ORIGINAL ARTICLE

Development and Validation of a Sensor-Integrated Metered Dose Inhaler for Adherence Assessment

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Abstract

Background: Poor adherence to inhaler therapy is a major challenge in the management of asthma and Chronic obstructive pulmonary disease (COPD). Smart inhalers can objectively track medication use, but the majority of available devices are costly and less feasible in resource-limited settings. **Aim:** The aim of the study was to develop a low-cost sensor-integrated metered dose inhaler (MDI) and evaluate its usefulness in monitoring adherence and improving disease control in asthma and COPD patients. **Methods:** The study was conducted in two stages. First, an MDI with an MQ2 gas sensor was built, including an ESP32 microcontroller, rechargeable battery, and Bluetooth/Wi-Fi-based data transfer. Second, we performed a prospective single-arm interventional study in 60 adults with asthma or COPD on MDI therapy. Participants were followed for 12 weeks, and adherence was objectively measured using sensor-recorded data. Disease control was evaluated with American College Testing (ACT) for asthma and Common admission test (CAT) for COPD at baseline, 4, 8, and 12 weeks. Exacerbations, satisfaction, and ease of use were also recorded. **Results:** Good adherence increased from 16.7% at baseline to 60.0% at 12 weeks, and poor adherence decreased from 30.0% to 6.7%. Mean ACT/CAT scores increased from 16.8 ± 4.1 to 23.0 ± 3.1 over 12 weeks ($P < 0.001$). Adherence was moderately positively correlated with disease control ($r = 0.62$; $P < 0.001$). Of the patients who were followed up, 66.7% had no exacerbations. The device was well received, with 80.0% of patients reporting satisfaction and 81.7% finding it easy or very easy to use. **Conclusion:** The MDI with integrated sensor improved asthma and COPD patients' medication adherence and disease control over 12 weeks. Its low cost, objective monitoring, and good usability support its potential use in routine clinical practice, especially in resource-limited settings.

Key words: American college testing score, asthma, chronic obstructive pulmonary disease, common admission test score, digital health, disease control, medication adherence, sensor-integrated metered dose inhaler, smart inhaler

INTRODUCTION

Asthma and chronic obstructive pulmonary disease (COPD) are chronic inflammatory diseases of the airways with airflow limitation and progressive loss of pulmonary function.[1,2] Management of both conditions depends on long-term pharmacological therapy, mainly delivered by means of inhaled medications.[3]

Inhaled medications are the first-line treatment for both asthma and COPD since they deliver drugs directly to the respiratory system, with rapid therapeutic effects and minimal systemic complications.[3] Medications such as inhaled corticosteroids, long-acting beta agonists, and long-acting muscarinic antagonists have shown clear benefits in patients by improving symptom control,

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reducing the frequency of exacerbations, and improving overall quality of life.[3,4] However, achieving optimal disease control in routine clinical practice remains challenging.[5]

Poor medication adherence is one of the key contributors to inadequate disease control. Adherence rates are often <50–60%. Non-adherence can be intentional or unintentional and is determined by multifactorial determinants, including cognitive, behavioral, and device-related factors.[6] Poor adherence is therefore associated with worse clinical outcomes such as increased symptom burden, exacerbation rates, risk of hospitalization, and economic burden.[7]

Traditional methods, such as patient self-reports, pharmacy refill checks, and clinician evaluations, rely heavily on subjective data and are frequently unreliable.[8,9] Recently, the interest in digital health solutions to address adherence-related challenges has been increasing. Smart inhaler systems have emerged as an innovative technological solution that integrates sensor-based and microcontroller-driven components with traditional inhalation devices.[10]

However, their universal use is limited by high cost, limited availability, and limited applicability in resource-constrained healthcare settings.[7] Thus, there is a need for a simple, affordable, and reliable sensor-integrated inhaler system that can be implemented in routine clinical practice, especially in developing regions.[10]

Therefore, the present study has been planned to develop a sensor-integrated metered dose inhaler (MDI) and to evaluate its efficacy in objective monitoring of patient adherence and improvement of clinical outcomes in asthma and COPD patients. The goal of this approach is to improve disease management and optimize patient care by addressing the gap between prescribed treatment and actual medication use.

MATERIALS AND METHODS

Study design

The study was carried out in two consecutive phases. The first phase was the design and development of a sensor-integrated MDI system for objective monitoring of medication adherence. The second phase was a prospective, single-arm interventional study to evaluate the efficacy of the developed device in improving adherence and clinical outcomes in asthma and COPD patients.

