ORIGINAL ARTICLE

Mobile Direct Observed Therapy (MDOT) for Inhaler Therapy in Children With Newly Diagnosed Asthma: A Pilot Study

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ABSTRACT

Objectives: We aimed to assess the acceptability of Mobile Direct Observed Therapy (MDOT) amongst the parents/caregivers of children with asthma.

Methods: This open-label pilot randomized controlled trial enrolled newly diagnosed children aged 5-15 years with asthma, who were followed up telephonically for six weeks. Parents of children in the intervention arm were requested to record share a video of the metered dose inhaler with spacer (MDI-S) technique of their child on a mobile phone and share it through WhatsApp with investigator who then provided corrective measures as required by text/video message. The children in the control arm continued follow-up telephonically without exchange of any videos for six weeks. The primary outcome measures were the acceptability of MDOT and the effect of such interaction on the correctness of the MDI technique. Secondary outcome measures were the level of asthma control as per GINA guidelines and the caregivers' perception and feedback about MDOT.

Result: A total of 30 children were enrolled, 15 in each arm. Thirteen (86%) parents uploaded good-quality videos. The average number of incorrect steps decreased from 2.64 in the first video to 0.18 after the fourth video and nil after the fifth video in the MDOT group. At six weeks of follow-up, the average number of incorrect steps was significantly lower in the MDOT group compared to the control group (0 vs 2.9; P <0.0001). The proportion of children having controlled asthma was better in the MDOT group compared to controls (85% vs 70%) (P = 0.39). All parents liked MDOT.

Conclusions: MDOT was well accepted by caregivers of children with astham and was helpful in improving the MDI-S technique.

Keywords: *Asthma, MDOT, Metered dose inhaler*

Trial Registry: CTRI/2019/06/019951

INTRODUCTION

Asthma is the most prevalent chronic respiratory disease worldwide, with a significant morbidity across all ages [1]. The mainstay of the treatment of asthma is inhaled corticosteroids (ICS) using a metered dose inhaler and a spacer (MDI-S). The correct technique of using MDI-S is one of the critical factors for the proper control of asthma. It is well established that asthma control is better among the users with correct technique. Repeated training of users with MDI-S may contribute to improving the inhaler technique [2]. Alexander et al observed that 75% of 7 to 17-year-old children who were completely confident regarding their technique missed an average of 1-2 steps on assessment [3]. Mobile Direct Observed Therapy (MDOT) is an emerging technique that evaluates adherence to the correct strategy. This includes using a mobile phone for making a video recording of the patient's technique and sending it to a healthcare provider for assessment. India has the world's second-largest mobile phone user base (over 900 million users). MDOT has been used for monitoring therapy in tuberculosis [4] and sickle cell disease [5], but there is a lack of data in asthmatic children. We performed

this pilot study to evaluate the feasibility of MDOT in asthmatic children and the effect of MDOT on the level of asthma control.

METHODS

We conducted an open-label randomized controlled trial in asthmatic children aged 5 to 15 years attending the pediatric out-patient department (OPD) and pediatric chest clinic of a tertiary care hospital from July 2019 to December 2020. The study was approved by the institute's ethics committee.

Children aged 5-15 years with newly diagnosed asthma whose parents could make a video of the inhaler technique were included. Children whose parents did not have smart phones or internet access were excluded. Diagnosis of asthma was made by pediatric pulmonologist. Videos were to be sent by the parents to a dedicated WhatsApp number provided by the investigator (AP).

A predecided sample size of 30 children was taken. The eligible children were randomized into two groups (15 children each), *viz.* intervention arm (MDOT group) and the control arm (conventional therapy without MDOT). Randomization was done using a computer-generated random number sequence with variable block sizes generated by a person not involved in the study execution generated the randomization list. Allocation concealment was done using the serially numbered opaque sealed envelope. The envelope was opened after fulfilling the inclusion criteria and obtaining the caregiver's consent. Blinding was not possible due to the nature of respective interventions.

