

Patient Satisfaction With Inhaled Medication for Asthma

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BACKGROUND: We sought to compare treatment satisfaction with inhaled medications among asthmatics using a metered-dose inhaler (MDI) or a dry-powder inhaler (DPI), and to correlate satisfaction with treatment adherence, pulmonary function, and airway inflammation. **METHODS:** Spirometry, fraction of expired nitric oxide (F_{ENO}), and asthma control were assessed in 200 adult subjects with asthma (69 men, 131 women) using MDI or DPI. Treatment satisfaction with inhaled therapy was assessed with the Treatment Satisfaction Questionnaire for Medication (TSQM) in 4 domains: Effectiveness, Side Effects, Convenience, and Global Satisfaction. The Medication Adherence Questionnaire (MAQ) was used to evaluate adherence to treatment. **RESULTS:** There were 115 and 85 subjects with asthma, using MDI and DPI, respectively. More MDI users (40.9%) had well-controlled asthma as compared to DPI users (17.6%). MDI users had greater treatment adherence and better TSQM domain scores for Effectiveness, Convenience, and Global Satisfaction than did DPI users. Multivariate linear regression analysis revealed no significant association between MDI/DPI use and TSQM domain scores. TSQM Convenience and Global Satisfaction domain scores were significantly correlated with MAQ scores (Spearman's coefficients 0.211 and 0.218, $P = .003$ and $P = .002$, respectively). There was no significant correlation between any TSQM domain score and pulmonary function or F_{ENO} concentration. **CONCLUSIONS:** MDIs were associated with better disease control and treatment adherence among subjects with asthma. Both MDI and DPI are likely to provide equivalent treatment satisfaction. *Key words:* asthma; inhaler devices; patient satisfaction; treatment adherence. [Respir Care 0;0(0):1–•. © 0 Daedalus Enterprises]

Introduction

Asthma medications are preferably delivered through the inhaled route. However, inhalers were considered taboo, socially unacceptable, or habit-forming by some

Indian patients, especially in rural areas. The situation has improved due to improved availability, reduced device cost, and emphasis on health education. A variety of metered-dose inhalers (MDIs) and dry-powder inhalers (DPIs) are manufactured and marketed by several Indian pharmaceutical companies, and a few international devices are also available. In general, clinical outcomes with either MDI or DPI appear similar if the dosing and technique of inhalation are appropriate.¹ As clinicians, we often focus on the level of asthma control as the hard end point to assess treatment efficacy, and patient-related factors such as treatment preferences, satisfaction, and adherence, among others, are not assessed routinely.

Patients may not be fully satisfied with their asthma medications for a variety of reasons, including cost, complexity of the device, adverse effects, perceived stigma, and suboptimal improvement in health status. This in turn may negatively influence adherence to therapy and may result in a lower likelihood of successfully achieving asthma treatment goals.^{2,3} A small Indian study noted that subjects newly trained to use a particular Indian DPI device were

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SATISFACTION WITH INHALERS

largely satisfied with its use.⁴ However, to our knowledge, no previous Indian study has explored various issues related to patient satisfaction among subjects with asthma who use long-term inhaled therapy. We therefore assessed treatment satisfaction with inhaled medications among stable asthmatics using either MDIs or DPIs, and we correlated satisfaction with the type of inhaler device, treatment adherence, lung function, and airway inflammation.

Methods

We enrolled 200 consecutive adult subjects with asthma (69 men, 131 women; age \geq 18 y) who attended the chest clinic of our institute from January 2015 to December 2015. Subjects were required to have used an MDI or a DPI manufactured by an Indian company for at least the past year. The diagnosis of asthma was based on a combination of typical symptoms (eg, wheezing, coughing, chest tightness, or shortness of breath) and documentation of air-flow limitation on spirometry. All subjects spoke and understood Hindi well. Proper inhaler technique had been demonstrated and verified on at least one previous out-patient visit for all subjects. Patients who experienced disease exacerbation requiring treatment augmentation, systemic corticosteroid therapy, or an emergency room visit in the last 4 weeks were excluded. Patients with asthma with coexisting medical conditions that could potentially worsen quality of life or impair the level of activity were also excluded, as were pregnant women. Informed consent was obtained from all subjects included in the study, and the study protocol was approved by our institutional ethics committee.

