Routine disinfection of the total dialysis fluid system

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Summary

The importance of bacteria and endotoxin free, sterile dialysis fluid for long term, high quality haemodialysis treatment is obvious and very much demanded (1,2). Dead spaces and connections between units (segments) of fluid production and delivery in elder systems are a continuous source for bacteria growth, biofilm generation and endotoxin release (3).

After varying success with routine disinfection of system components showing partly fast recovery and growth of bacteria (i.e. < 48 hours) we changed to routine disinfection of the entire fluid production and distribution system. We call this 'system disinfection'.

We report the methods and results from observation of practice over 28 months of disinfection. The fluid system is composed of a soft water tank, reverse osmosis (double RO), RO fluid loop, central bicarbonate production and delivery system and dialysis stations with and without ultrafilter and citric-thermal disinfection before and after each haemodialysis.

The system disinfection is carried out bimonthly with peracetic acid 3.5% in > 0.1% solution at a mean temperature of > 15 °C and at a minimum of 60 minutes of disinfection time.

Samples for microbiological testing and endotoxin measurement were assessed 3-4 monthly at 7 measurement points. The tests were carried out 7 times on the 11th day (mean value [MV]) after routine system disinfection. The result was in 0.2 CFU/ml (MV) in 40 tests.

The endotoxin levels (IU/L) were all < 0.25 except one at 0.325 in RO water. Endotoxin was assessed 5 times in 26 tests over 28 months. Samples were taken at 10.5 (MV) days after system disinfection. The Gel Clot or turbometric method was used.

Efficient and preventive routine system disinfection of an entire dialysis fluid production and distribution system – as standard in modern equipment – can support sufficient quality in dialysis fluid produced and distributed by elder and composed systems.

Key words

- Quality
- Bacteria
- Endotoxin
- Bicarbonate central delivery
- Routine disinfection
- Costs

BACTERIA AND ENDOTOXIN FREE WATER and concentrates for dialysis fluid is the requested standard today (1,2). Old fluid systems are composed of various individual elements for water treatment and concentrate production and distribution. Often, various manufacturers are involved in the construction of fluid systems, but they focus on the function and maintenance of their component and not on disinfection and cleaning of the full fluid system (2,3). Multiple and long connections between production, delivery and consumption demand frequent connections baring the risk of external contamination. They create dead spaces as a source for bacteria growth, biofilm generation and endotoxin release (2,3).

Modern systems provide all components for water treatment and production of dialysis fluid and are fully controlled and fully monitored systems. Cleaning and disinfection are automised and validated steps in the routine procedure.

Goals of the study were:

- To assess a step-by-step system disinfection process in a composed system
- To evaluate the method and the resources needed
- To test the microbial stability in RO water, self produced bicarbonate concentrate and unfiltered dialysis fluid on the day before the bimonthly disinfection

Production and distribution system

The Dialysis Fluid System of the clinic in Murnau was designed

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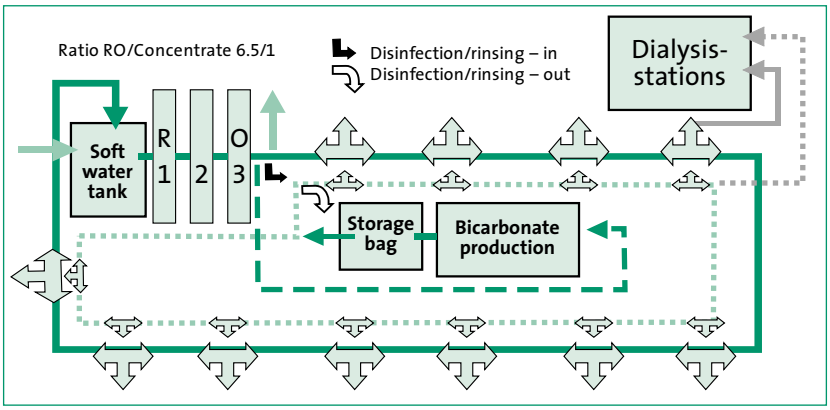