Children in both groups were prescribed medications as per standard guidelines. The technique of using metered dose inhaler plus spacer (MDI-S) was demonstrated step-wise by a respiratory nurse **[Box 1]**. The parents of children in the MDOT group were asked to make a video of their child's inhaler use and to send it via WhatsApp to the responding team while ensuring that the videos were not geotagged. Parents were asked to capture the all steps of MDI-S use. Parents were asked to send videos twice daily, for the initial five days. A dedicated WhatsApp number was used to receive the videos from parents. The research team member (AP) responded after each video by providing corrective actions as per the missing step (**Box 1**) via a text/ voice message. Another team member (KRJ) supervised the video assessment and randomly checked the feedback. The case requiring corrections were asked to send more videos till the technique was correct. Subsequently, parents were asked to send a video weekly for six weeks**.** Baseline data were collected. Primary outcome measures were the proportion of good quality video uploaded and the number of steps performed correctly as per **Box 1**. Secondary outcome measures were the level of asthma control as measured by Global Initiative for Asthma (GINA) guidelines [6] and the perception and feedback of caregivers for MDOT as assessed by a questionnaire (**Web Table I**). The duration of study was six weeks and all children were followed up telephonically. At 6 weeks, lung functions were performed by a single blinded researcher in all cases. A questionnaire was also administered to the caregivers at 6 weeks follow-up to ascertain the acceptability of MDOT. Patients were contacted telephonically in both groups for follow-up (**Fig. 1**).

Statistical analysis: Data were entered into Microsoft Excel and analyzed using Stata 12 (Stata Corp, College Station, TX). Categorical data were presented as percentage, while continuous variables were presented as mean (standard deviation, SD) if normally distributed and median (interquartile range, IQR) if skewed. Statistical analysis was performed using the Student's *t*-test/Wilcoxon rank sum and Chi-square test for

comparing continuous (e.g. age, spirometry parameters at baseline etc) and categorical (e.g. gender, asthma severity etc.) data respectively. *P* value of <0.05 was considered significant.

RESULTS

Thirty-three children with newly diagnosed asthma were randomized (15 in each arm) to receive either supervised follow-up aided with MDOT or the conventional follow-up without MDOT. The follow-up of patients was done over 6 weeks telephonically. The flow of participants is given in **Fig. 1**.

The baseline demographic and clinical characteristics of included children are shown in **Table I**. The median age, baseline severity and pulmonary function tests (PFT) were comparable in both groups. Most were boys 22 (73.3%), and the average onset of symptoms was at 4.3 years. The socio-economic status and education status of parents were comparable. The parents who were initially lost to follow-up were contacted telephonically. Among MDOT group, one parent explained that they had started nebulization treatment after consulting a local practitioner and therefore stopped using MDI and did not record any videos. Another parent clarified that his elder brother who was having a smart phone had left for his hometown so videos could not be recorded and shared.

The acceptability of MDOT was measured by the proportion of videos uploaded by parents and the quality of videos. Out of 15 children in the MDOT group, videos were uploaded for 13 (86.6%), and all videos were of good quality. **Table II** shows the number of missed steps from the first to fifth video. We found that after fourth video, there were no incorrect steps in the MDOT group. At six weeks of follow-up, 12 children in the MDOT group performed all steps correctly. A child in the MDOT group who did not respond after sending the first video performed five steps wrong at six weeks of follow-up. The median (IQR) number of steps missed was significantly less in the MDOT group compared to controls [0 (0, 0) vs 2 (2, 4), *P*= 0.001] at six weeks follow-up.

Eleven (85%) children were well-controlled, and 2 (15%) were partly controlled on treatment in the MDOT group, whereas in the control group, 7 (70%) were well-controlled and 3 (30%) partly controlled (*P* = 0.39) (**Table III**). At 6 weeks, 13 parents gave feedback regarding MDOT based on the questionnaire. All of them liked the MDOT and found it easy to make videos, twelve of them felt that no additional cost was incurred in sending videos, and it acted as a reminder, which improved compliance and technique, while a few parents suggested that an App may be helpful (**Web Table II**).

DISCUSSION

In this pilot study, we evaluated MDOT for inhaler therapy in 30 children with newly diagnosed asthma. We found that MDOT was acceptable to caregivers of asthmatic children and it improved the MDI-S technique.

A good adherence to MDOT was also noted. The adherence rate in our study (86%) was more than 42% reported by Dhadge et al [7] and 73% by Shields et al [8]. Dhadge et al [7] enrolled 70 newly diagnosed asthmatic adult patients and assessed inhaler technique by reviewing videos. Shields et al [8] enrolled 24 children aged 2-16 years with difficult to control asthma.

Despite teaching and demonstrating all the steps of use of MDI-S to children with asthma in the OPD, we found that the children do commit mistakes when they go home, even on day 1. After continuous rectification, there was an improvement in steps. At a follow-up of 6 weeks, children in the MDOT group had

significantly fewer incorrect steps than the control group. Delesha et al found improvement in 1.2 steps from baseline to post-video [9]. Assessment of the correct inhaler technique by video recording is reliable [10]. Shields et al performed a study on 22 children with difficult-to-treat asthma and found that at 12 weeks, the inhaler technique improved, and asthma control test (ACT) scores also improved. However, spirometry parameters did not change much [8].

