

MONITORING THE QUALITY OF WATER FOR DIALYSIS OVER THE YEARS

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INTRODUCTION

"The production of water for haemodialysis of the required quality is difficult, and it is much more difficult to maintain this quality in a long-term and demonstrable way".

All water treatment systems at B. Braun Avitum dialysis centres must achieve at least standard norms for water for dialysis. New or refurbished water treatment and reverse osmosis (RO) systems must be designed to achieve a higher standard for ultra-pure water for dialysis, and this requirement is already fulfilled by the majority of our dialysis centres.

In the Czech Republic, the quality of treated water for dialysis is defined by the Czech Pharmacopoeia and dialysis centres also use additional requirements defined in ISO 23500:2014 and IET/TR 62653 "Good Dialysis Practice". The water treatment and water distribution system must be certified under EU Directive 93/49 MDD for medical devices. This Directive specifies and monitors the content and amounts of organic and inorganic substances contained in water for haemodialysis.

AIM

The aim of our poster is to introduce water quality monitoring at our dialysis centre, including our experience with trend analysis using the ALS Webtrieve database.

METHODS

Testing the water quality for haemodialysis is performed in accordance with our internal standard that specifies the requirements for test frequency from distribution loop and dialysis machines, microbiological (CFU), endotoxin (LAL) and chemical analysis limits, daily water treatment plants checks, the disinfection of reverse osmosis and distribution loop as well as many others. Here are some examples of our requirements based on ISO 23500 and other requirements.

- The site of choice for microbiological and endotoxin sampling is the end of the water loop. Further samples can then be taken to isolate the area of concern if necessary.
- The microbiological purity of the dialysis water shall be monitored at least quarterly and the results should be documented. The sampling shall be done monthly if the microbiological and/or endotoxin limit is exceeded in a quarterly sample. If three consecutive monthly results are below limits again, the sampling can be done quarterly again.
- Microbiological and endotoxin samples will be taken before a scheduled disinfection. Endotoxin levels will be falsely raised following loop disinfection.
- Each dialysis centre shall have documented procedures, which come into effect once these limits are exceeded. In case the microbiological parameters are higher than 50cfu/ml, a further sample shall be taken. A risk assessment shall be made to identify if an extra disinfection has to be performed immediately, before the repeated test results are available. If the results remain above the defined parameters identified above, the disinfection and test cycle is to be repeated until the water has achieved the desired quality.
- **Microbiological and Endotoxin Limits for Pure Water:**
Microbiological Count < 100 cfu/ml (action point >50 cfu/ml)
Endotoxin Count < 0.25 eu/ml (action point >0,125 eu/ml)
- **Microbiological and Endotoxin Limits for Ultra-Pure Water:**
Microbiological Count < 0.1 cfu/ml (action point >0,125 cfu/ml)
Endotoxin Count < 0.03 eu/ml

RESULTS

The frequency of water quality testing at our dialysis centre has been adapted to the current state-of-the-art-technologies and previous CFU and LAL results. Due to the fact that we have achieved good water quality over the long-run, thanks to the use of modern technologies, technological processes and the successful implementation of the water preparation process, we have been able to reduce the frequency of sampling from a monthly to a quarterly basis and maintain the requested water quality for haemodialysis.

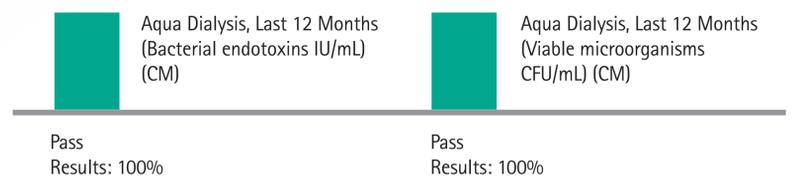


CFU	1.16	2.16	3.16	4.16	7.16	10.16
R01	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
R02	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
R03	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1	< 0.1
LAL	1.16	2.16	3.16	4.16	7.16	10.16
R03	< 0.025	< 0.025	< 0.025	< 0.025	< 0.025	< 0.025

The use of trend analysis with the help of the Webtrieve database has proven to be an excellent tool in our daily clinical practice. The dialysis centre staff has 24/7 on-line access to all the CFU and LA results; it is possible to identify the percentage of results above the required limits, to find out which sampling point or dialysis machine has been problematic during last 12 months and much more.

The following preview from the Webtrieve database demonstrates how clear and sophisticated results are made available to our staff.

Status Chart over time:



CONCLUSION

The importance of water purity for haemodialysis is further increasing with the increasing share of haemodialysis and the on-line preparation of the substitution solution. For this reason, dialysis centres should constantly focus on excellent water quality and the use of modern technologies that guarantee its high quality over the long-run. Well defined internal standards for water quality testing as well as the availability of a database allowing on-line access to all results and the use of trend analysis, as in our case with the Webtrieve database, is the right step to ensure the required water quality parameters while maintaining reasonable testing costs.