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EVALUATION OF TECHNIQUES OF INHALATION DEVICES AMONG PATIENT OF COPD AND BRONCHIAL ASTHMA

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ABSTRACT

Background: Chronic obstructive pulmonary diseases and bronchial Asthma are common respiratory diseases having a large burden on society in term of mortality and morbidity. Drugs and inhalational devices is a main stay in the treatment. Beside the nebulizer, the development of other devices other like PMDI/DPI made it possible to improve delivery of drugs to the lungs and produces local effect and decrease systemic side effect. **Material & Method**: Study conducted in patients who were known cases of Chronic obstructive Pulmonary Disease or Bronchial Asthma, between the Ages of 15 to 70 year. Patients were excludes as Age <15 or >70 years, Patients suffering from active tuberculosis infection, Patient with a co-morbid, condition**,** Patient unwilling to participate in the study. **Results:** 304 patient were enrolled having COPD & Bronchial asthma 83.9% patient had error in techniques while using inhalational devices, highest error within 41 to 60 year of age and male > female , rural > urban lower educated were did more error, COPD> bronchial asthma, MDI without spacer> with spacer > DPI ,frequently using and long duration users were made less error. Those patient are educated by doctor having least error & highest with self educator. **Conclusions:** Devices are complicated to use, requiring many step for a correctly perform inhalational maneuver. Here we found mistakes among educators and evaluation of inhalational technique for using prescribed inhalational devices in COPD and Bronchial Asthma patients.

KEY WORDS: Copd, Asthma, Devices, Inhalational Therapy, Errors, Metered Dose Inhaler, Dry Powder Inhalers.

INTRODUCTION

Chronic obstructive pulmonary diseases and bronchial Asthma are common respiratory diseases having a large burden on society in term of mortality and morbidity.[1] In India the prevalence of COPD is higher due to increasing trend smoking and use of bio fuel mass. Grossman (1994) described that the evolution of inhalation therapy can be traced to India 4000 years ago. The antecedents of contemporary inhalation therapy, however, began in the nineteenth-century industrial age with the invention of the glass bulb nebulizer. From there, inhaler technology evolved along two pathways characterized by refinements in existent nebulizer technology and the invention of a portable inhalation device. Drugs and inhalational devices is a main stay in the treatment because to their efficacy, cost, effectiveness, and lesser side effect.[2, 3] Inhaled way providing higher local concentration and least systemic side effect[4]. beside the nebulizer, the development of other devices other like PMDI/DPI made it possible to improve delivery of drugs to the lungs and produces local effect and decrease systemic side effect.[5] Devices are complicated to use ,requiring many step for a correctly perform inhalational maneuver.Reardon and Bragdon in 1993 showed that the metered-dose inhaler (MDI) is a miracle of modern technology, but its use can be burdened with problems.[6] Sub optimal techniques result in decrease drug delivery and inadequate therapeutic response[7,8] With proper education and techniques the drugs deposition increase up to12-20% Omer et al[9] de-Moraes et alshowes 94.2% patient committed at least one error in there inhalational technique[10,11] Benjaponpitak et al (1996) described that currently press-and-breath metered dose inhalers (MDIs) are widely prescribed but are often difficult for many patients to properly use However many medical personnel cannot use the MDIs correctly.[12,13] Here we planned study for evaluation of inhalational technique for using prescribed inhalational devices in COPD and Bronchial Asthma patients Using various inhalers devices. Vashaar (2002) described the efficacy of inhalational therapy depend on several factor, choice of devices, its correct use,[14,15] Appropriate education when prescribing inhalational devices and evaluation of inhalational techniques are of over whelming importance.[16,17,18]

