Original Article

Ease-of-use, preference, confidence, and satisfaction with Revolizer®, a novel dry powder inhaler, in an Indian population

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ABSTRACT

Context: While prescribing an inhaler device, it is important to take into account the usability, preference, confidence, and satisfaction of the patients. **Aims:** The present study assessed these parameters with Revolizer®, a novel dry powder inhaler (DPI), in patients with obstructive airway diseases and in device-naïve healthy participants. **Settings and Design:** In this open-label, prospective, multicentre study with 100 participants [*n* = 50 healthy participants, *n* = 45 mild asthma patients, and *n* = 5 mild chronic obstructive pulmonary disease (COPD) patients], all participants were instructed and trained on the use of Revolizer and then the participants subsequently demonstrated the inhalation technique at two visits. **Materials and Methods:** The average time required to execute three correct consecutive attempts and the number of errors (including critical errors) were recorded. Participants were asked about the ease of use, preference, confidence, and satisfaction by means of a questionnaire at each visit. **Results:** The average time required by the participants to achieve three correct consecutive attempts at visit 1 was 3.75 ± 2.10 min, which significantly reduced at visit 2 (3.07 ± 1.32 min, $P < 0.01$). The number of errors decreased from visit 1 to visit 2. More than 85% participants found the Revolizer easy to use, and it was preferred by more than 75% participants. Revolizer scored high on the confidence and satisfaction of all participants at both visits. **Conclusions:** Revolizer is an easy-to-use and a preferred device in patients with mild asthma and COPD, as well as in healthy participants with no previous experience of using inhalation devices. The participants felt confident and satisfied using the Revolizer.

KEY WORDS: Asthma, chronic obstructive pulmonary disease, dry powder inhalers, patient preference, Revolizer

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INTRODUCTION

Administering drugs through the inhalation route is the most efficacious form of drug delivery in obstructive airway diseases (OADs) such as asthma and chronic obstructive pulmonary disease (COPD).[1] In addition to being environmental-friendly and requiring minimum maintenance, the key aspects of an ideal inhalation drug delivery system include ease of use, reproducible dosing with optimal drug deposition, and a feedback mechanism to ensure correct dosing.[1]

Dry powder inhalers (DPIs) are one of the most preferred inhalation drug delivery systems. Their advantages of being breath-actuated, easy to use, and compact make the DPIs reasonably well accepted by patients and their prescribers.[2,3]

The two important factors that should be considered when prescribing an inhalation device are ease of use and patient preference, as these adversely impact a patient's adherence to prescribed therapy, possibly resulting in poor disease control and deteriorating quality of life.[1] The confidence and satisfaction with the inhaler device will improve patient acceptance towards the device and the therapy and may improve the treatment outcomes, potentially reducing the healthcare costs associated with uncontrolled disease.[4,5]

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There are various DPIs now available, and several studies document the safety and efficacy of these DPIs in OADs.[3] However, few studies have evaluated the ease of use, satisfaction, confidence, and patient preference with DPIs,[6-9] though these factors are associated with compliance and, therefore, efficacy.

Revolizer® is a novel unit dose DPI device having adequate drug deposition[10] and a simple inhalation technique, allowing patients to confirm dose delivery as they can see, hear, and taste the drug. This is the first study to assess the usability, confidence, satisfaction, and patient preference with Revolizer in healthy volunteers and in patients with asthma and COPD in India.

MATERIALS AND METHODS

Study design and methods

This was an open-label, prospective, multicentre study assessing the usability, preference, confidence, and satisfaction with Revolizer in healthy volunteers and in patients with asthma and COPD. Each participant enrolled in one of the two study centers had to complete two study visits. During visit 1 (Day 1), the investigator explained and demonstrated the inhalation technique of Revolizer and noted the time taken by the participants to achieve three consecutive correct attempts. At visit 2 (Day 4), the participants demonstrated the inhalation technique without retraining and the number and types of errors were noted. Irrespective of whether the technique was performed correctly or incorrectly, the participants were trained twice and the time taken to perform three consecutive correct attempts and the number and types of errors noted. At both visits, the participants were asked about the ease of use, preference, confidence, and satisfaction with Revolizer using a questionnaire adapted from Schulte *et al.*[9] The questionnaire was self-administered with 20 questions divided into four domains of usability, preference, confidence, and satisfaction [Appendix 1]. The questionnaire was based on a Likert scale where the responses for usability, preference, and confidence ranged from 1 to 6 and for satisfaction ranged from 1 to 5 (a score of 6 or 5 implied a positive response and a score of 1 implied a negative response). Revolizer is a novel unit dose DPI developed, manufactured, and marketed by Cipla Limited in India. It is a simple-to-use device and consists of a mouthpiece, capsule chamber, and base [Figure 1].

