AN EXPERIENCE OF HANDLING MICROBIAL CONTAMINATION OF PRODUCT WATER AT A HAEMODIALYSIS UNIT IN NORTH KARNATAKA OF INDIA

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ABSTRACT

BACKGROUND

Dialysis units need regular prophylactic disinfection of the dialysis water production and distribution circuit without which there can be chronic inflammation among patients using the facility.

The aim of the study is to present here our experience in containing an episode of microbial contamination of dialysis water.

MATERIALS AND METHODS

Our haemodialysis unit had a single pass reverse osmosis plant with facility for pretreatment of raw water and a distribution loop of medical grade PVC (polyvinyl chloride) feeding haemodialysis machines, bicarbonate preparation and dialyser reprocessing areas. After installation, the Reverse Osmosis (RO) membranes and distribution loop were disinfected every fortnight using formalin. Cultures of product water were sent from various sites in the product water loop every month.

RESULTS

From January to April 2011, 15 water samples out of 52 water samples grew Pseudomonas aeruginosa with a colony count over 200 Colony-Forming Units (CFU). The average monthly number of haemodialysis was reduced from 84.75 to 65. Two patients had intradialytic pyrexia and two others had mild lower respiratory infection. So, the reverse osmosis plant and product water distribution system were repeatedly disinfected using 2% formalin and 1% bleach ensuring contact time and thorough rinsing to address persistent cultures. When these measures could not eradicate microbial growth, the system was sanitised with Gramicid (48% w/w H_2O_2 + 500 ppm Ag) and all traces of the disinfectant were rinsed away before resuming haemodialysis.

CONCLUSION

The microbial contamination of dialysis water was eradicated by Gramicid and not by bleach or formalin without any adverse effects after thorough rinsing.

KEYWORDS

Polyvinylchloride Distribution Loop, Dialysis Water Microbial Contamination, Silver Stabilised Hydrogen Peroxide.

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BACKGROUND

About 1 lakh patients enter haemodialysis program in India every year. This number does not match the needs of an existing 0.8% of 1 billion population.[1,2] So, new dialysis units are being started by the government in the last few years. The new units understandably are on their learning curve. Way back in 1994, Dr. Rajapurkar expressed concern over the lack of Indian guidelines for the processing of dialysis water in India.[3] Dialysis water is regarded as a medicinal product with stringent chemical and microbial standards. Haemodialysis patients are exposed to 400 litres of water each week that is separated from the blood by only an interposing semipermeable dialyser membrane. When contaminated by microbial agents, there can be acute pyrogenic reaction and haemodynamic instability followed by chronic inflammation leading to increased morbidity and mortality.[4] Formation of biofilm over the reverse osmosis membranes reduces shelf-life of the reverse osmosis unit and increases the cost of maintenance. The source of bacterial contamination is the raw water supply or commercially available chemical concentrates that are used for preparing the dialysis solution. Chlorine or chloramine added to municipal water for suppressing bacterial growth is removed by carbon adsorption in raw water pretreatment, which promotes bacterial growth in reverse osmosis system. The reverse osmosis plant and water distribution system require regular maintenance and monitoring to prevent such untoward incidences.

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To obviate such incidences, Association for the Advancement of Medical Instrumentation (AAMI) had recommended that the product water for haemodialysis should contain less than 200 colony-forming units per mL (CFU/mL) of bacteria and less than 2 IU/mL of endotoxin levels. The European Pharmacopoeia recommends less than 100 CFU/mL of bacteria and <0.25 EU/mL of endotoxin, which is more stringent. Recently, AAMI has revised the guidelines to match the European guidelines and has recommended bacterial counts at which action must be initiated. The Indian Society of Nephrology made guidelines that were published in December 2012. These guidelines were adopted by the Government of India.

In spite of the several guidelines all over the world, a multicentre study has reported that 7-35% of water samples have bacterial growth of >200 CFU/mL.[4] Indian studies reporting bacterial contamination are rare due to lack of central monitoring practices.[5,6] In one study from Manipal of Karnataka, bacterial biofilms were found to be difficult to eradicate by subinhibitory concentrations of chlorine.[5] Use of medical grade PVC in the dialysis water distribution system though recommended by Indian guidelines is being abandoned by many centres in favour of PEX (cross-linked polyethylene polymer) or stainless steel.[7,8]

Variations in geographic conditions such as drought also contribute to bacterial contamination of dialysis water.[7]

A new haemodialysis unit was started at our medical college hospital in North Karnataka in February 2010. Here, we describe the occurrence of bacterial product, water contamination and means employed to contain the contamination.

