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Effect of reinforcement by pictograph versus audiovisual training on proper inhaler usage skills in asthma patients

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ABSTRACT

Objectives: Asthma is a disease in which the mainstay of therapy is aerosol therapy, which requires certain steps to be followed according to the device used. Training and reinforcing the inhalational skills are of paramount importance for good disease control.

Materials and Methods: The study was a prospective observational study conducted at the respiratory medicine department of a tertiary care centre, with inclusion criteria: recently diagnosed cases of asthma prescribed metered dose inhalers with valved spacer; ≥12 years and exclusion criteria: patients scoring full marks on National Institutes of Health (NIH) Expert panel 3 score after demonstration; already using inhaler; not using valved spacer. 100 patients were recruited and randomly divided into two groups with different reinforcement in the form of either a written leaflet or a video.

Results: The mean age was 39.83 years, with no significant difference in baseline demographic characteristics. This study found that both methods were able to show significant score improvement on baseline score, evidenced by the pre- and post-intervention scores in both groups. The video group (NIH expert panel 3 score, pre: 3.88, post: 6.14) was superior in comparison to the written group (NIH expert panel 3 score, pre: 4.28, post: 5.26). Peak expiratory flow rate (PEFR) measurements of the two groups showed improvement between pre- and post-intervention values. PEFR, as well as the asthma control test score, was suggestive of better asthma control in the video group.

Conclusion: Reinforcement is essential for better results of inhaler technique usage. Audiovisual is better than Pictograph as a tool for reinforcement. With the increasing affordability of smartphones in India and the world, the relevance of the study is increasing day by day. Also, playing videos in the outpatient department waiting hall could be a useful way for better inhaler compliance and asthma control.

Keywords: Asthma control test score, Asthma, Metered dose inhalers, NIH score, Reinforcement

INTRODUCTION

Asthma is a heterogeneous chronic airway inflammation with capricious limitation in expiratory airflow, along with respiratory symptoms, with 300 million prevalent cases.[1-3] Drug administration using aerosol therapy is the main treatment modality in respiratory disorders, with advantages of quick and local action, convenient to administer, easy portability, negligible systemic side effects and financial affordability.[4,5]

Aerosol therapy can be administered in the form of metered dose inhalers (MDIs), dry powder inhalers (DPI) and nebulisers. MDI devices, despite being an effective mode of therapy, struggled with challenges of coordination between the patient's breath and initiation of aerosol therapy for

effective drug deposition. Efficacy of aerosol therapy depends on accuracy in following the steps of administration of a particular device because improper execution of one or more of these steps can reduce the drug's effectiveness in the body, and the patient may end up with either less than therapeutic effects or more side effects due to increased local absorption of drugs; ultimately resulting in poor management of the disease.[6-8]

Repeated demonstration and rectification of faulty inhaler technique should always be done to reduce the rate of exacerbation.[1] Reinforcement by demonstration in person may not be feasible in all setups, and bias due to variation in techniques may be noted at the level of the person demonstrating. Hence, reinforcement by a structured visual or a written learning aid has been a help in decreasing the visits to the healthcare facility, thereby reducing the cost to the patient and decreasing the burden on healthcare providers.[9] Despite our understanding, there has been a paucity of literature on measures to ensure reinforcement of usage skills in aerosol therapy, wherein the small amount of work has been identified worldwide. As per our knowledge, this study is a landmark study in India to provide us with evidence for an effective way of reinforcement of MDI usage skills.