Figure 1: Dialysis fluid system of the clinic in Murnau

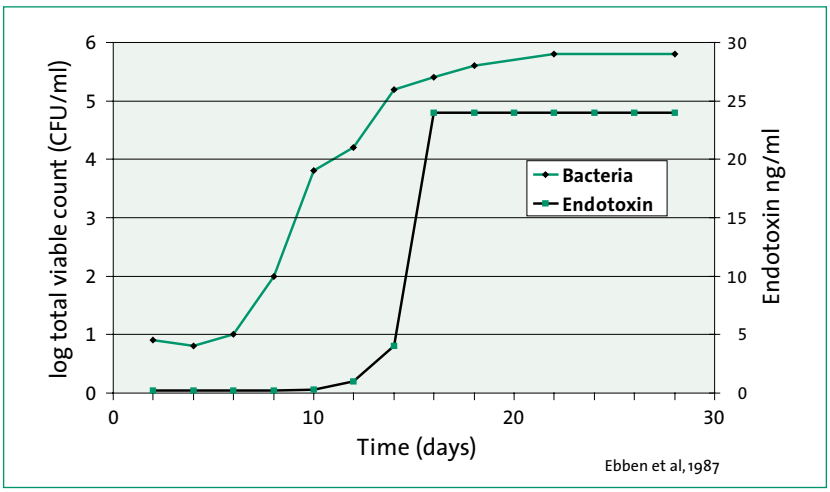

Figure 2: Bacteria and endotoxin in bicarbonate concentrate

18 years ago. It was modified several times. It consists of a duplex water softener, an optional charcoal column, a 10 µm and 5 µm particle filter, a soft water tank, a triple RO, a bicarbonate concentrate production system in 10 l batches, a fluid distribution loop for RO water and acid and bicarbonate concentrates. Due to economic reasons, unused RO water is collected for the heating, the steam and hot water system or is re-conducted to the soft water tank. 80-100 l of fluid is calculated to be the content of the fluid system (Figure 1).

The total fluid distribution tubing for RO water, acid, and bicarbonate concentrate was changed seven years ago. Regardless of their incorporation in the system disinfection access lines to dialysis machines are changed yearly according to a maintenance contract with the company. The bicarbonate production system can be disinfected by heat (93 °C, 20 minutes). The dialysis machines can be disinfected by various validated methods and we use chemo-thermal disinfection after each dialysis and heat disinfection before dialysis. All other elements of the fluid and concentrate conducting system can only be disinfected by chemicals (Figure 1).

Frequency of disinfection

The results from Ebben et al. (4) were used as a starting point to discuss the frequency of system disinfection. The contamination and growth of bacteria in a fluid system depends on many factors, such as the degree of concentration, temperature, nutrients, pH, electrolytes, material, the number of connections, the microbial status of connectors, dead space and areas of low flow. Connections from or into the system are always subject to risk of contamination as connectors can never be kept sterile on the surface or inside, as fluids have stagnated behind the connector and hands of nurses and technicians can easily contaminate the connector surfaces.

System Disinfection routine – every 14 days

Ebben et al. have shown that bacteria growth in bicarbonate can be found after 5 days and is at a maximum at 12 days. Biological activity of bacteria was documented after 10 days and at a maximum on the 14th day using the endotoxin test (4).

The results of the bacteria testing of Ebben were obtained from bicarbonate concentrate stored in clean containers. As our system produce and distribute bicarbonate centrally, which was seen as a weak point from a microbiological aspect, the work from Ebben was used as a rather strong indicator to fix the frequency of intervention (Figure 2).

Material and Methods

Chemical disinfectant

A chemical disinfectant containing peracetic acid 3.5% was chosen for routine procedures due to the compatibility with all components of our system including the membrane of the RO. We noted that the integration of both sides of the RO (permeate and concentrate side) is already visually of great benefit. The peroxide and acetic acid migrates easily through the membrane although the waste valve is closed due to maintenance of equal concentration in the system.

Concentration of disinfectant

The disinfection performance of the peracetic acid product is validated at 37 °C, in a solution of 0.1% and at 15 minutes of reaction time. Due to the average temperature of > 15 to < 20 °C in the RO water we ensure during disinfection that the concentration of the solution is more than 2 fold higher than validated, the contact 2 to 4 fold longer.

Procedure

We ensure that all dialysis stations are connected to the RO water and concentrate delivery system (5).

1. Rinsing

All lines and stations are rinsed with RO water of conductivity < 10 µS/cm over 20 minutes.

2. Disinfection process

The goal is to establish and maintain equal concentration of the disinfectant in all RO water and concentrate lines. Loss of concentrate begins when disinfectant is wasted slowly through the bicarbonate lines and stations.

- The waste valve of the RO is closed.
- The dialysis stations are switched off.
- RO water and peracetic acid 3.5% are mixed stepwise over the soft water tank and circled in closed loop through RO and RO fluid system.
- The bicarbonate delivery system is filled with the disinfectant.

The dialysis stations are switched on. The disinfectant moves slowly through the bicarbonate delivery system and through the dialysis stations, while the disinfectant continues to circle in a closed loop through the RO and RO fluid system.

Total contact time, temperature and concentration were:

RO fluid system	> 60 min
Bicarbonate loop	> 45 min
Dialysis stations	> 30 min
Temperature	14–17 °C (measured)
Concentration	0.15–0.22% (calculated)

3. Rinsing

All lines and stations are rinsed with RO water of conductivity < 10 µS/cm over 60 minutes.

4. Testing for disinfectant

The testing at all tapes and end valves is done per checklist, a special indicator paper for peracetic acid is used.

5. Disinfection of the bicarbonate production unit

Bicarbonate Mixing System (the RO supply line and distribution system is already included in the chemical disinfection) is disinfected by Hot Water Disinfection

Contact temperature and time: > 90 °C for 15 minutes
Total disinfection time: 1.40 hours
Change of Ultrafilter: every 14 days

Microbial quality

The monitoring of microbial quality was performed in general every 3 months under practice conditions. The sampling, storage, transport and testing were mostly performed according to the 'Guidelines of German Taskforce for applied hygiene' (5).

