Quality of water used for haemodialysis: bacteriological and chemical parameters

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Abstract

Background. The bacterial and chemical contamination of dialysate fluids are important problems in haemodialysis therapy and may be caused by the water used for dialysate preparation.

Methods. We performed a survey of the microbiological and chemical quality of the water used in seven dialysis wards. Special attention was paid to the effects of each water treatment step, for example ion exchange, reverse osmosis and UV disinfection, on the number of bacteria (measured as colony forming units, CFU), the amount of endotoxin (endotoxin units, EU) and various chemical parameters, the main focus being on calcium, magnesium, sulphate, aluminium and heavy metals.

Results. CFU values exceeding the European Pharmacopeia value, determined at an incubation temperature of 22 °C, were found in the samples of raw water (20.0%, n=25), after ion exchange (66.7%, n=12), after reverse osmosis (33.3%, n=18) and also in samples of the dialysis water taken at the inlets (12.5%, n=40) and outlets (50.0%, n=18) of the machines. Whereas all raw water samples from the wards showed high mean values for endotoxin (0.56–9.10 EU/ml) and the endotoxin levels were often enhanced after ion exchange (0.13–>9.49 EU/ml), treatment by reverse osmosis led to a satisfactory decrease in endotoxin in all samples (<0.03 EU/ml). Sufficient reductions in calcium, magnesium and sulphate could only be achieved by the combined application of ion exchange and reverse osmosis. Mercury contamination was observed in the samples after ion exchange at three treatment plants, this was possibly caused by polluted regenerants. Increased amounts of aluminium, copper and zinc were found in water samples from different sites in the treatment systems and were caused by materials in contact with the water.

Conclusions. A sufficient chemical water purification treatment system should consist of ion exchange and reverse osmosis. Attention has to be paid to the suitability of materials in contact with the water and of the chemicals used, for example regenerants or corrosion inhibitors. From the microbiological point of view, a safety UV disinfection step in the water-treatment system is favourable. To avoid bacterial recontamination periodic cleaning and disinfecting of the water-treatment and distribution systems, as well as the dialysis machine are essential. There is the need for complete guidelines regarding dialysis water that include all relevant chemical and microbiological parameters. Based on this standard, periodic examination of the water after each treatment step has to be performed.

Key words: bacteria; chemical parameters; endotoxin; heavy metals; haemodialysis; water treatment

Introduction

In 1943 the Dutch internal specialist W. J. Kolff successfully used the first dialysis machine (rotating drum) in a clinical application in an uraemic patient [1,2]. Since that time the number of dialysis patients and their survival time have increased continuously.

The fluid used in dialysis therapy is the dialysate, which consists of dialysate concentrate and mainly of water (one part concentrate and 34 parts of water). Whereas the concentrate is produced commercially at a consistent composition and with strictly controlled quality, the water used may vary widely in its composition and quality. Basically, the source of dialysis water is drinking (tap) water, which is used after purification by different types of treatment, or in rare cases even directly. The composition of the water depends on its source (ground water, surface water), its geographical origin, seasonal variations and the water-treatment processes used. During dialysis each patient is exposed indirectly to 15 000–30 0001 of water per year. Therefore, the chemical and microbiological quality of the water used for dialysis is essential if an additional health risk to haemodialysis patients is to be avoided. Beside cardiovascular diseases, infections are the most
frequent cause of death in dialysis patients, as there are shunt-infections as well as infections related to the dialysate and the water used for dialysate preparation [3]. In addition, endotoxin derived from Gram-negative bacteria may penetrate the dialyser membrane and is responsible for pyrogenic reactions in haemodialysis patients [4]. Furthermore, the chemical composition of the water may cause acute and chronic complications during dialysis. High magnesium and calcium contents, for instance, lead to headache or hypertension. Heavy metals may accumulate in the body and produce various toxic side-effects. Aluminium overload may cause anaemia, encephalopathy and osteopathy. Although the role of the quality of water used for haemodialysis has been emphasized by several authors [5–14], few standards have been developed so far, as there are recommendations from the Association for the Advancement of Medical Instrumentation (AAMI) [15,16] and European Pharmacopeia (EPh) [17]. Since these standards do not take into account all relevant parameters (e.g. nitrite, iron, nickel, manganese), we additionally used the Austrian drinking water guidelines (OLMB) as quality criteria for dialysis water in our study [18]. Relevant parameters for these standards compared with normal ranges for ion concentrations found in human blood are listed in Table 1.