Phase 1: Sensor-integrated MDI development

A compact, lightweight, and portable sensor-integrated MDI system was developed for objective monitoring of inhaler use. It was designed to be attached to a conventional MDI, without affecting normal drug delivery or ease of use.

The system was composed of three main parts: A sensing unit, a processing unit, and a communication unit. An MQ2 gas sensor was used as the sensing element and placed close to the inhaler nozzle to detect the aerosol plume released during actuation. The sensor converted the aerosol detection into electrical signals and sent them to an ESP32 microcontroller. The main processing unit chosen was the ESP32 due to its small size, power, and the presence of built-in Wi-Fi and Bluetooth connectivity. The device was powered by a rechargeable lithium-ion battery and was portable.

Working principle and data logging

The device works on the principle of aerosol release during operation of the inhaler. When the inhaler is pressed, the MQ2 gas sensor detects the aerosol particles being emitted and outputs an electrical signal proportional to the detected concentration. This signal is processed by the ESP32 microcontroller with a predefined threshold-based algorithm to differentiate between valid inhaler actuation and background environmental signals.

When a valid actuation event is detected, the device records the time and frequency of use of the inhaler. These data provide an objective measure of medication adherence and overcome some of the limitations of self-reported inhaler use. The data recorded can be transmitted wirelessly through Bluetooth or Wi-Fi to a mobile app or cloud-based platform, allowing healthcare providers to access and monitor it remotely. This feature might allow for timely intervention in patients with poor adherence.

Device validation and testing

After assembly and programming, the sensor-integrated MDI was tested in controlled conditions. The MQ2 sensor was tested for aerosol detection by performing repeated inhaler actuations. The device was also tested under different environmental conditions to reduce the chances of false positive readings. Threshold values and algorithm parameters were refined to improve detection accuracy and system reliability.

Phase 2: Clinical assessment

The clinical part of the study was performed in the Department of General Medicine, Saveetha Medical College and Hospital, Chennai. The study period was 3 months, and assessments were made on participants at baseline and at 4, 8, and 12 weeks.

Study sample

The study included adult patients aged 18–60 years with a confirmed diagnosis of asthma or COPD who were on regular MDI-based therapy. All patients were clinically stable and had been using their inhalers for at least 4 weeks before enrolment.

Inclusion criteria: Patients with acute exacerbation of COPD within the previous 4 weeks requiring ventilatory support and significant comorbid illness were excluded from the study. Pregnant or lactating women and patients who could not use the inhaler or sensor device properly were also excluded from the study. All participants provided written informed consent before enrollment.

Sample size

There were 60 participants in total. This was a pilot interventional study of a novel sensor-integrated inhaler device, and formal sample size calculation based on prior effect size was not feasible due to the lack of comparable published data. Pilot studies usually involve 30–60 participants to evaluate the feasibility, usability, and preliminary effectiveness of an intervention. Therefore, a sample size of 60 was considered sufficient to evaluate adherence trends and perform repeated measures analyses across follow-up visits.

RESULTS

Baseline clinical characteristics

Asthma was slightly more prevalent than COPD in the study population, representing 56.7% of cases, compared to 43.3% for COPD. The mean duration of illness was 5.2 ± 2.8 years, and the mean duration of inhaler use was 3.9 ± 2.1 years. Most patients had suboptimal medication adherence (poor adherence <70%, 70.0%) before the intervention [Figure 1]. The mean number of exacerbations in the previous year was 1.8 ± 1.1, indicating that many of the participants had chronic disease with poor adherence to their inhalers before using the sensor-integrated device.

Sensor-recorded medication adherence over time

Adherence data from sensors over study intervals are shown in Table 1. Mean adherence improved consistently from 61.4% at baseline to 73.6% at 4 weeks, 81.7% at 8 weeks, and 88.9% at 12 weeks. Repeated measures analysis of variance (ANOVA) demonstrated this upward trend to be statistically significant ($P < 0.001$), suggesting the efficacy of the sensor-enabled inhaler to improve medication adherence over time.

Adherence category distribution at baseline and 12 weeks

Table 2 shows the distribution of patients in the categories of adherence at baseline and at 12 weeks. The proportion of patients with poor adherence was significantly increased from 16.7% to 60.0% (80%). By the end of the study, a statistically significant shift towards higher adherence levels was observed (Chi-square test, $P < 0.001$).