MATERIAL & METHOD

The study was an observational study which was conducted in patients who were known cases of Chronic obstructive Pulmonary Disease or Bronchial Asthma attending the outpatient clinics or indoor patient of Department of Respiratory Medicine, S P Medical College Bikaner, evaluated for the technique of using inhalation devices as given by the European Respiratory society[40] of using the prescribed inhaler device. Patients were Include with these Criteria's Diagnosed cases of bronchial asthma and chronic obstructive pulmonary diseases using an inhalational device either pressurized MDI or DPI .Between the Age of 15 to 70 year. Patients exclude with these Criteria's Age <15 or >70 years, Patients suffering from active tuberculosis infection, Patient with a co-morbidities condition**,** which may interfere with use of an inhalation device. Patients unwilling to participate in the study. The personal data that included Name, Age, Sex, OPD/IPD Registration number, Education, Marital status, Occupation, Smoking History, Type of Device used, Frequency of use, Who imparted education about Inhaler technique were recorded and the inhalation technique was checked and interpretations were recorded. Methods of some devices are described here. pMDI (Pressurized metered dose inhalers).The pMDI was first introduced in 1956. The pMDI's contain propellants, which are currently being changed from chlorofluorocarbons to hydrofluoroalkanes. The pMDI produces a rapid-moving plume of aerosol, the duration of which is typically 0.1–0.4 s. Most of the pMDI's only deposit 10-20% of the dose in the lungs. Higher lung deposition and lower oro-pharyngeal deposition may be achieved when drug is formulated as a solution in HFA propellants.[19] Technique of using pMDI.[20,21] Remove Mouthpiece Cap, Shake Inhaler (suspension only),Hold Inhaler upright, Breathe out, Place mouthpiece between lips, Fire while Breathing in deeply and Place mouthpiece between lips, Fire while Breathing in deeply and Continue to inhale after firing, Hold Breath (10 seconds). Some time when needed pMDI can use with Spacer devices, are attachments to the inhaler mouthpiece with a volume ranging from 20-750 ml. Spacer overcome co-ordination problems. Tidal breathing from the spacer after firing a dose may be acceptable for some models because inhalation can take place either as the device is fired into the spacer or after a short pause, with the latter method being recommended for some models. Tidal breathing from the spacer after firing a dose may be acceptable for some models but multiple actuations, long delays between firing and inhaling, and the accumulation of static charge on some plastic spacer devices are likely to reduce the dose available for inhalation.[22,23] Specific handling and washing techniques for different spacers are generally recommended to minimize static charge build up.[24, 25] Though spacers are good delivery devices, they have

certain disadvantages like they make the entire delivery system less portable, compact and convenient than a standard pMDI.(DPI)Dry Powder Inhalers were first introduced in 1970,they contain powder formulation in a gelatin capsule. DPI tend to work better with rapid and forceful inhalation, since this disperses the powder formulation into small "repairable" particles as efficiently as possible.[26, 27,28] It is desirable that the rate of increase of inhaled flow rate at the start of inhalation should be as high as possible.[29] This is sometime called as high flow "acceleration" or high "early flow". Technique for using DPI.[30, 31] Remove cover (device specific).Load Dose (device specific).Pierce/break capsule, Breathe out, Place mouthpiece between lips, Inhale deeply and quickly, Hold Breath (10 seconds).

Observation: In this study, we included 304 patients (123 patients of bronchial asthma while 181 patients of COPD) and we found that out of total 304 patients, 255 patients had error in technique while taking inhaler and most of them 74(24.3%) cases were from 41-60 years age group and104(34.2%) were females and 151(49.7%) were males , 166 were from rural area while remaining 89(29.3%) were from urban area and statistically insignificant ($p>0.05$**).** Illiterate and primary level educated patients had more error in technique while higher and graduates did less error ($p<0.01$). That educational status was significantly associated techniques., 98 Error were made from Bronchial asthma while 157 errors were from copd patient ($p>0.05$). 101 from112 patient had error in technique while taking meter dose inhaler without spacer, and 11 had no error in technique and this difference was statistically significant ($p<0.05$).9 out 11 patients who had using MDI device with spacer 9 had error in technique while 2 had no error. 145 from 181 patients who had using DPI device with error, difference was also insignificant ($p>0.05$). Devices were different types**,**103 (Rotahaler), 45(Revoliser,) 27(Lupihaler,), 3 Octahaler and Readyhaler 3 and error were more in using devices for less time (1-2year), patients were using devices for long time and more frequently were made less error. According to educator Doctor educate 106 patients and errors were found in 77 patients, chemist educate 71 patients and errors were found in 62 patients ,paramedical staff educate 52 patients and errors found in 43 patients, and self educates were 75 and error was highest 73 with in self education**.** Among total(468) errors in MDI without spacer user(112),errors typing were Failure to remove mouth piece cap-4, 69 inhalers did not shakes the devices, inhaler upside down in 57,no exhalations/ incomplete exahalation in 53, 21 firing devices before start of inhalation, 23 firing devices at or after end of inhalation,27 Stopping inhalation as device is fired, fast inhalation in 69, 28 patients were poor seal around the mouth piece, no/short breath hold in 45, 17 patients Using open mouth

