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Effects of Air Purifiers on Patients with Allergic Rhinitis: a Multicenter, Randomized, Double-Blind, and Placebo-Controlled Study

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Purpose: Exposure to particulate matter (PM) is a well-known risk factor in the triggering and exacerbation of allergic airway disease. Indoor environments, where people spend most of their time, are of utmost importance. To assess the effects of air purifiers [equipped with high-efficiency particulate air (HEPA) filters] on allergic rhinitis (AR) in adult patients, we performed a multicenter, randomized, double-blind, and placebo-controlled study.

Materials and Methods: Patients with house dust mite (HDM)-induced AR were randomly assigned to either active or mockup (placebo) air-purification groups. Two air purifiers (placed in living room and bedroom) were operated for 6 weeks in each home environment. The primary study endpoint was to achieve improvement in AR symptoms and medication scores. Secondary endpoints were to achieve improvement in the quality of life (QoL) and visual analog scale (VAS) scores, as well as in the indoor (bedroom and living room) concentrations of $PM_{2.5}$ and PM_{10}.

Results: After 6 weeks of air purifier use, medication scores improved significantly in the active (vs. placebo) group, although subjective measures (symptoms, VAS, and QoL scores) did not differ. Bedroom $PM_{2.5}$ concentrations initially exceeded living room or outdoor levels, but declined (by up to 51.8%) following active purifier operation. Concentrations of $PM_{2.5}$ in living room and PM_{10} in bedroom and living room were also significantly reduced through active purification.

Conclusion: The use of air purifiers with HEPA filters significantly reduced medication requirements for patients with HDM-induced AR and significantly lowered indoor $PM_{2.5}$ concentrations, regardless of room placement. Active intervention to reduce household air pollutants may help improve allergic airway disease (clinicaltrials.gov NCT03313453).

Key Words: Air purifier, allergic rhinitis, house dust mite, indoor pollution, particulate matter

INTRODUCTION

Indoor air pollution is a critical issue, with up to 90% of daily living currently taking place indoors.[1] In this regard, children and elderly adults, often confined to their homes, are especially vulnerable.[2] Indoor air in schools and workplaces can be a factor affecting respiratory health.[3,4] Among known air pollutants, particulate matter (PM) is an acknowledged hazard with diverse effects on human health. Ambient PM exposure may adversely impact various cardiopulmonary conditions, including allergic airway disease.[5,6]

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PM concentrations vary considerably by country and city, based on geopolitical location and socio-economic status. According to the World Health Organization air quality guidelines (WHO AQG), 24-hour concentrations of <50 μg/m^3 for PM ≤10 μm (PM_{10}) and <25 μg/m^3 for PM ≤2.5 μm ($PM_{2.5}$) are recommended (annual mean: PM_{10}, <20 μg/m^3; $PM_{2.5}$, <10 μg/m^3).[7] However, the average annual PM_{10} level in the Seoul metropolitan area, which has climbed steadily since 2012 and now stands at 51.0 μg/m^3, exceeds the WHO AQG limit.[8]

It has been shown that the use of an air purifier equipped with a high-efficiency particulate air (HEPA) filter to reduce indoor air pollution helps control allergic diseases. A number of reports have indicated that air purifiers are beneficial for patients with allergic rhinitis (AR),[9-11] atopic dermatitis,[12] and asthmatic children.[13,14] In addition, air purifiers are credited with removing pollen, fungal spores,[15] house dust-mite (HDM) allergens,[10] and dog allergens.[16]

Previous studies evaluating the efficacy of air purifiers in relieving AR have focused solely on allergen removal, conducted research in lesser polluted countries, or had flawed study design (i.e., too few participants, single-center recruitment, or absence of a control/placebo group). This multicenter, randomized, double-blind, and placebo-controlled study of air purifiers in patients with AR was undertaken in an effort to overcome such limitations.

MATERIALS AND METHODS

Study design and ethical statement

By design, this was a 6-week multicenter, double-blind, and placebo-controlled study conducted at two centers in South Korea: Allergy and Asthma Center of Yonsei University in Seoul and Chonnam National University Medical School in Gwangju (clinicaltrials.gov NCT03313453). Our interventional protocol was approved by the Institutional Review Boards of Yonsei University Health System (Approval no. 4-2017-0588) and Chonnam National University Hospital (Approval no. CNUH-2017-184). The period of purifier operation lasted from late autumn to early winter in South Korea, out of pollen season without indoor heating (from October to November). The study was conducted in all of the enrolled individuals during the same 6-week periods.

Inclusion and exclusion criteria for enrollment

Inclusion criteria were as follows: 1) patients with AR, ages 18–65 years; 2) persistent moderate-to-severe AR sensitized to HDM, with retrospective rhinoconjunctivitis total symptom score (RRCTSS) ≥8; and 3) and written consent of voluntary participants. The severity of rhinitis was determined by RRCTSS during the month prior to the start of the study, based on six parameters: sneezing, rhinorrhea, nasal itchiness, nasal obstruction, ocular itchiness, and watery eyes. Each symptom was scored (0–3 points) as follows: 0, no symptom; 1, mild (mild symptoms/signs of rhinitis, well-controlled); 2, moderate (moderate symptoms/signs, difficult to control and interrupting daily activities or sleep); or 3, severe (severe symptoms/signs, difficult to control and interfering with daily activities or sleep).

