


## ORIGINAL ARTICLE

# Rinsing of oropharynx and storage place of respiratory medicine inhaler: A cross-sectional audit

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## Abstract

**Background:** In patients with bronchial asthma and those with chronic obstructive pulmonary disease (COPD), inhalation therapy and rinsing of the mouth and the oropharynx by gargling ("RMOG") after inhalation are recommended. We performed a cross-sectional audit aimed at investigating (a) the proportion of patients performing "RMOG" after inhalation and (b) storage place of patients' inhaler.

**Methods:** Patients with bronchial asthma and those with COPD were asked by medical aids at outpatient visits whether they did "RMOG every time," "RMOG sometimes," or "no RMOG" after inhalation, and where they stored their inhaler.

**Results:** During a six month study period up to September 2017, 330 consecutive patients with asthma and those with COPD were included in the study. Two hundred and thirty-two (70.3%) of the 330 patients answered "RMOG every time" and 98 (29.7%) of them did "RMOG sometimes" and did "no RMOG." There was a difference in the proportion of patients performing RMOG after inhalation with patient age. With regard to the storage location of inhaler, we found the proportion of patients performing RMOG was higher in those who stored inhalers in a room with running water than in those who stored inhalers at other places. This difference was found in patients with both bronchial asthma and those with COPD.

**Conclusions:** Further implementation of "patient education" on performing RMOG after inhalation for patients receiving inhaled medication is still necessary. Our results suggest that it is better to store inhalers in places where there is easy access to tap water used for RMOG.

## KEYWORDS

allergy, bronchial asthma, chronic obstructive respiratory disease, rinsing of oropharynx, storage place of inhaler

## 1 | INTRODUCTION

At present, inhaled corticosteroid (ICS), long-acting beta-agonist (LABA), combination of ICS and LABA (ICS/LABA), long-acting muscarinic antagonist (LAMA), and combination of LAMA and LABA (LAMA/LABA) are the most common drugs for bronchial asthma and chronic obstructive pulmonary disease (COPD).<sup>1</sup> It is well known that ICS may cause local adverse events (AEs), such as oropharyngeal candidiasis and hoarseness of the voice.<sup>2,3</sup> Inhaled beta-adrenergic stimulation may increase heart rate and the potential for cardiac arrhythmias.<sup>4,5</sup> As rinsing of the mouth and the oropharynx by gargling (RMOG) after inhalation is effective for prevention of local adverse effects, such as hoarseness and oropharyngeal candidiasis, RMOG is recommended to remove inhaled drugs, such as ICS, deposited on the oropharyngeal mucosa.<sup>6</sup> In addition, dry mouth is one of the treatment-related AEs in patients treated with inhaled LAMA, although the incidence is low.<sup>7-9</sup> There is no rationale for RMOG after inhalation of LAMAs. It is not necessary to recommend RMOG for all patients inhaling only LAMA. However, some patients who inhaled LAMA alone require ICS or LABA during their clinical courses. If side effects occur, a considerable number of patients will refuse taking inhaled medicine. Therefore, in Japan, physicians in several hospitals recommend uniformly performing RMOG to all patients after inhalation,<sup>10-12</sup> and some package inserts of LAMAs contain RMOG recommendations.<sup>13,14</sup>

Asthma and COPD are both highly prevalent conditions that can coexist in the same individual.<sup>15</sup> COPD guidelines suggest using ICSs in patients with severe airflow limitation or those at high risk of exacerbations.<sup>16</sup> It is not clear whether it is necessary for LAMA, and the package labeling of LAMAs does not recommend gargling. Although there is no recommendation for gargling with LAMA inhalation, ICS and ICS/LABA can be prescribed, not only for patients with asthma, but also for those with COPD. If it is evaluated that there is a coexisting asthma condition in patients with COPD, inhaled medicines, including ICS, will be prescribed. In addition, it is possible that triple inhaled combination of LAMA, ICS, and LABA will be administered in patients with asthma and those with COPD. Therefore, it is realistic to instruct "carry out gargling after medicine inhalation" rather than instructing separately whether to perform gargling or not depending on a difference in disease or drugs. In this study, patient behavior was evaluated from the viewpoint that it is desirable to gargle after inhalation.

In clinical practice, there has been no report that examined the proportion of patients performing RMOG while considering the storage location of the inhaler. To clarify the proportion of patients performing RMOG after inhalation in clinical practice, we performed a survey at three tertiary hospitals in Japan. In addition to this, we investigated where the inhaler was stored, and whether there was relationship between storage location and if patients were performing the RMOG. The findings of this study may provide useful information to mitigate the local AEs of inhaled medications.