Participants

The study included healthy volunteers and patients of asthma and COPD above 18 years of age [Figure 2]. As the questionnaire had been developed in English, participants were included in the study only if they were able to speak and write English. Participants with either mental or physical impairment (such as Parkinson's disease, tremors) were excluded.

Endpoints

The primary endpoint was the average (±SD) time in minutes taken by the participants at visit 1 and visit 2 for three consecutive correct attempts in using the Revolizer. Correct attempt was defined as demonstration of all the steps involved in the proper use of the Revolizer [Appendix 2].

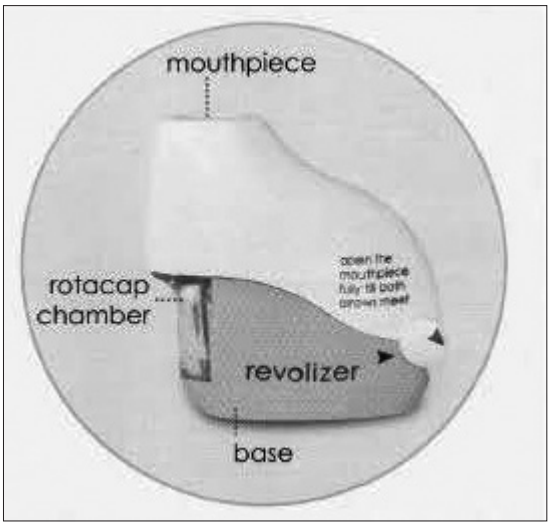

Figure 1: Study device – the Revolizer®

The secondary endpoints included the average (±SD) number of attempts required for the first correct attempt and the number and type of errors while using the inhaler device during both the visits. The errors were classified as critical errors – those that can have a significant effect on the drug delivery to the lungs (they include slow inhalation and not holding breath after inhalation) or non-critical errors – those that do not affect dose delivery to the lungs. These errors were classified as being critical or non-critical prior to the study by an expert committee which included the principal investigators, and were not revealed to the participant [Appendix 3].

The other secondary endpoints included the average (±SD) number and type of errors without retraining at visit 2, assessment of usability, preference assessment in patients using other devices prior to study enrollment, and an assessment of overall participant response to qualitative attributes, confidence, and satisfaction with the Revolizer.

The study was performed in accordance with the Good Clinical Practices and Declaration of Helsinki and was registered with the Clinical Trials Registry of India (CTRI number: CTRI/2009/091/000215). Ethics committee approval was obtained prior to the initiation of the study. The participants were explained the purpose of the study and the study procedures and a written informed consent was obtained. The device and study sponsorship was provided by Cipla Limited, India. Data management and statistical analysis were performed by an independent agency.

Statistical analysis

The demographic and baseline characteristics were analyzed and presented descriptively. All categorical variables were presented as counts and percentages. The

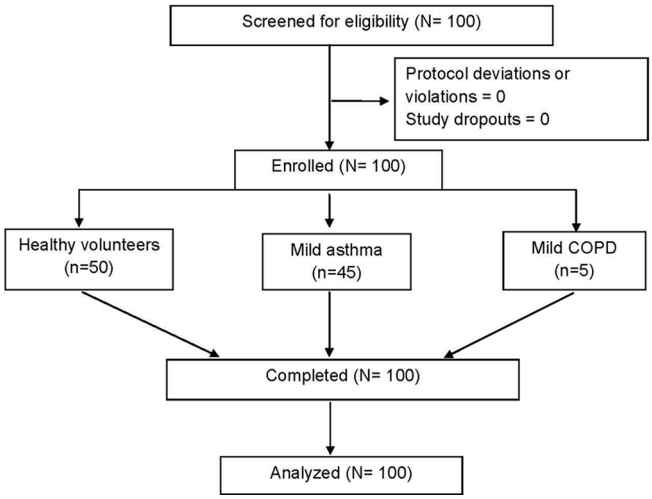

Figure 2: Patient flow and follow-up diagram

primary and secondary endpoint of the number of attempts required to achieve first correct attempt was analyzed using paired *t*-test at 5% level of significance. The other secondary endpoints were described in terms of frequency and percentage of each event, and the mean difference was compared between the two visits.

