J Renal Inj Prev. 2024; 13(1): e32154.

https://journalrip.com doi: 10.34172/jrip.2023.32154

Journal of Renal Injury Prevention

Bacteriological quality of water in hemodialysis unit using ozone disinfection; a 12-year experience

Nabadwip Pathak[1*], Sujitha Elan[2], Sheela Devi[2]

[1]Department of Nephrology, Pondicherry Institute of Medical Science, Puducherry, India
[2]Department of Microbiology, Pondicherry Institute of Medical Science, Puducherry, India

ARTICLE INFO

Article Type:
Original

Article History:
Received: 11 Dec. 2022
Accepted: 29 Oct. 2023
ePublished: 29 Jan. 2024

Keywords:
Hemodialysis
Renal replacement therapy
Product water
Colony forming units
Ozone
Disinfection

ABSTRACT

Introduction: A substantial quantity of pure/ultrapure water is required to initiate hemodialysis (HD)/hemofiltration (HF) therapy for patients with renal failure. Routine disinfection of the water treatment plant is highly needed to produce ultrapure/pure water for HD. To the best of our knowledge and belief, this study is the first of its type and origin to evaluate ozone disinfection levels in a HD unit.

Objectives: This study was conducted in the Pondicherry Institute of Medical Sciences (PIMS) HD unit and examined the treated product's bacteriological quality.

Methods and Materials: The hospital record was utilized to obtain the product water culture reports based on the ozone disinfection and product water culture strategy. The product water culture fraction was investigated in concordance with the recommended limits.

Results: Of 109 product water culture report samples, 108 (99.1%) aligned with the recommended limits. The product water was cultured via the sterile molten nutrient agar approach; satisfactory numbers of colony counts (<100 CFU/mL) were obtained within 24–48 hours of analysis. The product water purification/disinfection was undertaken per week via the 0.1 Parts-Per-Million ozone dose, administered consistently for 15 minutes.

Conclusion: The purification/disinfection of the product water in a HD unit may be undertaken by expert supervision via the ozone disinfection strategy.

Original

Implication for health policy/practice/research/medical education:
The study results revealed that merely 0.9% of water samples did not comply with the Association for the Advancement of Medical Instrumentation (AAMI) criteria, thereby indicating the high disinfection potential of ozone disinfection strategy in the hemodialysis unit's water treatment plant.

Please cite this paper as: Pathak N, Elan S, Devi S. Bacteriological quality of water in hemodialysis unit using ozone disinfection; a 12-year experience. J Renal Inj Prev. 2024; 13(1): e32154. doi: 10.34172/jrip.2023.32154.

Introduction

The high prevalence of end-stage renal disease (ESRD) in India leads to the increasing dependence of patients on hemodialysis (HD) for their survival. Most patients with ESRD in India (n = 120 000) require maintenance treatment with HD, which is a complex procedure requiring high-quality, freshly prepared dialysate sourced from product water (within microbiological range) and a fixed proportion of acid-base concentrates (1,2). Depending on the renal replacement therapy, the type of HD/hemofiltration (HF) technique determines the quantity of ultrapure/pure water required to initiate the procedure. A treatment plant is necessary to configure a large quantity of pure/ultrapure water effectively. The pretreatment plant is a part of the water treatment plant, and its essential components include a blend valve, multimedia filter, activated carbon filter, softener, and prefilter. It utilizes the reverse osmosis (RO) technique in the absence or presence of an ultrafilter/deionizer (3). The maintenance of the RO product water for hemodiafiltration (HDF) therapy, HF, or HD requires high compliance with microbiological and chemical standards. It is important to note the possible elevations in fibrinogen, interleukin-6 (IL-6), and high-sensitivity C-reactive protein (hs-CRP) due to the utilization of dialysate with product water not fulfilling microbiological standards. Patients who receive dialysate with microbiological contamination experience a high risk of residual renal function loss, malnutrition, poor erythropoietin response, and cardiovascular disorders (3). This is why the monthly, followed by three

***Corresponding author**: Nabadwip Pathak, Email: nabapthk88@gmail.com, info@pimsmmm.com

monthly, assessments of the endotoxins/culture of the RO product water are necessary to satisfy the recommended quality standards (Reference ranges: product water [≤100 CFU/mL], endotoxin levels [≤0.25 EU/mL], ultrapure water [≤0.1 CFU/mL]) (4).

