Study on the Reusing of Dialyzer

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Abstract

In this article, we recalled the history of the reusing of dialyzer and analyze its advantage in terms of cost efficiency, improving the biocompatibility of dialysis membrane and reducing first use syndrome as well as the potential risk. The prospect of the dialyzer reuse was discussed in the aspects of medical and economic. The results showed that reusing dialyzer can ease the economy pressure of patients. Although there are medical risks, in the modern economic context, dialyzer reuse is still an inevitable trend.

Keywords

Dialyzer, Reusing, Biocompatibility.

1. Introduction

“For an individual, contaminated disposable dialyzers and catheters may be able to destroy his/her life. Hospital is life-saving, and similarly, the medical devices are also used to heal the sick. Once they become killers, that is when the trust crisis of public confidence in them.” This is the feeling of a reporter in the early years after unannounced visits to several major hospitals. A lawyer, interviewed by the reporter on this issue, said: dialyzer is ‘absolutely illegal’. The legal basis for it is the State Drug Administration issued since April 1, 2000 implementation of the "Supervision and Regulation of Medical Devices "Article 27 of which states:" medical institutions disposable medical devices cannot be reused. Once used, they should be destroyed and recorded in accordance with relevant state regulations." After a period of time within the State Drug Administration to allow some use of dialyzers change the specification and to allow imports of dialyzer, and then later the national health authorities acquiesced dialyzer reuse, until August 1, 2005 formally promulgated the "Hemodialysis alternate practices."

Dialyzer reuse, from being strictly forbidden, acquiescence to approved, what is the advantages and disadvantage? This article will use a scientific approach to address this issue.

2. The Status of Dialyzer Reusing

2.1 Section Headings

Hemodialysis is the most common method in renal replacement therapy. It is an effective clinically method to treat acute and chronic renal failure at present. Also known as an artificial kidney, dialyzer is a necessary device for hemodialysis. The convection of blood (inner membrane) and dialysate (outer membrane), in the dialyzer, clear creatinine, urea and other toxic substances from patients’ body by the concentration gradient or pressure gradients. Patients need h 2 to 3 times per week, and because dialyzer is expensive, the patient is under great financial pressure, many dialysis centers, at home and abroad, gradually began to explore dialyzer reuse, in recent years.

According to the report in 1990, in United States, 70% of the dialysis center reuse dialyzers, 75% of patients receive treatment in those dialysis center. By 1997 the proportion of medical institutions which reuse dialyzers in United States has reached 82% with a highest reuse time up to 15[1]. Dialyzer reuse rate in Europe is lower, and dialyzer reuse is forbidden in Netherlands, Japan and a few other countries. Dialyzer reuse is allowed in Korea since 1985 dialyzer [2], China and other developing countries, due to the relative shortage of dialysis resources, most of dialyzer.

Dialyzer reusing is common in the world, because of China's national conditions it is even more popular in our country. Numerous studies show that dialyzer reuse can lower costs and reduce the incidence of first use syndrome, and to improve biocompatibility. It can also reduce the amount of disposed dialyzer, hence, reduce environmental pollution. However, the downsides of dialyzer reuse such as decline in clearance, pyrogenic reactions and viral infections are not negligible. The quality of reused dialyzer is directly related to the dialysis patient's quality of life and survival [1].

Dialyzer reuse process is accompanied by cleaning, sterilization and other treatments. The chemical composition of cleaning agents and disinfectants as well as the efficiency of cleaning and sterilization have a great impact on the quality of the reused dialyzers. Although there are modern reused dialyzer washing machine available, it is difficult to strictly control the cleaning process in the clinical environment as the industrial production. So, quality and safety use of reused dialyzer becomes a great concern of clinical hemodialysis. Because of the performance and biocompatibility of dialyzers varies with the change of dialysis membrane materials and the manufacturing method of multiplexing changes, coupled with the quite different acceptance of dialyzer reuse in the world, there is no international standards of reused dialyzer. In 1986, American Association of Medical Instruments (AAMI) developed a dialyzer reuse standards. In 2000 US NKF-K / DOQI hemodialysis adequacy working group recommended to follow the AAMI's standard of reused dialyzer. American national standards Institute (ANSI) recommended the implementation of the AAMI standard on 21st March 2003, and approved the standard on 7th November 2002. "blood dialyzer reuse practices" issued by National Ministry of Health regulated the standard and requirements of dialyzer reusing, hence, improved the capability of dialyzer reusing in the hospitals and has a great impact on the safety of medical devices.