MATERIALS AND METHODS

This study was a prospective, observational study conducted at Lilavati Hospital and Research Centre, Mumbai, from March 2016 to June 2018. All the inpatients and outpatients attending chest medicine at the institute from December 2016 to December 2017 were screened, and 100 patients were recruited based on our exclusion and inclusion criteria. Participants were interviewed, and demographic features and relevant medical history were recorded. They were given a standard demonstration of inhaler usage (as a part of regular practice in the hospital). Baseline scores of the NIH expert panel 3 guidelines scoring system using a standard checklist were calculated.[10] They were allocated into two groups, one of the groups received written instructions in the form of a pictograph (designed based on NIH panel 3 guidelines and is in English, Hindi and regional language) in the outpatient department (OPD) post-consultation or at the time of discharge in case of inpatients on MDI usage technique with a spacer. The other group received an audiovisual clip (prepared based on NIH panel 3 guidelines and is in English, Hindi and regional language was made with the help of the Biomedical Department of Lilavati), clearly demonstrating the technique of MDI usage with a spacer by the preferred method, i.e., direct transfer to mobile phones or through WhatsApp (patients' choice). The pictograph, as well as the audiovisual clip, was validated with the help of a pilot study. Baseline peak expiratory flow rate (PEFR) was calculated using a portable peak expiratory flow meter. After 6 weeks, both groups were reassessed with the NIH panel 3 checklist, PEFR and asthma control test (ACT) score. The study protocol is given in Figure 1.

Inclusion and exclusion criteria

Patients included in the study met the following criteria: (i) recently diagnosed cases of asthma prescribed MDI with valved spacer; (ii) age: 12 years and above. Patients were excluded based on the following criteria: (i) Patients not willing to give informed consent; (ii) asthma patients scoring full marks on the NIH Expert panel 3 score after demonstration; (iii) COPD patients, patients of asthma COPD overlap syndrome; (iv) asthma patients already using inhaler; (v) asthma patients not using valved spacer.

Statistical analysis

A sample size of 50 per group was calculated using SAS 9.2 software for the NIH score at 80% power, alpha = 0.05, with an assumed effect size of 0.5.[11] Data were analysed with Statistical Package for the Social Sciences 15.1. Data were given as Mean ± Standard deviation for numerical data and number (%) for categorical data. Student's unpaired *t*-test, Student's paired *t*-test, Chi-square test and Fisher's exact test were applied to compare different groups and pre- and post-data. All statistical tests were two tailed. The level of significance was taken as $P \leq 0.05$. S: Significant, NS: Not significant, DF: Degrees of freedom, *P*: Probability value.

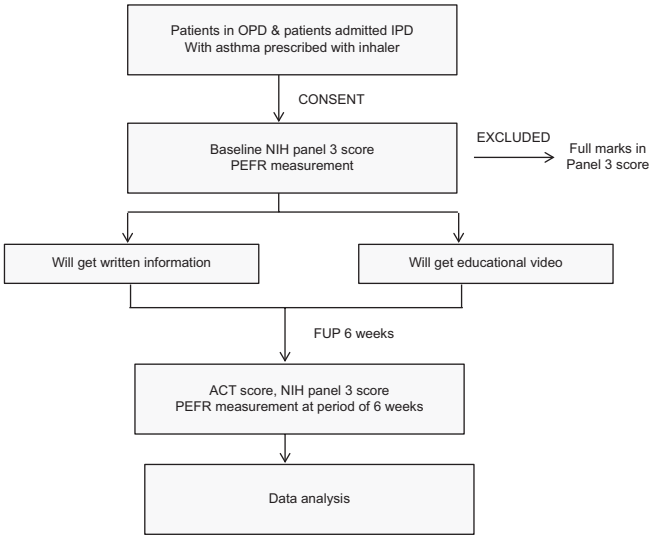

Figure 1: Flow diagram showing the study protocol. OPD: Outpatient department, IPD: Inpatient department, ACT: Asthma control test, NIH: National Institutes of Health, PEFR: Peak expiratory flow rate.