The ozone, thermal, and chemical disinfection strategies are recommended for processing the water treatment plant (5). Sodium hypochlorite or peracetic acid is the preferred chemical disinfection strategy for the water treatment plant. Furthermore, maintenance of a high temperature is needed to initiate thermal disinfection (6). To the best of our knowledge and belief, no study to date has investigated the utilization of ozone to disinfect the product water in a HD unit. This study aims to evaluate the bacteriological quality of the product water, following its treatment with the ozone disinfection approach, in the HD unit of the Pondicherry Institute of Medical Sciences (PIMS), Puducherry.

Methods and Materials

Study design

This study utilized a retrospective observational approach to evaluate the culture reports concerning the product water samples, generated between October 2009 and October 2020 in the PIMS HD unit. The results of these reports were authenticated in the PIMS Microbiology Department, wherein, the microbiological assessment of the product water was systematically performed. The PIMS Department of Nephrology provided data on the HD unit's water treatment approach and framework, including the ozone disinfection method and frequency for treating product water. We also investigated potential causes of non-compliant water culture results, which showed unacceptable levels of the bacteriological quality of the product water.

Statistical analysis

Descriptive statistics were conducted to quantify samples (%) of the treated water culture that concorded with the recommended AAMI benchmarks. The numerical values of the treated water culture samples were subsequently obtained and segregated every year.

Results

The 12-year data concerning the water treatment plant's product water culture samples (n = 109) was obtained from the hospital records. The water treatment plant included the following components: 1) Booster pump (2HP), 2) Sand filter, 3) Carbon filters in sequence (n = 2), 4) 5 Micron filter (n = 1), 5) Pump (5 HP), 6) RO membranes (n = 5), 7) Holding tanks (1000 L), 8) Booster pumps (n = 2), 9) Ultraviolet lamp, and 10) Delivery loop (traversing across the HD equipment and the tank). We utilized ozone-compatible chlorinated polyvinyl chloride to construct the pipeline system for the product water transportation across the HD apparatus.

Disinfection approach

The ozone disinfection apparatus was comprised of the ozone generator (with air compressor), tube (communicating between the holding tank and generator), and ozone diffuser. About 100 mg of ozone was administered for 15 minutes to disinfect 1000 L of product water (capacity of holding tank) with a calculated ozone concentration of 0.1 mg/dL in product water. The HD equipment was connected to the loop, which received ozonated water from the reservoir tank. The HD equipment required deactivation during the ozone disinfection process and was reactivated after 12 hours for subsequent processing. Since the ozonated water in the loop required drainage, a 5-minute interval was assigned to open the ports supplying the HD equipment. This step was mandated before utilizing the product water. The HD treatment utilizing the product water was initiated after collecting it in the loop, via the ultraviolet lamp, from the reservoir. The ozone disinfection was undertaken in the reservoir and the loop per week, following the last HD shift, on the night of every Saturday. The monthly collection of the product water culture samples from the water treatment plant loop was further ascertained; however, a few sample reports were found to be missing on the data acquisition date.

Microbiological assessment of product water

The product water sample collection was initiated under stringent ascetic conditions. The thorough cleansing of the RO plant's outlet tap was initiated by using a disinfectant solution, constituted of 70% isopropyl alcohol; it was subsequently left intact for drying. The pour plate method was used to prepare the quantitative culture of the RO water, based on the following steps.

1. The RO water (1 mL) and normal saline solution (9 mL) were added to a sterile test tube.
2. The RO water that required testing was serially diluted within the range of 1:10 and 1: 50.
3. The retrospectively labeled sterile petri dish was poured with the admixture of the serially diluted water sample (2 mL) and the sterile molten nutrient agar (18 mL).
4. The incubation of the serially diluted water samples was undertaken for 45 hours at a temperature of 37 °C.
5. The readings were obtained by the end of 24 and 48 hours, respectively.
6. The exact quantity of the colony-forming units was calculated by multiplying the sub-surface colony count by the number 10.
7. The Association for the Advancement of Medical Instrumentation (AAMI) guidelines were used to define the colony count reference value (i.e., <100 CFU/mL).