In our study, the level of asthma control after MDOT was measured as per GINA guidelines, and we found a trend towards better control in MDOT vs control group (85% vs 70%); however, the difference was statistically insignificant ($P = 0.39$), probably because the sample size was small. A study by Nawayesh et al enrolled 171 adult patients (control 83, intervention using mobile application 88) and found better ACT scores in the intervention group ($P < 0.05$) [11].

Caregivers' acceptability of MDOT was very good in our study, as assessed by the questionnaire. They found it easy to make and send the videos via WhatsApp. Digital care for asthma is upcoming and involves stand-alone digital inhalers, digital spirometers, and other mHealth devices for asthma care [12]. Some applications have helped improve asthma outcomes, such as the ACT score, decreasing inhaled corticosteroid doses, raising patients' education, and improving adherence [13]. In our study, twelve parents felt that no additional cost was incurred in sending videos, which act as a reminder for them, improving compliance and technique. All caregivers felt a sense of peace as a doctor observed the child directly.

The major strength of this study is that it is one of the few studies that have evaluated the acceptability of MDOT for follow-up in asthmatic children in developing countries. The limitations include a single centre setting with a small sample size. Follow-ups of all participants could not be completed due to the COVID-19 pandemic, and follow-up spirometry could not be done for the same reason.

In India and possibly in other developing countries, a large proportion of people, even low-income groups, have smart mobiles and internet connections. With the help of these devices, we can monitor the therapy remotely and take corrective actions immediately. It can avoid physical visits, thereby saving patients money and decreasing patient load on already busy hospitals. Adequately powered with larger sample sizes are required to assess the effect of MDOT on asthma control. There is a requirement for an application in which videos can be uploaded easily or some artificial intelligence tool that can give corrective directions in real-time while performing steps of MDI inhalation.

Ethics clearance: Institute ethics committee, All India Institute of Medical Sciences, New Delhi; IECPG-325/23.04.19, dated Apr 23, 2019.

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WHAT THIS STUDY ADDS?

- Mobile directed observational therapy is acceptable in children with asthma and is helpful in improving inhaler technique.

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Box 1 Steps of taking MDI with spacer

1. Holds inhaler upright and shakes well.
2. Breaths out gently
3. Puts mouthpiece of spacer between teeth (without biting) and close lips to form a good seal.
4. Attaches the inhaler to the spacer.
5. Presses down firmly on the canister. Starts to breathe in slowly through mouth.
6. Takes 5-6 tidal breaths.
7. Makes sure that the valves of the spacer open during inspiration.
8. Holds breath for about 5 seconds or as long as comfortable after 5-6 tidal breaths.
9. Breathes out gently.
10. If more than one dose is needed, removes the canister, shakes it and repeats all steps 3-9.
11. If using ICS, rinses mouth with water and spits after inhaling the last dose.

Table I Baseline Characteristics of Both the Groups

Characteristic	*MDOT group (n=15)*	*Control group (n=15)*	*P value*
Age (years)[a]	9.8 (7,13)	8.8 (7,12)	0.24
Boys, Girls[b]	9, 6	13, 2	0.09
Age at onset of symptoms (years)[c]	4 (2,6)	4 (2,5)	0.38
Baseline asthma severity[b] Mild Moderate Severe	 0 15 0	 0 15 0	 1.00
Number of emergency department visits in last one year[a]	1 (0,3)	1 (0,2)	0.53
No. of children with previous hospitalization	2	1	0.58
FVC, % of expected[c]	98.8 (16.5)	92.2 (17.3)	0.42
FEV1, % of expected[c]	102.8 (16.9)	93.7 (15.0)	0.24
FEV1/FVC, % of expected[c]	99.4 (10.9)	94.9 (5.3)	0.11

Values expressed as [a]median (IQR), [b]number, [c]mean (SD).
Baseline severity was assessed by treatment step requiring for asthma control, as per GINA guidelines FVC Forced vital capacity, FEV1 Forced expiratory volume in 1st second, MDOT Mobile direct observed therapy.

