

Review Article

Large-Bore Catheters as Vascular Access for Extracorporeal Detoxification Methods: Advantages, Disadvantages, and Necessary Improvements

Rolf Bambauer^{1*}, Ralf Schiel² and Octavio J Salgado³

¹Formerly: Institute for Blood Purification, Homburg/Saar, Germany

²Clinic for Metabolic Diseases, Medigreif Inselklinik, Heringsdorf, Germany

³School of Medicine, Universidad Católica de Cuenca, Ecuador

Abstract

After the introduction of large-bore catheters with the Seldinger technique into the vena cava superior via the internal jugular veins in 1979, the advantages of this puncturing technique versus the puncture of the femoral or subclavian veins were seen. However, complications and side effects of the puncture of the internal jugular vein, such as faulty punctures, bleeding, hemothorax, thrombosis and faults in catheter material and infections were observed, too. Infections, thrombosis, and stenosis are among the most frequent side effects associated with blood-contacting catheters. These side effects are usually related to surface properties and the material of these catheters. Surface treatment processes, such as ion implantation and ion beam assisted deposition, and microdomain structured surfaces, could be used to mitigate such complications. The complication rate was first retrospective about 28 %. A second retrospective study of surface treated catheters with silver versus un-treated catheters showed 75 % decline in the infection and thrombosis rate in the surface treated catheters. However, this cannot be confirmed with more available data of these patients. One reason may be that in the surfaces treated catheters only the outer surface was coated with silver and the possibilities of contamination by handling during treatments. New materials and technologies which include the outer

*Corresponding author: Rolf Bambauer, Formerly: Institute for Blood Purification, Homburg/Saar, Germany, Tel: +49 684168500; Fax: +49 684168561; E-mail: rolf.bambauer@t-online.de

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and inner surface are necessary to reduce the tremendous discomfort of patients and the high costs of the catheter-related infections.

Keywords: Catheter-related infections; Extracorporeal detoxification methods; Large-bore catheters, high costs of infections; New technologies; Surface treatment

Introduction

During the training in Nephrology, we became aware of the problems associated with vascular access points for acute hemodialysis. Despite all technical innovations in hemodialysis, the problem of finding a temporary or permanent vascular entry point appears to have found no satisfactory solution. Temporary vascular access, in particular, still presented considerable problems over years. For almost 2 decades, the method of choice a temporary vascular access for hemodialysis has been the Scribner Shunt, transcutaneous puncturing using the Seldinger technique to insert a large-bore catheter, traditionally in the femoral or subclavian vein (SCV) [1,2].

We introduced the cannulization of the superior vena cava over the Internal Jugular Vein (IJV) with a modified large-bore catheter using the Seldinger technique [3]. With the introduction of the catheterization of the IJV, the previously necessary application of a Scribner Shunt has become superfluous [4]. Catheterization of the IJV and SCV as temporary access points is suitable for almost all treatments of hemodialysis or therapeutic apheresis. This new technique marked a milestone in the history of central vein catheterization for hemodialysis, and it soon became the first-choice approach for all patients requiring a vascular access route for emergent hemodialysis and other acute extracorporeal therapies. The main reasons for this trend were both a lower incidence of puncture-related complications compared to the subclavian or femoral veins.

Contraindication for IJV catheterization are low such as inflammation at the point of puncture and unidentified anatomical conditions, e.g., extended stream or tumors in the neck area. The puncturing of the IJV can carry out with sonography. After insertion of the catheter in the IJV or SCV vein, the position of the catheter tip must be checked by x-ray, or with an intra-atrial electrocardiogram, than fixed the catheter with a suitable cutaneous suture [5]. The catheter lumen usually is kept free with a low-dose heparin or an antibiotic solution drip, between each individual treatment. More recently, the catheter was closed with a special developed mandarin, which completely fills the catheter lumen.

Catheter-Related Bacteremia (CRB), thrombosis and stenosis are among the most frequent complications associated with catheters, which are inserted in vessels as vascular access. These problems are usually related to the handling of the staff, the catheter materials, and the surface properties of the catheter. To improve the patient outcome and discomfort and to reduce the tremendous high costs of the CRB, new technologies are necessary.