Table 1 elaborates on the year-wise distribution of the product water culture samples. Besides product

Table 1. Year-wise distribution of product water samples

Year	Number of product water samples for culture in the HD unit
2009	3
2010	9
2011	12
2012	11
2013	10
2014	6
2015	6
2016	9
2017	10
2018	11
2019	11
2020	11
Total samples	**109**

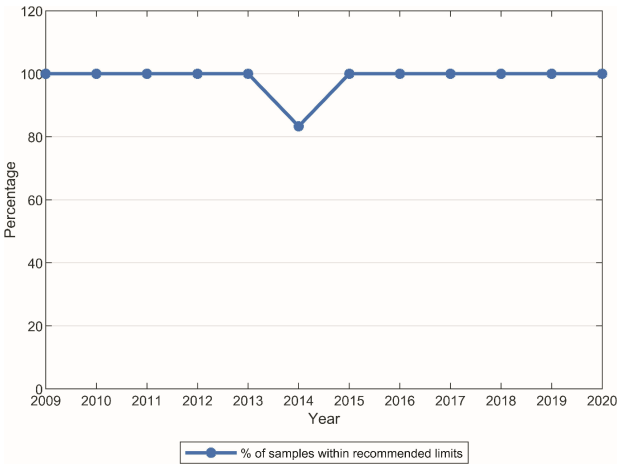

Figure 1. Yearly distribution (%) of product water samples as per the AAMI standards.

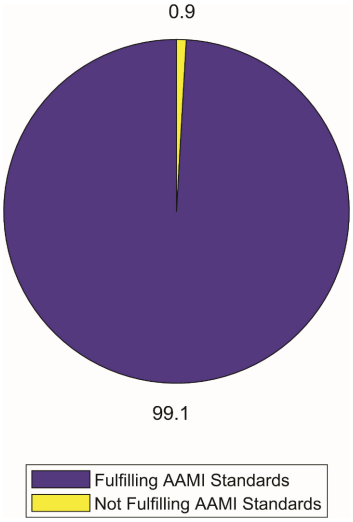

Figure 2. Distribution of overall (over 12 years) product water culture samples based on fulfilling AAMI standards.

water culture report on March 2014, all other cultures were within recommended limits (<100 CFU/mL). On evaluation during the above episode, a hole was found in tubing connecting ozone generator and reservoir tank, which we on correction subsequent product water cultures were found within recommended limits as mentioned in Figure 1. Figure 2 depicts the 12-year distribution of product water culture samples in concordance with the AAMI standards. We could not analyze the culture reports concerning the dialysate and the product water endotoxin levels due to the absence of relevant data.

Discussion

The ozone, thermal, and chemical disinfection strategies in the HD unit effectively assist in disinfecting the treated water (5). The chemical disinfection strategy is highly practiced to disinfect product water in the HD unit. Results from previous studies indicated that 2.6%-35.3% of product water samples did not comply with the recommended reference range (7-9). Our study is probably the first of its type to investigate the treated water's bacteriological quality via the ozone disinfection approach. Importantly, only 0.9% of the product water samples indicated a high level of bacteriological growth; this percentage is substantially less than the literature results. The findings from this study confirmed the significance of the ozone disinfection approach in disinfecting the product water in the HD unit. This study did not compare other disinfection approaches with the ozone disinfection method, due to the absence of the corresponding treatment arm.

Data in the contemporary literature do not provide any recommendation on the dosage of ozone, necessary to disinfect the product water in the HD unit. Alternatively, the ozone dosing rate, ranging between 0.5-1 PPM, is recommended by the National Associations of Nephrology Technicians (NANT) for a duration of 10-20 minutes to effectively disinfect the product water. Approximately, 10 PPM of ozone is the recommended total administered dose; however, NANT guidelines do not specify its actual impact on the overall bacteriological quality of the product water (10). We utilized a considerably lesser dose of 0.1 PPM for a duration of fifteen minutes in this study, and it effectively reduced the overall percentage of non-compliant water culture reports, thereby indicating a high bacteriological quality of the treated water in comparison to the findings in contemporary literature (7). Results from the 12-year duration revealed 1/109 non-compliant cultures with unacceptable bacteriological quality of the product water. Only product water sample which had unacceptable culture reports was seen in March 2014 which was due to noticeable leakage in tube connecting reservoir tank with ozone generator. Importantly, no unacceptable culture report concerning the product water

was obtained after correcting the leaking tube in last 6 years.

To date, no comprehensive investigation has been conducted to assess the frequency of ozone disinfection in relation to the product water within the HD unit. In our study, we implemented a weekly ozone disinfection protocol for the purpose of decontaminating the product water. This intervention yielded a significant enhancement in the bacteriological quality of the water.