RESULTS

Baseline and demographic characteristics

One hundred participants (46 males and 54 females; mean age ± SD = 42 ± 14 years) were screened and enrolled. They consisted of 50 healthy volunteers, 45 patients with mild asthma, and 5 patients with mild COPD (based on the clinical diagnosis), and all completed the study. All patients with asthma and COPD (except two) were experienced in using an inhalation device other than the Revolizer (DPIs, $n = 43$; pressurized metered-dose inhaler (pMDI) alone, $n = 3$; and pMDI + spacer, $n = 2$), whereas all healthy volunteers (and two patients) did not have experience of using any inhalation device [Table 1].

Table 1: Baseline and demographic characteristics

Total number of patients screened	100
Total number of patients analyzed	100
Total number of males	46
Total number of females	54
Age in years (±SD)	42 (±14)
Number of healthy volunteers	50
Number of patients	50
Mild asthma	45
Mild COPD	5

SD: Standard deviation, COPD: Chronic obstructive pulmonary disease

Primary endpoint

The average (±SD) time taken for three consecutive correct attempts was 3.75 (±2.10) min at visit 1 and 3.07 (±1.32) min at visit 2 ($P < 0.01$) [Figure 3]. The time taken for three consecutive correct attempts by the healthy participants was 4.07 (±2.34) min at visit 1 and 3.20 (±1.32) min ($P = 0.004$) at visit 2 [Figure 3]. In patients with asthma or COPD, the average time taken for three consecutive correct attempts was 3.44 (±1.81) min at visit 1 and 2.95 (±1.33) min at visit 2 ($P = 0.018$) [Figure 3].

Secondary endpoints

Number of attempts required for correct attempt

The mean (±SD) number of attempts required for the first correct attempt was significantly reduced at visit 2 [2.17 (±1.53) at visit 1 and 1.82 (±1.11) at visit 2, $P = 0.005$]. The average number of attempts required for the first correct attempt at visits 1 and 2 for healthy participants was 2.48 (±1.72) and 1.96 (±1.14) ($P = 0.017$), respectively, and for patients was 1.86 (±1.26) and 1.68 (±1.08) ($P = 0.151$), respectively [Figure 4].

Number and type of errors while using the study device during both the visits

The most frequent errors while using the device included improper or inadequate exhalation prior to inhalation and slow inhalation. The overall number and type of errors (including critical errors) reduced at visit 2 compared to visit 1, with patients already experienced in using inhaler devices making fewer errors than the healthy participants [Figure 5].

Number and type of errors without retraining at visit 2

Without retraining at visit 2, 44% of the participants completed single attempt with no error (critical or non-critical) and 74% of participants completed single attempt with no critical error. Fewer errors were made by patients compared to healthy participants at visit 2 (without retraining), of which the most frequently performed errors were slow inhalation and not holding breath after inhalation.

Assessment of usability of the study device

An average of 93.84% participants found the Revolizer easy to operate, understand, and remember when usability was assessed at both the visits [Figure 6].

Preference and overall participant response to qualitative attributes of the study device

Of the total number of asthma and COPD patients using an inhalation device other than the study device, 78% preferred the Revolizer over their current device.

Additionally, at both the visits, an average of 89.67% participants responded positively in terms of various qualitative attributes such as shape, color, portability, and likeability, and the comfort while operating and handling the device [Table 2].

Confidence and satisfaction of the participants with the study device

At both the visits, the confidence and satisfaction was assessed with Revolizer [Figures 7 and 8]. Overall, the participants felt confident and satisfied using the device. They found it easy to use and reported preference for the device.

