy, cardiovascular disease, refractory hypertension, nephro-encephalopathy, malnutrition etc.

The rationale for combining hemodialysis with hemoperfusion logically seeks to improve properties missing in each technique-inefficient middle,large melocular and protein-bound toxins removal in the former, and small solute removal in the latter.

Partial Uremia Toxin and Relative Complications

On 26th Oct. 2004, Zhang Mingrui, a professor in McGill University of Canada, proposed the concept of "Combined Artificial Kidney" in his academic report " Current State and New Technology of Hemoperfusion Around the World" in International Convention Center of Shenzhen University. After that, he introduced this innovative protocol of treatment to China.

HD+HP procedure makes advantage of each other for blood purification. In this way, metabolic product and uremic toxins produced by renal failure patient could be thoroughly removed and the water, as well as electrolyte could be regulated to balance. Eventually, internal environment remains balance and patient's life quality is improved.



Treatment Sketch

Professor Chen Xiangmei, former director commissioner of nephropathy association and director of nephrology department in General Hospital of the Chinese People's Liberation Army, demonstrated that there is no such way of blood purification that are more effective and thorough than the combined hemodialysis and hemoperfusion procedure.

HD + HP Treatment Protocol

This product is designed for the treatment of HD+HP, applying to the ESRD patients. Making choice of a suitable treatment according to ESRD patient's condition based on normal HD treatment.

Option1. Treatment frequency: one time every 2~4 weeks
It's advised to apply on the patient who has a short history of dialysis, no complication manifestation, and with stable condition after normal HD treatment.

Option 2. Treatment frequency: weekly in the first month and biweekly treatment ongoing after first month
After symptoms are completely improved, adjust the frequency to the suitable one.
It's advised to apply on the patient who has a long history of hemodialysis, and complication occurring.

Option 3. Intensification Treatment: 7~8 times of treatment successively for the 1st month, then turn to maintenance treatment when patients' condition is well controlled
Indications: ① Patients with severe pruritus, high level of parathormone or other severe complications; ② Patients with insignificant effect by maintenance treatment.

HD + HP Operating Instruction

1. The Hemoperfusion Cartridge should be performed in association with dialyzer by connection in front of dialyzer, hemoperfusion treatment time is recommended as 120 ~ 150 mins.

2. Materials Preparation

MG series Hemoperfusion Cartridge, connection tube, dialysis machine, common materials for hemodialysis, including heparin, 10mg of dexamethasone (for spare usage), 3500 mL ~ 5000 mL of normal saline and others.

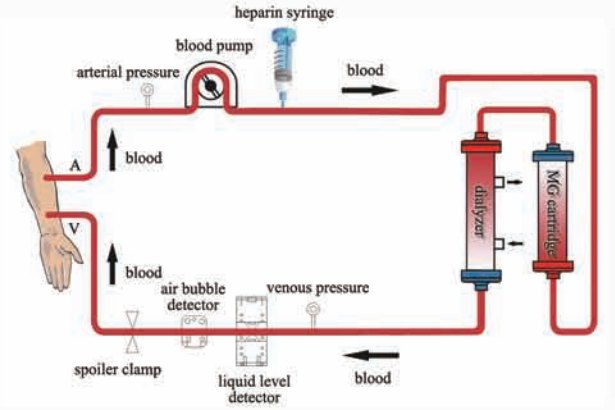
3. Rinse of Cartridge

(1) Preparation of rinse liquid: 500ml of 5% glucose (for optional use), 3000 mL of heparinized saline, 500 mL of normal saline. 5% glucose is utilised directly as rinse solution, and heparin is added into the first 2500 mL of saline in proportionation of 1875 ~ 2500 IU of heparin per 500 mL of saline (lower concentration), then 12500 IU of heparin is added into the final 500 mL of saline normal saline (higher concentration) for heparinized saline as rinse liquid.

(2) Rinse with glucose and lower concentration heparinized saline: Firstly, unscrew both caps of the cartridge ends, release the preservation liquid and fill the arterial line with rinse liquid, then connect the arterial line with the arteriovenous end of the cartridge. Secondly, connect the venous end of Hemoperfusion Cartridge with venous pipe of blood circuit after Hemoperfusion Cartridge is filled with rinse solution. Thirdly, rinse the hemoperfusion and pipeline successively with 500 mL of 5% glucose and the lower concentration heparinized saline at pump flow rate of 100 mL/min. During rinse process, please tap the cartridge and pipeline gently to remove the remaining air inside.