Several studies have already been performed to investigate selected quality parameters of fully treated dialysis water or dialysate [6,7,10–12]. The experimental design of these investigations varied in both the test parameters chosen and the samples taken. None of the studies performed so far have considered water samples taken after each single treatment step, although each single treatment step affects the water composition. These effects comprise microbial and chemical purifications on the one hand, and contamination, on the other hand. Therefore, the aim of our study was to investigate the quality of water used for the preparation of the dialysate in seven dialysis wards with particular consideration being given to the different water-processing systems and treatment steps. In respect to microbiological parameters (heterotrophic plate count, faecal indicator bacteria, endotoxin) and chemical parameters (with the main focus on calcium, magnesium, sulphate, aluminium and heavy metals) we tried to elucidate the weak points in the different treatment systems.

**Subjects and methods**

**Water-treatment systems in dialysis centres**

In total, the water treatment systems (for the water used to prepare dialysate) from seven dialysis centres were tested.

**Table 1.** Drinking water guideline OLMB\(^a\), the recommendations of AAM\(^b\) and EPh\(^c\) for dialysis water in comparison to the normal ranges of ion concentrations found in human blood

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Amount in blood (plasma/serum)</th>
<th>OLMB</th>
<th>AAMI</th>
<th>EPh</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Guideline value</td>
<td>Limit value</td>
<td></td>
</tr>
<tr>
<td>pH-value</td>
<td>7.35–7.45</td>
<td>6.5–8.5</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>KMnO(_4)-demand (mg/l)</td>
<td>0.20–0.80</td>
<td>0.05</td>
<td>0.5</td>
<td>0.2</td>
</tr>
<tr>
<td>ammonia (mg/l)</td>
<td>8–110</td>
<td>25</td>
<td>50</td>
<td>8.9</td>
</tr>
<tr>
<td>ammonium (mg/l)</td>
<td>17–24.3</td>
<td>150</td>
<td>70</td>
<td>50</td>
</tr>
<tr>
<td>nitrite (mg/l)</td>
<td>140–203</td>
<td>12</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>nitrate (mg/l)</td>
<td>25</td>
<td>250</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>calcium (mg/l)</td>
<td>82–110</td>
<td>400</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>magnesium (mg/l)</td>
<td>3403–3900</td>
<td>50</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>chloride (mg/l)</td>
<td>31</td>
<td>100</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>sulphate (mg/l)</td>
<td>1</td>
<td>250</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>fluoride (mg/l)</td>
<td>1.5</td>
<td>0.2</td>
<td>0.2</td>
<td></td>
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<tr>
<td>lead (µg/l)</td>
<td>50</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>cadmium (µg/l)</td>
<td>1</td>
<td>0.2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>mercury (µg/l)</td>
<td>1</td>
<td>0.2</td>
<td>1</td>
<td></td>
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<tr>
<td>aluminium (µg/l)</td>
<td>200</td>
<td>10</td>
<td>10</td>
<td></td>
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<tr>
<td>chromium (µg/l)</td>
<td>50</td>
<td>14</td>
<td></td>
<td></td>
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<tr>
<td>copper (µg/l)</td>
<td>762–1525</td>
<td>100</td>
<td>100</td>
<td></td>
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<tr>
<td>nickel (µg/l)</td>
<td>0.60–1.60</td>
<td>50</td>
<td>0.2</td>
<td></td>
</tr>
<tr>
<td>manganese (µg/l)</td>
<td>0.05</td>
<td></td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td>zinc (µg/l)</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td></td>
</tr>
<tr>
<td>colony forming units (CFU/ml)</td>
<td>100 (22°C)(^a)</td>
<td>200</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>endotoxin (EU/ml)</td>
<td>10 (37°C)(^a)</td>
<td>0.25</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(^a\)Codex Alimentarius Austriacus [18]. \(^b\)Association for the Advancement of Medical Instrumentation [16]. \(^c\)European Pharmacopeia [17]. \(^d\)Incubation temperature.
All systems received water from the public water supply. Five of them (wards A, D, E, F and G) consisted of ion exchangers followed by reverse osmosis. In two cases the water was additionally disinfected by UV irradiation (wards E and F). In one haemodialysis centre (ward C) single reverse-osmosis plants, one for each dialysis machine, were installed. We included two of these machines in our study. Untreated tap water was used for dialysis in one centre (ward B).