Changes in disease control scores over time

The changes in disease control scores during the study period are shown in Figure 2. The mean score consistently improved from 16.8 ± 4.1 at baseline to 19.2 ± 3.8 at 4 weeks, 21.3 ± 3.6 at 8 weeks, and 23.0 ± 3.1 at 12 weeks. Repeated measures ANOVA confirmed these improvements were statistically significant ($P < 0.001$). These results suggest improved adherence contributed to better disease control.

Comparison of disease control improvement by disease type

Table 3 shows a subgroup comparison between asthma and COPD patients. In asthma patients, ACT scores improved by a mean of 6.6 points (from 17.2 ± 4.0 to 23.8 ± 3.0). Using the reversed CAT scale, the mean improvement in COPD patients was 5.6 points (from 16.3 ± 4.2 to 21.9 ± 3.4). Both of these changes were statistically significant ($P < 0.001$) with a slightly greater effect in asthma patients.

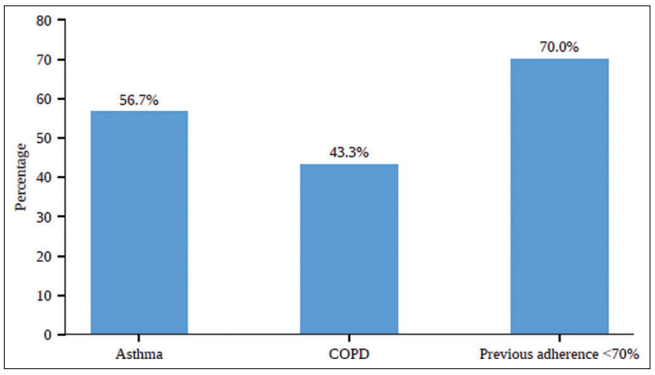

Figure 1: Baseline clinical characteristics of the study participants

Table 1: Mean medication adherence across follow-up time points

Time Point	Mean Adherence (%)	SD
Baseline	61.4	10.2
4 weeks	73.6	9.5
8 weeks	81.7	8.4
12 weeks	88.9	6.8

Statistical test: Repeated measures ANOVA.
P-value: <0.001 (statistically significant improvement)

Table 2: Comparison of medication adherence categories at baseline and 12 weeks

Adherence Category	Baseline n (%)	12 Weeks n (%)
Poor (<50%)	18 (30.0)	4 (6.7)
Moderate (50–80%)	32 (53.3)	20 (33.3)
Good (>80%)	10 (16.7)	36 (60.0)

Chi-square test *P* value: <0.001

Table 3: Comparison of disease control scores between asthma and COPD patients

Disease	Baseline Score	12-Week Score	Mean Improvement	P value
Asthma (ACT)	17.2±4.0	23.8±3.0	6.6	<0.001
COPD (CAT reversed scale*)	16.3±4.2	21.9±3.4	5.6	<0.001

*CAT scores are presented on a reversed scale for uniformity of comparison; t-test comparing baseline versus 12-week scores.

Table 4: Distribution of exacerbations during the study period

Number of Exacerbations	Patients (n)	Percentage (%)
None	40	66.7
One	14	23.3
Two	5	8.3
Three or more	1	1.7

Table 5: Patient satisfaction with the sensor-integrated inhaler device

Satisfaction Level	Frequency	Percentage (%)
Very satisfied	26	43.3
Satisfied	22	36.7
Neutral	8	13.3
Dissatisfied	4	6.7

Mean satisfaction score (Likert scale 1–5): 4.12±0.81

Frequency of disease exacerbations during the study period

Most participants had no exacerbations during the 12-week period of the study. 40 patients (66.7%) had no exacerbations, and 14 patients (23.3%) had one exacerbation. Exacerbations were recorded in five patients (8.3%) who had two exacerbations, and 1 patient (1.7%) who had three or more exacerbations. This implies that most of the participants were clinically stable during follow-up.

The number and percent of patients by frequency of exacerbations during follow-up are presented in Table 4. Most of the participants were without any exacerbations, while only a small proportion had recurrent exacerbations.

Patient satisfaction with the sensor-enabled inhaler

Table 5 provides a summary of patient satisfaction with the sensor-enabled inhaler. The majority of participants provided positive feedback (43.3% very satisfied and 36.7% satisfied). 13.3% reported a neutral response, and 6.7% reported dissatisfied. The mean satisfaction score on a 5-point Likert scale was 4.12 ± 0.81, indicating overall favorable acceptance of the device.