Baseline demographic and clinical details were gathered from all subjects. Asthma symptom control was categorized as good, partial, or poor according to Global Initiative for Asthma (GINA) guidelines.⁵ Spirometry was performed by trained technicians using a dry rolling seal spirometer (Spiro RS232; PK Morgan, United Kingdom) per standard guidelines.⁶ Subjects' observed FVC, FEV₁, and FEV₁/FVC ratio were compared to predicted norms previously derived for north Indians at our institute.⁷ An FEV₁/FVC ratio below the predicted lower limit of normal for an individual was considered to represent an obstructive defect. Fraction of expired nitric oxide (F_{ENO}) was measured orally through a portable online analyzer (NObreath, Bedfont Scientific, United Kingdom). The average of 3 reproducible measurements was expressed in ppb, with higher readings indicating more severe airway inflammation.⁸ Satisfaction with inhaled therapy was assessed using the Hindi adaptation of the Treatment Satisfaction Questionnaire for Medication (TSQM), version 1.4.⁹ This 14-item questionnaire provides transformed scores ranging from 0–100 in 4 domains (ie, Effectiveness, Side Effects, Convenience, and Global Satisfaction), with higher

QUICK LOOK

Current knowledge

Patients may not be fully satisfied with their asthma medications due to several reasons. The device used for inhaled therapy may influence patient satisfaction and adherence.

What this paper contributes to our knowledge

In a real-life clinical scenario, the use of metered-dose inhalers was associated with better disease control and treatment adherence compared to dry-powder inhalers. Both devices, however, seemed to provide equivalent treatment satisfaction. Treatment satisfaction with inhaled therapy correlated poorly with pulmonary function and airway inflammation.

scores suggestive of greater satisfaction. Subjects with asthma on inhaled therapy had participated in the original validation process of the TSQM, and the instrument has been used on patients taking inhaled medications for other respiratory disorders.^{10,11} Adherence to inhaled therapy was assessed with the Medication Adherence Questionnaire (MAQ), translated into the Hindi language.¹² The MAQ has 4 Yes/No questions that address ways in which patients failed to take their prescribed medications over the last 3 months.¹² Subjects with MAQ scores 0–1, 2–3, and 4 were considered to have low, medium, and high adherence to inhaled therapy, respectively.

All scores were summarized as medians and corresponding interquartile ranges (IQR). Group comparisons were made with nonparametric statistical tests (Mann-Whitney *U* test for scalar variables and Fisher exact test for categorical variables). Correlations between variables of interest were evaluated through Spearman's coefficient. Multiple linear regression analysis was performed to identify variables that significantly influenced TSQM domain scores. Statistical significance was tested at $P < .05$. The statistical software SPSS (version 21; IBM, Armonk, New York) was used for analysis.

Results

The study population had 69 (34.5%) men and 131 (65.5%) women who had asthma symptoms for a median (IQR) duration of 8 (4–15) y (Table 1). Subjects were using inhaled drugs for a median (IQR) duration of 3 (1–8) y, either as MDI (114 [57.5%] subjects) or as single-capsule DPI (85 [42.5%] subjects). Only 62 (31.0%) subjects had well-controlled asthma. Nearly half of all subjects (98 [49.0%] subjects) showed an obstructive defect on

SATISFACTION WITH INHALERS

Table 1. Demographic and Clinical Characteristics of the Study Population

Characteristics	Value
Gender	
Men	69 (34.5%)
Women	131 (65.5%)
Age, y	40 (30–50)
Residence	
Rural	108 (54.0%)
Urban	92 (46.0%)
Education	
Illiterate	36 (18.0%)
Primary	40 (20.0%)
Higher secondary	80 (40.0%)
Graduate or higher	44 (22.0%)
Tobacco smoking	
Smoker	4 (2.0%)
Non-smoker	196 (98.0%)
Disease duration, y	8 (4–15)
Duration of inhaled therapy, y	3 (1–8)
Type of inhaled drugs	
ICS alone	5 (2.5%)
SABA alone	21 (10.5%)
ICS + SABA combination	13 (6.5%)
ICS + LABA combination	158 (79.0%)
Others	3 (1.5%)
Inhaler device	
Metered-dose inhaler	115 (57.5%)
Single-capsule dry-powder inhaler	85 (42.5%)
Asthma control	
Well controlled	62 (31.0%)
Partly controlled	74 (37.0%)
Uncontrolled	64 (32.0%)
Spirometry result	
No obstruction	102 (51.0%)
Mild obstruction	49 (24.5%)
Moderate obstruction	37 (18.5%)
Severe obstruction	12 (6.0%)
% of predicted FEV ₁	73 (53–93)
% of predicted FVC	87 (65–102)
FEV ₁ /FVC, %	65 (57–74)
Fractional exhaled nitric oxide, parts per million	17 (8–25)