The reasons for study exclusion were as follows: 1) seasonal allergies sensitized to tree, grass, or weed pollen; 2) rhinitis due to other causes (vasomotor, infectious, gustatory, or drug induced); 3) substantial and potentially obstructive nasal defects, such as deviated nasal septum; 4) chronic use of systemic corticosteroids (continuous for ≥3 months in the 12 months prior to study); 5) planned move or residential change within study period; 6) current air purifier usage; and 7) exposure to indoor tobacco smoke.

Sensitization profiles were determined by skin-prick test (SPT) and serum specific immunoglobulin E (IgE) test. Inhalant allergens (53 types), including tree, grass, weed pollen, HDMs, animal danders, molds, insects [Allergopharma (Hamburg, Germany) or Hollister-Stier (Spokane, WA, USA)], were tested; as well as controls [negative: normal saline with 0.3% phenol and 50% glycerol; positive: 0.1% histamine (Allergy Therapeutics, West Sussex, UK)]. SPTs were considered positive if wheal diameters at allergen sites were >3 mm on average. AdvanSure AlloScreen (LG Life Sciences, Seoul, South Korea) or ImmunoCAP (Thermo Fisher Scientific, Waltham, MA, USA) assays were peformed to detect specific IgE in serum. Values >0.35 kUA/L were interpreted as positive. Paranasal sinus series or Waters' view x-rays were obtained to delineate nasal defects, and blood eosinophil counts were measured.

A total of 44 patients were randomly assigned to either active purifier (AP, n=22) or mockup (placebo) purifier (MP, n=22) groups. Randomization was 1:1 via computer-generated schedule (in the order registered) and was carried out by a non-participating third party. Results were undisclosed until the end of study period. During the 6-week trial, patients had unrestricted access to medications previously used for rhinitis. Hospital visits were mandatory for all participants before, during, and after air purifier operation.

Air purifiers

Two air purifiers (LG Electronics, Seoul, South Korea) were provided per subject (Supplementary Fig. 1, only online). High-capacity purifier (capacity: 91 m^2) was operated in the living room (AS281DAW, LG Electronics) (Supplementary Fig. 1A, only online), and low-capacity purifier (capacity: 58 m^2) was operated in the bedroom (AS181DAW, LG Electronics) (Supplementary Fig. 1B, only online). The purifier instructor team guided the subjects to the optimal position and orientation to operate the air purifiers. Both machines ran continuously for 24 hours/day without interruption during 6 weeks of research, as confirmed by the LG Electronics study center via remote (Wi-Fi) monitoring. Purifiers of the AP group were equipped

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with HEPA filters (Supplementary Fig. 1C, only online, green-colored cylindrical apparatus), whereas units of MP members were operated without HEPA filters. Attached stickers secured the units, preventing secretive access to HEPA filters, and blinding was maintained until the end of the study. All of the participants were provided with a manual of the operation, precautions, and emergency contact number for error.

Indoor and outdoor air analyses

Indoor $PM_{2.5}$, PM_{10} concentrations was measured by PPD4260B sensor (Shineyei, Kobe, Japan) equipped in the purifiers.[17] Detection limits of the sensor were as follows: PM size, 1.0 μm; range of PM concentrations, 8-999 μg/m^3. Capability of the sensor installed inside the purifiers was also well-correlated with that of Portable Aerosol Spectrometer Model 1.109 (GRIMM, Ainring, Germany, data not shown). For this study, we measured and collected 2.5 μm and 10 μm-sized PM concentrations using the optical particle measurement method.

The status of purifier operation and PM concentrations (living rooms and bedrooms) were sent to LG Electronics in real-time via Wi-Fi network machine mounted inside purifiers. All subjects agreed to wireless internet transmission of household PM concentrations and purifier operational updates to authorized centers. Display areas of all purifiers were blinded before study initiation. As a result, neither participant nor study personnel (medical staffs, clinical coordinator, LG researcher, and statistician) were not aware of the PM levels in their rooms until the end of the study.

Outdoor concentrations of $PM_{2.5}$ and PM_{10} were recorded using the Air Korea monitoring system (https://www.airkorea.or.kr/eng/), a service of the Korean Ministry of Environment and Korea Environment Corporation that publicly disseminates real-time air quality data online. Measurements obtained at observatory stations nearest to the various households were used for analysis. Locations of observatories and home sites are shown in Supplementary Fig. 2 (only online).

Primary and secondary endpoints

Clinical manifestations of AR were monitored at 0, 3, and 6 weeks using questionnaires based on the averages of the prior week. Each patient received a diary outlining questions pertinent to their symptoms, medication use, etc., and was asked to record daily, starting from 1 week before the beginning of purifier operation. All of the subjects were required to bring diaries to each of their three hospital visits.

The primary endpoint of the study was to achieve improvement of AR symptoms and medication scores. Four nasal symptoms (itchy nose, sneezing, runny nose, and blocked nose) were scored using a 4-point scale ranging from 0 (no symptom) to 3 (severe symptoms, interfering with daily activities or sleeping). Daily average medication scores were also based on a 3-point-scale: 1 (oral or topical antihistamine use); 2 (intranasal corticosteroid use, with or without anti-histamine); and 3 (oral corticosteroid use, with or without intra-nasal corticosteroid or anti-histamine).[18] Secondary endpoints were improvement in the quality of life (QoL) questionnaire scores (administered in Korean language);[19] visual analog scale (VAS) scores (0 to 10, larger numbers indicating more severe symptoms); and indoor PM concentration ($PM_{2.5}$ and PM_{10}), PM_{10} signifying coarse particles (2.5–10 μm) and $PM_{2.5}$ representing fine particulates (<2.5 μm).