MATERIALS AND METHODS

Description of Reverse Osmosis (RO) Unit- Municipal water supplying our dialysis unit is stored in a series of two 2000 L tanks, which feed the pretreatment sand filter of 25 L capacity at a pressure of 2-3 kg/cm^2 aided by gravity and pressure pumps. This water flows through activated carbon adsorption unit and water softener prior to reverse osmosis. A filter of 5 microns is set before the reverse osmosis. Reverse osmosis is through 5 membranes that collectively produce 1000 L of product water per hour. After reverse osmosis, water is collected in a temporary storage tank of 500L capacity prior to distribution. Pressurised product water is filtered through a series of 3 microfilters before reaching bicarbonate preparation area, haemodialysis machines and dialyser reprocessing area before returning to the product water storage tank in a loop. The loop of water distribution has no branches apart from the above mentioned and has no dead ends. The distribution loop is made of medical grade PVC (polyvinyl chloride).

Regular maintenance of RO plant and water distribution system is followed in the haemodialysis unit. Municipal water storage tanks are washed and disinfected with 1% bleach once in a fortnight. Sand filter and activated carbon are washed back and rinsed for 30 minutes every day. They are replaced half yearly. Water conductivity is tested once per fortnight. The water softener is refurnished with salt according to water conductivity. Microfilter before the RO membranes is replaced quarterly. Product water storage tank is disinfected with 1% bleach every week. The three microbial filters after storage are replaced quarterly. Haemodialysis machines are disinfected and cleaned according to recommendations of the manufacturer after every dialysis.

Water quality testing for chemical impurities is done at Department of Mines and Geology every year. Cultures of product water for testing bacteria are sent from various sites in the product water loop every month. The sample for bacteriological analysis is collected by using sterile precautions. Water is allowed to run freely and after rejecting the first few millilitres, a volume of 10 ml is collected in a sterile wide mouth container. The samples are then immediately transported to the microbiology laboratory and processed as per standard methods.

The total viable bacterial count is performed by spread plate technique on Tryptic soy agar (HiMedia) and incubated at 37°C for 48 hrs. The upper limit for the total bacterial count is set at 200 CFU/mL for treated water. In case of bacterial growth, the bacterial count is recorded and bacteria are identified by standard methods. A record of all these procedures is maintained and supervised. Institutional ethical clearance is taken for reporting this outbreak. Informed consent was waived off as this is a retrospective analysis of an outbreak and confidentiality is maintained.

RESULTS

From January 2010 to December 2010, a total of 27 samples sent for bacterial culture were sterile. In January 2011, water sample collected after RO membranes grew Pseudomonas aeruginosa (P. aeruginosa) with a colony count >200 CFU/mL, which persisted during subsequent cultures. Subsequently, culture from other sites as mentioned in table 1 also grew pseudomonas in cultures. All the bacterial counts were >200 CFU/mL.

RO maintenance personnel found a biofilm in sand and carbon filter. They recommended shielding the unit from sunlight and cleaned it with 1% bleach. RO plant was cleaned using 2% formalin. RO pressure was estimated to be 10 kg/cm^2, RO water conductivity was <10. The product water distribution system was cleaned with 2% formalin left in place for 6 hours and rinsed with 1000 L of water. When persistent cultures were grown in product water, the sand, carbon filters and water softeners were replaced. Formalin disinfection followed by rinsing of RO membranes and distribution loop were repeated. Continuous running of RO plant was recommended to prevent stagnation, which was followed. Despite this, there was persistent microbial growth from cultures and so the microfilters were changed. In April 2011, as per recommendation of the RO engineer and nephrologists, a chlorine dosing pump was fixed before the sand filters and 1% bleach was used to cleanse the distribution system. However, persistent growth of pseudomonas was detected.

The system was then sanitised with Gramicid (silver stabilised hydrogen peroxide) and all traces of the

disinfectant were rinsed away several times before resuming haemodialysis.

After this, culture of water samples from all sites did not yield any growth on repeated testing indicating that bacterial contamination was eradicated. Haemodialysis was resumed.

During January 2011 to April 2011, sixteen patients underwent 254 haemodialysis from January 2011 to April 2011. Two patients required paracetamol during haemodialysis for brief episodes of fever. Two others presented with mild cough and white mucoid sputum. They had bilateral scattered wheezing sounds. Their blood cultures and sputum cultures were sterile and their x-rays were normal. These patients required oral amoxicillin for lower respiratory infection. None of the patients required admission for any febrile episode or infection. There were no deaths due to fever or any infection.

However, the total numbers of haemodialysis were reduced (from January 2011 to April 2011) as the unit was closed for 30 days.

