ORIGINAL ARTICLE
Iran J Allergy Asthma Immunol
February 2025; 24(1):12-20.
DOI: 10.18502/ijaai.v24i1.18016

Effectiveness of the Nasal Irrigation Effectiveness in Treating Allergic Rhinitis in Children 6 to 12 Years Old

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Received: 23 July 2024; Received in revised form: 4 November 2024; Accepted: 18 November 2024

ABSTRACT

Nasal irrigation, a nonpharmacological intervention for alleviating nasal symptoms, has yet to gain widespread acceptance among caregivers due to procedural ambiguities and the absence of a standardized protocol. This study aimed to evaluate the efficacy of normal saline nasal irrigation in managing allergic rhinitis among children aged 6 to 12 years.

This prospective, randomized, single-blind trial enrolled children aged 6 to 12 with allergic rhinitis. Fourthy-eight patients were randomly assigned to receive either standard care (oral antihistamine and intranasal corticosteroid) or standard care plus nasal irrigation with saline solution. Symptom severity, assessed using the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ) at baseline, 1, and 3 months, included rhinorrhea, nasal congestion, sneezing, pruritus, ocular symptoms, and functional impairment.

The intervention group demonstrated statistically significant improvements in several domains post-intervention. Specifically, a marked reduction in sneezing frequency and nasal cleansing requirements was observed. Moreover, this group reported significantly lower ocular symptoms, including irritation, itching, and watering, relative to the control group. Although overall PRQLQ scores did not differ significantly between groups, the intervention group exhibited lower scores at the 1- and 3-month follow-ups, indicative of enhanced quality of life. These findings suggest a potential beneficial effect of the intervention on participant well-being.

The findings of this study indicate that nasal irrigation with 0.65% saline solution 4 times daily may serve as an effective adjunct treatment for children with allergic rhinitis. This regimen was associated with significant enhancements in both nasal symptom severity and quality of life.

Keywords: Allergic rhinitis; Nasal irrigation; Normal saline; Pediatric

INTRODUCTION

Allergic rhinitis (AR) is a type I hypersensitivity disorder of the nasal mucosa mediated by immunoglobulin E (IgE) upon allergen exposure.[1,2] This condition has emerged as a significant global health concern, with prevalence rates reaching 20% to 25% in Western populations.[3,4] While the incidence is increasing in regions with historically lower prevalence, it may be stabilizing or declining in areas with traditionally high rates.[5] Seasonal AR affects up to 40% of the population, whereas perennial AR prevalence is approximately 13%.[6] Beyond nasal symptoms, AR often manifests with ocular discomfort, including itching and

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burning, substantially impacting quality of life.[7] Children are particularly susceptible to AR, and inadequate management can lead to diminished quality of life and associated comorbidities such as otitis, sinusitis, and asthma. Notably, AR is considered a primary risk factor for asthma development.[8]

Contemporary management of AR encompasses desensitization, pharmacotherapy, and surgical interventions.[9] Symptomatic relief is typically achieved through antihistamines and nasal corticosteroids, whereas allergen immunotherapy is reserved for more severe or persistent cases.[10] Given the chronic nature of AR and associated concerns regarding long-term medication use, there is a growing interest in exploring nonpharmacological treatment alternatives.[11]

Recent studies have documented interesting results using nasal irrigation as an adjunctive treatment modality in many sinonasal diseases including AR.[12,13] In this regard, it has also been reported that an increased efficacy could be effected using hypertonic saline instead of normal saline.[14,15] However, statistical evidence to justify the widespread clinical use of nasal irrigation is still poor.[16,17] As a treatment for AR, nasal saline irrigation could wash out the thick mucus, allergens, and air contaminant in the nasal cavity, increase the hydration of the sol layer, enhance mucociliary function, and it has the advantages of safety, convenience, and reliability.[18] More specifically, to the best of our knowledge, no previous studies have investigated the efficacy of nasal irrigation using normal saline in the prevention of seasonal AR symptoms in pediatric patients. Therefore, this study aimed to investigate the effect of nasal irrigation with normal saline in the treatment of AR in children 6 to 12 years old.