Statistical analysis

Sample size was calculated using PASS v12 (NCSS LLC, Kaysville, UT, USA). A sample size of 22 for each of the two groups (1:1 allocation, 5% expected drop-out rate) was determined to achieve an 80% power, assuming a change in total nasal symptom score of 2.5 (as in a previous study),[9] standard deviations of 2.3 (group 1) and 1.4 (group 2), a significance level (alpha) of 0.050, and the use of a two-sided two-sample unequal-variance t-test. For group comparisons, SPSS Statistics v23.0 for Windows (IBM Corp., Armonk, NY, USA) and SAS v9.4 (SAS Inc., Cary, NC, USA) were used. For continuous data, t-test and Mann-Whitney U-test were applied for variables following normal and non-normal distributions, respectively. Chi-squared test or Fisher's exact test was used for categorical

Table 1. Characteristics of Study Population by Assigned Group

Variables	Mockup purifier (n=22)	Active purifier (n=22)	*p* value
Age (yr)	35.68±10.55	33.27±8.91	0.418
Sex (male:female)	6:16	9:13	0.340
Diagnosis			
Allergic rhinitis	22 (100)	22 (100)	-
Asthma	11 (50)	12 (54.6)	0.763
Allergic conjunctivitis	7 (31.8)	7 (31.8)	>0.999
Atopic dermatitis	5 (22.7)	3 (13.7)	0.698
Rhinoconjunctivitis symptom score	10 (9–12)	9 (8–11)	0.205
Allergy testing			
Total IgE (kU/L)	162.75 (63.3–457)	308 (157–524)	0.242
Blood eosinophils (cells/μL)	205 (100–460)	245 (170–400)	0.981
Wheal size to Dp (mm)	8.91±4.73	8.77±4.39	0.922
Specific IgE for Dp (kU_A/L)	7.93 (1.58–10.20)	10.5 (3.83–24.50)	0.153
Indoor furry animals	7 (31.8)	5 (22.7)	0.498
Scoring of allergic rhinitis			
Symptom score	6.8±2.1	6.8±2.5	>0.999
Medication score	1 (0.1–2.0)	0.8 (0.0–1.0)	0.223
Visual analog scale	5.5 (4.2–6.9)	5.6 (4.5–6.8)	0.672
Quality of life	70.8±13.5	69±17.7	0.711

IgE, immunoglobulin E; Dp, dermatophagoides pteronyssinus.
Continuous data are expressed as mean±standard deviation or median (interquartile range, 25 and 75 percentiles of data); categorical data are expressed as number (%). T-test was used for age and specific IgE for Dp; other continuous variables were compared via Mann-Whitney U-test. Chi-squared test was used for categorical data, except atopic dermatitis (Fisher's exact test).

data. Differing concentrations of PM were analyzed by place and group via linear mixed model. Outdoor and indoor PM levels were subjected to Pearson correlation analysis. Significance was set at $p<0.05$.

RESULTS

Population characteristics

Characteristics of the study population are shown in Table 1. No significant group-wise differences were observed. One MP group member dropped out of the study due to personal reasons, but the two groups did not differ in intention-to-treat or per-protocol analysis.

Indoor (bedroom/living room) and outdoor environments

During the study period, the average bedroom $PM_{2.5}$ concentration was 27.2±4.4 μg/m^3 (mean±standard deviation), which exceeded the WHO AQG limit. In living rooms, $PM_{2.5}$ concentration averaged 15.5±2.1 μg/m^3 (Fig. 1A). Therefore, the bedroom $PM_{2.5}$ level was 1.8 times higher than that of the living room ($p<0.001$), surpassing the outdoor average (23.5±4.8 μg/m^3) as well. The mean bedroom PM_{10} concentration was 33.4±5.6 μg/m^3, which was also higher than the living room level (18.1±2.5 μg/m^3; $p<0.001$) (Fig. 1B). During this study, the outdoor PM_{10} concentration was 42.0±7.2 μg/m^3 on average. The correlation between outdoor and indoor (bedroom and living room) levels is shown in Supplementary Table 1 (only online). Outdoor PM levels correlated better with determinations of the living room than with those of the bedroom.

Improvement in indoor PM concentration after air purifier operation

Amelioration of bedroom PM levels after air purifier operation is shown in Fig. 2. Average $PM_{2.5}$ concentration was reduced by 51.8% (from 27.2±4.4 μg/m^3 to 13.1±2.0 μg/m^3; $p=0.045$) (Fig. 2A). PM_{10} concentration also declined by 53.2% on average (from 33.4±5.6 μg/m^3 to15.6±2.5 μg/m^3; $p=0.048$) (Fig. 2B). Living room PM concentrations determined after air purifier operation are shown in Fig. 3. The mean $PM_{2.5}$ level fell by 30.5% (from 15.5±2.1 μg/m^3 to 10.7±2.5 μg/m^3; $p=0.026$) (Fig. 3A), and PM_{10} concentration showed 30.7% improvement (from 18.1±2.5 μg/m^3 to 12.5±3.2 μg/m^3; $p=0.035$) (Fig. 3B). The

