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Effectiveness of inhaled therapies in asthma among adults in Northern Sri Lanka, a low-income and middle-income country: a prospective observational study

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ABSTRACT

Background Inhaled corticosteroids (ICS) alone, or combined with long-acting beta$_2$-agonist (LABA), are recommended for chronic asthma. Limited access to inhaled medications hinders effective control of asthma in low-income and middle-income countries.

Objective This study aimed to compare the effectiveness of inhaled therapies in a cohort of adult patients with asthma who were receiving treatment in a tertiary hospital in Northern Sri Lanka.

Methods A prospective cohort study was conducted among adult patients with asthma on either ICS alone or ICS/LABA combination for at least 3 months. Participants were followed up for 6 months, with two follow-up interviews conducted 3 months apart. The primary outcome measure was asthma control, assessed by a locally validated asthma control patient-reported outcome measure. Secondary outcome measures included the use of short-acting beta$_2$-agonists (SABA) and the percentage of patients required nebulisations and hospitalisations. McNemar's test was used to determine the statistical significance. A p value≤0.05 was considered significant.

Results Of the 1094 participants, 827 (76%) were on ICS monotherapy and 267 (24%) were on ICS/LABA. Though there were no changes in the treatment, progressive improvement in asthma control was observed from baseline to second follow-up in both ICS (54%–72%) and ICS/LABA (76%–81%) groups. Significant improvement in asthma control (p<0.001) and SABA overuse (p<0.001) at both follow-ups and nebulisation (0.008) at the first follow-up were observed in the ICS group.

Conclusion Both ICS monotherapy and ICS/LABA were effective in controlling asthma. Though control was greater with ICS/LABA, the effect of additional monitoring during the follow-up was higher and significant in ICS monotherapy. Considering the low access to ICS/LABA, a treatment package comprising ICS plus non-pharmacological approaches could be a more realistic and cost-effective treatment strategy in the local context. ICS/LABA could be reserved for patients who fail to respond. However, this observation needs to be confirmed by interventional studies.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Inhaled corticosteroids (ICS) alone, or combined with inhaled long-acting beta$_2$-agonist (LABA), are recommended for the treatment of asthma. Poor availability and affordability limit the use of inhaled medications in low-income and middle-income countries (LMICs), particularly the ICS/LABA combination.

WHAT THIS STUDY ADDS

⇒ Findings of this observational study indicate that increased monitoring and frequent communication improve asthma control, particularly in those on ICS monotherapy.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Further interventional studies evaluating the effect of non-pharmacological measures such as improved monitoring and communication on asthma control would provide evidence to plan strategies to improve asthma care in LMICs.

INTRODUCTION

Asthma is one of the common global health problems affecting all age groups, and the prevalence of asthma is rising worldwide.[1] It was reported that in Sri Lanka, the prevalence of asthma in adults was 11%.[2] Though asthma is not curable, it is controllable with appropriate treatment.[3] Despite the availability of effective therapies and asthma treatment guidelines, more than half of the patients experience uncontrolled asthma.[4 5] Uncontrolled asthma increases the risk of exacerbations and economic burden to families and the healthcare system of the country.[6–8]

Currently, inhaled corticosteroids (ICS) alone, or with inhaled long-acting beta$_2$-agonist (LABA), are recommended as the first-line treatment of asthma.[1] In low-income

and middle-income countries (LMICs), the availability and affordability of inhaled medications for asthma are limited, which hinder effective asthma control in LMICs.[9–11] Since universal access to effective treatment is the key element in the management of non-communicable diseases (NCDs) including asthma, the WHO has set a target of 80% availability of medications required to treat major NCDs by 2025.[12] However, inhaled medications, particularly ICS/LABA combinations, are still less available and largely unaffordable in LMICs.[9 11 13 14] There is an urgent need to improve access to essential asthma medicines and explore sustainable alternative strategies to improve asthma care in these countries.