N = 200 subjects. Data are expressed as frequency (%) or median (interquartile range) as appropriate.

ICS = inhaled corticosteroid

SABA = short-acting β agonist

LABA = long-acting β agonist

spirometry, and 38 (19.0%) subjects had F_{ENO} levels > 25 ppb (Table 1). Only 62 (31.0%) subjects had well-controlled asthma symptoms, and only 43 (21.5%) were fully adherent to inhaled therapy. More MDI users (47 [40.9%] subjects) had well-controlled asthma compared to DPI users (15 [17.6%] subjects) (Table 2). MDI users also had significantly better MAQ scores than DPI users (median [IQR] 2 [1–3] vs 1 [1–3], *P* = .043) (Table 2).

On administering the TSQM, 169 (84.5%) subjects reported no adverse effects related to inhaled therapy. Scores for the other 3 domains (ie, Effectiveness, Convenience, and Global Satisfaction) were more variable and widely distributed, and in general were significantly higher for MDI users than for DPI users (Table 2). Women, subjects with well-controlled asthma symptoms, and those taking a combination of inhaled corticosteroids and long-acting β agonists had higher TSQM Effectiveness and Global Satisfaction domain scores (Table 3). TSQM Convenience and Global Satisfaction domain scores were significantly correlated with MAQ scores (Table 4). There was no significant correlation between any TSQM domain score and pulmonary function or F_{ENO} concentration (Table 4).

On multiple linear regression analysis, TSQM domain scores were not influenced by the type of inhaler device being used (Table 5). Asthma control significantly influenced Effectiveness and Global Satisfaction domain scores, and treatment adherence significantly influenced Convenience and Global Satisfaction domain scores (Table 5). However, the coefficient of determination (*R*²) was numerically small for all models. We also modeled the linear regression after adjusting for a potential interaction between device type and control of asthma. The inclusion of this interaction term did not alter the results of the regression analysis substantially (Table 5).

Discussion

Most of the subjects in this study were using MDIs, while others were using single-capsule DPIs. Single-capsule devices commonly used in India are modifications of the now discontinued Spinhaler (Aventis Pharma, Surrey United Kingdom) and Rotahaler (GlaxoSmithKline, Middlesex, United Kingdom). Despite being relatively inefficient as compared to standard MDIs, several subjects preferred these DPIs as they require much less hand–mouth coordination during inhalation, and they are available in smaller dose units, which makes them more affordable for poorer patients who could not otherwise afford a 200-dose MDI.

As compared to DPI users, MDI users in this study had higher prevalence of well-controlled asthma, showed greater adherence to inhaled therapy, and reported better satisfaction with treatment on 3 of 4 TSQM domains. Patient satisfaction with their medications is now increasingly recognized as an important patient-reported outcome in clinical practice.¹³ Previous studies have mainly evaluated patient satisfaction under clinical trial conditions, with specific inhaled drugs and devices being used by carefully selected subjects. Patient satisfaction with inhaled therapy depends not only on the inhaler device, but also on the administered drugs.^{14,15} If the drugs are similar, different devices may still show different levels of satisfaction.¹⁶