CRB is a major cause of morbidity among hemodialysis patients. Treatment with systemic antibiotics alone without removal of the

catheter fails to definite eradicate the infection in most patients [6]. CRB must be management by either catheter removal with delayed placement of a new catheter or management of the infected catheter with a new catheter over a guide-wire and additional systemic antibiotic therapy. These CRB complications are responsible for patient readmissions and longer hospital stay as well as patient discomfort morbidity, and occasional mortality, and are contributing factors to increasing cost of medical care.

The source of CRB is usually a bacterial biofilm consisting of a polysaccharide matrix that forms either in the lumen of the catheter or on the outer surface. The biofilm, most consisting of *Staphylococcus aureus*, cannot be destroyed or eliminated by a systemic antibiotic therapy, because of antimicrobial resistance [7]. Bacteriae could colonize to rough surfaces [8]. The combination of rough surfaces and protein deposits should be an ideal situation for the colonization of bacteria. The bacteria could produce and become covered with a slime layer, in which case antibiotic drugs have no influence on the bacteria. The bacteria under the slime layer use the organic substances of the catheter material for their metabolism. The toxins of the bacteria can penetrate the slime layer and enter the patient blood provoking a catheter infection [8]. Biofilm is a microbial derived sessile community characterized by cells that are irreversible attached to a substratum or interface to each other, embedded in a matrix of extracellular polymeric substances that have produced [9]. Such a biofilm can be the origin of fibrin sheath formations leading to catheter dysfunction due to blood reducing and to blood disturbances. The therapy must be to remove the catheter immediately, or exchange it over a guide-wire with a new catheter and additional systemic antibiotic therapy.

Continued nursing staff training and the introduction of newer catheter technologies have contributed to reduce the incidence of infection, to improved patients outcomes, reduced patient discomfort, and decreased the high costs of CRB and catheter-induced endothelial damage. Catheter-related complications represent a significant burden on the management of the renal replacement therapy program and mortality risk for the dialysis patient. The incidence of catheter-related complications is significantly higher than with arterio-venous fistula [10].

Biocompatibility of synthetic materials is a further major problem. The interaction of blood with a synthetic surface causes coagulation and activation of the complement system. This can lead to the adsorption of various proteins and the formation of a layer of protein on the synthetic surface. Thrombocytes, other cells and bacteria adhere to this layer of protein so that thrombi may form which can lead to blood flow disturbances and catheter dysfunction [11].

To influence CRB different new developments are available today, such as new catheter materials, coating of the material surface with antibiotic-heparin, or silver and silicone, cuffs on the outer surface, catheter for tunneling, installation of an antibiotic-anticoagulant lock into the catheter lumen after the HD, etc. [6,12,13]. The first results with available coated on the outer surface with silver or silicone catheters were encouraged [11,14,15].

Major medical device companies have recognized the importance of surface-engineered biomaterials because surface modification processes can reduces the rate of infection, thrombogenicity, and other catheter-related complications without adversely affecting the basic design function of catheters.

The surface-engineered biomaterials is still in its infancy, the range of service currently offered by surface treated vendors is varied and continually expanding. Surface modification processes can reduces the rate of infection, thrombogenicity, and other catheter-related complications without adversely affecting the basic design function of catheters. Examples include conventional coating process such as depending and spraying: vacuum-deposition techniques (e.g., sputtering), and surface modification approaches such as diffusion (e.g., nitriding, carburizing), laser and plasma process, chemical plating, grafting or bonding, and bombardment with energetic particles (as in plasma immersion or ion implantation). Of the available techniques, those based on ionized particle bombardment have particularly successful in biomaterial surface modification, primarily because they combine versatility and low-temperatures processing with superior control, reliability, and reproducibility [16, 17].

The ion beam-based technology used for the treatment of catheters covered herein is ion-beam-assisted deposition (IBAD; Spi-Argent®, Spire Corporation, Bedford, MA, USA) [14,16,18]. The process is typically performed at low temperature under high vacuum. The affected layer in the typical films deposited by the IBAD process is in the order of one μm or less vacuum-compatible catheter materials may therefore, be treated without adversely affecting bulk mechanical properties. The IBAD is line-of-directly: however, parts with complicated geometries may be manipulated for uniform coverage of all surfaces [18].