Table II Description of Videos as Per Steps Performed

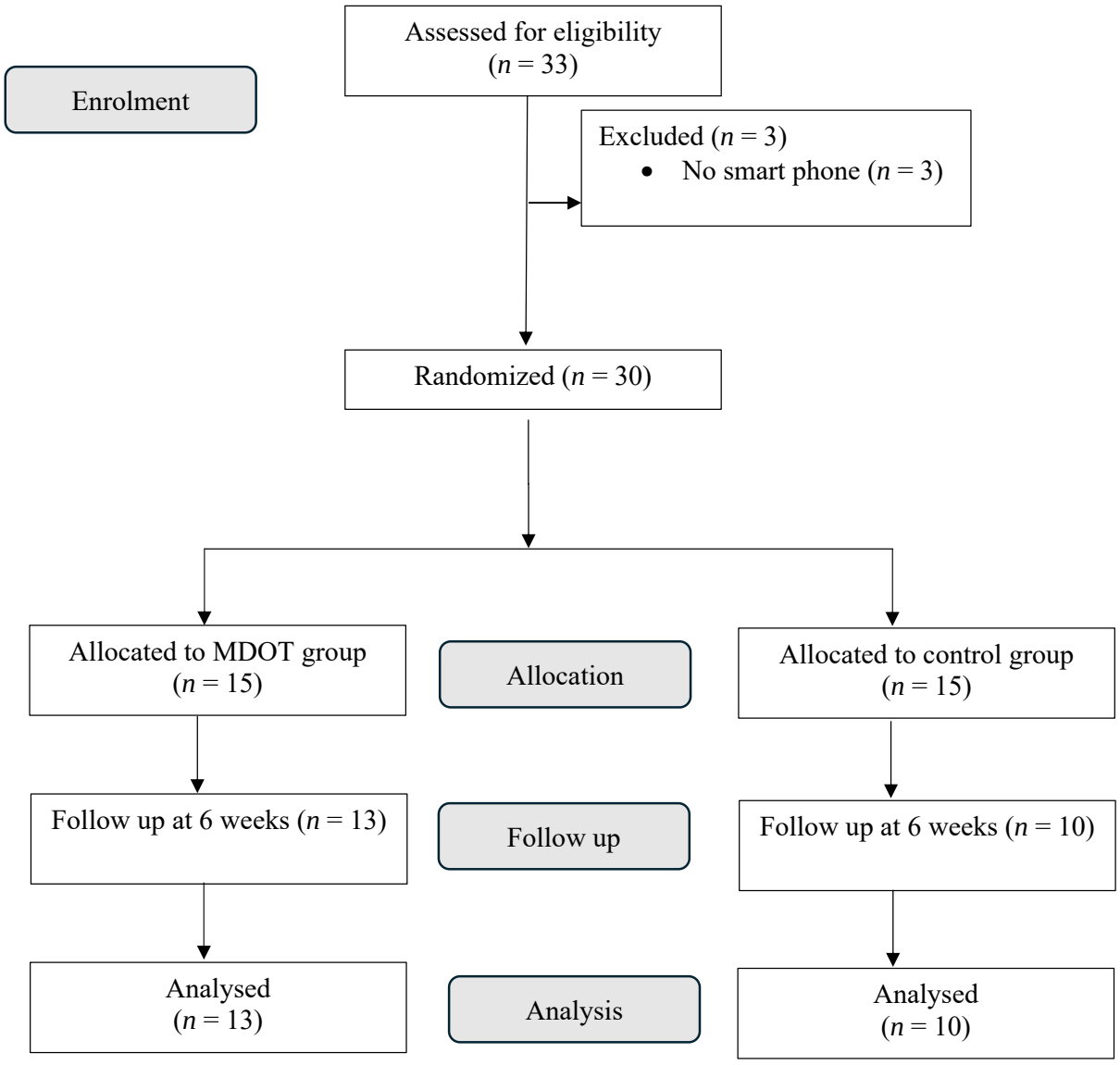
MDOT Group	*Number of children*	*Number of steps missed, median (IQR)*	*Number of steps missed, range*
After video 1	13	2 (2, 3)	0-7
After video 2	12	1 (0, 1)	0-2
After video 3	11	1 (0, 1)	0-1
After video 4	11	0 (0, 0)	0-1
After video 5	10	0 (0, 0)	0

IQR Interquartile range, MDOT Mobile direct observed therapy

Table III. Level of asthma control as per GINA guidelines at six weeks follow-up

Asthma control	*MDOT (n = 13)*	*Control (n = 10)*	*P value*
Well-controlled	11 (84)	7 (70)	0.39
Partly controlled	2 (16)	3 (30)	
Uncontrolled	0	0	

Values expressed as n (%), GINA Global Initiative for asthma, MDOT Mobile direct observed therapy.



MDOT Mobile direct observed therapy

Fig. 1 CONSORT flow diagram