**Samples and sampling**

The investigation included water samples before and after each treatment step, and samples were taken from raw water (RW), and after ion exchange (IE), reverse osmosis (RO) and UV irradiation (UV). All ion exchangers were cation exchangers. Samples of the finished dialysis water were taken either directly at the inlet of the dialysis machine or at different sites in the circulation systems at the ports connecting to the dialysis machines (in). In addition, water samples were taken, after routinely disinfecting and flushing the dialysis machine, at the outlets of the dialysis machines (out) during ‘water flushing modus’, immediately before the preparation of the machine for the next patient. The disinfection procedures performed in the dialysis centres and the intervals between disinfection varied widely. The chemicals used for disinfection were citric acid, peracetic acid and chlorine, respectively. Heat treatment for disinfection was used as single procedure or combined with chemical disinfectants. The disinfection intervals were daily or weekly. None of the dialysis machines tested was equipped with an ultrafilter at the treated water inflow. All water samples were obtained after rinsing and disinfecting the sampling taps.

The number of the sample sites was 37 in total. At each ward sampling was carried out at least three times at approximately weekly intervals. The number of samples taken at each site is shown in detail in the figures.

**Bacteriological analysis**

Heterotrophic plate count was performed with 1.0 ml and 0.1 ml samples by the pour-plate method using plate count agar (CM 325, Oxoid), the incubation conditions were 72 h at 22 °C and 48 h at 37 °C. The faecal indicator bacteria such as coliform bacteria, enterococci and *Pseudomonas aeruginosa* were each tested in a 100-ml water sample. The tests for coliform bacteria were performed using the most probable number (MPN) method in liquid medium, as well as for the membrane filtration technique according to the water examination standard of APHA [19]. Enterococci and *P. aeruginosa* were analysed using the membrane filtration technique [19].

To determine the concentration of endotoxin, a quantitativ- e chromogenic limulus amoebocyte lysate assay (QCL-1000, BioWhittaker) was employed in conformity with the FDA guidelines [20] and using microtitre plates. Microtitre plates were measured in an automatic reader (BioWhittaker). The test system is calibrated in endotoxin units (EU) per ml, the detection limit was 0.03 EU/ml.

**Chemical analysis**

Chemical parameters (pH, conductivity, hardness, calcium, magnesium, chloride, nitrate, nitrite, ammonium, sulphate and oxidizability measured as permanganate demand) were measured according to the Austrian national standards for drinking water. The concentrations of lead, cadmium, mercury, aluminium, chromium, copper and nickel were detected using flameless atomic absorption spectrophotometry (Zeeman 5000 with HGA 500, Perkin-Elmer). To determine the levels of iron, manganese and zinc flame-AAS-method (AAS 5000, Perkin Elmer) was applied.

All bacteriological and chemical tests were performed in duplicate. The results were expressed as the mean.

**Results**

**Microbiological parameters**

The numbers of CFU in the samples taken from the seven dialysis water systems are shown in Figures 1 and 2. The counts differed considerably and were independent of the distinct sampling site. The EPh [17] and AAMI [16] recommend colony counts of 100 CFU/ml and 200 CFU/ml, respectively, for water used for dialysis. Values exceeding the EPh [17] value for CFU determined at an incubation temperature of 22 °C were found in the samples of raw water (20.0%, n = 25), after ion exchange (66.7%, n = 12) and after reverse osmosis (33.3%, n = 18), as well as in the dialysis water taken at the inlets (12.5%, n = 40) and outlets (50.0%, n = 18) of the machines. Data obtained using an incubation temperature of 37 °C revealed values exceeding the recommendations only in the water samples taken at the inlets (10.0%, n = 40) and outlets (66.7%, n = 18) of the machines. However, it was noticeable, that in most cases the samples from the outlets of the dialysis machines had high CFU levels. It should be stressed that in the water samples after UV disinfection a value of 0 CFU/ml was found.

In the raw water and the samples taken directly after each treatment step no faecal indicator bacteria were found. In one case contamination with *P. aeruginosa* in 100 ml was detected in a sample taken at the inlet of a dialysis machine (ward A, ‘in3’). In two samples taken at the outlet of the dialysis machines one incidence of *P. aeruginosa* (ward F) and one of enterococci (ward C1) per 100 ml water volume occurred during the observation period.