Sri Lanka is a lower middle-income country with the majority of the people relying on free public sector healthcare services. However, a significant proportion of healthcare expenditure is from out-of-pocket, including the purchase of medications from private pharmacies, as these medications are not always available in the public sector.[15–17] In Sri Lanka, the availability of ICS monotherapy in the public sector was reported as 81%, meeting the WHO's target, whereas the availability of ICS/LABA was very low (17%). In the private sector, the availability of ICS monotherapy and ICS/LABA was 75% and 63%, respectively.[18] The price of ICS/LABA in Sri Lanka was two and a half times higher than ICS monotherapy, which could account for this disparity.[19] Like other LMICs, low availability in the public sector and unaffordability in the private sector could limit the use of ICS/LABA in the management of asthma in Sri Lanka as well.

Further, poor knowledge of the patient, lack of regular asthma review and inadequate communication between patients and doctors were identified as contributors to poor asthma control. Non-pharmacological approaches such as improving communication and regular monitoring are considered as cost-effective measures to improve asthma control.[20 21] These factors can influence the effectiveness of asthma treatment.

Many studies have been conducted to assess the effectiveness of different treatments for asthma, including inhaled therapies in high-income countries.[22–24] However, such studies are limited in LMICs. Our study aimed to compare the effectiveness of inhaled therapies (ICS monotherapy vs ICS/LABA) in asthma control in a cohort of adult patients who were receiving treatment at Teaching Hospital-Jaffna, a tertiary hospital in Northern Sri Lanka using a locally validated asthma control patient-reported outcome measure (AC-PROM).[25]

METHODS

This was a prospective cohort study among adult patients with asthma at Teaching Hospital, Jaffna, which is the largest tertiary care hospital in the Northern Province of Sri Lanka and offers primary, secondary and tertiary healthcare services to the people residing in Jaffna district.

Adult patients with asthma on either ICS monotherapy or ICS/LABA combination for at least 3 months were included in this study. Those with chronic obstructive pulmonary disease and tuberculosis were excluded. The sample size per group required to determine the statistically significant difference in asthma control between ICS monotherapy and ICS/LABA was estimated with 90% power,[26] using the proportion of patients with controlled asthma on ICS monotherapy (49%) and ICS/LABA (63%) as reported by Pauwls *et al*[27]

Case definition of asthma

In this study, asthma was defined as 'symptoms such as wheeze, shortness of breath, cough and chest tightness that vary over time and intensity together with variable airflow limitation'.[1]

Since the capacity of performing spirometry in the study setting is very limited and reserved for patients who are not responding to the treatment, diagnosis of asthma is made clinically based on the signs and symptoms.

Primary and secondary outcome measures

The primary outcome measure for the effectiveness of inhaled therapies was asthma control, determined by AC-PROM score.[25]

Secondary outcome measures included the frequency of usage of short-acting beta$_2$-agonist (SABA) and the percentage of participants who required nebulisation and hospitalisation due to exacerbation of asthma.

Study instrument

A pretested interviewer-administered questionnaire was used for data collection. The questionnaire was formulated through literature review. The questionnaire had three parts namely baseline, first follow-up and second follow-up. Baseline questionnaire sought information on sociodemographic characteristics, medication history, asthma care history, usage of SABA, number of nebulisations, number of hospital admissions and adherence. Follow-up questionnaires contained the same sections as the baseline questionnaire except the sociodemographic characteristics. All three parts contained AC-PROM to assess asthma control at the time of recruitment and first and second follow-ups. The AC-PROM was validated against forced expiratory volume in one second of patients with asthma. It contains eight items assessing symptoms (four items), exacerbation (two items) and limitation of activity (two items).[21]

Recruitment and follow-up

Around 2500 adult patients with asthma were being followed up in medical clinics. These patients were screened for eligibility using a pre-recruitment checklist. Those on inhaled medications for at least 3 months were recruited into the cohort consecutively from December 2019 to June 2020. Each participant was followed up for

6 months with two follow-up interviews at 3-month intervals. The first author personally collected the data. At the time of recruitment, interviews were conducted in person at the medical clinics. Most of the follow-ups were conducted over the phone and those who were not accessible through phone were interviewed in person during their clinic visits.