A further developed catheter material is the microdomain structured surface (PUR-SMA coated catheter, Gambro, Germany) [15]. Microdomain surfaces are considered the most biocompatible because the mimic the structure of natural biological surfaces. Microdomain structures are used to match the multiple requirements for improved catheter surfaces, which is reproduced thrombogenicity and improved antimicrobial properties. A SMA-modifies polyurethane coating consists of hydrophobic and hydrophilic microdomain in range below 50 nm. Up to 50 percent of the molecule is presented to the surface and creates microdomain-structured surfaces. If the domains are below a critical dimension of approximately 100 nm, theoretical considerations indicate that interaction with proteins, blood cells, or even bacteria will be unstable and therefore not occur as frequently as on non-microdomain structured surfaces.

However, new materials and surface treatment technologies are needed to save health care costs for hemodialysis catheters, to reduce infection rates and thrombus formations and to help improve the patients' outcome. The handling of the catheter by attending staff must be improved and done after the guidelines of different medical communities [19].

Statistical Analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS 13.0). All continuous data are presented as mean \pm standard Deviation (SD) or if the data showed no normal distribution, as median and range. Dichotomous data were presented as a number (n) or in percent (%). Univariate, unadjusted analysis were performed with the independent samples t-test, chi-square test, Fisher's exact test for frequencies at or below 5 and the Wilcoxon's rank sum test. Pearson's correlation coefficient was calculated and multivariate's analysis was used to evaluate the presence of associated variables. Significance was defined at the 0.05 level.

Catheter, Patients and Results

After introduction of the cannulizations of the vena cava superior over the internal jugular vein, complications were observed as faulty puncture, bleeding, hemothorax, infections, thrombosis and defective catheter material [3,4,15,20]. In about 27.7 % of all inserted catheters, these complications were seen. In subsequent years, improved catheter handling, stringent antiseptic measures, and new catheter technologies, such as catheter surface treatment [14,15,20,21], have been instrumental in reducing complications rate.

In the retrospective study from 1979-1990 with 2,626 large-bore catheters in 1,627 patients, the frequency of infections, thrombosis, bleeding and other side effects was investigated. All complications together are presented dependent upon vascular route and were seen in total in 728 treatments (27.7 %) (Table 1) (20). In the following retrospective study from 1992-2007, outer surface treated catheter with silver (n = 54) versus untreated catheters (n = 105) were investigated [11]. The results of this investigation showed 75 % decline in the infection rate with the surface treated catheter could not be confirmed with the other investigation (Table 2).

Table 1: Complications and side effects in large-bore catheters in the internal jugular (n = 2,105) and subclavian vein (n = 521) (20).

	Internal Jugular Vein (n = 2,105)		Subclavian Vein (n = 521)	
	n	%	n	%
Puncture not possible	4	0.2	25	5.0
Puncture of artery	84	4.0	5	0.9
Abscess	25	1.2	18	3.5
Sepsis	175	8.3	78	19.3
Thrombosis	6	0.3	25	4.8
Bleeding	21	1.0	12	2.4
Pneumo/Hemothorax	---	---	15	3.0
Emboli	---	---	---	---
Pain	---	---	---	---
Faults in catheter material	187	8.3	48	9.4
Total	502	23.9	226	44.3

Table 2: Microbiological results in acute and long-term catheter (n = 225) with (n = 113), and without (n = 112) surface treatment [11].

¹p = 0.1106; ²p = 0.0077; ³p = 0.0001; ⁴p = 0.0441; ⁵p = 0.0059; ⁶p = 0.0166

	Surface treated catheter			Non-treated catheter		
	Acute catheter	Long-term catheter	Total	Acute catheter	Long-term catheter	Total
Catheter (n)	67	46	113	62	50	112
Skin (n)	28 ¹	17 ²	45 (39.8 %)	39 ¹	35 ¹	74 (66.1%)
Bacteria:						
- S. epidermidis	20	14		14	28	
- S. aureus	4	3		12	7	
- Pseudomonas	4	---		---	---	
Blood culture (n)	5 ³	11 ⁴	16 (14.2%)	36 ³	28 ²	64 (57.1%)

Bacteria:						
- S. epidermidis	3	4		6	10	
- S. aureus	2	7		20	14	
- Saprophyte	---	---		2	---	
Catheter tip (n)	4 ⁵	5 ⁶	9 (8.0%)	30 ⁵	22 ⁶	52(46.4%)
Bacteria:						
- S. epidermidis	3	3		4	7	
- S. aureus	1	2		17	13	
- Saprophyte	---	---		1	---	

The decrease of infection rate in surface treated catheter in the preliminary study from 2001 cannot be seen in the new study of 1992-2007 [22] (Table 3). One possible explanation could be that all the patients in the record were included in the latter study and therefore data available for analysis was much larger. The untreated catheters showed a higher positive culture for bacteria of 55 % versus 52% to the surface treated catheters, but without significance. The procedure for both studies was the same.