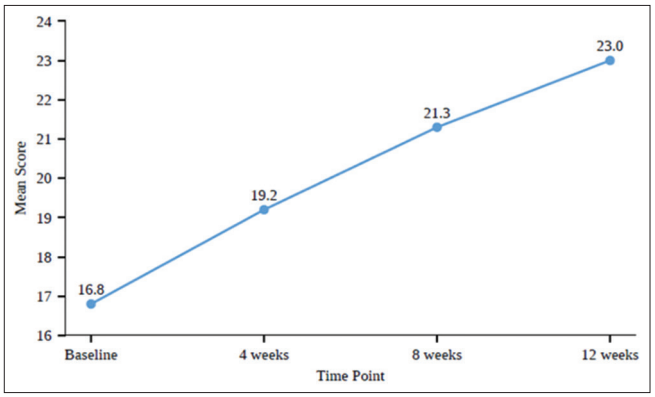

Figure 2: Changes in disease control scores over the study period

Correlation between adherence (%) and disease control scores (ACT/CAT) at 12 weeks

Medication adherence and disease control scores were moderately positively correlated. Higher adherence was associated with better ACT/CAT scores, suggesting that patients who used the inhaler more consistently had better disease control. The correlation was statistically significant ($r = 0.62$, $P < 0.001$), indicating that increased adherence played a meaningful role in improved clinical outcomes.

Figure 3 shows a positive correlation of the percentage of adherence with ACT/CAT scores. Greater adherence was associated with better disease control, with a statistically significant moderate positive correlation ($r = 0.62$, $P < 0.001$).

DISCUSSION

The majority of the study population was middle-aged, with 43.3% falling in the age group of 31–45 years. Male participants accounted for just over half of the sample (56.7%), and there was a higher proportion of participants from urban than rural areas (63.3%). This is consistent with epidemiological data published by GINA and GOLD showing a higher prevalence of asthma and COPD in the middle-aged population, particularly in urban areas with higher exposure to environmental pollutants and lifestyle-related risk factors.[1,2]

The most startling discovery was that 70% of the participants had poor baseline adherence (<70%) with an average adherence of 61.4%. This finding is consistent with previous work emphasizing the importance of training, preparation,

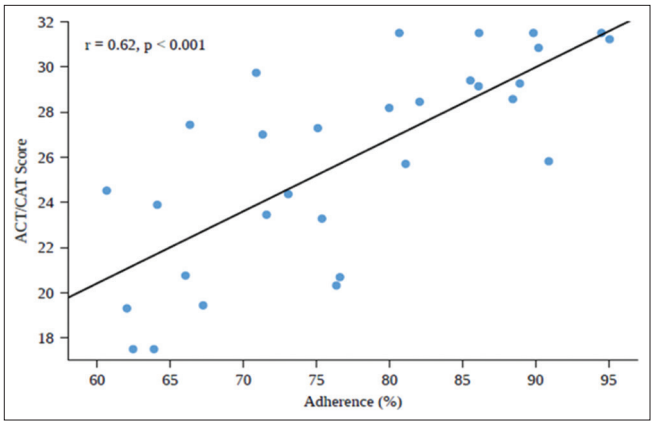

Figure 3: Correlation between medication adherence and disease control scores

and counselling in improving inhaled medication use.[11] It is also in agreement with more general evidence indicating adherence rates of about 40–60% in patients with chronic respiratory diseases.[5] The marginally higher baseline adherence in this study may reflect better access to health care in an urban-dominant population.[12]

The mean duration of disease was 5.2 ± 2.8 years, and the mean duration of inhaler use was 3.9 ± 2.1 years, but adherence was still suboptimal. The persistence of suboptimal adherence despite prolonged inhaler use highlights the need for additional adherence-support strategies, and previous studies have demonstrated that digital inhaler-based interventions can improve medication adherence and clinical outcomes in patients with asthma.[13] who found that longer duration of treatment does not necessarily lead to better adherence, pointing to the behavioral aspects influencing medication use.

The primary result of the study was a considerable increase in medication adherence from 61.4% at baseline to 88.9% at 12 weeks, an absolute improvement of 27.5% ($P < 0.001$). This is a statistically and clinically meaningful level of improvement and is comparable to the existing literature. For example, a Cochrane review by Chan *et al*.[10] showed that the use of electronic monitoring devices improved adherence by 14–23% among patients with asthma. The improvement observed in the present study further supports the potential role of objective monitoring and personalized feedback in promoting medication adherence.[14,15] This magnitude in the present study is larger, and this may be due to the combination of objective monitoring, real-time tracking, increased awareness on the part of the patient, and the simplicity of the device design.