Nasal irrigation has emerged as a potential adjunct therapy for various sinonasal conditions, including AR.[12,13] While some studies suggest enhanced efficacy with hypertonic saline, robust statistical evidence supporting widespread clinical application remains limited.[14,15] The proposed mechanism of action for nasal saline irrigation in treating allergic rhinitis involves the removal of mucus, allergens, and contaminants, improved mucociliary clearance through increased hydration, and overall safety, convenience, and reliability.[16,17] Notably, the efficacy of normal saline nasal irrigation in preventing seasonal allergic rhinitis symptoms in children has not been extensively explored.[18] Consequently, this study aimed to evaluate the impact of normal saline nasal irrigation on allergic rhinitis in children aged 6 to 12 years.

MATERIALS AND METHODS

This single-blind, clinical trial (IRCT code: IRCT20150426021944N4), randomized, and prospective study was conducted after obtaining permission from the ethics committee of Urmia University of Medical Sciences (IR.UMSU.REC.354.1401) at Urmia Shahid Motahari Hospital between 2022 and 2023. The diagnosis of AR was based on physical examination (children presenting with symptoms indicative of AR, including but not limited to rhinorrhea, nasal congestion, and sneezing) and was confirmed by specific IgE measurements.

Eligible children aged 6 to 12 years presenting with symptoms indicative of AR were enrolled in the study following informed consent. Participants were randomly allocated to either a control or intervention group using a block randomization method. The control group received standard care comprising oral antihistamines (sterizin 5 mL every 12 hours) and intranasal corticosteroids (mometasone) every 12 hours. The intervention group received the same standard care plus nasal irrigation with 0.65% saline solution spray (2 puffs every 6 hours) 4 times daily. To ensure randomization integrity, blocks of 6 participants with a ratio of 2 control to 4 intervention group members were created. All possible block combinations were generated and assigned allocation codes. Sixteen blocks were randomly selected using specialized software (a random allocation software that is a program created in Microsoft Visual Basic 6 and produced by Dr Mahmood Saghaei, Isfahan University of Medical Sciences, Isfahan, Iran) under the supervision of an epidemiologist.

The intervention commenced on April 30, 2023, and continued for 3 months. All participants exhibited sensitization to at least 1 relevant aeroallergen, as confirmed by specific IgE measurements. Exclusion criteria comprised adenoidal hyperplasia, septal deviation, nasal polyps, infectious rhinitis, concha bullosa, intranasal meningocele, vasomotor rhinitis, and rhinitis medicamentosa. These conditions were identified based on the presence of signs and symptoms indicative of non-allergic rhinitis, such as treatment refractoriness, fever, apnea, and excessive decongestant use.

Participants and their parents were instructed to maintain a daily symptom diary. Symptoms including sneezing, rhinorrhea, nasal pruritus, nasal obstruction, palatal pruritus, ocular symptoms, and disruptions to daily activities and sleep were recorded at baseline, 1,

and 3 months using the Pediatric Rhinoconjunctivitis Quality of Life Questionnaire (PRQLQ) (19). This instrument comprises 14 items rated on a 0 to 6 scale. Intergroup comparisons of PRQLQ scores were conducted. Participants were afforded the option to withdraw from the study at any time.

Sample Sizing

The sample size was determined using a power analysis based on a 2-sample *t* test with 95% confidence and power, referencing data from Satdhabudha et al's 2012 study.[15] This study reported mean and standard deviations of 2.61 and 3.15 for the first group, and 4.14 and 2.61 for the second group, respectively. Anticipating a 7% dropout rate per group, a total of 96 participants (48 per group) were consecutively recruited from the pediatric allergic rhinitis population attending allergy clinics at Urmia University of Medical Sciences.

$$\frac{\left(z_{1-\beta}+z_{1-\alpha/2}\right)^2\times\left(S_1^2+S_2^2\right)}{\mu_1-\mu_2},\quad \alpha=0.05\Rightarrow z_{1-\alpha/2}=1.96,$$
$$\beta=0.01\Rightarrow z_{1-\beta}=1.28,\quad S_1=0.15,\quad S_2=0.16$$

Statistical Analysis

Descriptive statistics, including means, standard deviations, frequencies, and percentages, were calculated for quantitative and qualitative variables respectively. Data were visualized using graphs and tables. Independent *t* tests were employed to compare mean differences between groups for quantitative variables across time points. Chi-square tests (or Fisher's exact test where appropriate) and Mann-Whitney test were used to analyze categorical data. Repeated measures ANOVA was conducted to assess the treatment effect and overall group mean differences. Statistical significance was set at $p<0.05$. All analyses were performed using SPSS version 21.

