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Endotoxin Burden in Dialysis Water: Seasonal Trends and Public Health Implications From a Year-Long Study in Iraq

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Abstract

Dialysis water quality is critical to patient safety, particularly in relating to bacterial endotoxins, which can pose major health hazards. Environmental variables, such as seasonal flocculation, may influence endotoxin levels in treated water. Purpose of this study was to evaluate the seasonal fluctuation in endotoxin concentrations in dialysis water across a number of hospital-based dialysis centers. Over a 12-month period, water samples were collected monthly from various places and tested for endotoxin levels using the Limulus Amebocyte Lysate (LAL) assay. The findings demonstrated considerable seasonal changes, with almost 55.5% of the samples surpassing the international threshold of 0.03 EU/mL. Peaks were seen during the warmer months (July-August 2025 and February-March 2025), whereas lower levels were more typical in the winter (November-December 2024). These findings highlight the requirement for seasonally adjusted monitoring and control strategies to maintain water quality and ensure patient safety in dialysis settings.

Keywords: Dialysis water quality, Endotoxins, Hemodialysis safety, Seasonal variation, Water monitoring

1. Introduction

Patients receiving hemodialysis are at serious risk for health problems due to bacterial endotoxins in the water they drink (Ward, 2022). Particularly in people with compromised renal function, these endotoxins, which are mainly lipopolysaccharides (LPS) derived from the outer membrane of Gram-negative bacteria, can cause severe inflammatory reactions (Catapano et al., 2025). Exposure to contaminated dialysis water can cause fever, hypotension, chronic inflammation, and, in severe cases, septic shock (Raimundo et al., 2023). The microbiological purity of dialysis water must therefore be preserved in order to ensure patient safety and the overall effectiveness of treatment (Hilinski et al., 2020). This necessitates rigorous monitoring protocols and the development of advanced detection technologies (Schneier et al., 2020).

In Iraq, dialysis treatment centers encounter environmental issues that increase the potential of endotoxin contamination in dialysis water (Humudat & Al-Naseri, 2020). Limited research has explored how seasonal environmental variables affect endotoxin levels in these systems. The study follows the ANSI/AAMI/ISO 23500:2024 standard, which sets a limit of less than 0.03 EU/mL for endotoxins in ultrapure dialysis water (ANSI/AAMI/ISO, 2019).

The objective of the study was investigates to examine and evaluate the influence of seasonal environmental factors on bacterial endotoxin levels in dialysis water systems in Iraq. By addressing this gap in knowledge by developing evidence-based practices for monitoring the environment and managing water quality in hemodialysis centers.

2. Materials and methods

2.1. Work strategy and sampling

This study examined hemodialysis water samples collected from several areas in Iraq between September 2024 and August 2025 from 18 dialysis centers at hospitals. A total of 72 samples were collected by randomly selecting 6 dialysis sites every month to

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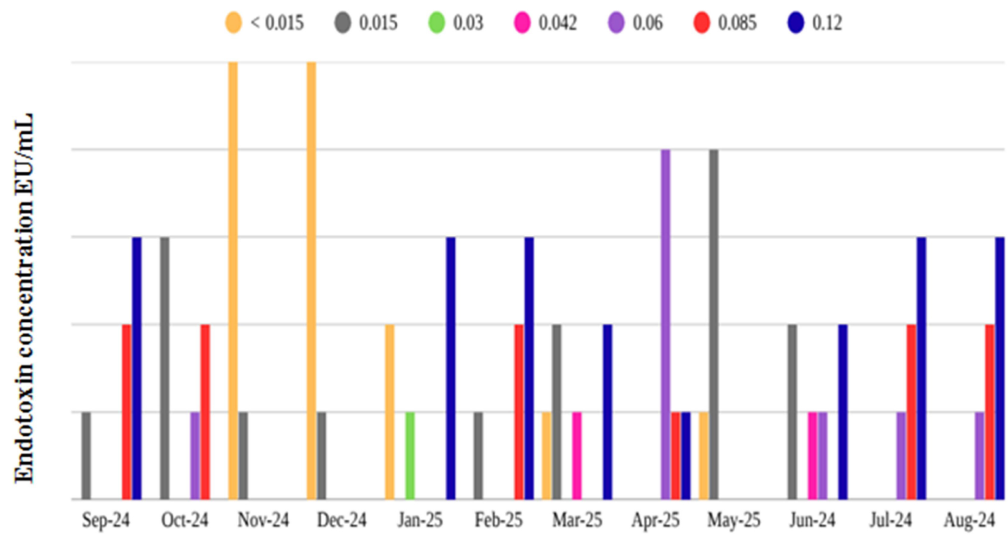

Fig. 1. Monthly distribution of endotoxin concentrations in dialysis fluids (September 2024 – August 2025).

provide wide geographic coverage. Samples were collected in sterile, endotoxin-free 100 mL vials made in a controlled laboratory setting and shipped the same day for immediate analysis.