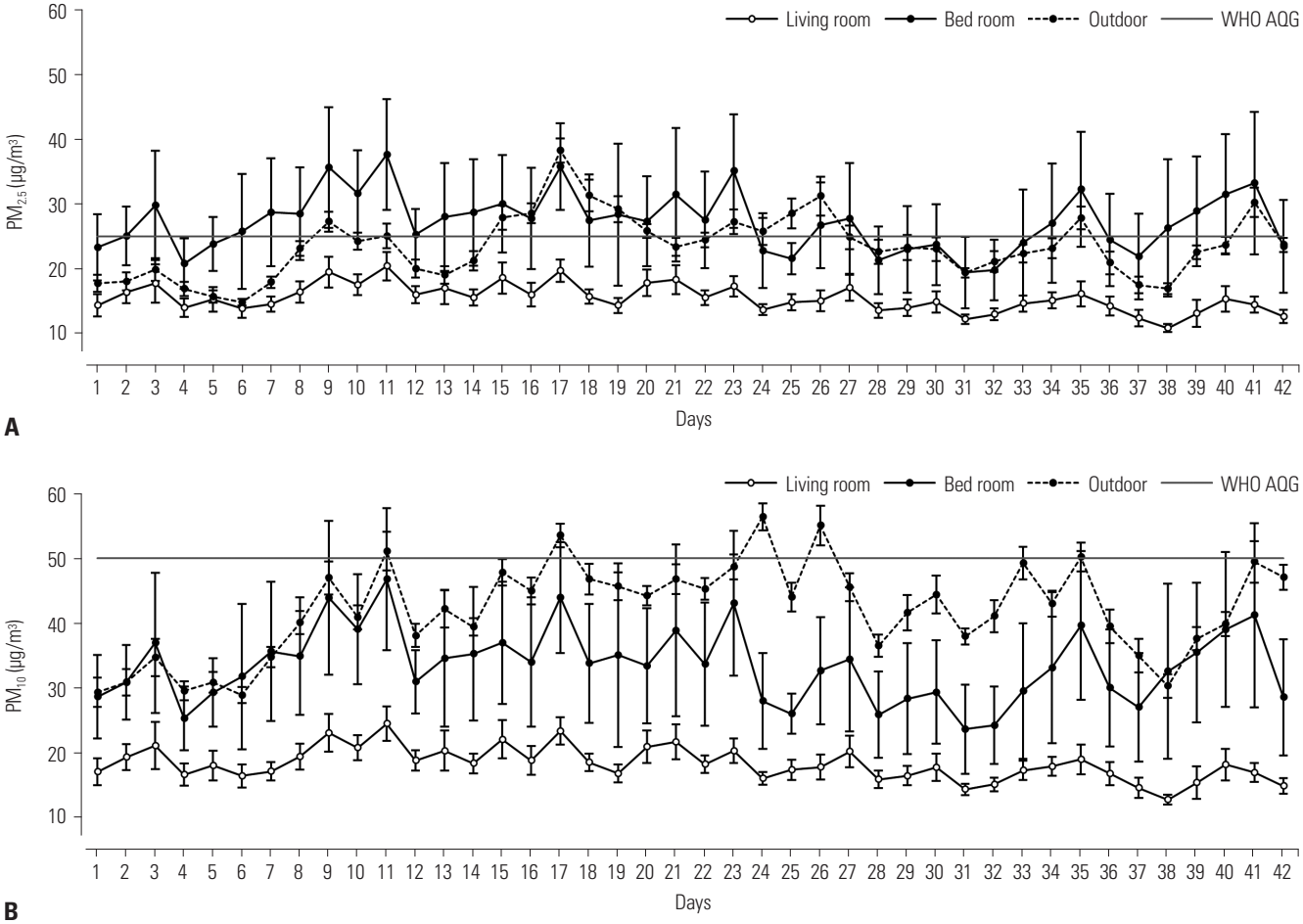

Fig. 1. Outdoor and indoor concentrations of $PM_{2.5}$ (A) and PM_{10} (B) during study period. PM, particulate matter; WHO AQG, World Health Organization air quality guideline.