**TABLE 1** Characteristics of 330 patients with bronchial asthma and those with chronic obstructive pulmonary disease

Age (y)	Median: 72, range: 26-95
Gender	
Male : female	215 (65.2%):115 (34.8%)
Pulmonary disease	
Bronchial asthma: COPD	222 (67.3%):108 (32.7%)
Detailed inhaler drugs	
ICS	22 (22 patients with BA)
ICS/LABA	153 (145 patients with BA, eight patients with COPD)
ICS/LABA+LAMA	60 (50 patients with BA, 10 patients with COPD)
SABA	1 (one patient with BA)
LABA	1 (one patient with COPD)
LAMA	30 (four patients with BA, 26 patients with COPD)
LAMA/LABA	63 (63 patients with COPD)
RMOG	
RMOG every time	232 (70.3%)
RMOG sometimes, No RMOG	33 (10.0%), 65 (19.7%)
Storage place of inhaler	
Living room	152 (46.1%)
Room with running water	127 (38.5%)
Bedroom	26 (7.9%)
Other places	25 (7.5%)
RMOG and storage place of inhaler	
Room with running water	
RMOG every time	109 (85.8%)
RMOG sometimes and no RMOG	18 (14.2%)
Other places than a room with running water	
RMOG every time	123 (60.6%)
RMOG sometimes and no RMOG	80 (39.4%)

COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; ICS/LABA, combination of ICS and LABA; LABA, long-acting beta-agonist; LAMA, long-acting muscarinic antagonist; LAMA/LABA, combination of LAMA and LABA; RMOG, rinsing of the mouth and the oropharynx by gargling; SABA, short-acting beta-agonist.

## 2 | MATERIALS AND METHODS

### 2.1 | Patients and methods

This was a cross-sectional audit was conducted at three hospitals (Mito Medical Center, University of Tsukuba-Mito Kyodo General Hospital, Hitachinaka General Hospital, and Ryugasaki Saiseikai Hospital) between April 2016 and September 2017.

In order to avoid "interviewer bias" and "following bias",<sup>17</sup> interviews of patients were not performed by attending chest physician in charge of treatment, but rather by medical aids without a conflict of interest with patients to be interviewed. At outpatient visit,

patients were asked two questions: (a) whether they did “RMOG every time,” “RMOG sometimes,” or “no RMOG” after inhalation, and (b) where they stored their inhaler. As far as possible to avoid speculation during the interview of each patient, we did not specify details such as water or mouthwash, the number of gargles, or time of gargling. Eligible patients were those with bronchial asthma or those with COPD more than 20 years old, treated with inhalers with ICS, ICS/LABA, LAMA, ICS/LABA+LAMA, and LAMA/LABA for more than three months.

## 2.2 | Ethics committee approval

All enrolled patients provided written informed consent. This study was approved by the Hospital's Ethics Committee of Mito Medical Center, University of Tsukuba-Mito Kyodo General Hospital (NO 16-39).

## 2.3 | Statistical analysis

Differences between the distributions of subpopulations between each group were analyzed using chi-square test. All statistical analyses were performed using SPSS 10.1 for Windows, and  $P < 0.05$  was considered a statistically significant result.

# 3 | RESULTS

## 3.1 | The patient cohort

During the study period, all the consecutive 330 patients with bronchial asthma or COPD, who agreed with the participation in this study, were included. The patient characteristics are shown in Table 1. Two hundred and fifteen were male and 115 were female. The median age was 72 years (range, 26-95 years). Two hundred

and twenty-two patients had bronchial asthma and 108 had COPD. Twenty-two patients had ICS, 153 had ICS/LABA, 60 had ICS/LABA + LAMA, 29 had LAMA, and 63 had LAMA/LABA.

Of 330 patients, 232 (70.3%) patients performed “RMOG every time,” 10.0% performed “RMOG sometimes,” and 19.7% performed “no RMOG.” The proportion of “RMOG every time” was 82.0% in patients with bronchial asthma and 46.3% in patients with COPD. The proportion of “RMOG every time” in female patients (85.2%, 98 of 115 patients) was higher than that of male patients (62.3%, 134 of 215 patients;  $P = 0.0001$ ). But the proportion of “RMOG every time” in patients over 75 years of age (68.9%, 91 of 132 patients) was not different to those under 75 years of age. (71.2%, 141 of 198 patients;  $P = 0.713$ ). The proportion of “RMOG every time” in patients treated with ICS-containing inhalation (83.0%, 195 of 235 patients) was higher than in those treated without ICS-containing inhalation (38.9%, 37 of 95 patients;  $P = 0.0001$ ).