(3) To connect cartridge in front of dialyzer with connection tube, rinse the entire circulation system using higher concentration heparinized saline at rate of no more than 50 mL/min to remove the remaining air & ensure sufficient heparinization of the adsorbent. Then adjust liquid level in arteriovenous pot in a comparative height to keep more room for air catching. Finally, fix cartridge in support vertically with arterial end downwards and venous end upwards.

(4) Rinse with non-heparinized saline: Rinse the extracorporeal circulation system with the left 500 mL of normal saline without heparin to release the higher concentration heparinized saline. Then the rinse of cartridge is finished.



Connection Diagram

4. Vascular access and anticoagulation

(1) Perform artificial arteriovenous fistula puncturation for vascular access.

(2) Anticoagulation: Systemic heparinization is usually utilised for anticoagulation. Initial heparin dosage of 62.5 ~ 100 IU/kg was intravenous injected 10 mins before hemoperfusion treatment begins, then additional heparin 1000 ~ 1250 IU was added per hour. Heparining would be stopped half an hour before treatment termination. If low molecular heparin is utilised to perform anticoagulation, 5000 ~ 6000 IU should be performed only one time 10 mins before hemoperfusion treatment, no additional low molecular heparin is necessary.

Heparin dosage depends on patients' individual difference, and average time for vitro blood coagulation is usually 20 ~ 30 mins. If conditions permit, values of PT, APTT and ACT should be tested to adjust heparin dosage accordingly. For the patients with normal coagulation function, we could test values of PT, APTT & ACT before hemoperfusion, retest them in 5 ~ 15 mins, prolong the values to be 180% of basic value and return them to be 140% after treatment. For the patients with bleeding tendency, we could test values of PT, APTT & ACT before hemoperfusion, retest them in 5 ~ 15 mins, prolong the values to be 140% of basic value and maintain them to be 140% after treatment. During the process, values of PT, APTT and ACT should be monitored per 30 mins to adjust heparin dosage in time.

5. Treatment

Adjust blood flow rate to 100 mL/min when treatment starts. If the patient condition is stable, blood flow rate could be soon adjusted to 180 ~ 200 mL/min. hemoperfusion time is 120 ~ 150 mins. Vitro circulation shoud be observed timely to avoid coagulation.

6. Blood Returning

(1) It is recommended that normal saline blood returning method should be utilised to return blood in cartridge and pipeline to patients after hemoperfusion finishes, and the procedures are as follows.

(a) Prepare a bottle of sterile normal saline, hung it upside down besides the bed, then adjust blood flow rate to 100 mL/min.

(b) Remove arterial puncturation needle and insert it into the prepared normal saline quickly to ensure the normal saline get into the circulation pipeline.

(c) Let normal saline flow into arterial pipeline, cartridge and connection tube by pump power. Turn off blood pump, clip arterial and venous pipelines of blood circulation when blood has returned to dialyzer and blood color in connection tube becomes faint. Disconnect the connection of arterial pipeline and cartridge as well as connection tube and dialyzer, then connect the arterial pipeline filled with normal saline and dialyzer to continue hemodialysis (HD) treatment, and the entire procedure should be completed within 3 ~ 5 mins.

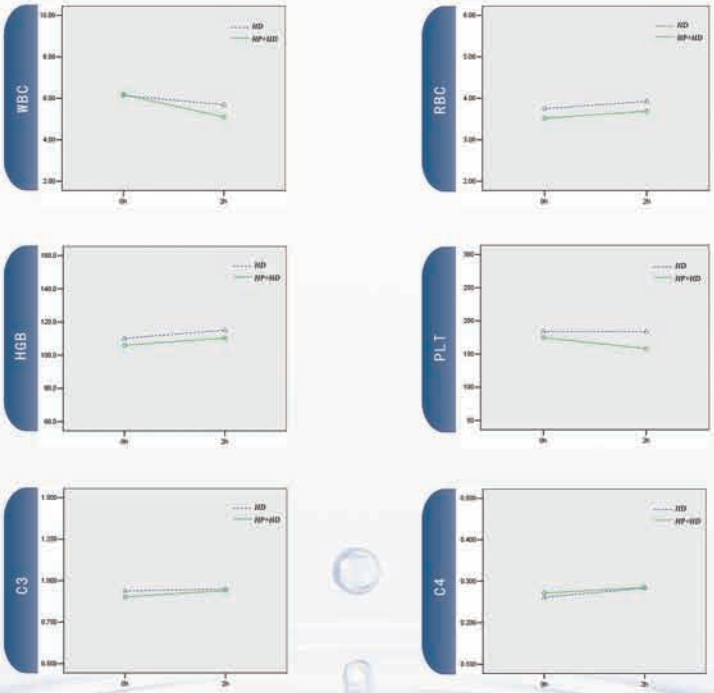
(2) For patients with bleeding tendency, protamine could be adopted to neutralize heparin, protamine dosage is 1/2 of total heparin dosage during HD+HP treatment, and it is adopted after hemodialysis. As protamine is of short half-life, if rebounding bleeding happens, then additional 1/2 of orignial protamine dosage could be adopted. For protamine usage, please kindly read its drug instruction.