inhalation technique, 55 Failure to maintain oral hygiene after each dose (rinsing, gargle, and spit). Errors in using MDI with spacer were fast inhalation & no / short breath holding, least common error was unable to remove mouth piece. Among the DPI users 707 Errors found in 185 patients typings of errors were Dirty/Clogged device in 83 patients, incorrect dose loading in 26 patients, failure to pierce/break capsule in 17 patients, no exhalation/incomplete exhalation found in 134 patients, breathing out into device was found in 7 patients, poor seal around mouth piece was found in 25 patients, not inhaling quickly enough was found 79 patients, insufficient acceleration was found in 61 patients, no/short breath hold was found in 91 patients, inappropriate storage was found in 28 patients, failure to maintain oral hygiene after each dose were found in 87 patients while not cleaning the device timely and properly and using before air dry was present in 69 patients.

DISCUSSION

Inhalational medication has emerged as the main stay of treatment in the management of Reversible obstructive disease (Asthma) & not fully reversible disease (COPD), the incorrect use of inhalational device can result in inappropriate treatment of respiratory disease[32, 33] However, in order to be effective, correct technique should be employed in their use. The present study was an observational study based on techniques for using prescribed inhalational devices in 304 patients of COPD& Bronchial asthma during September 2012 to February13. Out of 255(83.9%) patients doing error, 98(32.2%) had bronchial asthma and 157(51.6%) had COPD.[34] The difference is statistically insignificant ($p>0.05$).. 255(83.9%) patient had error in techniques, according to age group,[34,35] Maximum number of patients were in the age group 51-60 (n=94) and the maximum error was done by age group51-60(94),more error was made by male151(49.7%) then female104(34.2%), more by the rural patient 166,then urban89 patient. This is supported by Walia et al (2006), The education status of the patients is significantly associated with less error.Illiterate174 (57.2%) & primary education 39(7.9%) were made more error in compression to higher educator 14(5.3%), the illiterate & primary educated patient had more error while middle, secondary & higher secondary, graduates did less error).Similar results were observed by William et[38] al (2004). Persons were using MDI without spacer did more error 90.17 %,> with spacer 81.81% and patient did less error with DPI 80.1% in compression to MDI The difference is statistically significant ($p<0.05$). Souza at al[36].Regular user made less errors compaired with irregular user (79.4%)>98.76%. The difference was statistically highly significant ($p<0.001$).

The patient are educated by chemist(87.3%),by doctor 72.6%,paramedical staff 82& self educated 97.3%.Error was found with every educator but error was higher with self educator,[33,34,35] here error also present with MDI& MDI with spacer ,most common error type of error was fast inhalation61.6%, inhalers not shaking(61.1%) before using, incomplete exhalation ,failure to maintained oral hygiene.

With DPI users44% had no exhalation/incomplete exhalation. 29.93% patient no breath holding/short breath hold, patient compliers poor inhalational technique is associated with poor disease control.

TABLES

Table 1: Distribution of cases according to age group in relation to Error in technique while taking inhaler.

Age Group	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
≤ 20	2	0.7	17	5.6	19	6.3
21-30	7	2.3	22	7.2	29	9.5
31-40	3	1.0	23	7.6	26	8.6
41-50	12	3.9	74	24.3	86	28.3
51-60	20	6.6	74	24.3	94	30.0
61-70	5	1.6	45	14.8	50	16.4
Total	49	16.1	255	83.9	304	100

According to above table, out of total 304 patients, 255 patients had error in technique while taking inhaler and out of them 74(24.3%) cases were from each 41-50 years and 51-60 years age group, while 45, 23, 22 and 17 cases who had error in technique while taking inhaler were from age group 61-70, 31-40, 21-30 and ≤20 years respectively.

Table 2: Distribution of cases according to gender.

Gender	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Female	21	6.9	104	34.2	125	41.1
Male	28	9.2	151	49.7	179	58.9
Total	49	16.1	255	83.9	304	100
χ^2	0.073					
P	0.787					

Out of total 255 patients who had error in technique while taking inhaler 104(34.2%) were females and 151(49.7%) were males. On comparison to those who had no error in technique the difference was statistically insignificant (p>0.05).

Table 3: Distribution of cases according to residential area.