Data analysis

Descriptive statistics such as frequency, percentage, mean and SD were used to present the results. Asthma control was determined using the AC-PROM score. The cut-off value of the AC-PROM score for asthma control was ≥28.5.[25] The use of SABA four or more than four times per week was considered as overuse indicating inadequate control of asthma.[28] Monthly household income was categorised based on the latest (2016) Sri Lankan household income.[29] McNemar's test was performed to determine the significance of changes within the group over a period of 6 months. Multivariable logistic regression was performed to determine the factors associated with asthma control. OR with 95% CI were calculated, with ≤60 years, men, low-income group, primary education group, employed participants, non-smokers, no comorbidities, ICS monotherapy group, asthma for <5 years, forgot to take medicine and stopped medicine when felt better as the reference group. A p value≤0.05 was considered statistically significant.

Patient and public involvement

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination of this study.

RESULTS

A total of 1200 participants were recruited for this cohort. Participants on SABA alone (n=2) and those who were taking oral medications in addition to inhaled therapy (n=22) were excluded from the analysis. Data from 1094 participants were analysed. Out of 1094 participants, three-fourths (n=827, 75.6%) were on ICS monotherapy (beclomethasone dipropionate) and one-fourth (n=267, 24.4%) were on ICS/LABA (fluticasone propionate/salmeterol=245 and budesonide/formoterol=22) (figure 1). During the follow-up, no changes were observed in the treatment of asthma in any of the participants in either group.

Table 1 shows the sociodemographic characteristics of the participants. The mean age of the participants was 61.2 years (SD±11.6) and the majority (n=654, 59.8%) were over 60 years. Around three-quarters of the participants (n=794, 72.6%) were women. The majority of the participants (n=788, 72%) had secondary or higher educational level. Most of the participants (n=656, 60%) were housewives. More than half (n=630, 57.6%) had low monthly household income. None of the participants in either group were current smokers. The majority of the patient (n=545, 49.8%) were on asthma treatment for more than 10 years. There was no significant association between asthma control and sociodemographic factors in either group.

A multivariable logistic regression analysis was performed on baseline data to determine factors associated with asthma control, taking controlled asthma as reference (table 2). Type of inhaled therapy, taking medicine without forgetting and smoking were associated with asthma control. Those on ICS/LABA (OR 1.394, 95% CI 1.286 to 2.486; p<0.001) and those did not forget to take the medicine (OR 4.412, 95% CI 3.374 to 5.692; p<0.001) had better control of asthma than their counterparts. Control of asthma was less in ex-smokers (OR 0.476, 95% CI 0.282 to 0.964; p=0.023) compared with non-smokers.

Table 3 shows the changes in variable over a period of 6 months, and figure 2 compares the baseline and end of follow-up data. The McNemar's test was performed to determine the significance of changes within the group in the outcome variables and those who forgot to take medicine at first (between 0 and 3 months) and second (between 3 and 6 months) follow-ups.

Primary outcome measure

A progressive improvement in asthma control was observed in both groups. Asthma control was greater in ICS/LABA group at all time points compared with ICS group. However, the improvement was significant in those on ICS monotherapy at first (X^2=67.63; p<0.001) as well as second (X^2=30.23; p<0.001) follow-ups but not in those on ICS/LABA.

Secondary outcome measures

All the secondary outcome measures (overuse of SABA, nebulisation and hospitalisation) showed a progressive improvement in both groups. Statistically significant reduction was observed in overuse of SABA at first (X^2=42.29; p<0.001) and second (X^2=12.129; p<0.001) follow-ups and nebulisation at the first follow-up (X^2=7.024; p<0.008) in those on ICS monotherapy. No significant changes were observed in the secondary outcome measures in the ICS/LABA group.

Both ICS group and ICS/LABA group showed significant improvement in those forgetting to take medicine at first (ICS group, X^2=189.77; p<0.001 and ICS/LABA group, X^2=69.77; p<0.001) as well as second (ICS group, X^2=63.06; p<0.001 and ICS/LABA group, X^2=27.13; p<0.001) follow-ups. Whereas those stopped the medicine when felt better remained almost the same throughout the study period in both groups.