Clinical Trial Report

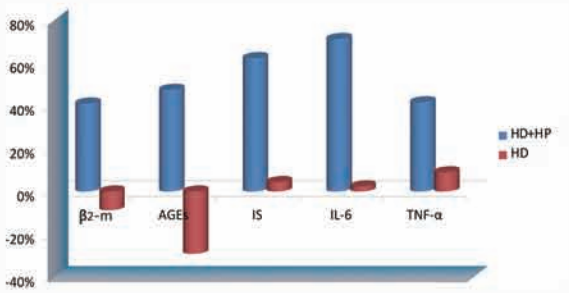
Contrast investigation was conducted between combined artificial kidney（MG Series HD+HP）group and HD group. The results are as below:

ANOVA Table of Evaluation index (Descent Rate) (HD+HP *VS* HD)

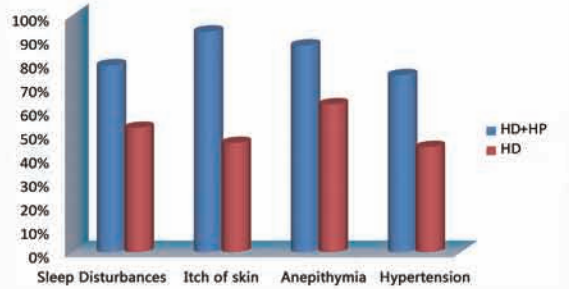
Group	Case Load	β2-m	AGEs	IS	IL-6	TNF-α
HD+HP	132	41.1%	47.5%	62.3%	71.25%	41.70%
HD	132	-8.7%	-29.1%	4.4%	2.35%	8.97%
		F=180.764 P<0.001	*F=36.012 P<0.001*	*F=150.032 P<0.001*	*F=28.181 P<0.001*	*F=14.834 P<0.001*



Blood Routine Examination and Estimated Complement Marginal Mean Outline Drawing

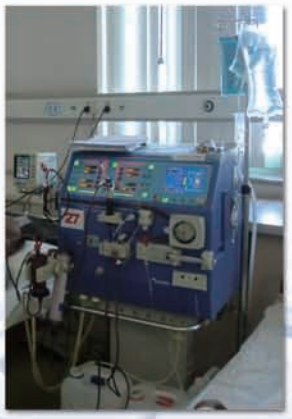


Uremic Toxins Removal Rate (HD+HP *VS* HD)



Improvement in various symptoms related to long-term dialysis treatment (HD+HP *VS* HD)

MG Series Hemoperfusion Cartridge is effective in removal of middle and large molecular and protein-bound uremic toxins. Patients showed relief in various symptoms related to long-term hemodialysis treatment. The results suggest that MG Series Hemoperfusion Cartridge is useful in preventing the progression of dialysis-related symptoms.



Clinical Photo

References

1. *The Clearance of Various Blood Purification Methods on Protein-bound Toxins*
—— Chen Xiangmei, Chinese Journal of Blood Purification, 2005, 4(11): 581-584

Toxin Clearance Principle Comparison and Effectiveness Comparison by Different Blood Purification Methods

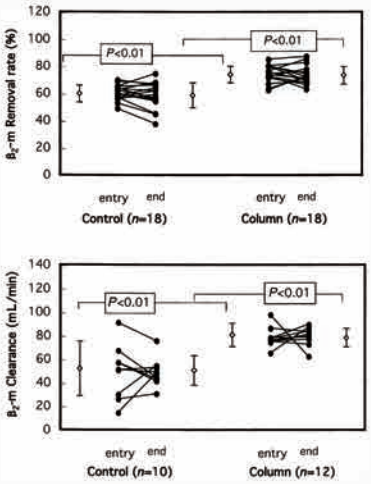
Methods	Small molecular toxins	Middle and large molecular toxins	Protein-bound toxins
Hemodialysis (HD)	High	Non to low	Non
High-flux dialysis	Medium to high	Low	Low
Hemofiltration	Medium to high	Low	Low
Hemodiafiltration	High	Medium	Low
Hemoperfusion	Different	High	High
HD+HP	High	High	High