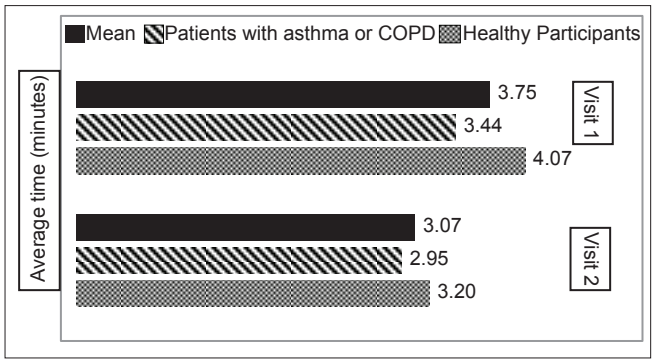

Figure 3: Time taken by participants for three consecutive correct attempts

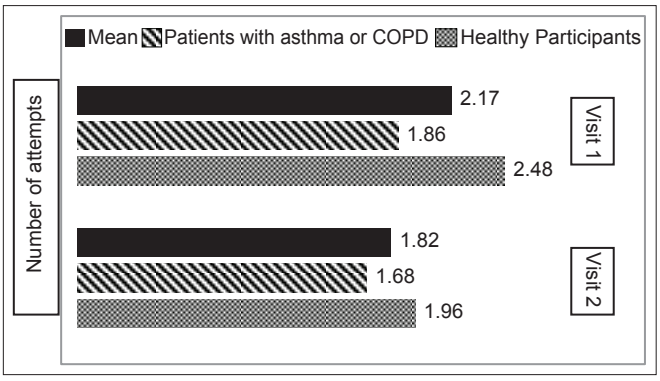

Figure 4: Number of attempts required by the participants for the first correct attempt

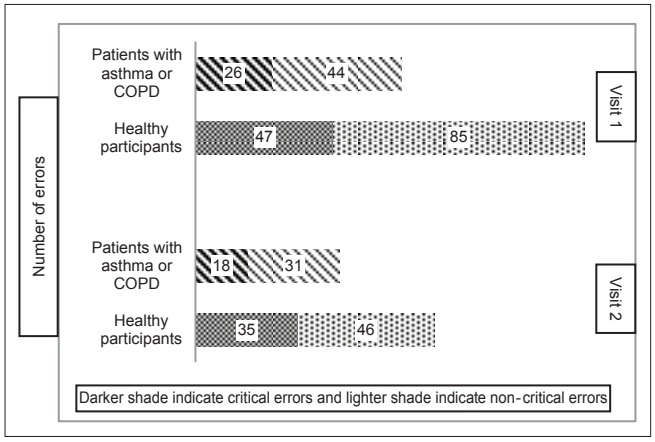

Figure 5: Overall number and type of errors

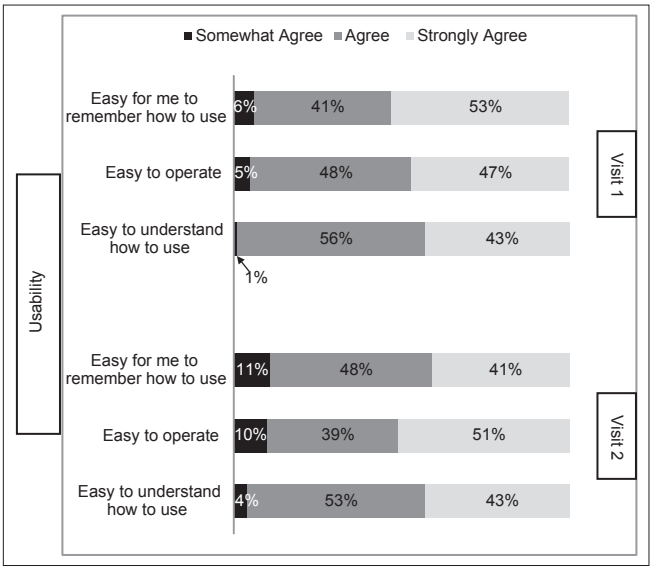

Figure 6: Ease-of-use with Revolizer®-in participants

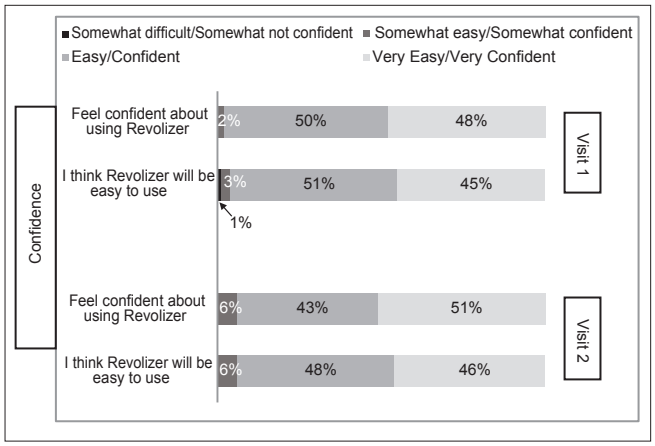

Figure 7: Participants' confidence with Revolizer®

The Revolizer scored high on usability, response toward qualitative attributes, confidence, and satisfaction of patients at both the visits [Table 3].

During the study period, no adverse events were reported in any patient.