Table 2 shows a comparison of clinical information between 232 patients who answered they did “RMOG every time” and 98 patients who answered “RMOG sometimes” or “no RMOG.” The proportion of “RMOG every time” was higher in patients with bronchial asthma, female gender, patients treated with ICS-containing inhalation, and patients treated with LAMA and other drug-containing inhalation. In addition, the proportion of “RMOG every time” was higher in patients who stored inhaler in a room with running water such as kitchen or bathroom than in patients who stored inhalers in a room with running water such as kitchen or bathroom.

Table 3 shows a comparison of clinical information between 222 patients with bronchial asthma and 108 patients with COPD. The proportion of “RMOG every time” was higher in female gender, patients treated with ICS-containing inhalation, and patients treated with LAMA and other drug-containing inhalation. There was no difference in the inhaler storage place in patients with bronchial asthma and those with COPD.

**TABLE 2** Comparison between 232 patients who answered they did “RMOG every time” and 98 patients who answered they did “RMOG sometimes” or “no RMOG”

	Number of patients who answered they did		P-value
	“RMOG every time”	“RMOG sometimes” or “no RMOG”	
Age (median, range), (y)	73, 26-93	71, 41-95	0.4046
Gender, M/F	134/98	81/17	0.0001
Diagnosis			
Asthma/COPD	182/50	40/58	0.0001
ICS-containing drugs			
Included/not included	195/37	40/58	0.0163
LAMA			
LAMA only/LAMA and other drugs	8/224	21/77	0.0001
Storage place			
Room with running water/other places	109/123	18/80	0.0001

COPD, chronic obstructive pulmonary disease, ICS, inhaled corticosteroid, LAMA, long-acting muscarinic antagonist, RMOG rinsing of the mouth and the oropharynx by gargling.

Table 4 shows the proportion of “RMOG every time” and “RMOG sometimes” or “no RMOG” in 222 patients with bronchial asthma. The proportion of “RMOG every time” was higher in female gender and patients treated with ICS-containing inhalation, respectively. There was a significant difference in the inhaler storage place in these patients.

Table 5 shows the proportion of “RMOG every time” and “RMOG sometimes” or “no RMOG” in 108 patients with COPD. “RMOG every time” was higher in patients treated with ICS-containing inhalation, and patients treated with LAMA and other drug-containing inhalation, respectively. There was a significant difference in the inhaler storage place in these patients.

## 4 | DISCUSSION

In the present study, we investigated (a) the proportion of performing “RMOG” after inhalation and (b) the storage place of patients’ inhalers. Herein, we show four interesting findings. First, the proportion of patients who answered they “always did RMOG” was 70.3%. Ten percent and 19.7% of them answered they performed “RMOG sometimes” and did “no RMOG,” respectively. Second, the proportion of “RMOG every time” was more than two-thirds of patients with bronchial asthma, but less than half of patients with COPD. For both diseases, the proportion of patients with “RMOG every time” was higher in those treated with ICS including inhalation than that in those treated without ICS including inhalation. Third, the proportion of “RMOG every time” was significantly higher in female patients

than that of male patients in both diseases. But age of the patients had nothing to do with performing “RMOG in both diseases.” Fourth, with regard to the storage location of inhaler, we found that performing “RMOG” was higher in patients who stored inhalers in a room with running water such as kitchen or bathroom than in patients who stored inhalers at other places. This difference was also found in both patients with bronchial asthma and those with COPD.

Local adverse effects, such as hoarseness and dry mouth associated with inhalation therapy or bronchial asthma and COPD, have been attributed to the deposition of drugs in the oropharynx during administration.<sup>18–20</sup> Hira et al<sup>21</sup> reported the relationship between salivary secretion and hoarseness in 232 patients with bronchial asthma and COPD. According to their study, hoarseness was negatively correlated with the volume of saliva secreted and the dose of ICS administered.<sup>21</sup> Ruffin et al<sup>22</sup> reported that 56% of the emitted aerosol dose was deposited in the oropharynx, and this might persist in situ for up to 3 hours, and that a prompt mouthwash could remove 60% of this residue from the oropharynx. There were two previous studies on local adverse effects caused by inhaled drugs.<sup>23,24</sup> In a study by Kajiwarra et al<sup>23</sup> with 892 patients with bronchial asthma, the absence of RMOG after ICS was associated with topical adverse symptoms. They reported that the absence of gargling or mouth washing was identified to be a risk factor in females only and not in males, when stratified by gender in the multiple regression model.<sup>23</sup> In a study with 6740 patients with bronchial asthma and COPD, Malimard et al<sup>24</sup> reported the high prevalence of oropharyngeal adverse effects and the association of adherence with ICS in patients with COPD, especially in relatively new ICS users. In our present study, there was no difference in the incidence of local adverse effects between two diseases, and the incidence was higher in males than females. In the article by Kajiwarra et al, the majority of subjects were female, but only 34.8% were female patients in our study. In the article by Malimard et al, ICS was administered to all patients, but 18 of 108 COPD patients were received ICS including inhalation in our study. The causes of the differences are beyond our knowledge, but we suppose that they might be related to these backgrounds of the study subjects. Taking their results into consideration, in order to lower the frequency of local adverse effects, it can be necessary to start guidance of RMOG at the time of starting ICS inhalation therapy for COPD patients. Alternatively, as COPD patients may inhale drugs containing ICS, so it may be desirable for them to start guidance of RMOG at the time of starting inhalation therapy regardless of the type of inhaled drugs.