2. *The Next Step from High-Flux Dialysis:Application of Sorbent Technology*
—— James F. Winchester, et al., Blood Purif, 2002, 20: 81-86

"The current foci of renal replacement therapy with dialysis are middle molecular weight toxins, consisting of small proteins, polypeptides and products of glycosylation and lipoxygenation. Conventional high-flux dialysis is not efficient at removing these molecules, explaining the increased interest in using sorbents to supplement dialysis techniques. Prototype biocompatible sorbents have been developed and investigated for middle molecule removal; these have been shown, in man, to remove $ß_2$-microglobulin, angiogenin, leptin, cytokines and other molecules, without reducing platelets and leukocytes.Extensive clinical studies are underway to demonstrate the clinical utility and safety of adding routinely a sorbent hemoperfusion device to hemodialysis."

3. *Arresting Dialysis-Related Amyloidosis: A Prospective Multicenter Controlled Trial of Direct Hemoperfusion with a β_2-Microglobulin Adsorption Column*
—— Fumitake Gejyo et al., Artificial Organs, 2004, 28(4): 371-380

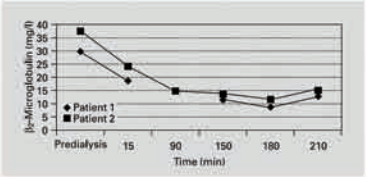
"We investigated the clinical efficacy of direct hemoperfusion with a β_2-microglobulin (β_2-m) adsorption column for the treatment of patients with dialysis-related amyloidosis. A 2-year prospective controlled study was performed to compare the effects of passaging blood through a (β_2-m) adsorption column (Lixelle) before it is passaged through the dialysis polysulfone membrane on the severity of amyloidosis in these individuals. Patients (n= 22) whose blood went through the Lixelle column prior to dialysis had a higher β_2-m removal rate compared to an equal number of controls, and they showed earlier improvement in their symptoms which included impaired daily activities, joint stiffness, and pain. The appearance of additional bone cysts was prevented in pre-adsorbed patients but not in the controls. Thus, the Lixelle column is useful in preventing the progression of dialysis-related amyloidosis and in ameliorating or arresting the progression of the symptoms of this disorder."



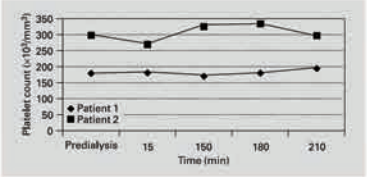
β_2-m removal ratio and β_2-m plasma clearance at the first (entry) and last (end) treatments of the patients in the adsorption column and control groups

4. *First Clinical Experience with an Adjunctive Hemoperfusion Device Designed Specifically to Remove ß2-Microglobulin in Hemodialysis*

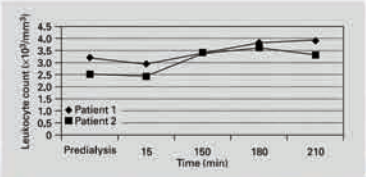
—— Claudio Roncoa, et al., Blood Purif , 2001, 19:260–263



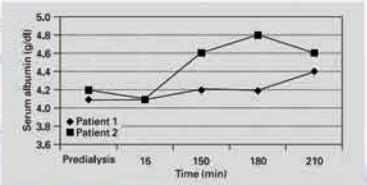
β_2-Microglobulin concentration throughout the session of combined hemoperfusion-hemodialysis



Platelet count during different moments of the combined hemoperfusion-hemodialysis session



Leucocyte count during different moments of the combined hemoperfusion-hemodialysis session

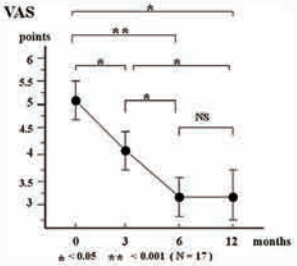


Serum albumin concentration throughout the session combined hemoperfusion-hemodialysis