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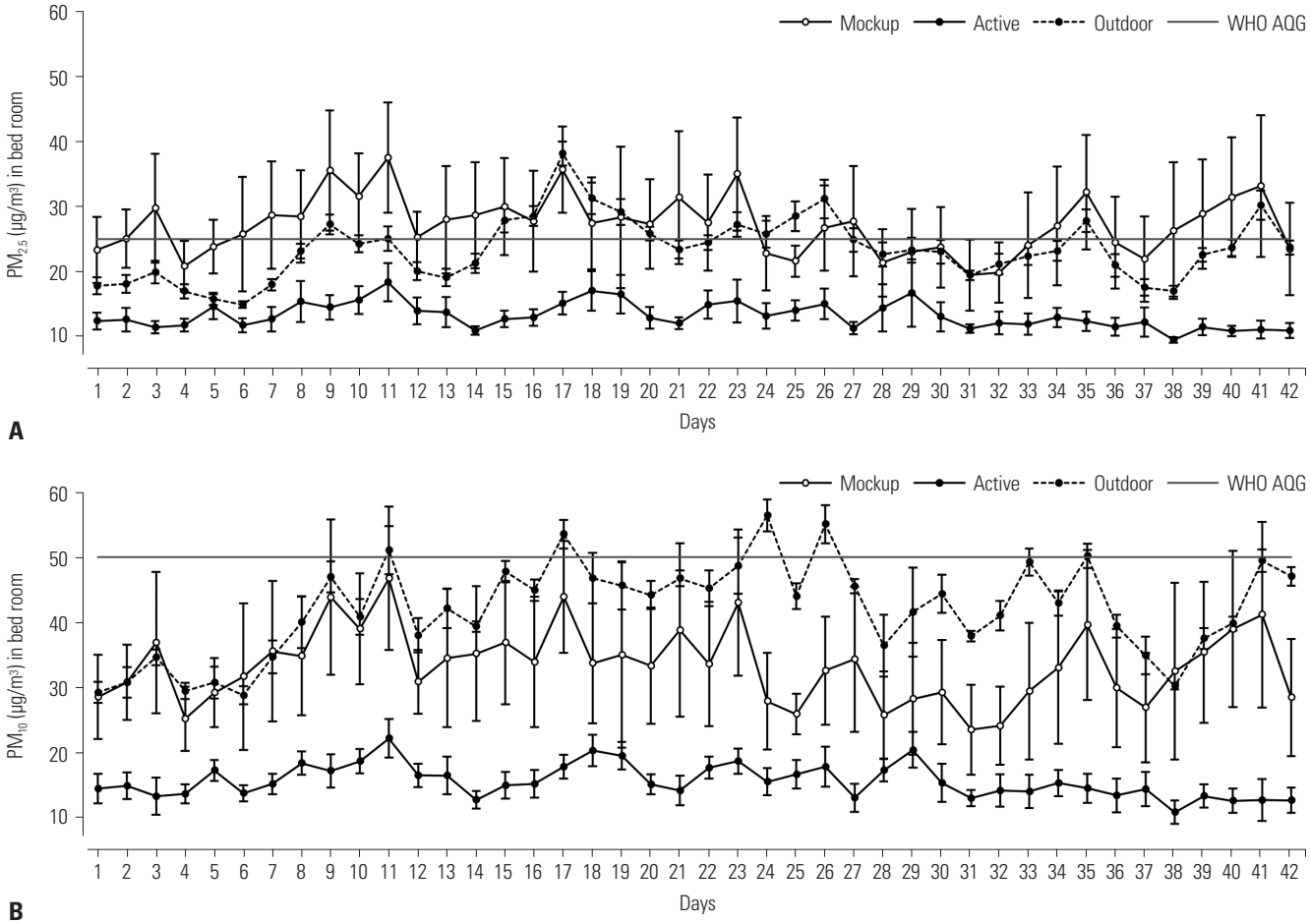

Fig. 2. Changes in bedroom $PM_{2.5}$ (A) and PM_{10} (B) concentrations after air purifier operation. PM, particulate matter; WHO AQG, World Health Organization air quality guideline.

number of days at levels beyond the WHO AQG limits was significantly lower after air purifier operation, especially in terms of bedroom $PM_{2.5}$ concentrations (Table 2). Since this study involved two South Korean cities that were 167.8 miles (270 km) apart, we also checked for city-wide differences in air quality before and after operating the air purifiers. However, we found no difference between the two cities.

In addition to average PM concentrations, the exposure times to high concentrations of PM were significantly reduced after air purifier use. Due to various indoor activities, the concentration of fine dust was expected to surge and then diminish gradually (Fig. 4A, MP group depiction). However, PM levels declined rapidly under such circumstances in AP (vs. MP) households. (Fig. 4B, AP group depiction). When calculated, the time required for $PM_{2.5}$ concentration in bedrooms to fall from >150 μg/m³ to <25 μg/m³ (WHO threshold) was reduced by 38.1% (from 249.3±209.0 min to 153.6±187.9 min; p<0.001) (Fig. 4C).

Table 2. Comparison of the Number of Days Exceeding WHO AQG Standards by Group

	Mockup purifier (total of 924 days*)	Active purifier (total of 924 days*)	*p* value†
Bed room			
$PM_{2.5}$ (>25 μg/m³)	239 (25.9)	58 (6.3)	<0.001
PM_{10} (>50 μg/m³)	94 (10.2)	18 (2.0)	<0.001
Living room			
$PM_{2.5}$ (>25 μg/m³)	72 (7.8)	22 (2.4)	<0.001
PM_{10} (>50 μg/m³)	8 (0.9)	14 (1.5)	0.200

PM, particulate matter; WHO AQG, World Health Organization air quality guideline.
*Total days: 22 sites (per group)×42 days (air purifier operation period), †*p*-value was calculated by chi-square test.

Improvement in allergic rhinitis after operation of air purifiers

Subjective measures of AR, such as symptoms, VAS, and QoL scores improved similarly in both AP and MP groups (Fig. 5A, C, and D), but objective medication scoring showed significantly greater improvement in the AP group at 6 weeks, compared with placebo (Fig. 5B). AP group members registered a 26.3% reduction in AR medication use at 6 weeks (p=0.033). These differences emerged in the third week of air purifier operation and persisted until the end of the study. In addition, AP