3. The Advantages of Dialyzer Reusing

3.1 Cost Savings

Reuse of dialyzers were originally because of economic factors. Reusing dialyzer can reduce the cost of dialysis, so that more patients can receive relatively inexpensive dialysis. According to the principle of adequate dialysis, renal failure patients need to receive twice weekly dialysis.

A report from Canadian notes: By reuse each dialyzer five times, a patient can save $3629 per year.[3] At the same time, in China, based on 200RMB for each dialyzer and 150RMB for each cannula, the cost of per patient per year is 36400RMB. If reuse dialyzer five times, the cost will be reduced to 7280RMB, a 29120RMB cost reduction. In our country in 1999, for example, when the health cost was 435.18 billion yuan, the population of dialysis patients was about 4.2 million. Not reusing dialyzer, the annual cost of dialysis would be 15.3 billion yuan, 3.52 ‰ of the national health expenditure. If the dialyzers were reused for five times, the annual costs of dialysis would be only 306 million yuan, just 0.71 ‰ of the national health expenditure. We can get an annual cost saving of 1.2 billion yuan by reusing dialyer!

In China, except for a few patients enjoy full free medical care, the others pay the cost of the dialyzer and tubing mostly or entirely by their own expense. Dialyzer reuse reduces their economic pressure, some patients would not give up because of financial problems treatment. In fact, dialyzers are sterilized by the hospital for free, the biggest beneficiaries of dialyzer reuse are those patients with economic difficulties.

3.2 Reducing the First Use Syndrome

The first use syndrome, referring to the syndrome induced by the reduction of white blood cells when using a new dialyzer. First proposed in 1980 by Ogden, a new dialyzer syndrome is an allergic reaction occurs within a few minutes use of new dialyzers. In 1983, Henderson divided it into two types of reaction (A type and B type).[4] A type reaction is the more serious type of reaction, usually occurs within 10 ~ 30min dialysis due to patients allergies to the residual disinfectant, ethylene oxide (ETO), which manifested by difficulty of breathing, chills, fever, low blood pressure, there may be a serious sense of impending doom, cardiac arrest and even death. After dialyzer reuse, the amount of

residual ethylene oxide is reduced. Hence, propylene oxide allergic reaction is reduced. B-type reactor is mainly due to the allergic reactions to the endotoxin-like substances released from the dialysis membrane materials. B type usually occurs after 1h dialysis, mainly as chest pain, back pain, urticaria and other reactions. Robson reported that dialyzer reuse can significantly reduce the incidence of allergic reactions described above.[5] Improve allergy symptoms may be associated with allergic multiplexed active substances and ETO clearance, dialysis membrane biocompatibility improvement and improving relevant complement activation.

3.3 Improving the Biocompatibility of Dialysis Membranes

Biocompatibility of Dialysis membranes refers to the specific and nonspecific reactions when blood contact dialysis membranes. Improve the biocompatibility of the patient feel comfortable and side effects dialysis. Many studies have confirmed that phenomena, such as activation of the complement system, blood cells (including neutrophils, lymphocytes, monocytes, platelets, etc.) activation, cytokine production, occurs when blood contacts dialysis membrane. Such reactions are called biocompatibility of dialysis membrane. Synthetic membranes (polysulfone membrane, polyacrylonitrile film, polyacrylic film) have better biocompatibility compared to cellulose membranes. Scholars have long found dialyzer reuse can reduce complement activation, leukocyte activation, and thus has better biocompatibility. In recent years, more attention has been paid on the effect of cytokine on the biocompatible of dialysis membrane. Studies have shown that, changings of interleukins, tumor necrosis factor (TNF), interleukin-1 receptor antagonist, soluble TNF receptor occurs in the hemodialysis process, and reuse can reduce the production of cytokine caused by cellulose membranes. Most reported that, the mechanism of the improvement of biocompatibility in dialyzer reuse is the adsorbed plasma protein on the surface of the dialysis membrane, which prevents direct contact between the blood and dialyzer membrane, thus, reducing the activation of the complement of blood and blood cells.