Residential Area	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Rural	34	11.2	166	54.6	200	65.8
Urban	15	4.9	89	29.3	104	34.2
Total	49	16.1	255	83.9	304	100
χ^2	0.336					
P	0.562					

Table no. 3 shows distribution of cases according to residential area in relation to error in technique while taking inhaler. Out of total 304 patients 200 patients were from rural area while remaining 104 patients were from urban area. Out of total 255 patients who had error in technique while taking inhaler 166 were from rural area while remaining 89(29.3%) were from urban area. Patients who had no error in technique were 49 and out of them 34 and 15 were from rural and urban area respectively and the difference was statistically insignificant (p>0.05).

Table 4: Distribution of cases according to educational status.

Educational Status	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Illiterate	19	6.3	155	51.0	174	57.2
Primary	14	4.6	45	14.8	59	19.4
Middle	2	0.7	22	7.2	24	7.9
Secondary	6	2.0	11	3.6	17	5.6
Hr. Secondary	2	0.7	12	3.9	14	4.6
Graduate	6	2.0	10	3.3	16	5.3
Total	49	16.1	255	83.9	304	100
χ^2	17.150					
P	0.004					

It is clearly depicted here that educational status was significantly associated while patients had error and no error in technique. Illiterate and primary level educated patients had more error in technique while graduates and less error in technique while taking inhaler (p<0.01).

Table 5: Distribution of cases according to disease (COPD or Bronchial Asthma).

Diagnosed Case of	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Bronchial Asthma	25	8.2	98	32.2	123	40.5
COPD	24	7.9	157	51.6	181	59.5
Total	49	16.1	255	83.9	304	100
χ^2	2.704					
P	0.100					

According to table 5, out of total 304 patients 123 patients were diagnosed cases of bronchial asthma while 181 patients were diagnosed cases of COPD. Error in technique was present in 98 patients of bronchial and 157 patients of COPD. This difference was found statistically insignificant (p>0.05).

Table 6: Distribution of cases according to type of device used.

Type of Device	Error				Total		χ^2	P
	No		Yes					
	No.	%	No.	%	No.	%		
MDI without spacer	11	3.6	101	33.2	112	36.8	5.201	0.023
MDI with Spacer	2	0.7	9	3.0	11	3.6	0.036	0.850
DPI	36	11.9	145	47.7	181	59.6	10.138	0.071

Out of total 112 patients who had using MDI device without spacer, 101 had error in technique while taking inhaler and 11 had no error in technique and this difference was statistically significant (p<0.05) while out of total 11 patients who had using MDI device with spacer 9 had error in technique while 2 had no error and the difference was not significant. Out of total 181 patients who had using DPI device, 145 patients had error in technique while remaining 36 patients had no error and this difference was also insignificant (p>0.05).

Table 7: Distribution of cases according to type of DPI used.

Type of DPI	Error				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Lupihaler	6	2.0	21	6.9	27	8.9
Octahaler	0	0	3	1.0	3	1.0
Readyhaler	0	0	3	1.0	3	1.0
Revoliser	13	4.3	32	10.5	45	14.8
Rotahaler	17	5.6	86	28.3	103	33.9
Total	36	11.9	145	47.7	181	59.6

Out of total 181 patients who had using DPI device, 103, 45, 27, 3 and 3 had using Rotahaler, Revoliser, Lupihaler, Octahaler and Readyhaler respectively.

Table 8: Distribution of cases according to Duration of Using Device.

Duration (years)	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
<1	7	2.3	65	21.4	72	23.7
1-3	12	3.9	61	20.1	73	24.0
3-5	17	5.6	61	20.1	78	25.7
>5	13	4.3	68	22.4	81	26.6
Total	49	16.1	255	83.9	304	100
χ^2	4.043					
P	0.257					

In present study, 255 patients had error in technique while using inhaler and out of them 65, 61, 61, 68 had their duration of using device was <1, 1-3, 3-5 and >5 years respectively, while on other hand patients who had no error were 7, 12, 17, 13 in duration <1, 1-2, 3-5 and >5 years respectively.

Table 9: Distribution of cases according to Compliance.

Compliance	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Irregular	1	0.3	70	23.0	71	23.4
Regular	48	15.8	185	60.9	233	76.6
Total	49	16.1	255	83.9	304	100
χ^2	14.826					
P	<0.001					

Table 9 shows distribution of cases according to compliance. Regular compliance was present in 233 patients and out of them 185 patients had error in technique while 48 had no error in irregular compliance out of total 71 patients, 70 had error in technique. On statistical comparison the difference was statistically highly significant ($p<0.001$).