DISCUSSION

This study has generated evidence on the effectiveness of ICS monotherapy and ICS/LABA, as opposed to

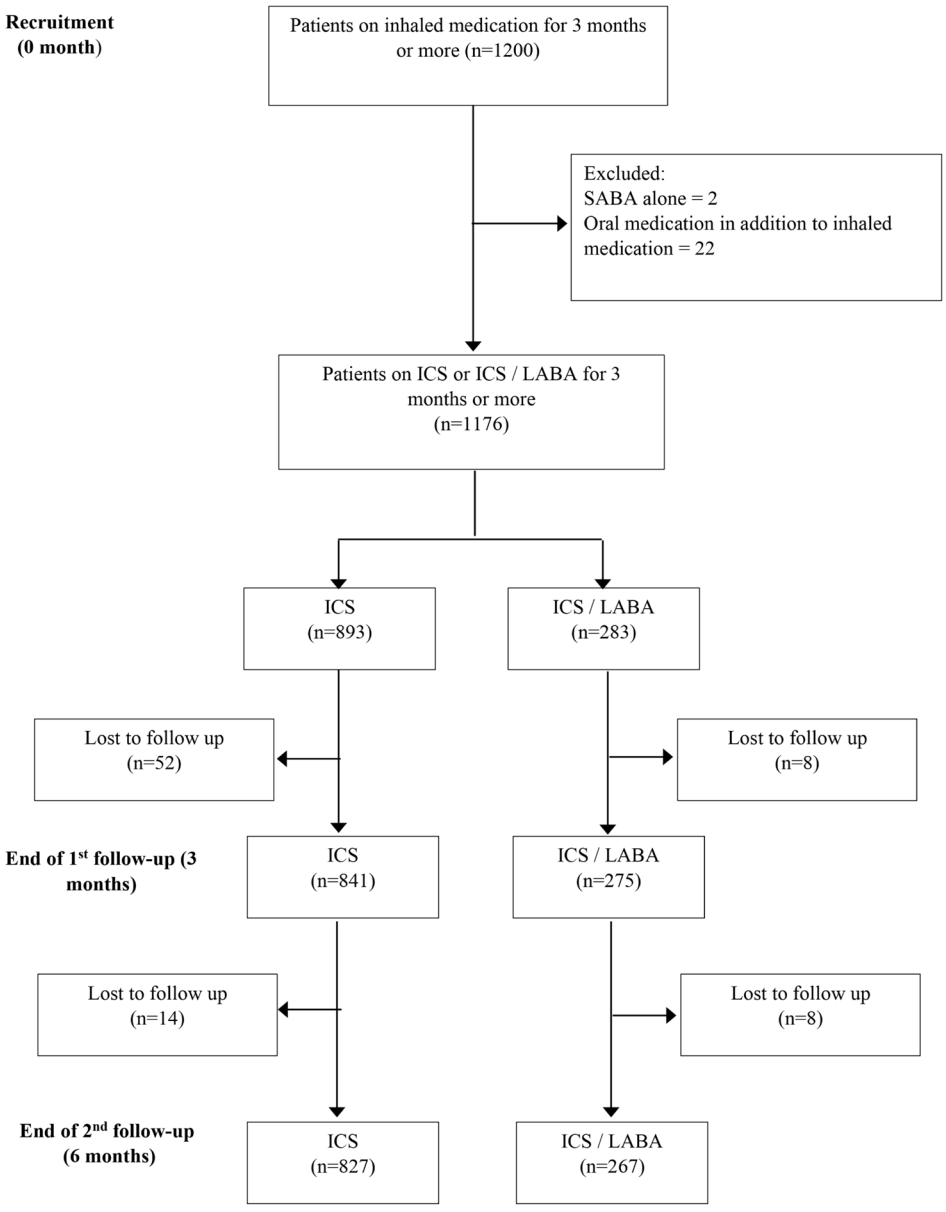

Figure 1 Consolidated Standards of Reporting Trials flow diagram of the asthma cohort. ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist; SABA, short-acting beta$_2$-agonists.