Table 3: Microbiological examination of 105 untreated and 54 surface treated catheters [22].

Microorganism	Untreated Catheter		Surface treated		p-value
	(n)	%	(n)	%	
Negative	47	45	26	48	n.s.
Staphylococcus aureus	31	29	21	38	n.s.
Staphylococcus epidermis	7	7	1	2	n.s.
Pseudomonas	1	1	0	0	n.s.
Enterobacter	1	1	1	2	n.s.
Others	18	17	5	10	n.s.

The PUR-SMA coating prevents contact of blood components with barium sulphate, possibly leading to leaching as particles or dissolved in the surrounding media. The advantage of the PUR-SMA surface treatments is the coating of the inner and outer surface in contrast to the ion beam-based surface treatment technologies in which can be treated only the outer surface of the catheters. Preliminary results with these PUR-SMA coated catheters showed good biocompatibility with no deposits of hematic debris and low thrombogenicity and coagulation activity. Bacterial growth was very low and those of the Spi-Argents catheters [17,23,24]. However, more studies with a higher number of patients with large-bore catheters are needed to show the expected better outcomes with PUR-SMA catheters.

Dialysis catheters are used for vascular access in 65 % of incident Hemodialysis (HD) patients, and in 25 % of the prevalent HD populations [25]. The first choice of vascular access is the vena cava superior over the internal jugular vein [26]. However, large-bore catheters used for extracorporeal detoxification need large improvements, due to the complications rates. Catheter improvements must develop together from scientists, physicians and industries, which are involved in the catheter production.

Discussion

Catheter-related bacteria is a major cause of morbidity among hemodialysis patients. Treatment with systemic antibiotics alone without removal of the catheter fails definitely eradicates the infection in

most patients [27]. CRB must be managed by either catheter removal with delayed placement of a new catheter or management of the infected catheter with a new catheter over a guide-wire and additional systemic antibiotic therapy. These CRBs are contributing factors to increasing cost of medical care. They are responsible for readmissions and longer hospital stays as well as patient discomfort, morbidity, and occasion mortality.

The source of CRB is in most patients a bacterial biofilm, which forms in the catheter lumen or on the outer surface. Biofilm is an organized aggregate of microorganisms living an extracellular polymeric matrix that they produce and irreversibly attached to a living surface which will not remove unless rinsed quickly [28]. This biofilm, most consisting of *Staphylococcus aureus*, cannot be destroyed or eliminated by a systemic antibiotic therapy because of antimicrobial resistance [29]. Bacteria could most of the time colonize, on rough surfaces [30]. The combination of rough surfaces and protein deposits should be an ideal situation for colonization of bacteria. The bacteria could produce and become covered with a slime layer, in which case antibiotic drugs have no influence on the bacteria. The bacteria under the slime layer use the organic substances of the catheter material for their metabolism. The toxins of the bacteria can penetrate the slime layer and enter the patient blood provoking a catheter infection [31]. Biofilm is a microbial derived sessile community characterized by cells that are irreversibly attached to a substrate or interface to each other, embedded in a matrix of extracellular polymeric substances that have produced [32].

Bacterial colonies in a biofilm generally consist of many types of micro-communities. These micro-communities coordinate with one another in multiple aspects. This coordination plays a crucial role in exchange of substrate, distribution of important metabolic products and excretion of metabolic products [28]. Such a biofilm can be the origin of sheath formation leading to catheter dysfunction due to blood clots and to blood disturbances. The therapy must be to remove the catheter immediately, or exchange it over a guide-wire with a new catheter and additional systemic antibiotic therapy. Novel therapeutic strategies are thus urgently needed to combat the threat of biofilm [33].

The interaction of blood with a synthetic surface causes coagulation and activation of the complement system. This can lead to the adsorption of various proteins and the formation of a layer of protein on the synthetic surfaces. Thrombocytes, other cells and bacteria adhere to this layer of protein so that thrombi may form which can lead to blood flow disturbances and catheter dysfunction [11,22,34].