RESULTS

A total of 43 participants were excluded from the study due to various factors, including participant dissatisfaction (n=13), medication non-adherence (n=21), and lack of response (n=9) during the initial or third month of follow-up. The final analysis included 96 participants, equally distributed between the intervention and control groups.

Demographic characteristics were comparable between groups. Gender distribution (34% girls, 66% boys in the control group; 41.7% girls, 58.3% boys in the intervention group) and mean age (9.58±2.32 years in the treatment group; 9.4±2.01 years in the control group) did not differ significantly ($p=0.44$ and $p=0.47$, respectively). Additionally, no significant difference in residence location was observed, with a majority of participants residing in urban areas ($p=1$). However, a statistically significant disparity was found in family history of asthma/allergy ($p=0.01$), with a higher prevalence in the intervention group (52.09%) compared to the control group (25%) (Table 1).

Table 1. Demographic characteristic of studied patients

Variables	Intervention group n=48	Control group n=48	*p*
Mean Age	9.58±2.32	9.4±2.01	0.47*
Gender			
Boy	28 (58.3%)	32 (66%)	0.44**
Girl	20 (41.7%)	16 (34%)	
Place of residency			
City	36 (75%)	37 (77.8%)	1**
Urban	12 (25%)	11 (22.2%)	
Allergy/asthma history in first-degree relative			
Yes	25 (52.09%)	12 (25%)	0.01**
No	23 (47.91%)	36 (75%)	

* Mann-Whitney test; ** Pearson chi-square.

Table 2 presents a comparative analysis of mean scores for selected questionnaire variables across the intervention and control groups. Baseline levels of daily activity at home or work were comparable between groups, with mean scores approximating 2 points on the scale. A reduction in this score was observed at both 1- and 3-month follow-ups for both groups, although no significant intergroup differences emerged ($p=0.97$). Similarly, initial outdoor activity levels were comparable between groups. Subsequent measurements at 1 and 3 months indicated a decrease in both groups, with minimal and nonsignificant differences observed between the intervention and control groups ($p=0.97$).

Baseline sneezing frequency was higher in the control group compared to the intervention group (4.4 ± 1.4 and 3.58 ± 1.4, respectively) and 3 months after the treatment in the 2 groups were 1.31 ± 0.82 and 0.95 ± 0.95, respectively. A significant reduction in sneezing frequency was observed in both groups at 1 and 3 months, with a more pronounced decrease in the intervention group ($p=0.002$).

Prior to the intervention, sleep disorder scores were comparable between the intervention and control groups (2.1 ± 1.83 and 1.72 ± 1.74, respectively). Scores decreased in both groups 1 month after the intervention, with an average around 1 point (1.02 ± 1.03, 1.13 ± 1.15, respectively). This decrease continued at 3 months, with the intervention group showing a slightly lower average score compared to the control group (0.65 ± 0.7 and 0.96 ± 1.02, respectively). However, statistical analysis revealed no significant difference between the groups in sleep disorder scores over time ($p=0.94$).

Baseline assessments indicated a slightly higher mean need to rub eyes or nose in the intervention group (4.4 ± 1.4) compared to the control group (3.91 ± 1.5). This score decreased in both groups one month after the intervention (2.3 ± 1.06 and 2.34 ± 0.91, respectively). The decrease continued at 3 months, with the intervention group showing a slightly lower mean score compared to the control group (1.52 ± 0.8 and 1.74 ± 0.64, respectively). However, statistical analysis revealed no significant difference between the groups in the need to rub eyes or nose over time ($p=0.79$).

Prior to the intervention, eye irritation scores were similar between the intervention and control groups, (2.67 ± 1.6 and 2.3 ± 1.64, respectively). Scores decreased in both groups one month after the intervention, with a mean around 1.3 points (1.3 ± 0.69 and 1.41 ± 1.04, respectively). This decrease continued at 3 months, with the intervention group showing a slightly lower mean score compared to the control group (0.91 ± 0.63 and 1.02 ± 0.8, respectively). However, statistical analysis revealed no significant difference between the groups in eye irritation scores over time ($p=0.81$).