RESULTS

A total of 100 patients were recruited, and the mean age was 39.83 years. They were divided into two groups, with mean age in the audiovisual group and pictograph group being 39.20 + 11.19 years and 40.46 + 11.60 years, respectively, whilst both groups were similar in age with no significant difference observed between the two ($P = 0.6$). In our study, we found a slight female predominance, 57% were females and 43% were males. The audiovisual group had 38% males and 62% females pictograph group had 48% males and 52% females, respectively, with no statistically significant difference. In our study, the percentage of graduates was 56% (64% for the pictograph and 48% for the audiovisual group). The percentage of high school graduates was 41% in total (36% for the pictograph group and 46% for the audiovisual group). The percentage of those below high school was 3% in our study. In our study, the mean body mass index (BMI) was 25.78. Amongst subgroups, BMI of 25.44 + 3.05 and 26.02 + 2.33 was seen for pictograph and audiovisual groups, respectively, which was not a statistically significant difference. Table 1 shows baseline demographic features in both groups. Table 2 shows the change in NIH expert panel 3 score pre- and post-intervention values for both groups. Our results showed that when inhaler technique was reinforced either in the form of pictograph (4.28 ± 1.07, 5.26 ± 1.38) or audiovisual clip (3.88 ± 1.12, 6.14 ± 1.13), there was an improvement noted in the performance of inhaler technique (based on number of steps one could follow) as compared to the baseline manoeuvre (live demonstration of inhaler technique in the OPD/inpatient department [IPD] setting). Furthermore, improvement in inhaler technique was noted up to 60% with written instructions and up to 90% post-video demonstration, as shown in Figure 2. No significant difference between the groups at baseline, while both groups showed significant improvement, the audiovisual group was significantly better than the pictograph group. Stepwise details of the pre- and post-performance in both groups are shown in Figure 3. Improvement in inhaler technique can be seen for nearly all steps as identified by NIH. Table 3 shows detailed values of PEFR at the baseline and at the end of 6 weeks after intervention (reinforcement). In the pictograph group, PEFR values pre-intervention were 339 mL, which increased to post-intervention values of 378 mL (mean improvement of 39 mL), whilst in the audiovisual group, the values were 357 mL and 432 mL (mean improvement of 75 mL), respectively. There is no significant difference at the baseline between the groups. Individually, both groups showed significant improvement, and audiovisual showed significantly more improvement than pictograph, as shown in Table 3. The ACT score was measured at the end of 6 weeks of intervention in our study, which showed a value of 20.16 for the pictograph group and for the audiovisual group, the value was 20.94, which showed a significant difference between the groups ($P = 0.018$), as shown in Table 4.

DISCUSSION

Aerosol therapy is the mainstay of therapy for asthma. It requires certain steps which need to be followed according to the device used. Training and reinforcing the inhalational skills are of paramount importance for good disease control. In our study, 100 asthma patients with a mean age of 40 years were recruited. They were randomly divided into the video group and the written group having mean age of 39 years and 40 years, respectively. Akhila *et al.* reported in a study that Asthma is more common amongst individuals of 0–25 years, followed by 26-40 years (33.3%), 41–60 years (21.66%), and 61 and above (5%).[12] Our study excluded the paediatric age group and was carried out in adult OPD/IPD settings. After excluding the paediatric and young adults, the mean age in our study is similar to the mean age of asthma patients in the adult population. We also found a slight female predominance similar to the findings of other studies.[13] Schatz *et al.* conducted a study on 606 paediatric (aged 2–17 years) and 680 adults (aged 18–54 years)

Table 1: Baseline demographic characteristics of patients in pictograph group and audiovisual group.

Baseline	Pictograph group	Audiovisual group	Test value and *P*-value
Mean age (years)±SD	40.56±11.60	39.20±11.19	t=0.6, *P*=0.6
Gender (%)			
Male	19 (38.0)	24 (48.0)	F=0.42, *P*=0.42
Female	31 (62.0)	26 (52.0)	
Education (%)			
Below high school	0 (0.0)	3 (6.0)	CS=4.8, DF=2, *P*=0.48
High school	18 (36.0)	23 (46.0)	
Graduate and above	32 (64.0)	24 (48.0)	
Mean BMI±SD	25.44±3.05	26.02±2.33	t=1.1, *P*=0.3

P: *P*-value, t: t-value, F: F value, CS: Chi-square, DF: Degree of freedom, SD: Standard deviation, BMI: Body mass index

Table 2: Change in NIH expert panel 3 score pre and post-intervention values for written group and video group both.