A limit value of 0.25 EU/ml has been fixed by the EPh for the concentration of endotoxin in water used for dialysis [17]. Whereas all raw water samples showed high mean values for endotoxin (0.56–9.10 EU/ml) and the endotoxin values were often enhanced after ion exchange (0.13–>9.49 EU/ml), treatment by reverse osmosis led to a sufficient decrease in endotoxin in all samples (<0.03 EU/ml) as demonstrated in Figure 3. Nevertheless, after the water had passed through the tubing system of the dialysis machines an increase in endotoxin was observed. Similar to the results of the colony counts, large amounts of endotoxin were found in 57.1% of the samples (n = 21) taken at the outlet of the dialysis machines.
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Fig. 1. Concentrations of colony forming units (CFU/ml), at an incubation temperature of 22°C, in the water samples taken at various sampling sites. The columns indicate the mean of concentrations measured at each sampling site, standard deviations are shown by bars. RW, raw water; IE, ion exchanger; RO, reverse osmosis; UV, UV disinfection; in, inlet of the dialysis machine; out, outlet of the dialysis machine. A–G, dialysis wards of seven hospitals. The guideline value for CFU in dialysis water is 100 CFU/ml according to the European Pharmacopeia [17].

Chemical parameters

The chemical parameters (pH, chloride, nitrate, nitrite, ammonium and permanganate demand) in the raw water samples, and in the treated dialysis water, revealed inconspicuous results with respect to the drinking water guidelines [18] and the limit values of the EPh [17] (Table 1). The nitrate concentration of the raw water used for ward G exceeded the maximum level suggested by the AAMI [16], but the treatment process resulted in a sufficient nitrate reduction. All raw water samples had concentrations for calcium (40–86 mg/l, n = 21) and magnesium (8–23 mg/l, n = 21), that exceeded the guideline values of the AAMI [16] and EPh [17]. A too high level of sulphate (EPh) was only observed in the raw water of plant G (80 mg/l). Treatment of raw water by ion exchange combined with reverse osmosis resulted in the complete elimination of calcium, whereas reverse osmosis alone (ward C) revealed Ca concentrations that were slightly too high (3 mg/l). As expected, there was only an insignificant reduction in the amount of sulphate after cation exchange. The decrease in magnesium was sufficient using either ion exchange or reverse osmosis (0–1.2 mg/l).

The concentrations of lead, cadmium, chromium, iron, manganese and nickel in the samples of raw water and treated water were within the levels suggested for drinking water guidelines as well as the limits suggested by the EPh [16] and AAMI [17] standards. Surprisingly, after ion exchange, we noticed in the water samples of three systems (E, F and G) mercury in remarkably higher concentrations (mean values: 2.6–3.5 µg/l) than had been found in the untreated waters (mean values: 0.12–0.19 µg/l). In general after reverse osmosis only low amounts of mercury were found in the water samples, although the reverse osmosis system of ward C1 did not reduce mercury levels sufficiently (mean value: 0.58 µg/l). A number (n = 33, 18.2%) of the samples of the finished dialysis waters revealed mercury concentrations which were too high (mean values: 0.24–0.71 µg/l) compared with the AAMI guidelines [16].

With the exception of wards A and G, the amount of aluminium measured in the raw water samples (n = 21) exceeded the limits suggested by the EPh [17] and AAMI [16] (Figure 4). In the treated water samples from wards E and F after ion exchange, extremely high concentrations were found. After reverse osmosis
aluminium was sufficiently eliminated, but we found a renewed increase in aluminium in some samples taken at the inlet of the dialysis machines (wards D and F).

Measuring the concentration of copper showed noticeable data for the raw water samples of wards C and D (mean values: 76 µg/l) as shown in Figure 5. After reverse osmosis the samples revealed distinctly reduced values for copper, although at one sampling site after dialysis a conspicuously high level appeared (mean value: 106 µg/l).

As shown in Figure 6, the zinc concentrations in the water samples varied from one sample site to the other, but were below the limits recommended by the AAMI [16], EPh [17] and OLMB [18]. It is remarkable that in some of the treated water samples we observed levels of zinc that were even higher than in the raw water samples.