Baseline assessments revealed comparable mean eye itching scores between the intervention and control groups (2.67 ± 1.6 vs 2.3 ± 1.64). Scores decreased in both groups 1 month after the intervention (1.3 ± 0.96 and 1.41 ± 1.04, respectively). This decrease continued at 3 months, with the intervention group showing a slightly lower mean score (0.91 ± 0.63) compared to the control group (1.02 ± 0.8). However, statistical analysis indicated no significant difference between the groups in eye itching scores over time ($p=0.81$).

Before the treatment, the mean score of eye-watering in the intervention and treatment groups was 2.67 ± 1.6 and 2.3 ± 1.64, respectively. Scores decreased in both groups one month after the intervention (1.3 ± 0.96 and 1.41 ± 1.04, respectively). This decrease continued at 3 months, with the intervention group showing a slightly lower mean score compared to the control group (0.91 ± 0.63 and 1.02 ± 0.8). However, statistical analysis revealed no significant difference between the groups in eye watering scores over time ($p=0.81$).

Prior to the treatment, the intervention group reported a slightly higher mean frequently nose cleaning (3.65 ± 1.43) compared to the control group (3.74 ± 1.5). This score significantly decreased in the intervention group one month after the intervention, reaching an average of 1.63 ± 0.99, while the control group only showed a moderate decrease to 2.35 ± 0.95. The decrease continued in both groups at 3 months, with the intervention group maintaining a statistically significant lower mean score (1.1 ± 0.63) compared to the control group (1.76 ± 0.89) ($p=0.01$).

Baseline assessments revealed a higher mean nasal congestion score in the intervention group (4.4 ± 1.4) compared to the control group (3.91 ± 1.5). Scores decreased in both groups 1 month after the intervention (2.3 ± 1.06 and 2.34 ± 0.91, respectively). This decrease continued to 3 months, with the intervention group showing a slightly lower mean score (1.52 ± 0.8) compared to the control group (1.74 ± 0.64). However, statistical analysis indicated no significant difference between the groups in nasal congestion scores over time ($p=0.79$).

Published by Tehran University of Medical Sciences (http://ijaai.tums.ac.ir)

Table 2. Comparison of the mean score of usual daily activity at home or at work in the time periods of the two groups under study

Variables	Before treatment	One month after treatment	Three months after treatment	*p*
Mean daily activity at home or at work				
Intervention	1.96±1.36	1.08±0.78	0.85±0.66	0.97
Control	2±1.48	1.11±0.98	0.77±0.76	
Mean outdoor activities such as exercising				
Intervention	1.96±1.36	1.08±0.78	0.85±0.66	0.97
Control	2±1.48	1.110.98	0.77±0.76	
Mean sneezing				
Intervention	3.58±1.4	1.67±1	1.31±0.82	0.002
Control	4±1.4	2.55±1.02	1.96±0.95	
Mean sleep disorder				
Intervention	2.1±1.83	1.02±1.03	0.65±0.7	0.94
Control	1.72±1.74	1.13±1.15	0.96±1.02	
Mean eye and nose rubbing				
Intervention	4.4±1.4	2.3 (1.06)	1.52 (0.8)	0.79
Control	3.91±1.5	2.34 (0.91)	1.74 (0.64)	
Mean eye irritation				
Intervention	2.67±1.6	1.3 (0.96)	0.91 (0.63)	0.81
Control	2.3±1.64	1.41 (1.04)	1.02 (0.8)	
Mean eye itching				
Intervention	2.67±1.6	1.3±0.96	0.91±0.63	0.81
Control	2.3±1.67	1.41±1.04	1.02±0.8	
Mean watery eyes				
Intervention	2.67±1.6	1.3±0.96	0.63±0.91	0.81
Control	2.3±1.64	1.41±1.04	1.02±0.8	
Mean frequent nose cleaning				
Intervention	3.65±1.43	1.63±0.99	1.1±0.63	0.01
Control	3.74±1.5	2.35±0.95	1.76±0.89	
Mean nasal congestion				
Intervention	4.4±1.4	2.3±1.06	1.52±0.8	0.79
Control	3.91±1.5	2.34±0.91	1.74±0.64	
Mean thirsty feeling				
Intervention	2.04±1.81	1.04±0.98	0.76±0.64	0.77
Control	1.77±1.79	1.13±1.26	0.75±0.82	
Mean irritability				
Intervention	2.04±1.81	1.04±0.98	0.76±0.64	0.77
Control	1.77±1.79	1.13±1.26	0.75±0.82	
Mean total score of the questionnaire				
Intervention	38.95±13.10	19.1±7.56	13.54±5.45	0.26
Control	37.27±12.99	23.1±7.82	16.98	
***p*	0.55	0.01	0.006	