Steps	Groups	NIH expert panel 3 score baseline mean	NIH expert panel 3 score post-intervention mean	Test value (t) and *P*-value (P)
Step 1	Pictograph	0.92±0.27	0.94±0.24	t=1.0, *P*=0.3
	Audiovisual	0.94±0.24	0.98±0.14	t=1.4, *P*=0.2
	Audiovisual versus Pictograph	t=0.4, *P*=0.7	t=1.0, *P*=0.3	
Step 2	Pictograph	0.54±0.50	0.64±0.49	t=2.3, *P*=0.024
	Audiovisual	0.50±0.51	0.86±0.35	t=4.0, *P*<0.001
	Audiovisual versus Pictograph	t=0.4, *P*=0.7	t=2.6, *P*=0.01	
Step 3	Pictograph	0.86±0.35	0.92±0.27	t=1.8, *P*=0.08
	Audiovisual	0.86±0.3	0.96±0.20	t=2.3, *P*=0.024
	Audiovisual versus Pictograph	t=0.0, *P*=1.0	t=0.8, *P*=0.4	
Step 4	Pictograph	0.46±0.50	0.60±0.50	t=2.8, *P*=0.007
	Audiovisual	0.38±0.49	0.82±0.39	t=4.8, *P*<0.001
	Audiovisual versus Pictograph	t=0.8, *P*=0.4	t=2.5, *P*=0.015	
Step 5	Pictograph	0.30±0.46	0.62±0.49	t=4.8, *P*=0.000
	Audiovisual	0.26±0.44	0.82±0.39	t=7.9, *P*<0.001
	Audiovisual versus Pictograph	t=0.4, *P*=*P* = 0.7	t=2.3, *P*=0.02	
Step 6	Pictograph	0.20±0.40	0.54±0.50	t=4.6, *P*=0.000
	Audiovisual	0.12±0.33	0.76±0.43	t=8.6, *P*<0.001
	Audiovisual versus Pictograph	t=1.1, *P*=0.3	t=2.3, *P*=0.02	
Step 7	Pictograph	1.00±0.00	1.00±0.00	NA
	Audiovisual	0.82±0.50	0.94±0.24	t=2.6, *P*=0.013
	Audiovisual versus pictograph	t=3.3, *P*=0.01	t=1.8, *P*=0.06	
Total	Pictograph	4.28±1.0	5.26±1.38	t=6.2, *P*<0.001
	Audiovisual	3.88±1.12	6.14±1.13	t=11.7, *P*<0.00
	Audiovisual versus pictograph	t=1.8, *P*=0.07	t=3.5, *P*=0.001	

NA: Not applicable, Steps are as per NIH Panel score steps, For *p*-value and t- value, unpaired and paired t tests were used for between groups and before after comparisons respectively.

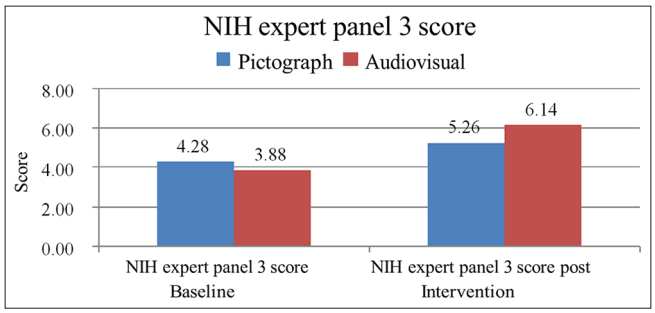

Figure 2: NIH expert panel 3 score pre and post-mean values for both the groups. NIH: National Institutes of Health.

patients with asthma and observed that the sex ratio varied significantly by age, but with female predominance in each category.[14] Suresh *et al.*, in a study done in the south Indian population, showed that the mean BMI was 26.38; similar to our study, the mean BMI is above 25.[15,16]

In our study, percentage of graduates were 56%, high school pass outs were 41%, below high school was 3% which resembles data of other studies, i.e., Luder *et al.* on found that 10.4% were below high school and 89.6% were high school and above,[17] Purohit *et al.* in a study conducted in north Indian population showed that, 69% were below high school and only 31% were educated to high school level or above.[18] Huovinen *et al.* and Eagen *et al.* have shown a protective effect of higher education in the prevalence of asthma and attributed it to the better understanding of the control of the disease. However, there was no significant difference in the baseline educational qualification and socioeconomic status of the groups, which makes the comparison of reinforcement methods possible without any major confounding factors.[13,19,20]

Inhaler therapy plays a pivotal role in the treatment and control of Asthma, stressing the importance of correct and consistent following of inhaler techniques. With errors in inhaler use becoming more frequent over time, repeated training using a standard checklist has been shown to markedly improve technique and reduce mistakes. Several studies have used five to eleven steps to evaluate inhaler techniques and have included

Table 3: PEFR pre and post-intervention mean values for both the groups (pictograph group and audiovisual group).