Surface modification processes can reduce the rate of infection, thrombogenicity, and other catheter-related complications without adversely affecting the basic design function of catheters. Examples include conventional processes such as dipping and spraying; vacuum-deposition techniques (e.g., sputtering), and surface modification approaches such as diffusion (e.g., nitriding, carburizing), laser and plasma processes, chemical plating, grafting or bonding and bombardment with energetic particles (as in plasma immersion or ion implantation). Of the available bombardment, have particularly successful in biomaterial surface modification, primarily because they combine versatility and low-temperature processing with superior control, reliability, and reproducibility [17].

A further developed catheter material is the microdomain-structured surface (PUR-SMA coated catheter, Gambro, Germany) [34]. Microdomain surfaces are considered the most biocompatible

because they mimic the structure of natural biological surfaces. Microdomain structures are used to match the multiple requirements for improved catheter surfaces that are reduced thrombogenicity and improved antimicrobial properties. A SMA-modified polyurethane coating consists of hydrophobic and hydrophilic microdomains in range below 50 nm. Up to 50 percent of the molecules are presented to the surface and create microdomain-structured surfaces. If the domains are below a critical dimension of approximately 100 nm, theoretical considerations indicate that interaction with proteins, blood cells, or even bacteria will be unstable and therefore not occur as frequently as on non-microdomain structured surfaces.

New materials with better biocompatibility must be developed to reduce catheter-related side effects and, above all, to remain in situ for longer endothelial damage, since a good part of dialysis patients have vascular problems, which has been done increasingly common in recent decades. Patients with vascular access problems represent about 30 % of the entire hemodialysis population and tend to be more frequent in older patients [35].

Drugs such as antibiotics on the catheter surfaces or administration to the patient or disinfection substances is that they can develop resistance by mutation or other mechanisms. Therefore, the need for new surgical techniques and materials is necessary [36]. However, it appears impossible to create a surface with an absolute "zero" adherence due to thermal-dynamical reasons and due to the fact that a modified material surface is *in vivo* rapidly covered by plasma and connective tissue proteins.

Recent data have suggested that Methicillin-resistant *Staphylococcus aureus* (MRSA) and Vancomycin intermediate *Staphylococcus aureus* (VISA) organisms have increased [37]. One of the proposed mechanisms of Vancomycin-resistance is the bacterial cell wall thickening following Vancomycin exposure [38]. Vancomycin's activity may be decreased as activity may be decreased due to the thickness of the bacterial cell; the results are MRSA and VISA [39].

Other concepts of the prevention of implant-associated infections must involve the impregnation of the devices on the inner and outer surface with antibiotics, antimicrobial substances and/or metal [40,41]. Another point is to understand the process leading to the development of CRB in order to offer effective preventive and therapeutic possibilities [42]. Such as new polymer-antibiotic systems in inhibiting bacterial biofilm formation and in reducing neutrophil activation after surface contact on different biomaterials, thus reducing the risk for biomaterial-mediated inflammatory reactions [43-45], or the development of new biofilms to serve in a communication system termed quorum sensing [46], or molecules that inhibit quorum sensing signal generation among organisms could block microbial biofilm formation [47].

Central-venous-catheter bloodstream infections are an important cause of hospital-acquired infection associated with morbidity, mortality, and cost. Consequences depend on associated organisms, underlying pre-morbid conditions, timelessness, and appropriateness of the treatment [48]. These CRBs are contributing factors to the increasing costs of medical care. They are responsible for patient readmissions and longer hospital stays as well as patient discomfort, morbidity, and occasional mortality. Feldman, et al. calculated in 1996 that the morbidity due to catheter infections would soon exceed \$ 1 Billion per year [49]. To reduce access-related morbidity, it is necessary to develop strategies to not only prevent and detect appropriately

synthetic vascular access dysfunction, however to better identify the patients in a whom radial arterio-venous fistula is a viable clinical option. The representative health care cost savings for hemodialysis catheters, given specific infection rates and potential reductions.