Prior to the intervention, the intervention group reported a slightly higher mean thirst score (2.04±1.81) compared to the control group (1.77±1.79). Interestingly, the scores diverged 1 month after the intervention. The intervention group's thirst score decreased to 1.04±0.98, while the control group's score remained relatively stable at 1.13±1.26. However, by three months, both groups showed similar mean thirst scores (intervention group: 0.76±0.64; control group: 0.75±0.82). Overall, despite these fluctuations, statistical analysis revealed no significant difference in thirst scores between the intervention and control groups across the measured time points (p=0.77).

Before the treatment, the mean irritability score in the intervention and treatment groups were 2.04±1.81 and 1.77±1.79, respectively. The mean score obtained one month after the intervention in 2 groups was 1.04±0.98 and 1.13±1.26, respectively. In 3 months after the treatment, the mean score of this area in the two groups was 0.76±0.64 and 0.75±0.82, respectively. Despite these fluctuations, statistical analysis revealed no significant difference in excitability scores between the intervention and control groups across the measured time points (p=0.77).

Before the treatment, the mean total score of the questionnaire in the intervention and treatment groups was 38.95±13.10 and 371.27±12.99, respectively. The mean score obtained one month after the intervention in the two groups was 19.1±7.56 and 23.1±7.82, respectively. In three months after treatment, the mean score of this area in two groups was 13.52±5.45 and 16.98±5.97, respectively.

The PRQLQ questionnaire revealed a lower overall score in the intervention group compared to the control group at the time points measured after the intervention. The mean total score with standard error for the control and intervention groups was 25.79±1.21 and 23.86±1.22, respectively. While the intervention group's mean score was lower (95% confidence interval 23.38–28.17) compared to the control group (95% confidence interval: 21.43–26.28), this difference was not statistically significant (p=0.26).

Interestingly, a more granular analysis of each measured time period showed a statistically significant difference (p=0.01) in the average questionnaire score 1 month after the intervention, with the intervention group scoring lower. This pattern continued at 3 months, with the intervention group again demonstrating a statistically significant lower average score compared to the control group (p=0.006).

DISCUSSION

Allergic rhinitis is a common intermittent and persistent complication that affects both adults and children.[19] Patients experience symptoms of nasal congestion, runny nose, sneezing and itchy nose, which can affect their quality of life.[20] Based on a review of the available literature, inflammatory responses caused by inflammatory immunological mediators play an important role in the pathophysiology of allergic rhinitis, and washing with saline as the second line of treatment plays an important role in eliminating inflammatory mediators and reducing the symptoms of allergic rhinitis.[21,22] Therefore, this study investigated the effect of nasal irrigation with normal saline in the treatment of allergic rhinitis in children 6 to 12 years old.

The use of nasal irrigation is currently recommended as an adjunctive treatment modality in many sinonasal diseases such as rhinosinusitis, allergic rhinitis and other sinonasal diseases.[23,24] In particular, Xiong et al have previously reported that nasal wash is efficient in the treatment of seasonal allergic rhinitis in adults.[25] These authors, employing a patient-reported nasal disease-specific questionnaire, documented a significant improvement in symptoms score after nasal irrigation with hypertonic saline. The results of our trial are in line with this report.

According to this study's results, compared to the standard treatment group, the intervention group exhibited statistically significant improvements in various aspects following the intervention. This included a notable decrease in sneeze frequency and a reduced need for cleaning the nose. Additionally, the intervention group reported significantly lower scores for eye irritation, itching, and watering compared to the control group. While the overall PRQLQ questionnaire scores did not reveal a statistically significant difference between the groups, the intervention group did show significantly lower scores (indicating better quality of life) at 1 and 3 months following the intervention, suggesting a potential positive impact on participants' well-being. Nasal saline irrigation may be more easily accepted by children's parents, because that helps to dispel parents' concerns about using steroid hormone in children. Cases with adverse reactions were operated with disposable syringes.[22]