DISCUSSION

Chronic respiratory diseases such as asthma and COPD have an increasing prevalence worldwide.[11] Inhalation therapy is the most recommended and accepted form of treating these chronic respiratory diseases.[12] Recent years have seen an exponential increase in the types of inhaler devices both in India and the world over. However, not all inhalers are patient-friendly and easy to use, with each having their own advantages and disadvantages.

DPIs are the widely prescribed inhalation devices globally.[3] Revolizer, a novel DPI, is widely marketed in India and our study demonstrates that it scores high on the ease of use, confidence, satisfaction, and preference in patients with asthma and COPD, as well as in healthy participants with no previous experience of using inhalation devices. Similar studies have assessed the handling, preference, and satisfaction with different DPIs in asthma and COPD.[6,9,13] This was the first study to assess all the parameters which need to be taken into account while selecting an inhaler device for the patient, such as ease of use, preference, confidence, and satisfaction in patients as well as in healthy participants.

It is further important to analyze whether the device prescribed is easy for the patient to remember and use.[12] The

Table 2: Participant responses towards qualitative attributes of the Revolizer®

Device Likeability	Bad (%)	Below average (%)	Above average (%)	Good (%)	Very good (%)
How do you like the device					
Visit 1	0	0	4	57	39
Visit 2	0	1	9	47	43
How does it feel to hold the device					
Visit 1	0	0	4	57	39
Visit 2	0	0	5	55	40
How do you like the shape and color of the device					
Visit 1	1	2	9	47	41
Visit 2	0	4	9	41	46
How do you like the inhalation maneuver with this device					
Visit 1	0	0	11	53	36
Visit 2	0	0	11	56	33
How did you like overall handling the device					
Visit 1	0	2	5	56	37
Visit 2	0	0	7	59	34

Device portability and comfort	Very uncomfortable (%)	Uncomfortable (%)	Somewhat uncomfortable (%)	Somewhat comfortable (%)	Comfortable (%)	Very comfortable (%)
How comfortable is the device to carry						
Visit 1	0	1	1	2	42	54
Visit 2	1	0	1	3	48	47
Is the mouthpiece of the device comfortable						
Visit 1	0	0	1	9	62	28
Visit 2	0	0	1	13	55	31

Device preparation and ease of inhalation	Difficult/somewhat difficult (%)	Somewhat easy (%)	Easy (%)	Very easy (%)
How easy is it to open the device and prepare				
Visit 1	1	7	38	54
Visit 2	1	15	38	46
Was it easy or difficult to inhale long and deeply with the device				
Visit 1	1	11	57	31
Visit 2	0	13	51	36

Device handling	Strongly disagree (%)	Disagree (%)	Somewhat disagree (%)	Somewhat agree (%)	Agree (%)	Strongly agree (%)
I can easily see whether I inhaled correctly with this device	0	0	1	7	50	42
Visit 1	0	0	1	2	54	43
Visit 2						
I can easily see how much medication remains in the device						
Visit 1	0	2	0	6	47	45
Visit 2	0	2	1	10	42	45
The device can be used quickly in case of emergency if necessary						
Visit 1	6	1	5	12	41	35
Visit 2	7	5	6	8	39	35

Table 3: Overall assessment scores of the participants

Parameter	Mean (±SD) scores		Maximum score
	Visit 1	Visit 2	
Usability	16.31 (±1.35)	16.10 (±1.52)	18
Qualitative attribute response	63.26 (±5.09)	62.89 (±5.59)	72
Confidence	10.86 (±1.01)	10.85 (±1.05)	12
Satisfaction	13.41 (±1.42)	13.28 (±1.37)	15

SD: Standard deviation

average time taken by the participants in our study to execute three consecutive correct attempts in using the Revolizer was less than 4 min. The participants in our study were able to correctly use the Revolizer for the first time in less than three attempts at visit 1 and required a maximum of two attempts at visit 2, suggesting that the Revolizer has an inhalation technique which is easy to remember. Remembering the inhaler technique is an important aspect as it can significantly impact the adherence to therapy and can possibly affect disease control.[14,15] More than 90% of the participants in our study found the Revolizer technique easy to understand and operate at both the visits, which could probably mean that the Revolizer has a potential to become a device of choice for patients having cognitive or physical impairment, though this would need confirmation in clinical studies.