In our study, the proportion of patients who answered they always did RMOG was 70.3%, which was higher than the results of the previous study with a smaller number of 19 patients who used ICS.<sup>25</sup> Recent patient education may be related to improving the proportion of performing RMOG. However, our results of the proportion of performing “RMOG” after inhalation were not satisfactory, and indicated that further implementation of “patient education” on performing RMOG after inhalation for patients receiving inhaled medication is necessary.

In the present study, we also showed that performing “RMOG” was higher in patients who stored inhalers in a room with running

**TABLE 3** Comparison between 222 patients with bronchial asthma and 108 patients with chronic obstructive pulmonary disease (COPD)

	Bronchial asthma	COPD	P-value
Age (median, range), (y)	71, 26–95	73, 41–89	0.0194
Gender, M/F	117/105	98/10	0.0001
Diagnosis			
Asthma/COPD	182/50	40/58	0.0001
ICS-containing drugs			
Included/not included	180/2	18/90	0.0001
LAMA			
LAMA only/LAMA and other drugs	2/180	25/83	0.0001
RMOG			
Every time/sometimes or no	182/40	50/58	0.0001
Storage place			
Room with running water/other places	89/133	38/70	0.4017

COPD, chronic obstructive pulmonary disease, ICS, inhaled corticosteroid, LAMA, long-acting muscarinic antagonist, RMOG, rinsing of the mouth and the oropharynx by gargling.

**TABLE 4** Proportion of “RMOG every time” and “RMOG sometimes” or “no RMOG” in 222 patients with bronchial asthma

	Number of patients who answered they did		P-value
	“RMOG every time”	“RMOG sometimes” or “no RMOG”	
Age (median, range), (y)	72, 26-93	70, 41-95	0.6244
Gender, M/F	87/95	30/10	0.0026
ICS-containing drugs			
Included/not included	180/2	37/3	0.0419
LAMA			
LAMA only/LAMA and other drugs	2/180	2/38	0.1496
Storage place			
Room with running water/other places	86/96	3/37	0.0001

COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; LAMA, long-acting muscarinic antagonist; RMOG, rinsing of the mouth and the oropharynx by gargling.

**TABLE 5** Proportion of “RMOG every time” and “RMOG sometimes” or “no RMOG” in 108 patients with chronic obstructive pulmonary disease

	Number of patients who answered they did		P-value
	“RMOG every time”	“RMOG sometimes” or “no RMOG”	
Age (median, range), (y)	74, 46-87	72, 41-89	0.3845
Gender, M/F	47/3	51/7	0.3345
ICS-containing drugs			
Included/not included	15/35	3/55	0.0006
LAMA			
LAMA only/LAMA and other drugs	6/44	20/38	0.0071
Storage place			
Room with running water/other places	23/27	15/43	0.0428

COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; LAMA, long-acting muscarinic antagonist; RMOG, rinsing of the mouth and the oropharynx by gargling.

water such as kitchen or bathroom than in patients who stored inhalers at other places. This was the most remarkable results of this study. To our best knowledge, there has been no report on the relation between storage place of inhaler device and the proportion of patients with RMOG. We believe it is important to evaluate the target group of patients and to properly instruct them. The information on the relationship between the storage place of inhaler and performing “RMOG” is likely to help physicians better manage patient education. To encourage future enlightenment, we do believe that reference to this result contributes to improving the proportion of RMOG.

The current study has certain limitations. The study was without a large number of patients, and involved patients with several treatment periods with several drugs and devices. These irregularities could be obstacles to generalizing results. However, the results obtained in this study were those in unselected patients in daily clinical practice. Well-planned prospective studies should be performed to confirm the results of this study. We are currently planning to perform such studies.

In conclusion, further implementation of “patient education” on performing RMOG after inhalation for patients receiving inhaled medication is still necessary. To increase the proportion of RMOG, it may be useful to propose patients to store inhalers in places where there is easy access to tap water used for RMOG.

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## CONFLICT OF INTEREST

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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