The cost was calculated using the literature and the available costs of different companies, which distribute these catheters (Table 4) [50]. Potential health care cost reduction that could be achieved through the use of surface treated of surface catheters by an annual usage of 124,971 hemodialysis catheter devices and an infection rate of 5 – 20 % savings per year of \$ 17,7 million, reduction about 40 %. Despite the high number of patients who die to end-stage renal disease, the costs of these infections are increasingly steady. After Schwebel et al. the costs are \$ 2,118/intensive care unit day, and after Pronovost et al \$ 45,000 per each infection [51,52]. Toccanelli, et al. estimated in 2009 the costs associated with ESRD in four European countries (France, Germany, Italy, and UK) between € 35,9 and € 163,9 million per year [53].

Table 4: Potential health care cost reduction that could be achieved by the use of surface-treated catheters [50].

Device	Hemodialysis	Average infection (%)
Annual usage (devices) in 1996	125,971	
Infection rate	5 - 20	Rate 12
Cost (\$) of complication (due to infection)	3,517	
Cost (\$) of surface treatment	12	
Reduction of infection (%)	10-65	Reduction 40
Market size (1997) (\$)	12,6 million	
Price (\$) of each device (surface treatment)	120	
Savings (\$) per year by using surface-treated devices	17,7 million	Reduction 40

Central Venous Catheters (CVC) are the most common source of hospital-acquired bloodstream infections in the USA. Each infection has an estimated additional cost of \$ 25,000 per episode [54]. Up to 250,000 episodes are reported in the USA per year, each episode increasing the cost and duration of the hospital stay. The Centers of Disease Control and Prevention (CDC) have released many guidelines to help prevent and reduce CRB, and this has helped bring down the rate of infections significantly. However, the number of CVC remains close to 15 million catheter-days per year. The CDC reports a 50 % decrease in Central Line-Associated Bloodstream Infection (CLABSI) rate from 2008 to 2014 and a 9 % decrease between 2013 and 2014. The CDC introduced general guidelines to decrease and prevent CLABSI in 2009: Nevertheless, about 30,100 CLABSIs still occur in the intensive care units and wards of US acute care Facilities each year [54].

A high incidence of temporary dialysis catheter lumen dysfunction presented in patients with COVID-19 infection. Catheter placed via a femoral vein access had more frequent dysfunction with shorter indwelling time [55]. Several factors are involved in selecting appropriate venous site, such as the procedure’s duration and frequency, patient’s vascular anatomy, and staff’s experience [56].

Because of the tremendous high costs, scientists, physicians, bioengineers and others should keep engaged in the development of new

techniques and new materials to reduce these high costs and increase the improvement of patients. However, besides the high costs due to catheter-related infections, the patients’ longer hospital stays and patients discomfort, mortality, and occasionally mortality are the most important problems, which must be resolved. To reduce these complications it is necessary that the handling of the catheters must be done first after the numerous recommendation and guideline available in the literature [57,58].

For various authors is important, if the use of a large-bore catheter is inevitable, insertion in the right internal jugular vein is preferred, as the incidence of complications is less likely [3,21,59- 61]. Treatment of elderly patients who commence HD with a large-bore catheter should be planned considering aspects of individual clinical risk assessment [62].

Most important is the improvement of the handling of the catheters by attending staff, which is recommended in numerous available guidelines to reduce the tremendous high costs treat the CRB and the discomfort and morbidity of the patients. The nursing staff insuring dialysis connection and disconnection usually CVC care. The incidence of CVC-related complications is clearly associated with nursing staff experience and respect of catheter-handling protocols [10]. For each dialysis facility, a specific training program and a protocolized handling procedure should be defined and adapted to their results. Aseptic rules for manipulating CVC at the time of dialysis connection and disconnection should be applied at all times. They include for the nurse, the use of sterile materials and additive protecting barriers and resort to an auxiliary caregiver to facilitate connection to the dialysis machine while preventing contamination [62].

New materials, more effective surface treatments, and innovative technologies are needed to tackle the overwhelming costs of hemodialysis and apheresis catheters by preventing complications. Lowering infections rates and thrombus formation would improve patient outcomes while reducing associated costs. Recently, new engineering techniques and biomedical materials such as micro/nano surface patterning and conjugation of antimicrobial peptides, enzymes, metal cations, and hydrophilic polymers (e.g., poly (ethyl glycol)) on the surface, has been suggested recently [63]. These new catheter technologies are not enough to solve these problems. Large-bore catheters for extracorporeal detoxification methods need more large improvements to decrease the tremendous discomfort of patients and the high costs of complications [34].

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