many interventional studies, which have documented the efficacy of these therapies. Effectiveness relates to how well a treatment works in real-life non-ideal circumstances, as opposed to efficacy, which measures how well it works in randomised controlled trial (RCT), or laboratory studies.[30] In fact, high-quality postmarketing observational studies are now considered as very important complement to the results of RCT in providing evidence on safety and effectiveness.[31]

The age and gender distribution of our cohort (60% over 60 years, female preponderance) reflects the demography of the country.[29] Hence, our data could be generalisable to the country. However, there can be some inter-regional variation depending on other determinants of effectiveness, such as appropriate use of inhaled medications, adherence and inhalation technique.[32]

Previous studies have documented that the unavailability and unaffordability limited the use of inhaled medications in LMICs.[9 11 13 14] In our cohort, only about one-fourth (24.4%) of the participants were on ICS/LABA. This figure was very much lower than that in high-income countries,[22 33 34] but it was higher than the figures reported from LMICs, such as Kyrgyzstan, Nepal, Peru and Uganda.[9–11 13] A survey in Sri Lanka reported that the availability of ICS monotherapy in the public and private sectors was 81% and 75%, respectively, whereas the availability of ICS/LABA in the public and private sector was 17% and 63%, respectively.[18] Since our cohort comprises patients receiving treatment in a public hospital, the low figure of 25% being on ICS/LABA is not unexpected. Poor economic access in the private sector could be the main cause for minimal use of ICS/LABA

Table 1 Sociodemographic characteristics and asthma treatment of the participants

Variables	Total population n=1094 (%)	ICS monotherapy n=827 (%)	ICS/LABA n=267 (%)
Age in years			
≤60	440 (40.2%)	341 (41.2%)	99 (37.1%)
>60	654 (59.8%)	486 (58.8%)	168 (62.9%)
Gender			
Male	300 (27.4%)	221 (26.7%)	79 (29.6%)
Female	794 (72.6%)	606 (73.3%)	188 (70.4%)
Educational level			
Primary	306 (28%)	216 (26.1%)	90 (33.7%)
Secondary	655 (59.9%)	515 (62.3%)	140 (52.4%)
Higher	133 (12.1%)	96 (11.6%)	37 (13.9%)
Employment status			
Employed	254 (23.2%)	185 (22.4%)	69 (25.8%)
Housewife	656 (60%)	537 (64.9%)	119 (44.6%)
Pensioner	63 (5.7%)	36 (4.4%)	27 (10.1%)
Unemployed	121 (11.1%)	69 (8.3%)	52 (19.5%)
Monthly household income			
Low	630 (57.6%)	521 (63%)	109 (40.8%)
Middle	260 (23.8%)	176 (21.3%)	84 (31.5%)
High	133 (12.1%)	130 (15.7%)	74 (27.7%)
Smoking history			
Smokers	0 (0%)	0 (0%)	0 (0%)
Ex-smokers	62 (5.7%)	45 (5.4%)	17 (6.4%)
Non-smokers	1032 (94.3%)	782 (94.6%)	250 (93.6%)
Duration of asthma treatment			
<5 years	303 (27.7%)	252 (30.5%)	51 (19.1%)
5–10 years	246 (22.5%)	186 (22.5%)	60 (22.5%)
>10 years	545 (49.8%)	389 (47%)	156 (58.4%)

ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist.

in this cohort of patients receiving treatment from public sector. Furthermore, we noticed that (table 1) a greater proportion (63%) of participants on ICS monotherapy had low household income compared with those on ICS/LABA (41%). This strengthens our argument that poor economic access is the main cause of minimal use of ICS/LABA. In addition, we noticed that distribution of other sociodemographic factors such as age, sex, educational level, employment status and smoking showed comparable trends in both groups. These observations also show that access, as opposed to evidence and guidelines, determined the type of inhaled medication for asthma in the present study.