**Discussion**

Tap water represents the main component of the dialysate and huge amounts of water are in indirect contact with the dialysis patient, yet insufficient attention is paid to its quality, in particular with regard to each single treatment step. Because of the differing water quality and the specific water composition, which depends for example on the origin of the water, water ingredients may cause infectious diseases or intoxication. Therefore the treatment of water used for haemodialysis is obligatory. One of the dialysis centres investigated in our study possessed some dialysis machines which were supplied directly with untreated tap water. These machines were in use periodically, according to the need for additional dialysis capacity. Thus, we took the opportunity to also include untreated dialysis water in our study to compare it with waters processed in different ways.

The results of our study showed that, on the one hand, as expected, the microbiological and chemical quality of tap water is not sufficient for the preparation of dialysate, but on the other hand, during different treatment steps severe chemical and microbial contamination may occur.

Some CFU values in the investigated tap water exceeded the limit of 100 CFU/ml, but there was also a problem of bacteriological contamination during water-treatment processes. In studies performed so far, only finished, treated, dialysis water has been investigated. Therefore, for the purpose of comparison with...
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Fig. 3. Concentrations of endotoxin (EU/ml) in the water samples taken at various sampling sites. The columns indicate the mean of concentrations measured at each sampling site, standard deviations are shown by bars. RW, raw water; IE, ion exchanger; RO, reverse osmosis; UV, UV disinfection; in, inlet of the dialysis machine; out, outlet of the dialysis machine. A–G: dialysis wards of seven hospitals. The guideline value for endotoxin in dialysis water is 0.25 EU/ml according to the European Pharmacopeia [17].

previous findings we use results from the ‘in’ samples. We found values exceeding the guideline value of the EPh for CFU at incubation temperatures of 22°C and 37°C by 12.5% and 10.0%, respectively. Similar results were found by Bambauer et al. [6,7] who reported that 17.8% of fully treated dialysis water samples did not comply with the AAMI guidelines. Investigations by Klein et al. [11] and Laurence and Lapierre [12] showed higher numbers of non-compliant samples (>200 CFU/ml) at 30% and 35.3%, respectively. It has to be pointed out that in each study different methods were used for the bacteriological tests (incubation conditions, culture media), since to date no standard methods have been defined. Therefore, these results are hardly comparable.

The main reason for the bacterial recontamination of water in tubing systems is water stagnancy [8,21]. As long as the water flow is continuous, the risk of bacterial regrowth is minimized. However, some parts of the treatment system, for example filters or ion exchangers, generally promote bacterial growth. In our study most of the samples taken at the outlets of the dialysis machines had high numbers of CFU at an incubation temperature of 37°C. Because of water stagnacy in the treatment and supply systems at elevated temperatures (room temperature or even higher), and also because the water is heated to 37°C within the dialysis machine, bacteria preferring these temperatures, for example P. aeruginosa, can grow perfectly well and endanger the patient. Nevertheless, the same attention has to be paid to the estimation of CFU incubated at a temperature of 22°C to measure the number of cultivable indigenous water-specific bacteria. Thus, it is essential to control regularly the CFU at both incubation temperatures of 22°C and 37°C. The colony counts clearly depend on the incubation conditions, time and temperature, as well as culture media, as shown by Klein et al. [11]. Therefore results for colony counts without these specifications are not meaningful and limit values in standards have to be completed by detailed methods.

To reduce the number of reproductive bacteria a UV-disinfection step within the water-treatment process is recommended. Irradiation of water with UV light (wavelength: 253.7 nm) represents an effective technique to inactivate bacteria and viruses and has been established in practice as a reliable disinfection method for drinking water [22,23]. Moreover, UV irradiation has proved useful in reducing bacterial regrowth and therefore diminishing indirectly the amount of endotoxins [8,21]. The principle of this physical technique is based on the specific damage...
concentrations of aluminium (mg/l) in the water samples taken at various sampling sites. The columns indicate the mean of concentrations measured at each sampling site, standard deviations are shown by bars. RW, raw water; IE, ion exchanger; RO, reverse osmosis; UV, UV disinfection; in, inlet of the dialysis machine; out, outlet of the dialysis machine. A–G: dialysis wards of seven hospitals. The guideline value for aluminium in dialysis water is 10 mg/l according to the European Pharmacopeia [17] and the recommendations of the Association for the Advancement of Medical Instrumentation [16].