Source of Product Water	Number of Sterile Cultures	Number of Cultures Positive for Pseudomonas Aeruginosa
Product water storage inlet	10	8
Bicarbonate preparation tap	14	4
Branches feeding dialysis machines	25	3
Product water for dialyser reprocessing	3	0

Table 1. Results of Water Cultures

Month	65
January 2011	44
February 2011	86
March 2011	59
April 2011	63.5
Mean	65

Table 2. Average Number of Haemodialysis

Average monthly number of dialysis during 2010	76
Average monthly number of dialysis during 2011	84.75
Average monthly number of dialysis from January 2011 to April 2011	63.5

Table 3. Reduced Number of Dialyses During a Period of Bacterial Contamination

DISCUSSION

Product water contamination has been reported from several dialysis centers across the world. Once contamination occurs, eradication is difficult. A review article draws attention to lack of uniform preventive disinfection practices by mentioning that 7-35% of water samples had growths of more than 200 CFU per mL in various studies conducted in the USA, Canada and Europe and 28% of centres disinfected at least monthly.[4] From the inception of our dialysis unit, regular chemical disinfection was practiced. Our RO generated more water than required at that time. There is also a product water storage tank to tide over periods of non-availability of municipal water. This stagnation might have caused microbial growth. The situation is similar to dialysis units in other countries facing periods of drought.[13] Stagnation was handled by recirculating the water in a loop continuously.

A study in our country reported formation of biofilms of pseudomonas and Acinetobacter species resistant to routine chlorine disinfection with a paradoxical increase in biofilm on exposure to subinhibitory concentrations of chlorine.[5] In our unit also the persistent bacterial cultures could have been due to biofilms formed on inner surface of PVC distribution loop unresponsive to chlorine disinfection.

Our distribution loop is of medical grade PVC (polyvinyl chloride). This is compliant with the Indian Society of Nephrology Guidelines and Government of India Guidelines published in 2012. Recently, several studies have preferred elimination of PVC in preference to stainless steel or PEX (cross-linked polyethylene polymer) or polyvinylidene fluoride as there have been reports of bacterial contamination associated with PVC.[7,8] However, our facility never faced water contamination subsequently in spite of PVC.

Our dialysis unit had a single pass reverse osmosis facility. Most of the dialysis facilities abroad recommend dual pass reverse osmosis or single pass with electrode ioniser.

Routine disinfection of product water distribution loop using 1% bleach every week was practiced in our unit with 2% formalin disinfection when bleach was ineffective. Neither was able to eradicate the contamination once pseudomonas growth occurred. We could clear the bacterial contamination using silver stabilised hydrogen peroxide (Gramicid). All traces of the disinfectant were rinsed away using at least 1000L of purified water before resuming haemodialysis and there were no adverse effects attributed to this disinfectant. Other studies have reported methemoglobinemia and haemolysis attributed to this disinfectant when it was added to the hospital's plumbing for general use and which inadvertently had contaminated the product water supply of dialysis.[9] Complete rinsing of the compound after its use did not allow such an occurrence in our centre.

All the samples in our study were cultured on Trypticase soy agar by spread plate method at 37°C for 48 hours. Tests for endotoxin were not available then at our facility. A review discusses the effects of different culture media and the incubating temperatures on the bacterial colonies. It observes that the colony counts of bacteria in water incubated in Tryptone glucose extract agar for 7 days at 17°C to 20°C will be 100 to 1000 times higher than the colony counts when the water is cultured in Tryptone soy agar with 48 hours of incubation at 35°C.[10] By this, the bacterial growth in our study would be a gross underestimate. Another study conducted in Italy on the other hand mentions improvement in water quality associated with microbiological monitoring in a hi-tech laboratory, which does not test mesophiles at 22°C, but at 37°C for frequently pathogenic bacteria commonly detected in summer months (Escherichia coli and Pseudomonas

aeruginosa)."[7] The conditions in which the organisms grow in product water are closely related to ambient temperatures of the product water tank and the distribution loop rather than to the human body temperature of 37°C in which the pathogens grow. Average mean room temperatures and average high temperatures in North Karnataka are much higher than in Italy.[7,11] So, more studies are needed to confirm the role of setting incubation temperatures in this region. The guideline making authorities must also consider the variation in ambient temperatures across our subcontinent.

In our study, there was occurrence of two cases of pyrogenic reactions and two cases of lower respiratory infection that did not require admission during that period. However, the unit was closed for 30 days during, which period patients had to seek dialysis elsewhere. The study conducted in the Netherlands also mentions withdrawal of hemodiafiltration temporarily when purified water was noncompliant in addition to repeated cultures in some centers and no action except reculture in some other centers.[8]

Our dialysis unit was started in 2010 February and the occurrence of this bacterial contamination during the initial phase helped us update and stringently enforce preventive disinfection till now. Now, we have 6 additional haemodialysis machines and all have Diasafe plus filters to achieve ultrapure dialysis water production.

CONCLUSION

Regular cleaning, regular culture of water samples, replacement of filters, avoidance of stagnation and preventive disinfection are recommended for maintenance of product water unit. In our series, the contamination responded to careful use of Gramicid and not to bleach or formalin.

Future Scope- The guidelines for product water quality must be revised regularly to keep up with the rest of the world while studies maybe undertaken for establishing standards of water culture to suit the regional needs based on ambient temperatures. Central auditing facilities for maintaining product water standards should be established and trends studied.

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