Groups	Baseline PEFR mean	PEFR post-intervention mean	Between baseline and post-intervention value
Pictograph	339.0±69.82	378.40±77.50	t=11.2, *P*<0.001
Audiovisual	357.40±85.23	432.80±121.17	t=9.5, *P*<0.001
Audiovisual versus pictograph	t=1.2, *P*=0.2	t=2.7, *P*=0.009	

P: *P*-value, t: t-value. PEFR: Peak expiratory flow rate. Unpaired and paired t-tests were used for between groups and before after comparisons respectively.

Table 4: ACT score after intervention in both the groups (Pictograph group and Audiovisual group).

Group	ACT Score after intervention mean	*P*-value
Pictograph	20.16±1.25	t=2.4, *P*=0.018
Audiovisual	20.94±1.93	

ACT: Asthma control test. Unpaired and paired t-tests were used for between groups and before after comparisons respectively.

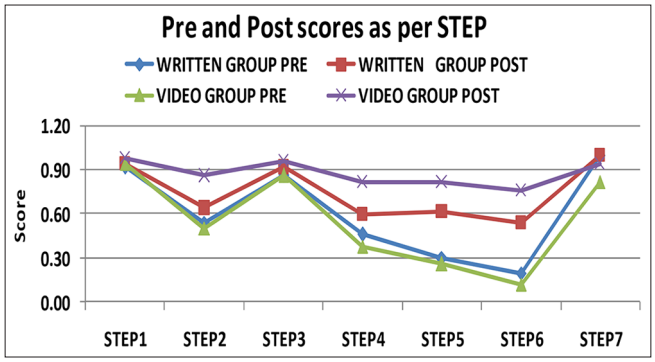

Figure 3: Stepwise analysis of change in score by pictograph (written) vs audiovisual (video) methods of reinforcement. The steps are: Step 1 (Taking off the cap and shaking the inhaler), Step 2 (breathing out all the way), Step 3 (holding the inhaler with the spacer the way instruction was given), Step 4 (pressing the canister and breathing in slowly within 5 s), Step 5 (breathing in slowly and deeply), Step 6 (holding the breath for 10 s and Step 7 (waiting for 1 min between two puffs).

different steps in their checklist. Various methods of educational intervention and reinforcement of inhaler skills have been employed, such as live demonstration, educational video, written pictorial leaflets and multimedia interactive tools.[21] In our study, we chose to allocate written pictorial leaflets and an educational video with similar content, comprising of steps of inhaler usage. Amongst all studies considering improvement showed in steps as the major outcome showed change in inhaler technique improvement was variable from 16 to 90% for different interventions considered in different studies. The highest value was similar to the improvement in steps (90%) shown in the video group of our study. However, the interventions were different in each study, hence a head-to-head comparison does not give a clear edge to any method.[22-25]

Our results showed that when the inhaler technique was reinforced either in the form of a written leaflet or educational video, there was an improvement noted in the performance of the inhaler technique (on the basis of the number of steps one could follow) as compared to the baseline manoeuvre (live demonstration of inhaler technique in the OPD/IPD setting). Furthermore, improvement in inhaler technique was noted up to 60% with written instructions and up to 90% post-video demonstration. Shah and Gupta in Ecuador, in the South American population, conducted a similar study where baseline performance was equivalent in each group, showing that audiovisual training was significantly more effective than the pictograph method (3.6 points vs. 0.4 points change).[26] Poureslami *et al.* in a clinical trial of 91 patients showed that the mean score improvement in inhalational skills was more in the clinical video group (3.9–(6.8) than the written pamphlet group (4.8)–(6.6).[27] Many studies have shown results similar to our study like, Dudvarski Ilic *et al.* showed significant improvement of disease control from visit 1 to visit 2 (53.9% and 74.5%) and from visit 2 to visit 3 (74.5% and 77%) with reinforcement at every visit.[28,29] Our findings were in concordance with the available literature that reinforcement of inhaler technique is a worthwhile intervention to favourably affect the overall asthma management. When the two methods of reinforcement were compared, video was found to be superior to written form. The most plausible reason for video or live demonstration to be superior to written instruction was better retention of the same steps available to the patient at their ease every time they perform the inhaler technique on their own. On the other hand, written instructions are comparatively not easy to memorise and may still warrant assistance in coordinating between the steps mentioned.

