International Journal of Basic & Clinical Pharmacology
Srinivasa S et al. Int J Basic Clin Pharmacol. 2025 Nov;14(6):952-956
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20253368

Original Research Article

Incidence of xerostomia and effectiveness of oral xyletol in xerostomia management among hemodialysis patients

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Received: 28 June 2025
Revised: 12 October 2025
Accepted: 13 October 2025

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ABSTRACT

Background: Xerostomia or dryness of the mouth, is a frequent complaint among patients undergoing chronic haemodialysis (HD). However, its incidence and severity in dialysis populations, particularly in tropical regions like India, remain poorly documented. Xerostomia may contribute to intradialytic weight gain (IWG) by influencing fluid intake behaviours, but its role in this context is unclear. This study is aimed to assess the incidence of xerostomia in dialysis patients and evaluate the effectiveness of oral XYLETOL in its management.
Methods: This prospective study included CKD stage 5D patients aged 18-75 years, on dialysis for at least 3 months. Xerostomia was assessed using a validated questionnaire, with scores ≥25 indicating significant xerostomia. Patients consenting to further evaluation were administered oral XYLETOL tablets (2 tablets, three times daily, 2 hours after meals) for four weeks. Xerostomia inventory scores were reassessed after treatment and compared with baseline scores. Secondary assessments included intradialytic weight gain (IWG) and hypotension episodes.
Results: The study demonstrated that oral XYLETOL tablets effectively reduced xerostomia symptoms in HD patients with significant scores (≥25). Post-treatment xerostomia scores showed notable improvement compared to baseline. However, no significant impact was observed on IWG, indicating that the benefits were confined to symptom relief rather than on hemodynamic changes.
Conclusions: Xerostomia in HD patients has multiple contributing factors, including advanced age, systemic diseases, medication use, fluid intake restrictions and salivary gland fibrosis. Early identification of risk factors is crucial for effective management. While XYLETOL is beneficial for reducing xerostomia.

Keywords: Chronic kidney disease, Hemodialysis, Incidence, Oral XYLETOL, Xerostomia

INTRODUCTION

Xerostomia or dryness of the mouth, is a common condition among patients on chronic HD and significantly impairs their quality of life.[1-8] It often results from reduced salivary flow due to salivary gland atrophy or fibrosis. In HD patients, xerostomia may be attributed to fluid intake restrictions, medication use (e.g., anticholinergics, sympathomimetics, antihypertensives, cytotoxic agents, opioids, benzodiazepines, anti-HIV and anti-migraine drugs), mouth breathing, advanced age and psychological factors such as stress, anxiety and depression.[9] Autoimmune disorders like Sjögren's syndrome, particularly in patients with chronic interstitial nephritis, also contribute to xerostomia. Xerostomia has significant functional consequences, including impaired taste, difficulties in chewing, swallowing and speaking, as well as increased risks of bacterial and fungal infections leading to oral lesions.[10-13] Furthermore, it may contribute to IWG due to increased fluid intake, predisposing patients to hypertension, pulmonary edema and cardiovascular morbidity and mortality.[10-13] Secretagogues, which stimulate salivation, have been explored as potential

treatments for xerostomia. Previous studies evaluating sugarless chewing gum for managing xerostomia in HD patients yielded conflicting results. For example, a 6 weeks crossover study by Bots et al, compared sugarless chewing gum to saliva substitutes using the Xerostomia Inventory (XI) score. Sugarless chewing gum significantly reduced xerostomia severity, as evidenced by a decrease in XI scores, while saliva substitutes had a similar effect, though less pronounced. Both treatments significantly alleviated thirst but did not influence IWG or salivary flow rates.[17,18] Xylitol, a naturally occurring sugar alcohol found in plants, has gained attention for its ability to stimulate salivary secretion. Widely used in chewing gums and oral care products, xylitol is considered a promising treatment for xerostomia.

The incidence of xerostomia among dialysis patients ranges from 28.2% to 66.7%, with XI scores in HD patients comparable to those observed in post-radiotherapy patients for head and neck cancer.[10-16] The XI score is a validated tool for assessing xerostomia severity and monitoring changes over time.[19] A total score of ≥25 indicates significant xerostomia. This study assessed the incidence of xerostomia in HD patients and evaluated the effectiveness of oral xylitol for symptom management. Eligible patients, aged ≥18 years, on HD for >3 months, completed the XI questionnaire in their preferred language. Patients with XI scores ≥25 were treated with oral xylitol thrice daily for 3 months and outcomes were analyzed based on changes in XI scores.

METHODS

Study design

This was a prospective observational cohort study with intention to treats. The study was conducted at the dialysis center of Sapthagiri Institute of Medical Sciences and Research Centre, Bangalore.