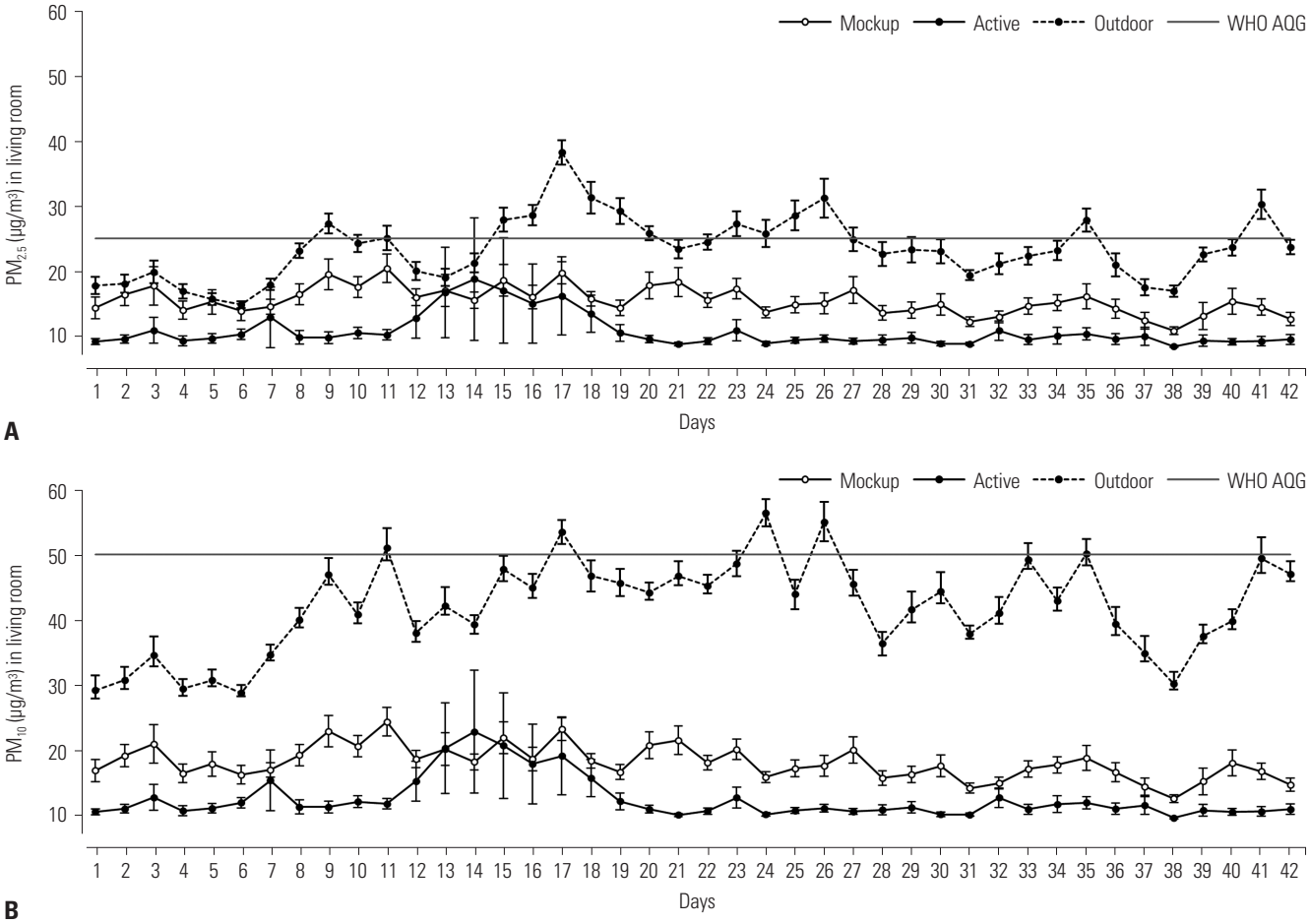

Fig. 3. Changes in living room $PM_{2.5}$ (A) and PM_{10} (B) concentrations after air purifier operation. PM, particulate matter; WHO AQG, World Health Organization air quality guideline.

group members were using 1.26 times the AR medications used by the MP group at study onset. After 6 weeks of use, this figure was reduced to 0.67 times (p=0.033).

DISCUSSION

The results of this intricately designed study clearly demonstrate that air purifiers are beneficial for adults with persistent AR, underscoring the importance of indoor air pollution as a critical environmental issue. Despite apparent placebo effect reflected in subjective measures, we nevertheless confirmed objective gains in AR medication scores for users of active air purifiers, as opposed to mockup devices. Therefore, managing indoor pollutants on an individual basis may have merit in AR patients.

There are several explanations for the reduction of medication scores observed in this study. Air purifiers effectively reduce the levels of PM, a well-known risk factor in patients with allergic airway disease linked to indoor allergen exposure. Levels of household PM are attributable to outdoor PM, cooking fumes, cigarette smoking, microorganisms, and other sources such as HDM allergens.[20] Patient's exposure times to high concentrations of PM are also significantly reduced by air purifier use; and $PM_{2.5}$ concentrations, which may be especially noxious to patients with allergic airway disease, are effectively reduced by air purification. It has been established that small-caliber PM poses a comparatively greater health hazard. In one previous study, an increased hospitalization rate due to respiratory diseases correlated more closely with $PM_{2.5}$ than PM_{10} levels.[2] Most of the studies heretofore in PM over airway allergy have been conducted in asthma,[21,22] and the current study has the value to shed some light in the specific field of AR.