The current study builds upon the work of Nguyen et al[23] which investigated the impact of adding isotonic sodium chloride solution to standard corticosteroid

therapy on the quality of life in children with allergies. Their study employed the PRQLQ questionnaire, similar to the one used here. They observed improvements in quality of life at 4 and 8 weeks after the intervention, with a decreasing trend in average scores across all questionnaire domains compared to baseline. Notably, their study reported no adverse effects like nosebleeds or discomfort, potentially due to the single-group design and the reduced likelihood of encountering confounding variables. Building on the work of Malizia et al[26] who evaluated buffered hypertonic saline nasal irrigation in children with seasonal allergies, the current study corroborates their findings. Their investigation demonstrated that hypertonic saline irrigation improved quality of life and reduced nasal symptoms compared to normal saline. While both solutions provided some symptom relief, consistent with our findings, hypertonic saline exhibited significantly greater efficacy.

Our findings align with the broader body of research on saline irrigation for allergic rhinitis, as highlighted in the systematic review and meta-analysis by Wang et al.[18] Their work, alongside studies by Li et al[21] and Malizia et al[26] supports the efficacy of saline irrigation, particularly in children, for improving quality of life and reducing nasal symptoms. Similar to the Italian and Thai studies included in Li et al's work,[21] which demonstrated a significant decrease in post-intervention nasal symptom scores and antihistamine use, our study provides further evidence for the effectiveness of saline irrigation across diverse populations and potentially even with different saline solutions or concentrations.

Our study aligns with prior research on the effectiveness of saline irrigation for allergic rhinitis, demonstrating a reduction in symptom scores when used alongside standard treatment. Similar studies have positioned saline irrigation as a nonpharmacological treatment option for allergies.[28,29] However, other studies highlight the limited evidence base in this area. For instance, a review based on less than 20 trials concluded that while saline irrigation produced a statistically significant difference in average symptom scores (NSS), the clinical significance of this difference might be small (6 ± 2.1 vs 8 ± 1.3, $p < 0.01$).[30] This finding resonates with our own observations, where a significant statistical effect on nasal symptoms coexisted with a potentially modest clinical impact. Overall, our results contribute to the ongoing discussion regarding the role of saline irrigation in managing AR.

Notably, our intervention group reported no adverse effects like headaches, sinusitis, or bleeding. While rare side effects associated with saline use have been mentioned in other studies.[31,32]

Other study supporting our findings[33] suggests that saline irrigation, with its minimal complications, can be a valuable addition to standard treatment regimens for both children and adults with AR. Given the bothersome nature of AR symptoms and their impact on quality of life, such safe and cost-effective interventions warrant exploration across all age groups.[34]

Limitation of Study

This study was only a preliminary study with a small sample size and short time of follow-up, thus differences detected had with low power. Significant differences were detected in clinical symptoms and quality of life between groups, but further study with an appropriate sample size and longer term of follow-up would help confirm these findings.

Allergic rhinitis, characterized by bothersome nasal symptoms, significantly reduces quality of life. Therefore, exploring cost-effective and low-complication methods for symptom control is highly valuable. While intranasal corticosteroids remain the standard, safe, and effective treatment, a complementary approach lacking side effects and with a logical physiological mechanism holds significant promise. Our study suggests that rinsing with 0.65% saline 4 times daily represents a reasonable adjunctive therapy for children with AR. This approach yielded significant improvements in both nasal symptom scores and quality of life. Further studies are warranted to solidify these findings and explore the full potential of saline irrigation as a complementary treatment for AR.

STATEMENT OF ETHICS

Research involving human subjects complied with all relevant national regulations, institutional policies and is in accordance with the tenets of the Helsinki Declaration (as amended in 2013) and has been approved by the Ethics Committee of Urmia University of Medical Sciences with code IR.UMSU.REC.354.1401.

FUNDING

This research did not receive any specific grant from

funding agencies in the public, commercial, or not-for-profit sectors.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

ACKNOWLEDGMENTS

The authors would like to express their gratitude to the clinical research development unit of Imam Khomeini Hospital, Urmia University of Medical Sciences, for English editing.

DATA AVAILABILITY

Upon reasonable request from the corresponding author via email.

AI ASSISTANCE DISCLOSURE

No artificial intelligence was used in preparing this manuscript.

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