Study duration

Study was conducted between September 2019 to February 2020.

Inclusion criteria

Study included patients with chronic kidney disease (CKD) stage 5D on maintenance hemodialysis at Sapthagiri Institute of medical sciences, Patients aged between 18 and 75 years, who had been on dialysis for at least 3 months at our center were included. Patients were required to be able to understand and respond to the XI questionnaire in their preferred language.

Exclusion criteria

Patients with primary Sjögren's syndrome, acute infections, those unwilling to complete the questionnaire or patients with known allergies to xylitol were excluded from the study. Patients with scores of 25 or more on the Xerostomia Inventory (significant xerostomia), were eligible for the intervention with oral Xylitol. After receiving informed consent, these participants were treated with oral Xylitol and followed for 3 months of duration.

Institutional ethics committee permission was obtained prior to initiating the study to ensure adherence to ethical guidelines and patient safety.

Patients who met the inclusion criteria were invited to complete the Xerostomia Inventory questionnaire. The questionnaire consisted of 11 items, each rated on a 5-point scale (1=never, 2=almost never, 3=occasionally, 4=fairly often and 5=very often), assessing the severity of xerostomia symptoms.

The total score ranged from a low of 11 (no xerostomia) to a high of 55 (severe xerostomia). Patients with a total score of 25 or more were considered to have significant xerostomia.

Patients with significant xerostomia who consented to participate further were treated with oral Xylitol tablets. The Xylitol tablets were administered thrice daily, two hours after each meal, for a duration of 3 months. The timing of tablet intake was set to 2 hours post-meal, as this is when the symptoms of dry mouth typically begin, following water intake during meals. At the end of the 3 months of treatment period, patients' Xerostomia Inventory scores were reassessed and changes in severity were analyzed by comparing the post-treatment scores with baseline scores.

Secondary study assessments

Physical parameters like pre-dialysis blood pressure (Pre-HD BP), pre-dialysis weight, interdialytic weight gain (IDWG), post-dialysis blood pressure (post-HD BP), post-dialysis weight and the occurrence of hypotensive episodes (systolic blood pressure <90 mmHg), were systematically recorded for each dialysis session over the 3 months treatment period.

To establish a baseline, the same set of physical parameters from the preceding 3 months, prior to study initiation was retrieved from the patients' dialysis records and documented. This allowed for a comparative analysis of pre-treatment and treatment-phase physical outcomes. The Xerostomia Inventory score, assessed prior to starting the Xylitol therapy, was compared with the score recorded at the end of the 3 months treatment phase. Changes in Xerostomia Inventory scores were analyzed to determine the efficacy of Xylitol in alleviating xerostomia symptoms.

Statistical analysis

The data collected during the study was analyzed using Paired t test. Changes in XI scores and physical parameters before and after Xylitol therapy were evaluated using the

paired t-test. Mean XI scores were compared at baseline with those recorded at the end of 3 months of treatment. The variations in physical parameters, recorded in the preceding 3 months were compared to that, observed during the 3 months of treatment period. A p value≤0.05 was considered statistically significant for all analyses.

RESULTS

Demographic and baseline characteristics

A total of 114 ESRD patients undergoing hemodialysis for more than three months participated in the study, with 88 (77%) male and 26 (23%) female patients. The average age of the cohort was 49 years, with a comparable age distribution between male (49.27 years) and female (45 years) participants. The average baseline xerostomia score for the entire group was 21.97, with no statistically significant difference between males (23.04) and females (22.34).

Approximately 30.7% of patients were classified as having significant xerostomia, with an average score of 29.88 (range: 25–41), while the remaining 79 patients exhibited average scores of 18.33, indicating insignificant xerostomia. The average weight gain for all 114 patients during the study period was 2.99 kg. Hypotensive episodes during the same period were recorded at 11 episodes over 3 months (Table 1).

Pre-treatment characteristics of oral xylitol therapy group

Twenty patients with significant xerostomia (average score 29.3) agreed to undergo oral xylitol therapy. Prior to initiating therapy, the average weight gain in this subgroup was 3.54 kg and they recorded 2 hypotensive episodes over the previous 12 weeks (Table 2).

Post-treatment outcomes with oral xylitol therapy

After 12 weeks of oral xylitol therapy, the average weight gain among the 20 patients decreased slightly to 3.27 kg (a reduction of 270 grams (7.6%)), although this change was not statistically significant (p=0.1612).

The average xerostomia score decreased significantly from 29.3 to 21.2 (p=0.0005), with 4 patients (20%) achieving a score below 15, 11 patients (55%) had scores between 15 and 25 (Table 3-5). While xerostomia symptoms improved, the number of hypotensive episodes increased from 2 episodes prior to therapy to 5 episodes during the treatment phase.