In addition, the short follow-up time may partly explain the high adherence rates. Change in Category of Adherence Apart from improvements in mean adherence, we observed a large shift of adherence categories. The percentage of good adherence (>80%) increased from 16.7% at baseline to 60.0% at 12 weeks, and the percentage of poor adherence (<50%) decreased from 30.0% to 6.7%. This represents a clinically relevant increase of 43.3% in optimal adherence.[10]

However, other studies, such as the ACCEPTANCE trial by van de Hei *et al*.[13] have demonstrated improvements in adherence categories, but typically with smaller absolute changes. These results suggest that objective monitoring may be more effective than traditional behavioral strategies alone for promoting sustained adherence.[13] The study achieved clinically relevant targets, as optimal therapeutic outcomes are seen in patients with adherence above 80%.[7]

Greater adherence was associated with significant improvement in disease control scores. ACT/CAT scores improved from baseline (16.8 ± 4.1) to 12 weeks (23.0 ± 3.1) with a mean improvement of 6.2 points ($P < 0.001$). This exceeds the minimal clinically important difference estimated to be around 3 points for ACT and 2.5 points for CAT,[16] indicating the clinical relevance of the results.

Prior work has demonstrated that adherence-focused interventions can result in gains of 3–5 points on ACT scores.[17] The better improvement observed here could be attributed to the cumulative effect of improved adherence and objective monitoring to ensure consistent delivery of medication.[7] These results further support the notion that adherence is an important factor for control of disease and that simply improving adherence can have a significant clinical benefit without any changes in pharmacological therapy.[7]

Both groups of asthma and COPD showed significant improvement in disease control, but patients with asthma showed slightly higher mean improvement in disease control (6.6 points) than those with COPD (5.6 points). This discrepancy is not surprising considering the underlying pathophysiology. Asthma is an inflammatory disease that is reversible and therefore responds better to optimized therapy. COPD is characterized by structural damage to the airways with limited reversibility.[18]

Similar results have been reported in other studies where adherence interventions lead to greater functional improvement in asthma than in COPD, attributed to the greater reversibility of airflow limitation.[10] However, both groups derived significant benefits, indicating that improved adherence is beneficial irrespective of the type of disease.[5,19]

Exacerbation outcomes

At 12-week follow-up, 66.7% of participants had no exacerbations, and only 1.7% had three or more exacerbations. Better adherence translates into better disease control, as evidenced by the low rate of exacerbation. Previous cohort studies have shown that inhaled corticosteroid adherence reduces the risk of exacerbations in both asthma and COPD. While there was no baseline comparison in this study, the

observed results suggested that improving adherence is clinically beneficial. The device was well accepted by the patients, 80% of whom were satisfied, with a mean satisfaction score of 4.12 ± 0.81. In addition, 81.7% of patients found the device easy or very easy to use.

These findings are consistent with previous work on smart inhalers that has suggested ease of use and minimal disruption to routine practice as important factors in sustained adoption. The high usability observed in this study supports the feasibility of implementing such devices in routine care, including resource-constrained settings. The scores for Connection Adherence and disease control were moderately positively correlated ($r = 0.62$, $P < 0.001$); adherence accounted for approximately 38% of the variance in disease control.

Limitations

There are some limitations of the study to take into consideration. The absence of a control group means that the results cannot definitively connect the intervention with better outcomes. The follow-up period was also relatively short, which may not fully reflect long-term adherence behavior. We cannot exclude a Hawthorne effect, that is, that participants improved their inhaler use because they knew they were being monitored. Moreover, even though the device reliably logs actuation of the inhaler, it does not assess correct inhalation technique by the patient or proper deposition of the medication in the airways.

CONCLUSION

The sensor-integrated MDI developed in this study showed the potential to objectively monitor medication adherence in asthma and COPD patients. Medication adherence improved substantially over the 12-week follow-up period, with significant improvements in disease control scores and a low frequency of exacerbations. The positive association between adherence and disease control underscores the importance of regular inhaler use in obtaining better clinical results. The high levels of patient satisfaction and ease of use also suggest the device is acceptable and feasible for routine use. The simplicity of design, possibility for objective monitoring and potential affordability may be especially useful in resource-poor health care settings. However, larger controlled studies with longer follow-up periods are needed to determine its long-term effectiveness and clinical utility.

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