The inhalation technique varies with each type of DPI, and like any other inhaler device, optimum drug delivery depends on the correct inhalation technique. Errors made by the

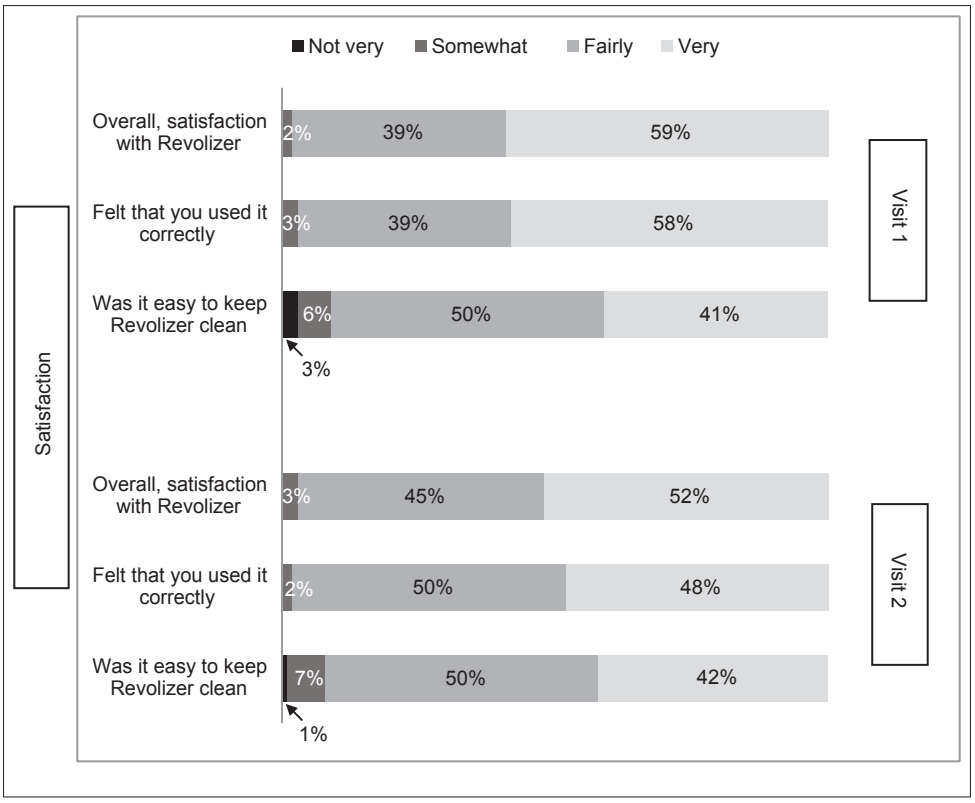

Figure 8: Participants' satisfaction with Revolizer® at both the visits

patients while using an inhaler device can lead to reduced drug delivery adversely impacting the disease control.[16] The most common errors observed in our study while using Revolizer were inadequate exhalation prior to inhalation and slow inhalation, which are not device dependent but patient dependent and can be overcome by proper instruction and training.[17] Before retraining at visit 2, the most common errors observed were slow inhalation and not holding the breath after taking the inhalation dose, which were identified as critical errors, and around 74% participants were able to complete a single attempt without any critical error. The patients with asthma and COPD made fewer errors while using the Revolizer compared to the healthy participants throughout the study. The reason for this difference could be that the patients were already using some device prior to the study. Healthy volunteers, on the other hand, probably had no experience with the inhalation therapy at all. The number of errors and critical errors decreased from visit 1 to visit 2 in both patients and healthy volunteers. Our results indicate that with proper instruction and training, correct inhalation technique can be achieved.

In addition to ensuring correct inhalation technique, it is equally important to take the patient preference into account for an inhalation device and this approach is also recommended by the Global Initiative of Asthma Management (GINA).[6] Patients' attitudes and preference vary from one device to another, even within the DPI category, as seen in previous studies.[18] In our study, 78% patients preferred the Revolizer over their previous inhaler device that included the pMDI with or without a spacer. The major reasons for such a preference were that the device was easy to remember, use, operate, carry, and clean. More than 75% participants found the Revolizer favorable in terms of shape, color, handling, comfort, portability, and inhalation technique. Patient preference for an inhalation device has the potential to improve satisfaction with the device as well as therapy.[19]

We not only assessed satisfaction but also confidence with the Revolizer because if participants including the device-naïve were confident of using the prescribed device, they would also be confident of the prescribed therapy, eventually leading to better adherence. To our knowledge, the present study is the only one to have assessed the confidence of the participants about using an inhaler device. There is definitely a need to develop more validated instruments that can assess the patient confidence along with the ease of use, preference, and satisfaction with an inhaler device.