This real-life prospective cohort study demonstrated that both ICS monotherapy and ICS/LABA were effective in controlling asthma in majority of the patients throughout the study period. Our findings show that asthma control was greater and SABA overuse was lower in ICS/LABA compared with ICS monotherapy, indicating better control of asthma with combination therapy. These finding were in line with the previous studies.[35–37] However, improvement in asthma control over a period of 6 months was higher and significant in ICS monotherapy compared with ICS/LABA. Traditionally, the frequency of SABA use and number of acute attacks were the commonly used predictors for uncontrolled asthma.[23 33 38] We noticed that there was a significant reduction in overuse of SABA and nebulisation in ICS group, which was not seen in ICS/LABA group. This finding indicates a greater reduction in exacerbation of asthma in the ICS monotherapy compared with ICS/LABA.

Interestingly, improvement in asthma control in our cohort occurred without any change in the treatment of asthma. This brings in an important component in the treatment of asthma, close follow-up, which ensures adherence. Furthermore, a significant improvement in missed doses was observed from baseline to second

Table 2 Factors associated with asthma control

Variable	Adjusted OR (95% CI)	P value
Age group (years)		
≤60	Reference	
>60	0.889 (0.556 to 1.441)	0.105
Gender		
Male	Reference	
Female	1.359 (0.683 to 1.698)	0.829
Income		
Low	Reference	
Middle	0.791 (0.581 to 1.034)	0.072
High	0.959 (0.437 to 2.222)	0.911
Educational level		
Primary	Reference	
Secondary	0.756 (0.568 to 1.025)	0.066
Higher	0.789 (0.477 to 1.287)	0.313
Employment		
Employed	Reference	
Housewife	1.060 (0.678 to 1.691)	0.919
Pensioner	0.845 (0.157 to 1.076)	0.062
Unemployed	0.710 (0.426 to 1.219)	0.201
Smoking status		
Non-smoker	Reference	
Ex-smoker	0.476 (0.282 to 0.964)	0.026
Comorbidities		
Absent	Reference	
Present	0.796 (0.389 to 1.195)	0.148
Type of inhaled therapy		
ICS monotherapy	Reference	
ICS/LABA	1.394 (1.286 to 2.486)	<0.001
Duration of asthma treatment		
<5 years	Reference	
5–10 years	0.978 (0.607 to 1.978)	0.234
>10 years	0.833 (0.592 to 1.504)	0.182
Forgot to take the medicine		
Yes	Reference	
No	4.412 (3.374 to 5.692)	<0.001
Stopped medicine when felt better		
Yes	Reference	
No	2.132 (0.794 to 4.842)	0.121

Statistical test—multivariable logistic regression.
ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist

Table 3 Changes in variables over a period of 6 months

Variable	ICS monotherapy (n=827)	ICS/LABA (n=267)
Asthma control		
Baseline	450 (54.4)	203 (76.0)
First follow-up	547 (66.1)	212 (79.4)
Second follow-up	593 (71.7)	216 (80.9)
Overuse of SABA		
Baseline	410 (49.6)	75 (28.1)
First follow-up	330 (39.9)	65 (24.3)
Second follow-up	296 (35.8)	64 (24)
Nebulisation		
Baseline	93 (11.2)	28 (10.4)
First follow-up	68 (8.2)	24 (9.0)
Second follow-up	64 (7.7)	23 (8.6)
Hospitalisation		
Baseline	15 (1.8)	7 (2.6)
First follow-up	12 (1.4)	6 (2.2)
Second follow-up	6 (0.7)	5 (1.9)
Forgot to take the medicine		
Baseline	312 (37.7)	119 (44.6)
First follow-up	69 (8.3)	33 (12.4)
Second follow-up	4 (0.5)	4 (1.5)
Stopped medicine when felt better		
Baseline	808 (97.7)	262 (98.1)
First follow-up	820 (99.2)	261 (97.8)
Second follow-up	820 (99.2)	267 (100.0)

ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist; SABA, short-acting beta$_2$-agonists.

follow-up in both groups also indicates the improvement in adherence.

In the local settings, because of the low availability, ICS/LABA is often reserved for moderate-to-severe asthma. These patients are characterised by poor symptom control despite the regular treatment.[39] This could be the reason for lack of significant improvement in asthma control and predictors in those on ICS/LABA in the present study. However, without the information about the degree of severity of the asthma, this claim cannot be confirmed.