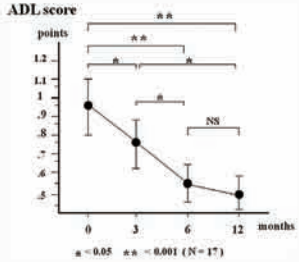
5. *Long-Term Efficacy and Safety of the Small-Sized β_2-Microglobulin Adsorption Column for Dialysis-Related Amyloidosis*

—— Yuichiro Yamamoto,et al., Therapeutic Apheresis and Dialysis, 2011, 15(5): 466–474

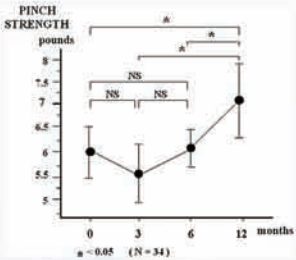
"Dialysis-related amyloidosis (DRA) is one of the major complications often seen in long-term dialysis patients, and is one of the factors that decreases quality of life. β_2-microglobulin (β_2-m) is considered to be a major pathogenic factor in dialysis-related amyloidosis. The Lixelle adsorbent column, with various capacities, has been developed to adsorb β_2-m from the circulating blood of patients with dialysis-related amyloidosis. Using a minimum type of β_2-m-adsorbing column (Lixelle S-15),we evaluated its therapeutic efficacy and safety in dialysis patients. Seventeen hemodialysis patients with DRA were treated with the S-15 column for one year. Treatment was performed three times a week in this study. During the study period, pinch strength, visual analog scale for joint pain, and activities of daily living were evaluated every three months, and blood sampling was performed everysix months. After one year's treatment with the S-15 column, the β_2-m level decreased from 29.3 ± 9.6 mg/L to 24.7 ± 5.1 mg/L ($P < 0.05$), and the high sensitive C-reactive protein level decreased from 2996 ± 4380 ng/mL to 1292 ± 1774 ng/mL. After one year of S-15 column use, pinch strength increased from 5.9 ± 3.0 pounds to 7.2 ± 3.2 pounds ($P < 0.05$), and the visual analog scale for joint pain and activities of daily living score also improved. Long-term use of the Lixelle S-15 column is safe and effective for improvement of quality of life in chronic dialysis patients. Improvement of chronic inflammation may be one of the mechanisms through which the beneficial effects of the column is effected."



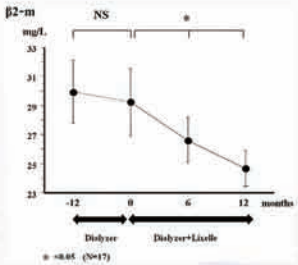
Change in the visual analog scale (VAS) evaluation for joint pain, which was significantly decreased from 5.04 ± 1.91 points before to 3.24 ±2.27 points after therapy ($P < 0.05$)



Change in the activities of daily living (ADL) score,which was calculated using the modified Stanford Health Assessment Questionnaire. The ADL score was significantly improved from 0.959 ± 0.560 points before to 0.518± 0.394 points after therapy ($P < 0.001$)



The alterations of the muscle power were evaluated using the pinch strength test. The pinch power significantly increased from 5.9 ± 3.0 pounds before to 7.2 ± 3.2 pounds after therapy ($P < 0.05$)



Change in the β_2-microglobulin level (β_2-m).All patients were dialyzed by same dialyzer for at least one year before the start of this study, and the hemodialysis conditions were kept constant from 12 months before the start of the hemoperfusion study until the end of the study. During the one year of dialysis alone, the β_2-m level remained unchanged (29.9 ± mg/L and 29.3 ± 9.6 mg/L at one year before the start of this study and for one year after the start of the study). After one year of treatment with the Lixelle S-15 column, the β_2-m level significantly decreased from 29.3 ± 9.6 mg/L to 24.7 ± 5.1 mg/L ($P < 0.05$).

Frequently Asked Questions

1. What is the difference between MG adsorbent and activated charcoal?

Charcoal is limited in its adsorption of water, urea and acidic species. Adsorbent of MG Series Hemoperfusion Cartridge is hydrated cross-linked polystyrene resin, of pore structure designed to remove certain substances, middle and large molecular and protein-bound toxins.

2. What is the adsorption principle of MG Series Hemoperfusion Cartridge?

Adsorbent in MG Series Hemoperfusion Cartridge is the medical porous adsorptive resin processed by unique technology, whose adsorption capacity depends on the molecular sieve effect of three-dimensional network structure and the affinity between resin molecular groups and the adsorbed material as well as Van der Waals interaction between molecular groups, and high adsorption capacity is performed to middle, large molecular and protein-bound toxins.