The difference we encountered in PM concentrations of bedroom and living room spaces was an unexpected finding, and may constitute a relative breakthrough in indoor air pollution management. Prior to this study, it was assumed that PM concentration in the living room (i.e., the gathering place and center of daily family activities) would exceed levels in more static bedroom environments. Moreover, the living room is closer to the kitchen, where cooking activity inordinately adds to the PM load. However, the opposite phenomenon was observed in this study. The higher levels of PM (both $PM_{2.5}$ and PM_{10}) in bedrooms compared to living room in this study may

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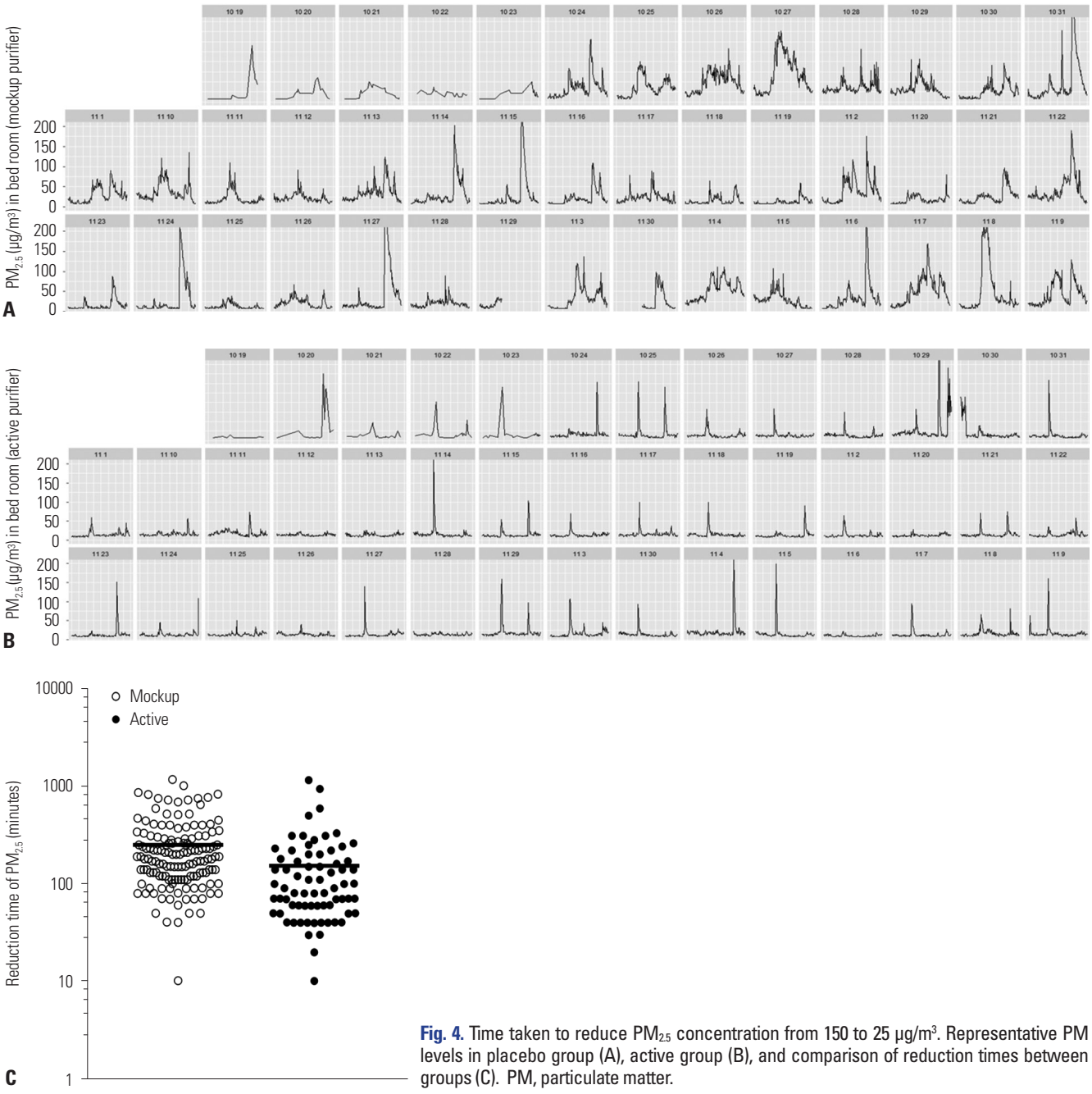

Fig. 4. Time taken to reduce $PM_{2.5}$ concentration from 150 to 25 μg/m³. Representative PM levels in placebo group (A), active group (B), and comparison of reduction times between groups (C). PM, particulate matter.

be explained by the effect of ventilation rate, which is typically lower than the standard setting.[23] Although differing bedroom and living room ventilation rates were not fully investigated, a lower ventilation rate may be anticipated in the bedroom by comparison. An alarming fact is that similar conditions may exist in nursing homes, hospitals, or nurseries, rendering disadvantaged, marginalized, or inactive occupants more vulnerable to this type of indoor pollution. Further studies are needed to gather more related evidence. However, this premise is untenable if outdoor air is unexpectedly tainted by forest fires, dust storms, or seasonal pollen peaks.