The improvement in inhalational techniques is often correlated with measures of clinical improvement, measured as PEFR changes and ACT score. As far as PEFR changes in our study are concerned, individually, both groups showed significant improvement, and the video showed significantly more improvement than the written. Rahmati *et al.* in a randomised trial comprising 90 subjects found out that the intervention groups demonstrated a statistically significant improvement in PEFR immediately following the intervention when compared to the control group ($P = 0.000$). Although the mean increase in PEFR was higher in the spacer group (63 mL) than in the non-spacer group (56 mL), this difference did not reach statistical significance ($P = 0.5$).[23] These findings align with the results reported by Boskabady *et al.*, who observed enhanced bronchodilator response, including increased PEFR, following structured

instruction on correct inhaler technique in patients with asthma.[30] Similarly, Al Amoudi, in a study involving 106 individuals over the age of 13, reported a notable improvement in PEFR after patients received appropriate inhalation technique education.[31] Aforementioned studies showed that improvement in inhalational skills is reflected and correlated with a change in PEFR values.

Al Moamary *et al.* showed that improvement in ACT score is seen with subsequent reinforcements[32] and correlates well with improved inhalational skills and PEFR changes. It can be inferred that a better ACT score is related to better clinical control, which further endorses the view that the video group was superior to the written group.[33] A literature review by Usmani *et al.* (2018) highlighted that a higher frequency of inhaler technique errors is associated with poorer disease outcomes. Consequently, there exists a positive correlation between regular reinforcement of inhaler technique and improved disease control in patients with COPD and asthma.[34] Our study also demonstrated similar results with ACT score showing proper control in both the intervention group, video group score being statistically significantly superior to the written group.

Limitations of this study were that it is a study with a small sample size carried out on an urban, educated population with a good socioeconomic background. Furthermore, only MDI with a spacer was the device included, thereby excluding other inhaler devices such as DPI and MDI alone.

Many studies focusing on mastery of inhaler techniques in one way or the other have shown their positive effect on disease control, and their results go with the recommendations of reinforcing the importance of achieving optimal inhaler technique, from GINA and GOLD guidelines, to reduce exacerbation risk and to improve disease control.[35-38] We hereby recommend that inhaler techniques must be explained well to the patient in detail before prescribing and should be ensured in every follow-up visit.

Reinforcement of inhaler techniques should be weighed with due importance to ensure a good therapeutic outcome. Amongst various methods of reinforcement like an educational video, a written leaflet or serial live demonstration, the Educational video is the method of choice, in view of excellent performance and easy usability, especially with the advent of the era of smartphones (ensuring uniformity and easy availability). With the increasing affordability of smartphones in India and the world, the relevance of the study is increasing day by day. Furthermore, playing videos demonstrating the steps for inhaler usage in the OPD waiting hall of pulmonary medicine could be a useful way for better inhaler compliance and asthma control.

CONCLUSION

This study showed that reinforcement of inhaler usage techniques can help in improvement of inhaler usage skills and ultimately aerosol therapy in asthma patients. Both pictograph and audiovisual clip can bring improvement in inhaler usage skills and consolidate the already acquired skills. However, an audiovisual clip is more effective as a reinforcement technique than a pictograph. Large-scale studies on reinforcement of inhaler skills should be done at multiple centres with varied populations with varied reinforcement methods, to get suitable reinforcement techniques for different healthcare setups. Inhaler devices are associated with lots of advantages, namely a lower dose, better side effect profile, less systemic exposure, but one drawback of the complicated delivery technique. Reinforcement of the inhaler technique, preferably with the help of audiovisual clips, is essential for better inhaler compliance and asthma control.

Ethical approval: The research/study was approved by the Institutional Review Board at Lilavati Hospital and Research Centre, approval number 9/16 dated 18th October 2016, agenda no. 3(a), dated 21st November 2016.
Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.
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Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript, and no images were manipulated using AI.

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