SATISFACTION WITH INHALERS

Table 2. Comparison of MDI vs DPI for Inhaled Therapy for Asthma

Characteristics	MDI	DPI	Total	P
Asthma control				
Well controlled	47 (40.9%)	15 (17.6%)	62 (31.0%)	.001
Partly controlled	40 (34.8%)	34 (40.0%)	74 (37.0%)	
Poorly controlled	28 (24.3%)	36 (42.4%)	64 (32.0%)	
Lung function				
F _{ENO} ≤ 25 ppb	92 (80.0%)	70 (82.4%)	162 (81.0%)	.72
F _{ENO} > 25 ppb	23 (20.0%)	15 (17.6%)	38 (19.0%)	
Overall	15 (6–23)	12 (7–22)	14 (6–22)	.90
% Predicted FEV ₁	81.5 (63.4–94.9)	73.0 (53.2–93.3)	77.1 (59.5–94.1)	.044
MAQ score				
High adherence, 4	27 (23.5%)	16 (18.8%)	43 (21.5%)	.11
Medium adherence, 2–3	46 (40.0%)	25 (29.4%)	71 (35.5%)	
Low adherence, 0–1	42 (36.5%)	44 (51.8%)	86 (43.0%)	
Overall	2 (1–3)	1 (1–3)	2 (1–3)	.043
TSQM score				
Effectiveness	72.2 (66.7–83.3)	66.7 (61.1–77.8)	72.2 (61.1–83.3)	.004
Side Effects	100 (100–100)	100 (100–100)	100 (100–100)	.91
Convenience	72.2 (66.7–83.3)	66.7 (55.6–77.8)	72.2 (61.1–77.8)	.02
Global Satisfaction	71.4 (64.3–78.6)	71.4 (57.1–78.6)	71.4 (60.7–78.6)	.035

Data are expressed as number (%) or median (interquartile range) as applicable.

MDI = metered-dose inhaler

DPI = dry-powder inhaler

F_{ENO} = fraction of expired nitric oxide

ppb = parts per billion

MAQ = Medication Adherence Questionnaire

TSQM = Treatment Satisfaction Questionnaire for Medication

Table 3. Impact of Demographic and Clinical Characteristics on TSQM Domain Scores

Characteristics	Effectiveness	Side Effects	Convenience	Global Satisfaction
Gender				
Men	66.7 (61.1–77.8)*	100 (100–100)	66.7 (61.1–77.8)	71.4 (57.1–78.6)*
Women	72.2 (61.1–83.3)	100 (100–100)	72.2 (61.1–77.8)	71.4 (64.3–78.6)
Residence				
Rural	72.2 (61.1–83.3)	100 (100–100)	66.7 (61.1–77.8)	71.4 (57.1–78.6)
Urban	72.2 (63.9–80.6)	100 (100–100)	72.2 (61.1–83.3)	71.4 (64.3–78.6)
Symptom control				
Well controlled	77.8 (72.2–83.3)*	100 (100–100)	77.8 (66.7–83.3)*	78.6 (71.4–92.9)*
Partly/poorly controlled	66.7 (61.1–77.8)	100 (100–100)	66.7 (61.1–77.8)	71.4 (57.1–78.6)
Inhaled drugs				
ICS + LABA combination	72.2 (66.7–83.3)*	100 (100–100)	72.2 (61.1–77.8)	71.4 (64.3–78.6)*
Other drugs	63.9 (55.6–72.2)	100 (100–100)	66.7 (55.6–77.8)	64.3 (50.0–78.6)

* P < .05. Data are expressed as median (interquartile range).

TSQM = Treatment Satisfaction Questionnaire for Medication

ICS = inhaled corticosteroid

LABA = long-acting β agonist

Other studies have reported similar levels of satisfaction between MDIs, DPIs, and other new devices.^{17,18} DPIs are also available in both single-dose and multi-dose formats, and there is some suggestion that patients derive greater satisfaction with the latter.^{19,20} Unfortunately, no data are available to correlate the type of inhaler device with pa-

tient satisfaction in real-world scenarios. Our study is a preliminary attempt to fill this knowledge gap, and after adjusting for covariates in a multiple linear regression model, we found that the type of inhaler was not significantly associated with treatment satisfaction domain scores. This suggests that in real-life situations, both MDI and

SATISFACTION WITH INHALERS

Table 4. Correlations Between TSQM Domain Scores and Demographic and Clinical Characteristics

Characteristics	Effectiveness	Side Effects	Convenience	Global Satisfaction
Age	0.11	0.18	0.01	0.11
Years of having asthma	-0.02	0.03	0.04	0.04
Years of inhaler use	-0.01	-0.07	0.01	0.06
% Predicted FEV ₁	-0.01	-0.01	0.17*	0.02
F _{ENO}	-0.13	-0.08	-0.09	-0.09
MAQ score	0.13	0.05	0.21*	0.22*

* $P < .05$.