Generally, such device handling studies are of short duration as single- or two-visit studies to ascertain the usability, preference, confidence, and satisfaction with a particular device.[8,9] The parameters such as usability, preference, confidence, and satisfaction for an inhaler device should ideally be assessed in a larger and heterogeneous patient population including non-English speaking patients, preferably with a comparator device. These have not been done in this study, which is a study limitation. We are in the process of developing questionnaires on the currently assessed parameters to suit the linguistic diversity for capturing more data from a larger population.

We did not measure the breathing pattern such as rapid and deep inhalation objectively, which could be one of the limitations of our study. The lesser number of COPD patients and short study duration were the other limitations of our study. As errors generally develop over time, it would be worthwhile to perform a study analyzing the number and type of errors with a significant time gap between training and retraining visits. It would also be interesting to repeat a similar study in this population which consists mainly of elderly individuals.

In conclusion, we confirm that the Revolizer is an easy-to-use and a preferred device. It scores high on the satisfaction and confidence in patients and individuals who have never used an inhaler device. Revolizer is a patient-friendly, portable, and comfortable device which is easy to operate and handle. It has the potential to become the device of choice for both patients and physicians alike.

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APPENDIX 1: QUESTIONNAIRE

(Please encircle the appropriate option)

I) Confidence assessment

1.Overall I think the inhaler will be easy to use.

6	5	4	3	2	1
Very easy	Easy	Somewhat easy	Somewhat difficult	Difficult	Very difficult

2.Overall I feel confident about using the inhaler.

6	5	4	3	2	1
Very confident	Confident	Somewhat confident	Somewhat not confident	Not confident	Definitely not confident

II) Usability assessment

1. I found it was easy to understand how to use the inhaler.

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

2. I found it was easy to operate the inhaler.

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

3. I found it was easy for me to remember how to use the inhaler.

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

III) Preference assessment

1. How do you like the device?

6	5	4	3	2	1
Very good	Good	Above average	Below average	Bad	Very bad

2. How does it feel to hold the device?

6	5	4	3	2	1
Very good	Good	Above average	Below average	Bad	Very bad

3. How do you like the shape and color of the device?

6	5	4	3	2	1
Very good	Good	Above average	Below average	Bad	Very bad

4. How comfortable is the device to carry?

6	5	4	3	2	1
Very comfortable	Comfortable	Somewhat comfortable	Somewhat uncomfortable	Uncomfortable	Very uncomfortable

5. How easy is it to open the device and prepare it for inhalation?

6	5	4	3	2	1
Very easy	Easy	Somewhat easy	Somewhat difficult	Difficult	Very difficult

6. Is the mouthpiece of the device comfortable?

6	5	4	3	2	1
Very comfortable	Comfortable	Somewhat comfortable	Somewhat uncomfortable	Uncomfortable	Very uncomfortable

7. Was it easy or difficult to inhale long and deeply with the device?

6	5	4	3	2	1
Very easy	Easy	Somewhat easy	Difficult	Somewhat difficult	Very difficult

8. How did you like the inhalation maneuver with this device?

6	5	4	3	2	1
Very good	Good	Above average	Below average	Bad	Very bad

9. I can easily see whether I inhaled correctly with this device.

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

10. I can easily see how much medication remains in the device.

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

11. The device can be used quickly in case of emergency, if necessary

6	5	4	3	2	1
Strongly agree	Agree	Somewhat agree	Somewhat disagree	Disagree	Strongly disagree

12. How did you like overall handling of the device? (preparation, handling, inhalation maneuver, storage, and cleaning)

6	5	4	3	2	1
Very good	Good	Above average	Below average	Bad	Very bad

IV) Satisfaction assessment

1. Was it easy to keep the inhaler clean?

5	4	3	2	1
Very	Fairly	Somewhat	Not very	Hardly at all

2. After you have used the inhaler, do you have the feeling that you used it correctly?

5	4	3	2	1
Very	Fairly	Somewhat	Not very	Hardly at all

3. Overall, considering your responses to the previous questions, were you satisfied with the inhaler?

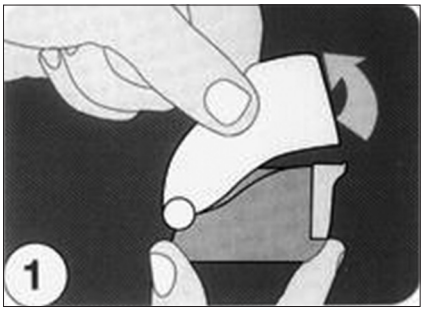
5	4	3	2	1
Very	Fairly	Somewhat	Not very	Hardly at all