2.2. *Ethical considerations*

Ethical approval was not required for this study as it involved only water samples from dialysis units and did not include any human participants or animals.

2.3. *Endotoxin testing*

Endotoxin concentrations in dialysis water were determined using the gel-clot Limulus Amebocyte Lysate (LAL) assay, which has a sensitivity of 0.015 EU/mL and was performed according to the manufacturer's instruction (Wako-pyrostar, 2012). Briefly, 0.1 mL of reconstituted endotoxin reagent was added to each reaction tube, followed by 0.1 mL of the test sample. The tubes were incubated in a water bath at 37 ± 1°C for 60 ± 2 minutes without agitation. After incubation, each tube was gently tilted 180°; the formation of a firm, non-deforming gel was considered a positive result, while the absence of a stable clot indicated a negative result. All samples were tested in duplicate and at two serial dilutions to ensure reproducibility. Endotoxin levels were expressed in endotoxin units per milliliter (EU/mL). Descriptive temporal analysis, including monthly means and standard deviations, was conducted to identify trends and seasonal variations in endotoxin concentrations.

2.4. *Statistical analysis*

Data were entered and analyzed using Microsoft Excel 2010.

3. Results

Fig. 1 demonstrates seasonal flocculation in endotoxin concentrations in dialysis water samples collected over a 12-month period from several hospital dialysis centers. The data illustrate notable temporal variations in water quality, with about 55.5% of the samples exceeding international standard of 0.03 EU/mL for ultrapure dialysis water.

Endotoxin concentrations ranged from <0.015 to 0.12 EU/mL, with notable increases appearing during summer months (July–August 2025) and once again in 2025 (February–March). In contrast, a higher proportion of low-endotoxin samples (<0.015 EU/mL) was recorded during winter months (November–December 2024), indicating improved bacterial control during the cold season.

4. Discussion

The results shows in Fig. 1 reveal notable seasonal fluctuations in endotoxin concentrations within dialysis water samples collected during a 12-month period from multiple hospital-based dialysis centers monitoring. These variations underscore the dynamic kind of water quality and the potential impact of environmental factors on the bacterial load in dialysis water treatment. A concerning description is that specifically 55.5% of the water samples had endotoxin levels above 0.03 EU/ml, which is the guideline concentration for ultrapure dialysate. This finding is concerning because elevated endotoxin levels in dialysate can lead to patient complications.

Dialysis water should be considered a medicinal product due to its direct interaction with the patient's bloodstream during treatment (Canaud et al., 2025). Ensuring its high quality is, as a result, critical for patient prophylaxis. Permanent disinfection of the entire water distribution and dialysis fluid pathway is essential to prevent bacterial growth and endotoxin formation. Incorporating routine endotoxin testing into standard quality control protocols is strongly recommended to maintain safe and effective hemodialysis practices.

Endotoxin levels peaked notably during the summer months (July–August 2025), as well as in early 2025 (February–March), suggesting that ambient temperature warmer temperatures also resulted in an increase of biofilm, and possibly fluctuating municipal water conditions may contribute to increased bacterial proliferation and biofilm formation in water treatment systems (Smeets et al., 2003). Higher temperatures are usual to contribute to supporting microbial activity, and our findings align with previous studies that have declared seasonal variation in preserving microbiological quality in dialysis water, especially during hotter periods of the year (Grilo et al., 2021; Erdei-Tombor et al., 2024).

On the other hand, during the winter season (November–December 2024), a higher proportion of samples showed lower endotoxin levels (<0.015 EU/mL), which means more effective bacterial suppression, potentially due to lower surrounding temperatures and slower bacterial metabolism. This is presumably due to lower water temperatures enhancing bacterial suppression in water systems by slowing down metabolism, reducing growth rates, and minimizing biofilm formation, extending bacteria's survival and protecting them from disinfectants (Nocker et al., 2021).

These seasonal patterns highlight the importance of adapting maintenance schedules and disinfection protocols to environmental conditions. Hospital water treatment teams may gain from enhanced preventive measures during warmer months and adopting real-time control tools to rapidly detect high endotoxin levels. Additionally, these data recommend a proactive, rather than reactive, approach to water safety management in dialysis settings—one that considers seasonal variability as a critical factor in patient risk attenuation. Furthermore, staff training in water handling, proper sample collection techniques, and timely system maintenance are essential components of a comprehensive infection prevention strategy.

5. Conclusion

This research emphasized significant about endotoxin contamination in dialysis water in Iraq, with seasonal variations influencing these levels, particularly during warmer months. The study appears that over half the water samples exceeded international standards, suggesting a potential microbiological risk to dialysis patients, especially during the summer and early spring when endotoxin levels were higher. The study suggests a link between temperature and bacterial activity, implying a role for environmental factors in endotoxin management.

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Conflict of interest

Author declare no conflicts of interest related to the content findings of this study.

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