3. How long does it cost for HD+HP treatment?

The MG Series Hemoperfusion Cartridge should be connected in front of dialyzer to avoid coagulation. At present, we recommend using HD+HP for 2 hours each time. After that, remove hemoperfusion cartridge for another 2 hours hemodialysis treatment.

4. How do I know it's reliale? Is there any clinical data of the product?

See page 8 to page 10 in this manual for reference.

5. What is the relation among hemoperfusion, high-flux dialysis and hemodiafiltration in uremic toxins removal?

The discovery of uremic toxins, include middle and large molecular and protein-bound uremic toxins, other than urea and creatinine, has stimulated several investigations on alternatives to standard or high-flux hemodialysis, to remove these molecules. These methods include hemodiafiltration with or without dialysate regeneration using sorbents, as well as hemoperfusion. Conventional high-flux dialysis is not efficient at removing these molecules, explaining the increased interest in using sorbents to supplement dialysis techniques.High-efficiency hemodiafiltration may reduce some of these proteins, with the high cost of ultrapure replacement fluid; on-line generation of replacement fluid may become practical in the future. Sorbent hemoperfusion for removal of these toxins is attractive in offering low cost and high-efficiency removal for certain substances. Current literatures prove that hemoperfusion combining hemodialysis is effective in removal of middle, large molecular and protein-bound toxins and is useful in preventing the progressing of dialysis-related symptoms.

6. Why is it necessary to use MG product?

Removal of middle and large molecular and protein-bound uremic toxins by dialysis is limited to the combined effect of slow diffusion and a comparable long diffusive pathway (the dimension of hemodialysis membrane devices is optimized for urea removal). Like dialysis, hemoperfusion relies on diffusion for solute transport but, unlike dialysis, the diffusion distance is shorter and the tortuous pathway adds a convective component. The transport process in hemoperfusion cartridges therefore allows clearance from total plasma water, while hemofiltration is limited to the filtration fraction.Hemoperfusion is efficient at removing these molecules. The rationale for combining hemodialysis with hemoperfusion logically seeks to improve properties missing in each technique-inefficient middle, large melocular and protein-bound toxins removal in the former, and small solute removal in the latter. After removal of these toxins by HD+HP, various symptoms related to long-term hemodialysis treatment can be improved.

7. What precautions should we take when using the products?

Refer to Product Instruction.

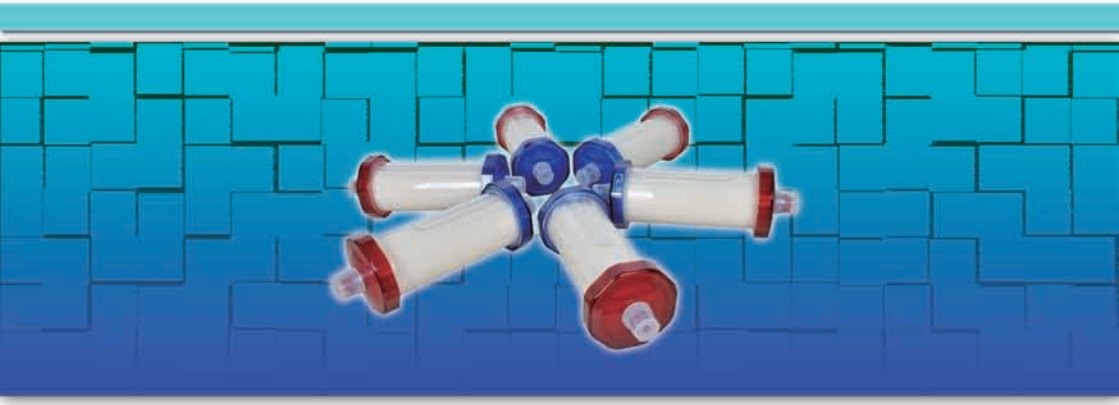
8. Any side-effect of the products?

Hemoperfusion therapy is one of widely applied and highly proven blood purification technologies, however, even under the precondition of hemoperfusion treatment quality & normal operation, a few patients would present with complications such as allergy, hypotension, heart failure, bleeding, heart arrest, shock, arrhythmia, similar to those for hemodialysis.

9. What is the treatment protocol and usage frequency?

See page 6 in this manual for reference.

Priority to Quality
Care for Life



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