QUESTIONS FOR PATIENTS ALREADY USING INHALER DEVICE

- Which device do you use currently? _____
- Do you prefer Revolizer over your current device?
  Yes ☐ No ☐
  If yes, specify reason:----------
  _____
  _____
  _____
  _____
  _____
  _____
  If no, specify reason:_____
  _____

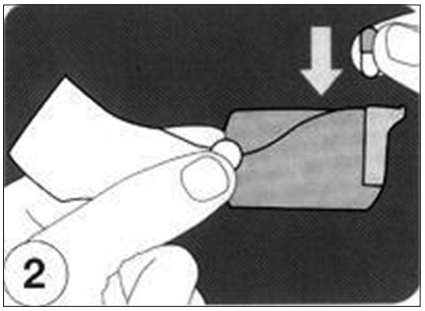
APPENDIX 2: REVOLIZER – HOW TO USE

Step 1



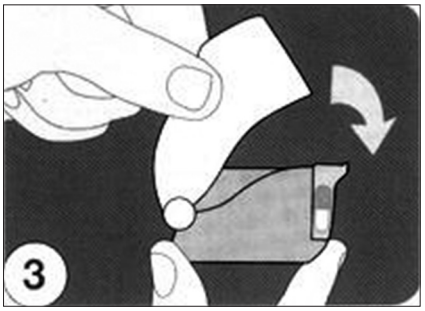
To open the Revolizer, hold the base of the Revolizer with one hand and pull back the mouthpiece till the arrows meet.

Step 2



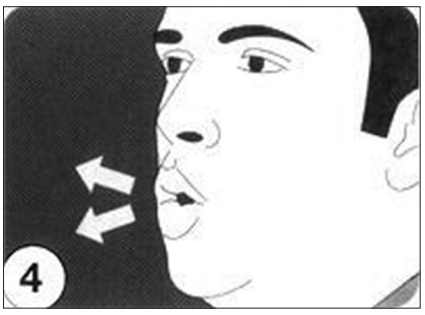
Remove a medication capsule from the Rotacap bottle; place it in the capsule chamber, with the transparent end first.

Step 3



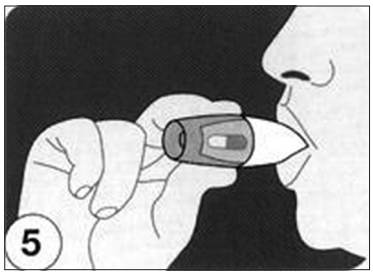
Close the mouthpiece firmly until a click sound is heard which indicates proper locking of the Revolizer.

Step 4



Breathe out completely.

Step 5



Grip the mouthpiece between your teeth and seal your lips around it.

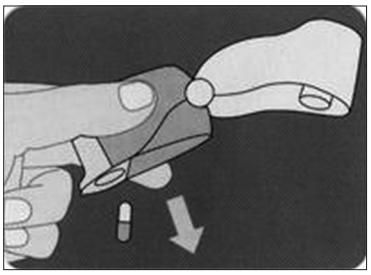
Step 6

Keep your head upright and breathe in through your mouth as deeply as you can. If done correctly, the Rotacap will vibrate inside the Revolizer.

Step 7

Remove the Revolizer from your mouth and hold your breath for 10 s. Hold your breath as long as comfortable and then resume normal breathing. At times, step 6 may be repeated to ensure that all the powder has been inhaled which can be seen through Rotacap chamber.

Step 8



After every use, open the mouthpiece again to discard the used medication capsule. Close the mouthpiece and store in the pouch provided for the next use. Clean the Revolizer when needed by wiping the mouthpiece and the capsule chamber with a dry cloth. Avoid breathing out into your Revolizer. For subsequent use, take a fresh Rotacap and follow steps 1–8.

Appendix 3: Description of errors while using the Revolizer

Steps while using the Revolizer	Errors
1	Arrows did not meet
2	Did not insert the Rotacap transparent side into the capsule chamber
3	Did not lock the Revolizer properly
4	Did not exhale properly prior to inhalation
5	Did not grip the mouthpiece
6	Inhalation was slow
7	Did not hold the breath after inhalation
8	Did not discard the used Rotacap

Of these, steps 6 and 7 were termed as critical steps since they affect the drug delivery