It has been documented that non-adherence to medications is an important cause for poor asthma control.[40 41] Factors contributing to non-adherence include low perceived need for asthma medications, inadequate communication between patients and physicians, perceived concern regarding medications and inadequate knowledge.[13 24 41 42] Studies have also reported that close monitoring, frequent interactions with healthcare team and repeated instructions improve adherence to medications.[28 43 44] Patient education improves the patients' understanding and adherence, resulting in better asthma control.[45 46] All these can be addressed by a structured patient education programme which includes close monitoring, frequent interactions

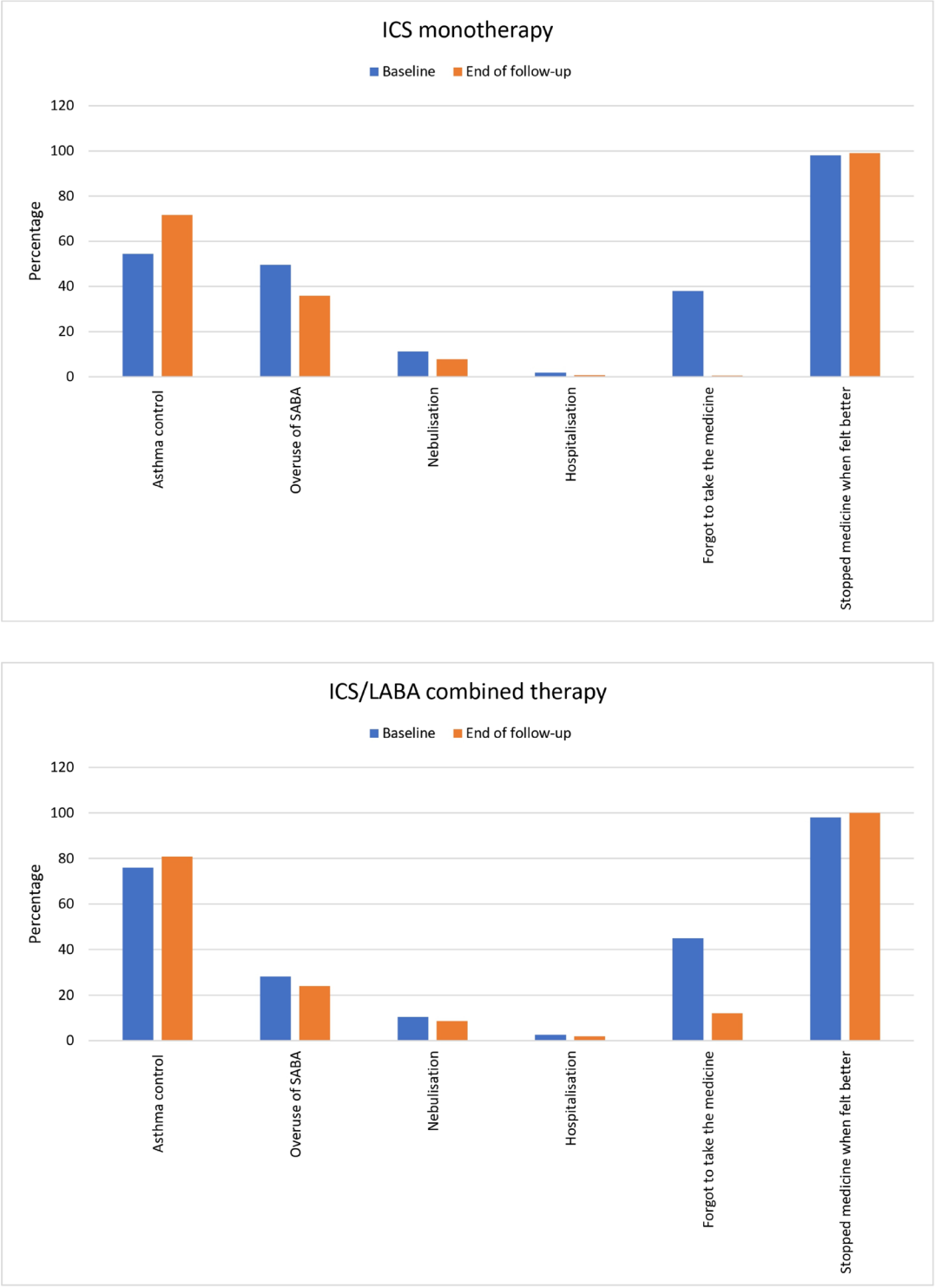

Figure 2 Comparative bar diagram showing the baseline and end of follow-up data of ICS monotherapy and ICS/LABA. ICS, inhaled corticosteroid; LABA, long-acting beta$_2$-agonist; SABA, short-acting beta$_2$-agonists.