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4. The Potential Risks of Dialyzer Reusing

4.1 Pyrogenic Reactions

Pyrogenic reactions caused by dialyzer reuse is one of the biggest drawbacks of dialyzer reuse. Most of the pyrogenic reaction are caused by the pyrogen, bacteria, free protein and pharmaceutical compositions introduced in the process of hemodialysis. It can also been induced by pyrogenic substance which formed by the interactions between body fluids/blood and membrane. Residual endotoxins adsorbed in the dialyzer membrane which are not completely remove can cause pyrogenic reaction. Most of these pyrogenic substances are caused by incomplete sterilization or contamination of tube and dialyzer during operation. Therefore, it is safer to keep the endotoxin content, in the water used to make the disinfectant, less than 1ng / ml (1 ng per milliliter). This shortcoming is completely avoidable, as long as reuse water is strictly regulated and the standard operation procedures are carefully followed.

4.2 Infections

The biggest problem facing the dialyzer reuse is microbial infections caused by inadequate disinfection. Infection is the most common complication in hemodialysis patients and is an important cause of death in patients, the rate was l2% ~ 22%. Sepsis is the biggest threat amongst different infections, and it is an independent risk factor of dialyzer reuse.

In addition, hemodialysis patients are a high-risk group of infection of hepatitis B (HBV) and hepatitis C (HCV), especially in recent years infection rate of hepatitis C infections has a rising trend, mainly related to blood transfusions and dialyzer reuse. Therefore, HBV and HCV patients should be separated from other patients. Dedicated rooms, dialyzer, operator and instruments for them, and chemical disinfection of dialyzer between shifts are effective measures to reduce the incidence of infection. Since current method of dialyzer reuse can effectively kill the HBV and HCV virus, the key is to avoid cross-infection in the reuse process (ie. dialyzer for infection or carrier should be separated from others), meanwhile ensure that there is no HBV or HCV residual virus in the reused equipment after dialyzer reuse. Do not reuse dialyzers of HBV and HCV patients, if possible.

In order to better prevent infection, one should strictly enforce the principle of aseptic operations and avoid puncture in inflamed or damaged skin area. Keep the pipeline not been contaminated. If it is contaminated or suspected contaminated, it should be replaced immediately. Avoid exposing venous catheter in the air for a long time. Deep vein intuitive observe patients at the eye of a needle without swelling and abnormal secretions, dressing twice a week to prevent infection at the eye of a needle.

Reuse of dialyzers and tubing must be responsible by specialist. Keep rinse chamber clean and at a suitable temperature. The excessive oxygen acid residues can be effectively reduce by increasing dialysate temperature, reducing the volume and shortening the time of pre-rinse. Other actions that can reduce the incidence of cross-infection are: wet cleaning desktops and the ground with chlorine disinfectant wipe, cleaning the ground of hemodialysis room daily with containing 1% disinfectant benzalkonium bromide disinfection, keeping the door and windows closed, illuminating the room daily with ultraviolet light for 30 mins and strict distinction between sterile and non-sterile zone area.

4.3 Toxic and Side Effects of Disinfectants

Residual disinfectants and insufficient disinfection will cause infection and immunological response. Immunological reactions are all kinds of toxicity, acute and chronic formalin toxic reactions caused by the residual disinfectant in the reused dialyzer. Acute toxic reactions, that is, symptoms of vein puncture site burning sensation, sweating and breathing difficulties when the blood flowing back, severe symptoms (large amount of accumulated formalin) can even lead to cancer. Thoroughly rinsing can reduce the toxicity of formalin, sodium hypochlorite, formaldehyde and other disinfectants. Formalin reused dialyzers should be rinsed before dialysis, so that the formalin concentration should be lower than 5ppm (parts per million), otherwise anti -N- erythrocyte antibodies would be produced and cause hemolysis or other side effects. Sodium hypochlorite can also induce anti -N- red cell antibodies. Blood components of patients may be deposited in the dialyzer in dialysis which can be changed by reusing process. when the protein re-enters the dialysis patient, it acts as an antigen to stimulate the body to produce antibodies.

To reduce the side effect of residual disinfectants, one should strictly control the quality of reused blood tubing. Before using the dialyzer, carefully check the patient's name, times of reuse, operators name, date, and dialyzer relevant data. Strictly implement aseptic technique and the dialyzer standard operation procedure. Strengthening the concept of sterile, accuratly preparing disinfectants, strictly controlling the concentration of various disinfectants [hemodialysis required residual disinfectant levels should be achieved: formalin <5ppm (5ug / L), peracetic acid <1ppm (1ug / L), Peracidin <3ppm (3ug / L)]. Formalin sterilized dialyzer can be kept for two weeks, peracetic acid disinfectant can be kept for one week. If expired, re-sterilized before use. Pipeline must be stored in clean, dry storage tank. Store sterilized and unsterilized of dialyzers separately in temperature of about 4 ℃ environment. Sterilization time must be longer than 24h.