Measurement points (MP) were:

MP1 – RO fluid at outlet
MP2 – RO fluid end of loop
MP3 – Bicarbonate concentrate hub
MP4 – Bicarbonate tap in the loop
MP5 – Dialysis fluid 1 – not ultrafiltered
MP6 – Dialysis fluid 2 – not ultrafiltered
MP7 – RO fluid inlet of the machine.

From each MP 100 ml fluid was sampled in sterile and endotoxin free bottles for either bacteriological or endotoxin tests. 1-5 litres of fluid was wasted before sampling. Disinfection of tapes and connectors was done by heat or alcohol 70% (Hansen connectors receive a routine disinfection treatment after each dialysis). Storage and transport was done at < 4 °C. Culture media used was Trypton Glucose Extract Agar (TGEA). Temperature for cultivation was 22 °C ± 2 °C general / 37 °C only dialysis fluid. Evaluation was carried out after 3 and 7 days. Endotoxin tests were performed by GEL-Clott or turbimetric method.

Results

Study time	28 months
System disinfection processes	59
Time spent per disinfection – mean value (MV)	4.2 hours
Disinfectant used peracetic acid – MV	4.12 litres
Conductivity 30 minutes past start of disinfection time – MV	316 µS/cm (225-442)

Bacteriological tests (59) from MP1 – 6 on the 11th day (MV min 5 / max 13) following the disinfection process. 7 test runs were done during the observation period. The MV was 0.2 CFU/ml. In 4 of 59 tests 1-3 CFU/ml were detected.

Endotoxin tests (26) from MP 1–6 on the 11th day (MV) following the disinfection process. 5 test runs were done during the observation period.

Measure points	Bacteria CFU/ml	Endotoxin test
1. RO fluid at outlet	0 (n = 5) 3 (n = 1)	< 0.05 (< 0.05-0.005)
2. RO fluid end of loop	0 (n = 5) 2 (n = 1)	< 0.325 (< 0.325-0.008)
3. Bicarbonate concentrate hub	0 (n = 6)	< 0.10 (< 0.10-0.25)
4. Bicarbonate tap in the loop	0 (n = 5) 1 (n = 1)	< 0.10 (< 0.10-0.25)
5. Dialysis fluid 1 not ultrafiltered	0 (n = 6)	< 0.25 (< 0.25-0,005)
6. Dialysis fluid 2 not ultrafiltered	0 (n = 5) 1 (n = 1)	< 0.25 (< 0.25-0.005)
7. RO fluid inlet of the machine	not tested	< 0.125 (only 1 test)

Discussion

The study was conducted under certain conditions. It could be questioned whether the results are compromised by the methods used not always being clean. During the observation period, we did not sample the total number of probes as planned for bacterial and endotoxin tests.

We chose to disinfect every 14 days according to the study from Ebben et al (4). The conditions of the Ebben study were different to ours; nevertheless, the expected result was not

compromised by a single contaminated microbial test. The question remains how results from published studies can be used in the specific reality of a dialysis unit. Time and money is not sufficient to test current practise under various protocols.

The growth of bacteria and generation of endotoxin seem to be under control. It remains open whether routine disinfection of this frequency and intensity prevents biofilm generation or even destroys biofilm. Microbial checking every 12 weeks seems to be sufficient as per results of our observation.

No contamination of samples was observed during the observation period despite the use of Hansen connectors to collect dialysis fluid. Hansen connectors are a known risk factor; they are rinsed in cold chemical disinfectant (0.5% cold disinfectant of glutar-aldehyde, benzal-coniumchloride, dimythyl-amonium-cloride) and are then connected for chemical head disinfection.

The cost implications were assessed according to the use of disinfectant, water and energy and staff time. The method was rather time consuming with 110 staff hours per year. The system disinfection was carried out in the evening when there was less chance of needing the machines. We came up with approx. EURO 170 per method equalling EURO 4500 per year.

Conclusion

Disinfection of the complete system for preparation of dialysis fluid at least every 14 days kept bacteria growth and endotoxin release under control in our composed system. The process proved to be reliable and reproducible, but it requires perfect knowledge of the system and process and experienced staff.

The integration of the RO was felt to be vital in decreasing the bio burden on the concentrate side. The colour of the foam coming from the waste valve improved during the first three months of disinfection. There is only visual observation but no tests available. The level of clearing of the waste side and the improvement of the absorption capacity of the RO should be of importance for the recontamination of the clean side and the growth of biofilm. The question remains whether the intensity or frequency of the disinfection process is responsible for the lack of bacterial growth and endotoxin in the system after 13 days. No problems were found in external contamination in the sampling procedure.

We can conclude that high quality dialysis fluid is possible even with rather old production and distribution systems.

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