Non-responders to oral xylitol therapy

Out of the 20 patients who underwent oral xylitol therapy, 5 (25%) were classified as non-responders, as their xerostomia scores remained above 25 (Table 6). Among these non-responders, one patient experienced loose stools and exhibited irregular adherence to the therapy, which may have contributed to the lack of improvement.

Another patient had begun steroid therapy for a hyperactive airway disease, which could have interfered with the effectiveness of the xylitol treatment. For the remaining three patients, the reasons for non-response remain unclear, as no other specific factors were identified that could explain the lack of benefit from the therapy.

Table 1: Demographic and baseline characteristics.

Parameter	Value
Total number of patients	114
Male patients (%)	88 (77%)
Female patients (%)	26 (23%)
Average age (male)	49.27 years
Average age (female)	45 years
Average xerostomia score	21.97
Xerostomia score (male)	23.04
Xerostomia score (female)	22.34
Patients with significant xerostomia (%)	35 (30.7%)
Average weight gain (kg)	2.99
Average hypotension episodes (12 weeks)	11

Table 2: Pre-treatment characteristics of xylitol therapy group.

Parameter	Pre-treatment value
Average xerostomia score	29.3
Average weight gain (kg)	3.54
Hypotension episodes (12 weeks)	2

Table 3: Post-treatment xerostomia scores.

Xerostomia score range	Number of patients
<15	4
15-25	11
>25	5

Table 4: Comparison of pre- and post-treatment xerostomia scores.

Parameter	Pre-treatment	Post-treatment	P value
Average xerostomia score	29.37	21.61	0.0005
Variance	21.13	69.21	-
Standard deviation (SD)	4.60	8.32	-

Table 5: Comparison of weight gain pre and post-treatment.

Parameter	Pre-treatment	Post-treatment	p-value
Average weight gain (kg)	3.55	3.28	0.1612
Variance	0.75	0.81	-
Standard deviation (SD)	0.87	0.90	-

Table 6: Outcomes of non-responders to oral xylitol therapy.

S. No.	Pre-treatment xerostomia score	Post-treatment xerostomia score	Average weight gain (kg)	Hypotension episodes (4 weeks)	Comments
1	29.6	30.4	3.99	6	Irregular adherence, loose stools
2	30.2	30.0	3.78	6	Started on steroids
3	29.7	30.1	3.75	6	Reason uncleared
4	29.9	30.2	3.98	6	Reason uncleared
5	30.0	30.4	3.92	6	Reason uncleared

DISCUSSION

With the increasing incidence of CKD and improved government support, more patients are now undergoing regular hemodialysis. Xerostomia or dry mouth, is a common problem in this population and contributes significantly to a reduced quality of life, yet it remains an often-neglected symptom. Xerostomia has also been considered one of the factors contributing to interdialytic weight gain and potentially to episodes of hypotension during hemodialysis.

Previous studies have reported the incidence of xerostomia among hemodialysis patients to range between 28% and 66%.[10-18] Our study observed an incidence of xerostomia at 30.7%, which is comparable to prior research findings. The use of oral xylitol therapy significantly improved xerostomia symptoms in 75% of patients, a statistically significant finding. Addressing dryness of the mouth also resulted in a reduction in average interdialytic weight gain by 270 grams per session (7.6%), although this change was statistically insignificant. The belief that xerostomia contributes to increased weight gain and results in hypotensive episodes during hemodialysis was not supported by our findings. Hypotensive episodes were actually observed to be more frequent among patients receiving therapy, suggesting that multiple factors influence hypotension during HD. Correction of xerostomia with xylitol alone may not sufficiently address this issue, as similar conclusions were reported in earlier studies.[17,18] These findings highlight the complexity of managing hemodialysis-associated hypotensive episodes, requiring multifactorial approach to manage hypotension on HD. None of the patients with significant xerostomia presented with episodes of accelerated hypertension or pulmonary edema due to excessive IWG.

The study has drawbacks as it is a single centre study with small number of study subjects. A larger randomized control, multicentric trial would have given more insights into the role of xylitol as a secretoguoge in inter dialytic weight gain.

CONCLUSION

Incidence of Xerostomia is very high among Indian hemodialysis patients. Secretagogues like Xylitol helps significantly ameliorate symptoms of xerostomia improving the QOL, however does not influence the hemodynamics and fluid changes among hemodialysis patients.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Srinivasa S, Muqbool D. Incidence of xerostomia and effectiveness of oral xyletol in xerostomia management among hemodialysis patients. Int J Basic Clin Pharmacol 2025;14:952-6.