4.4 Effects of Reuse on Solute Removal

Dialyzer reuse influence the effectiveness of dialysis in at least two aspects. One is the reduction in the dialyzer solute clearance rate, caused by accumulation of blood and blood components side when reusing dialyzer. USRDS reported that, in 1986, the average number of dialyzer reuse times is 9, 14 in 1994. The average number of reuse times is 23 to 30 in some dialysis institutes. The other is the

different effect of disinfectants treatment on dialysis with various membrane materials. Prezegh and Ouserph reported that as long as the total cell volume (TCV) is larger than 80%, there is no difference between the old and the new dialyzer in terms of the clearance of small molecules. However, the clearance mid-sized molecular may be reduced. With the increasing of the reuse time, and ultrafiltration rate and solute clearance rate of dialyzer will decline. Ultrafiltration rate can not be accurately predict by the changing of TCV. However, since it is easy to acquire TCV, and it is correlated with the dialyzer ultrafiltration rates and clearance rate, it is the most commonly used indicators to monitor the dialyzer clearance. TCV is not a substitute for regular actual clearance testing, clinical assessment and evaluation of dynamic model of urea. A 20% drop of TCV corresponds to a 10% drop of the clearance rate of urea nitrogen. In general, the effect of dialyzer reuse on the clearance rate of urea nitrogen is minor. There is only (1.0 ±0.3)% drop of urea nitrogen clearance rate after reusing a high-flux dialyzer for 10 times. The drop ratio of a low-flux dialyzer is (1.9 ± 0.3)%. In the 1980s Gotch reported that, urea nitrogen clearance rate can be maintained at above 90% as long as the dialyzer TCV reached 80% of the original capacity, With the increasing in the number of dialyzers reuse times, clearance rate of small molecule such as chromium and phosphorus decreases significantly. Researchers compared small molecular clearance rate of peracetic acid reused dialyzer and new dialyzer, the results show that although reusing reduces the clearance of small molecules, but the clearance rate still remained in the acceptable range. Kes 1997 proposed that by increasing the dialysis duration time by 30 mins, when using dialyzers which were reused more than 10 times, the sufficient dialysis can be ensured. For those dialyzer that are reused less than 10 times, the dialysis efficiency is unaffected. According to NKF-DOQI guidelines (renal anemia treatment guidelines), causes of inadequate dialysis in dialyzer reuse includes: frequent faulty uses of dialysis, TCV reduction by different manual reuse, different relationship between clarance rate and reuse time of different dialyzer and reduced resistance to TCV in high-flux dialyzers.

4.5 Effects of Reuse on Long-term Survival of Patients

The reports of whether dialyzer reuse would affect the quality of life in hemodialysis patients or not vary. Some reported that reuse does not affect the survival of patients while other says that reuse cause inadequate dialysis and mortality may take five years to be noticed[3], which is related to the dialyzer reuse factor (annual dialyzer reuse time/ annual number of total dialysis). In France, dialyzer reuse factor is 11.2, the patient survival rate is higher than 90%, while in the United States reuse factor greater than 2.2-year and survival rate is less than 80%. After adjusting the factors such as hematocrit, comorbidities, basal metabolic rate, serum albumin, primary disease severity, type of dialysis membrane, scholars has not found significant differences in the death ratio of hemodialysis patients whether they reuse dialyzer or not.

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5. The Prospect of Dialyzer reuse

The main reason that dialyzer reuse is popular worldwide is the economic factor. Many patients cannot afford the high costs of disposable dialyzer and cannot receive adequate dialysis. The poor cannot enjoy the modern medicine and can only wait for slowly dying. So, many dialysis centers gradually began to explore dialyzer reuse, in recent years.

From an economic perspective, dialyzer reuse reduces the cost of dialysis, as well as social and personal medical costs, so that more patients can be treated. Meanwhile, with the emerging dialyzer

reuse technology has become more sophisticated, security dialyzer reuse is improved. The development of dialysis membrane material from regenerated cellulose type to the modified cellulose-based and to the synthetic membrane makes high-flux dialyzer widely used. It can be more efficient in removing mid-sized molecule metabolites. Renal bone disease, dialysis-related amyloidosis and other long-term complications associated with dialysis can be relief.

Although almost all the dialysis center in China reuse dialyzer and patients recognize dialyzer reuse, from the medical safety point of view, the author is not in favor of dialyzer reuse. How to really safely reuse dialyzer remains a question to hospital administrators and health care workers.

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