with healthcare team, providing basic facts about treatment, reassurance regarding side effects and repeated instructions. Reduction in patients who forgot to take medication regardless of type of therapy in our study indicates improvement in adherence. Although there was no formal patient education programme in our study plan, participants were free to communicate with the investigators during the follow-up. This could have given opportunity to the participants to clarify their concerns regarding the treatment, which could have contributed to the improvement in adherence leading to improved asthma control. However, there was no significant change in the proportion of participants who stopped the treatment when they felt better in either group. This indicates

inadequate knowledge of disease among the participants. As there was no formal patient education in our study, the impact on knowledge of disease among the participants would be less. This could explain why the proportion of participants who stopped asthma medication when they felt better remained high.

It is noteworthy that there were no changes in the treatment in either group, despite asthma remained uncontrolled in about 30% of ICS group and about 20% of ICS/LABA group. This observation highlights another important problem in the clinical practice, failure in identifying the patient required escalation of treatment. Improved communication between the doctor and patients and close monitoring would address this issue as well.

Strengths of this study are: as it was a real-world study it has generated evidence regarding effectiveness in resource-limited setting; it has shown the issues in LMICs where healthcare system is overstressed; and findings of this study could be useful in planning researches and alternative strategies in asthma control in LMICs where access to inhaled medication remains an issue. There are limitations in this study: since this was an observational study, we were unable to establish the casual relationship between asthma control and non-pharmacological approaches; we did not have the information on degree of severity of the asthma and basis of choosing initial treatment. Knowing the above information could have given a better understanding of the changes occurred during follow-up; another limitation was that we did not get the information on working exposure or air pollution exposure which are among the risk factors of uncontrolled asthma; as the participants were interviewed by a healthcare professional, there might be self-reporting bias; we did not use a standard tool to assess the adherence; finally, we did not check the performance of inhalation technique which also plays an important role in asthma control.

CONCLUSIONS

This prospective cohort study has shown that both ICS monotherapy and ICS/LABA were effective in controlling asthma in majority of the patients and control was greater in ICS/LABA. Despite the fact that there was no change in the treatment in either group, a progressive improvement in asthma control and exacerbation was observed in both groups. This observation suggest that close monitoring and frequent communication with patients during the follow-up period could have contributed to improvement observed in asthma control. Though asthma control was greater in ICS/LABA than ICS monotherapy, the effect of close monitoring during the follow-up was significant in those on ICS monotherapy, but limited in patients on ICS/LABA. Considering the low availability and affordability of ICS/LABA in the local settings, implementing non-pharmacological measures such as regular follow-up, patient education and improving communication between patients and doctors before switching to ICS/LABA could be a feasible and even cost-effective management strategy. The combination therapy with ICS/LABA could be offered to those who fail to achieve control with regular ICS monotherapy plus non-pharmacological measures. However, the causal relationship between the asthma control and non-pharmacological approaches needs to be established through well-designed interventional studies before incorporating them into the local guidelines.

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Contributors YG, TSN, GS and SSR were involved in the research conception. The study was conceptualised by all four authors. YG was the principal investigator and responsible for the data collection, entry and analysis with TSN and SSR for manuscript preparation. All authors agree to be accountable for all aspects of the work. YG is the guarantor of this manuscript.

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Patient consent for publication Consent obtained directly from patient(s).

Ethics approval This study involves human participants and was approved by ethics review committee, faculty of medicine, University of Colombo, Sri Lanka, (number EC-18-108). Participants gave informed consent to participate in the study before taking part.

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