Our data may also be applicable to other health conditions associated with PM, which presumably would benefit from the reductions achieved through air purification. PM is a reported risk factor in asthma hospitalizations,[6] cardiovascular disease/mortality,[24] pediatric atopic dermatitis,[25] emergency room visits,[26] and lung cancer.[27] Long-term exposure to PM is reportedly associated with mortality rates.[28,29] Likewise, various circulating inflammatory and thrombogenic indices,[5] as well as stress hormone levels, have shown improvement in healthy patients after air purifier operation.[30]

Ultimately, this study had some limitations. First, the outdoor air of each home was not tested, and we relied instead on monitoring stations. However, the linear distance between

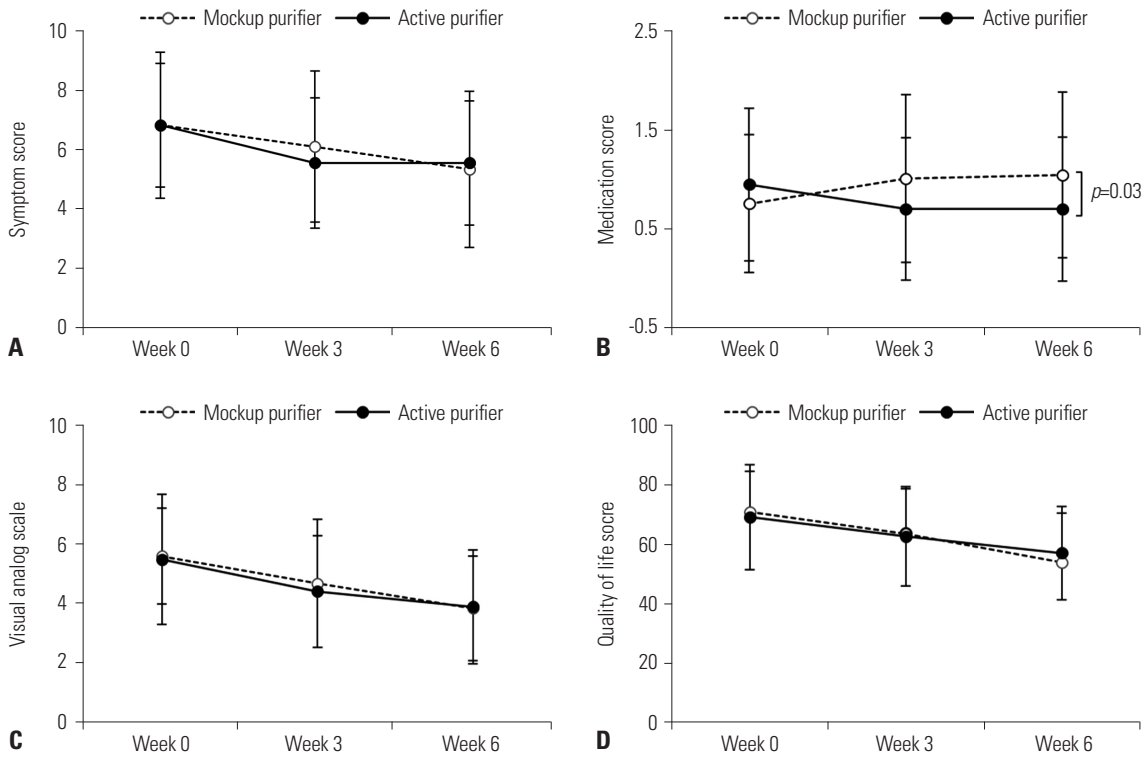

Fig. 5. Changes in symptoms (A), medication use (B), visual analog scale (C), and quality of life scores (D) of allergic rhinitis after air purifier operation. Values are expressed as mean±standard deviation.

observatory and residence locations (1.2 miles/1.9 kilometers on average) seemed acceptable for extrapolation. Another issue is that the lifestyles (i.e., in-home exposure times, proportionate bedroom/living room indoor occupancy, or cooking patterns and time spent in kitchens) of participants were not considered. Furthermore, we did not compare household indoor allergen levels. An attempt at monitoring HDM allergens using the Petri dish method[31] was unproductive. Therefore, it was impossible to determine whether AR medication scores improved due to lower allergen concentrations, PM concentrations, or both. Although allergic biomarkers were not measured in our study, further research about either nasal or serum biomarker changes will help to support out findings. Finally, we could not check the efficacy of purifiers in reducing the PM of smokers, as exposure to indoor smokers disqualified study candidates.

In conclusion, the findings in this study confirm that the use of air purifiers with HEPA filters may mitigate medication requirements for patients with HDM-induced AR. We also determined that interventional air purification significantly lowered indoor $PM_{2.5}$ and PM_{10} levels, regardless of room location, ensuring an overall healthier environment.

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AUTHOR CONTRIBUTIONS

Conceptualization: Jung-Won Park and Kyung Hee Park. Data curation: Kyung Hee Park, Da Woon Sim, Sang Chul Lee, Sunyoung Moon, Eunju Choe, Sung Ryeol Kim, and Jae-Hyun Lee. Formal analysis: Kyung Hee Park and Hyejung Shin. Funding acquisition: Jung-Won Park, Hyung Ho Park, and Deok Huh. Investigation: Jung-Won Park and Kyung Hee Park. Methodology: Hyejung Shin. Project administration: Jung-Won Park and Kyung Hee Park. Resources: Jung-Won Park, Hyung Ho Park, and Deok Huh. Software: Hyejung Shin and Sunyoung Moon. Supervision: Jung-Won Park. Validation: Jung-Won Park. Visualization: Kyung Hee Park. Writing—original draft: Kyung Hee Park. Writing—review & editing: Jung-Won Park. Approval of final manuscript: all authors.

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