Conclusion

The utilization of ozone disinfection has proven to be a highly effective approach for decontaminating the product water within the HD unit.

Limitations of the study

The main limitation of our study is the absence of the comparator arm concerning a different infection mode. We, therefore, could not compare the ozone disinfection effectiveness for the product water with a contemporary potential indicator. In addition, our findings are also devoid of potential data indicating the endotoxin levels in the product water of the HD unit.

Authors' contribution

Conceptualization: Nabadwip Pathak.
Data curation: Nabadwip Pathak.
Formal analysis: Nabadwip Pathak.
Investigation: Sujitha Elan, Nabadwip Pathak.
Methodology: Nabadwip Pathak, Sujitha Elan.
Resources: Sujitha Elan, Nabadwip Pathak, Sheela Devi.
Supervision: Sheela Devi.
Validation: Nabadwip Pathak.
Visualization: Nabadwip Pathak, Sujitha Elan.
Writing–original draft: Nabadwip Pathak, Sujitha Elan.
Writing–review and editing: Sheela Devi.

Conflicts of interest

The authors declare that they have no competing interests concerning this study.

Ethical issues

This research effectively adhered to the tenets mentioned under the Declaration of Helsinki. The protocol and framework of this study were approved by the CDSCO-registered Institutional Ethical Committee of Pondicherry Institute of Medical Sciences (Reg. No ECR/400/Inst/Py/2013 RR-20). This study did not require informed written consent, due to the exclusion of human participants. Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

Funding/Support

This study did not require any funding assistance.

References

1. Varughese S, Abraham G. Chronic Kidney Disease in India. Clin J Am Soc Nephrol. 2018 May 7;13:802–4. DOI: 10.2215/CJN.09180817.
2. Kohn OF, Kjellstrand CM, Ing TS. Dual-concentrate bicarbonate-based hemodialysis: know your buffers. Artif Organs. 2012;36:765–8. doi: 10.1111/j.1525-1594.2012.01524.
3. Coulliette AD, Arduino MJ. Hemodialysis and water quality. Semin Dial. 2013;26:427-38. doi: 10.1111/sdi.12113.
4. Mineshima M, Kawanishi H, Ase T. 2016 Update Japanese Society for Dialysis Therapy Standard of fluids for hemodialysis and related therapies. Ren Replace Ther. 2018;4:15. doi: 10.1186/s41100-018-0155-x.
5. Pérez-García R, García Maset R, Gonzalez Parra E, Solozábal Campos C, Ramírez Chamond R, Martín-Rabadán P; Comisión de Expertos de la Sociedad Española de Nefrología para la creación de la Segunda Edición de la Guía de Gestión de Calidad del Líquido de Diálisis. Guideline for dialysate quality of Spanish Society of Nephrology (second edition, 2015). Nefrologia. 2016;36:e1-e52. doi: 10.1016/j.nefro.2016.01.003.
6. Toapanta Gaibor NG, Gil Sacaluga L, de la Cerda Ojeda F, Molas Cotén JR, Salgueira Lazo M. Thermal disinfection in hemodialysis using the A0 concept as a dispenser. Nefrologia (Engl Ed). 2019;39:482-488. doi: 10.1016/j.nefro.2019.02.005.
7. Verma S, Indumathi VA, Gurudev KC, Naik SA. Bacteriological Quality of Treated Water and Dialysate in Haemodialysis Unit of A Tertiary Care Hospital. J Clin Diagn Res. 2015;9:DC14-6. doi: 10.7860/JCDR/2015/14681.6692.
8. Masakane I, Takemoto Y, Nakai S, Tsubakihara Y, Akiba T, Watanabe Y, et al. Bacteriological water quality in the central dialysis fluid delivery system from the survey of the Japanese Society for Dialysis Therapy. Blood Purif. 2009;27 Suppl 1:11-6. doi: 10.1159/000213491.
9. Bambauer R, Schauer M, Jung WK, Daum V, Vienken J. Contamination of dialysis water and dialysate. A survey of 30 centers. ASAIO J. 1994;40:1012-6.
10. Tarrass F, Benjelloun M, Benjelloun O. Current understanding of ozone use for disinfecting hemodialysis water treatment systems. Blood Purif. 2010;30:64-70. doi: 10.1159/000317123.