TSQM = Treatment Satisfaction Questionnaire for Medication

F_{ENO} = fraction of expired nitric oxide

MAQ = Medication Adherence Questionnaire

Table 5. Multiple Linear Regression Analysis to Assess Variables Significantly Influencing TSQM Domain Scores

Regression Coefficients	Effectiveness		Convenience		Global Satisfaction	
	Model 1	Model 2	Model 1	Model 2	Model 1	Model 2
Constant	75.97	69.57	57.98	57.99	63.57	63.70
MDI use	3.26 (.10)	2.85 (.21)	3.16 (.10)	3.11 (.16)	2.13 (.34)	1.69 (.51)
Well-controlled asthma	9.15 (< .001)	8.03 (.038)	4.14 (.051)	4.02 (.28)	11.82 (< 0.001)	10.60 (.02)
MAQ score	0.44 (.58)	0.44 (.59)	1.90 (.02)	1.90 (.02)	1.84 (.042)	1.84 (.043)
% Predicted FEV ₁	-0.05 (.25)	-0.05 (.26)	0.06 (.12)	0.06 (.12)	-0.03 (.45)	-0.03 (.47)
F _{ENO} (ppm)	-0.06 (.33)	-0.06 (.33)	-0.00 (.95)	-0.00 (.95)	0.03 (.68)	0.03 (.68)
MDI use × well-controlled asthma		1.60 (.73)		0.18 (.97)		1.76 (.73)
R ²	0.14	0.14	0.11	0.11	0.16	0.16

Figures in parentheses are significance values for regression coefficients. All models are based on data from 100 subjects each using an MDI or a DPI.

TSQM = Treatment Satisfaction Questionnaire for Medication

MDI = metered-dose inhaler

MAQ = Medication Adherence Questionnaire

F_{ENO} = fraction of expired nitric oxide

ppm = parts per million

DPI may provide equal treatment satisfaction when other clinical variables are accounted for. We acknowledge, however, that our regression models explain only a small proportion of the variability in the model, and it is likely that other factors that are not evaluated in this study are more important determinants of patient satisfaction.

Most subjects in our study had well-controlled airway inflammation, as evidenced by F_{ENO} levels (Table 2). Pulmonary function was, however, better in the MDI users. This discrepancy between F_{ENO} and clinical parameters (asthma control and spirometry) is not entirely surprising, as F_{ENO} may be useful only as a complementary marker to other asthma assessment tools.²¹ Previous investigators have also reported poor correlation between F_{ENO} levels and other clinical markers of asthma.^{22,23}

More importantly, we found that subjects using MDIs reported better TSQM domain scores for Effectiveness, Convenience, and Global Satisfaction. This may partly be linked to our observation that MDI users had better-controlled disease (Table 2). Subjects using MDIs also showed greater overall adherence to treatment, and this is likely a

result of greater treatment satisfaction among MDI users. However, after adjusting for treatment adherence, lung function, airway inflammation, and overall asthma control, MDI use did not significantly influence TSQM domain scores (Table 5). Both DPIs and MDIs provide equivalent clinical effect when taken appropriately and thus may provide equivalent patient satisfaction with long-term use. We also demonstrated a significant positive correlation between MAQ score and the Global Satisfaction and Convenience domain scores of the TSQM (Table 3). This association between medication adherence and treatment satisfaction has been previously noted for several chronic medical conditions.²⁴

Our study has certain limitations. All subjects using DPIs were inhaling their medications through single-capsule devices. This might limit the generalizability of our data because multi-dose devices are commonly used in other settings. Although all subjects had been previously trained to use their inhaler devices properly, we did not specifically verify the correctness of inhaler technique at the time of evaluation in this study. We also used a generic

SATISFACTION WITH INHALERS

instrument to assess satisfaction with inhaled therapy, as some of the more inhaler-specific questionnaires used in other clinical trials were not available in our local language.

We conclude that MDIs are associated with better disease control and treatment adherence among subjects with asthma. Even though the subjects using MDIs derived greater treatment satisfaction than those using commonly available DPIs in India, after adjusting for other clinical variables, both devices seemed to provide equivalent treatment satisfaction.

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