Fig. 4. Concentrations of aluminium (μg/l) in the water samples taken at various sampling sites. The columns indicate the mean of concentrations measured at each sampling site, standard deviations are shown by bars. RW, raw water; IE, ion exchanger; RO, reverse osmosis; UV, UV disinfection; in, inlet of the dialysis machine; out, outlet of the dialysis machine. A–G: dialysis wards of seven hospitals. The guideline value for aluminium in dialysis water is 10 mg/l according to the European Pharmacopeia [17] and the recommendations of the Association for the Advancement of Medical Instrumentation [16].

caused to microbial nucleic acids by the absorption of UV rays. There is no addition of chemicals and, therefore, no risk of contaminating the dialysate with harmful substances. Nevertheless, we have to mention that the microbicidal effect of this method only takes place at the actual place of irradiation and does not disinfect the following tubing system. Moreover, UV irradiation does not remove bacterial cells from the water per se, which means that endotoxins remain in the water. Although UV disinfection does not eliminate endotoxin, it reduces the absolute number of reproductive microorganisms and therefore the increase in levels of endotoxin in the water. Because regrowth may occur even inside the tubing system of the dialysis machine, as confirmed by our data, periodic maintenance, cleaning and disinfection of the dialysis machines, including all parts of the tubing system, are essential.

The subject of interest in this study was the water used for the preparation of the dialysate and its contribution to the composition and quality of the dialysate. For the sake of completeness it has to be pointed out that the type of the dialysis concentrate (acetate, bicarbonate) also influences the susceptibility to bacterial contamination. In this respect a bicarbonate concentrate is an excellent nutrient, very high concentrations of bacteria may develop, particularly if the concentrate is stored for a long time and is handled without care.

The raw water samples, and some of the samples after ion exchange, had concentrations of endotoxin, which far exceeded the limit of 0.25 EU/ml stated by the EPh [17]. This underlines that untreated tap water is not suitable for dialysis. Similar results were found by Laurence and Lapierre [12], who performed a study on dialysis water from different dialysis centers including three wards which used tap water directly. None of these tap-water samples complied with the limits given in the national recommendations for chemical parameters and endotoxin.

Our results showed that treatment by reverse osmosis led to a sufficient decrease in endotoxin levels, even related to the strict limit value of the EPh (0.25 EU/ml). Our findings are in agreement with those of Klein et al. [11] showing that most of the dialysis water samples contained ≤0.25 EU/ml. Nevertheless, Laurence and Lapierre and Bambauer et al. found endotoxin values in their studies which were 35% and 12.2% in excess of a guide value of 5 EU/ml [6,7,12]. These results clearly indicate that endotoxin is able to
pass through reverse osmosis membranes or osmosis units. This may be because of microlesions, leakages or active penetration in particular by Gram-negative bacteria [21]. Therefore it is very important to prevent, as far as possible, any increase in the levels of bacteria and endotoxin during the whole water-treatment process in order to minimize the risk of pyrogenic reaction in haemodialysis patients. Moreover, owing to bacterial growth, the endotoxin concentration in the water may increase while in the water mains on the way to the dialysis machine. Therefore, the latest technology involves the application of an ultrafilter as a last safety step installed either in the circulating system or at the water inlet of the dialysis machine to produce, as far as possible, sterile and endotoxin-free dialysis water. Such filters, consisting for instance of hollow-fibre membranes made of polyether sulphon, are already on the market. To date, few water-treatment systems or dialysis machines are equipped with these filters.

In our study we showed that, in principle, a satisfactory chemical water quality can be obtained only by the combined application of ion exchange and subsequent reverse osmosis. Laurence and Lapierre [12] drew the same conclusion from their study monitoring the water quality in haemodialysis centres and refining and optimizing the treatment processes. However, several sources of chemical contamination occur during transportation, storage and treatment, which may lead to enhanced levels of metals in the dialysis water. In this respect we found increased concentrations of aluminium (wards E and F), zinc (wards C1 and D) and copper (ward C1) caused by materials in contact with the water. This clearly demonstrates that heavy-metal pollution of the water due to corrosion of the water installation system also has to be considered in dialysis. The first but most expensive choice of an installation material for dialysis water is stainless steel, followed by high-quality synthetic materials.

The material making up the drinking-water systems installed in buildings may also negatively affect the chemical quality of the water used as raw water in the dialysis centre. This was shown by the suspiciously high levels of copper in the raw water from wards C1, C2 and D, which are situated in buildings with water distribution systems made of copper.

While heavy-metal contamination is mostly the result of the corrosion of the metal tubing systems, aluminium is often released from different synthetic materials (for example polyethylene). In most cases reverse osmosis devices were able to eliminate aluminium sufficiently, but, based on our results, we agree with Mascher et al. [13] that aluminium ions may pass
Fig. 6. Concentrations of zinc (mg/l) in the water samples taken at various sampling sites. The columns indicate the mean of concentrations measured at each sampling site, standard deviations are shown by bars. RW, raw water; IE, ion exchanger; RO, reverse osmosis; UV, UV disinfection; in, inlet of the dialysis machine; out, outlet of the dialysis machine. A–G: dialysis wards of seven hospitals. The guideline value for zinc in dialysis water is 0.1 mg/l according to the European Pharmacopeia [17] and the recommendations of the Association for the Advancement of Medical Instrumentation [16].

through reverse osmosis membranes. In this way aluminium can be absorbed by the patient. Since aluminium hydroxide is used as a phosphate binder in dialysis therapy, an additional aluminium intake, including input from the dialysis water, has to be taken into account. High chronic aluminium concentrations may result in encephalopathy and osteopathy by interfering with the calcium–phosphate equilibrium [24].

Another point requiring attention, is the fact that chemicals used in water treatment, for example regenerants or corrosion inhibitors, may contain significant levels of heavy metals such as lead or mercury. This was shown in the results of our investigation for wards E, F and G, where we found remarkably higher concentrations of mercury after ion exchange than in the raw water. In 18.2% of the fully treated water samples we found levels exceeding the AMMI guideline value, whereas Laurence and Lapierre [12] reported that 3.7% of samples contained excessive levels. The authors argue, beside other possible causes, that the mercury contamination may stem from the feed water and that purifying systems are not very efficient in removing mercury. Our results, based on sampling each single treatment step, did not show excess levels in the different feed waters but clearly identified the ion exchangers as the source of the high mercury levels. Possible causes could be leaching after resin exhaustion or contamination from the chemicals used for its regeneration, for example caustic soda lye.

Pollution with other heavy metals has been described previously for various chemicals used in water treatment [9,12,13]. This implies the need to use chemicals in water treatment with an appropriate high-degree of purity to prevent heavy-metal pollution of the dialysis water.

Conclusions

The quality of potable water varies from one location to another and is generally not sufficient for preparing dialysis fluids.

A reliable treatment system is essential, consisting of an ion exchanger, reverse osmosis and a UV-disinfection device.

To avoid a health risk due to bacterial contamination in the dialysis water, a low colony count in the raw water, a safety UV-disinfection step in the water treatment and periodic cleaning and disinfection of the dialysis machines, including all parts of the tubing
system, are fundamental. The finished treated water should be distributed using circulation systems. Storage tanks, unused branches and dead legs have to be avoided. An additional safety step for minimizing the risk of contamination of the dialysis water by bacteria and endotoxin is the use of ultrafilters either installed in the circulating system or at the water inlet of the dialysis machine.

To reduce heavy metal contamination of the dialysis water, the material making up the water installations and the purity of chemicals used in water treatment have to be selected carefully. The best material for that purpose would be stainless steel followed by a high-quality plastic material.

A suitable standard that includes all relevant chemical and microbiological parameters has to be developed. The AAMI monograph [16] includes guideline values for some important parameters, but other essential values are missing, for example iron, manganese and nickel, metals involved in corrosion and nitrite as a toxic substance. Furthermore, the high limits for disinfectant residuals (0.5 mg/l for chlorine and 0.1 mg/l for chloramine) suggested by the AAMI seem questionable and should be lowered as a maximum value of only 0.3 mg/l chlorine is permitted even in drinking water [18].

From a microbiological point of view, the culture conditions used to estimate the CFU have to be optimized and standardized (incubation time, temperature and culture medium). Moreover, water samples should be tested for the presence of defined indicator bacteria, such as pseudomonads, in volumes of at least 100 ml. A guideline value for the level endotoxin in dialysis water as given in the EPh has to be included. B1, 'Drinking water’, 1993

To minimize a potential risk due to water used for haemodialysis it is of enormous importance to control the water quality during the whole treatment procedure indicating weak points in time. Therefore we recommend at least monthly bacteriological and quarterly selected chemical examinations of the water including samples of each treatment step.

References

37. Anonymus. OLMB. Codex Alimentarius Austriae, Chapter B1, ‘Drinking water”, 1993

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