Table 10: Distribution of cases according to Frequency of use (per day).

Frequency of use Device	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
1-2	30	9.9	138	45.4	168	55.3
3-4	8	2.6	62	20.4	70	23.0
5-6	11	3.6	51	16.8	62	20.4
>6	0	-	4	1.3	4	1.3
Total	49	16.1	255	83.9	304	100
χ^2	2.404					
P	0.493					

Out of total 304 patients, 168 patients were used device 1-2 time per day while 70, 62 and 4 patients were used device 3-4, 5-6 and >6 times per day. Out of total 255 patients who had error in technique, 138, 62, 51 and 4 were using device 1-2, 3-4, 5-6 and >6 times per day. On statistical comparison the difference was statistically insignificant ($p>0.05$).

Table 11: Distribution of cases according to Educator.

Educator	Error in technique				Total	
	No		Yes			
	No.	%	No.	%	No.	%
Chemist	9	3.0	62	20.4	71	23.4
Doctor	29	9.5	77	25.3	106	34.9
Paramedical staff	9	3.0	43	14.1	52	17.1
Self	2	0.7	73	24.0	75	24.7
Total	49	16.1	255	83.9	304	100
χ^2	20.619					
P	<0.001					

According to educator, 62, 77, 43, 73 patients had error in technique whose educator were Chemist, Doctor, Paramedical and self respectively, while no error was present in 9, 29, 9, 2 cases while their educator were chemist, doctor, paramedical staff and self respectively. On statistical comparison the difference was statistically highly significant ($p<0.001$).

Table 12:Distribution of cases according to Type of Error while using MDI inhaler without spacer.

S.N.	Type of Error	Frequency of errors	%	χ^2	P
1	Failure to remove mouth piece cap	4	1.3	0.779	0.377
2	Inhaler not shaken	69	22.7	17.152	<0.001
3	Inhaler upside down	57	18.8	13.481	<0.001
4	No exhalation/incomplete exhalation	53	17.4	12.335	<0.001
5	Firing device before start of inhalation	21	6.9	4.335	0.037
6	Firing device at or after end of inhalation	23	7.6	4.781	0.029
7	Stopping inhalation as device is fired	27	8.9	5.694	0.017
8	Fast inhalation	69	22.7	17.152	<0.001
9	Poor seal around the mouth piece	28	9.2	5.926	0.015
10	No/short breath hold	45	14.8	10.149	0.001
11	Using open mouth inhalation technique	17	5.6	3.460	0.063
12	Failure to maintain oral hygiene after each dose (rinsing, gargle, and spit)	55	18.1	12.903	<0.001
	Total no of errors in 112 patients	468			

Total number of cases using MDI without spacer-112.

Out of total 101 patients who had using MDI device without spacer total 4 had error or failure to remove mouth piece cap, 69 had error of inhaler not shaken, 57 had error of inhaler upside down, 53 patients had no exhalation/incomplete exhalation, 21 patients had firing device before start of inhalation, 27 patients stopping inhalation as device is fired, 69 patients had error of fast inhalation, 28 patients had error of poor seal around the mouth piece, 45 patients had no/short breath hold, 17 patients had error of using open mouth inhalation technique and 55 patients had error or failure to maintain oral hygiene after each dose (rinsing, gargle and split).

Table 13: Distribution of cases according to Type of Error while using MDI inhaler with spacer.

S.N.	Type of Error	No. of Cases	%	χ^2	P
1	Unable to remove mouth piece cap	2	0.7	0.387	0.534
2	Inhaler not shaken	5	1.6	0.779	0.377
3	Inhaler upside down	1	0.33	-	-
4	No exhalation	6	1.97	1.579	0.209
5	Long delay before inhalation	3	0.98	0.193	0.661
6	Multiple actuation	5	1.6	1.987	0.159
7	Weak inhalation	1	0.33	-	-
8	Inhaling through nose	0	-	-	-
9	Stopping inhalation as device is fired	5	1.6	0.779	0.377
10	Fast inhalation	7	2.3	1.377	0.241
11	No/Short breath hold	7	2.3	1.176	0.278
12	Failure to maintain oral hygiene after each dose	2	0.7	0.387	0.534
	Total	44			

Table 14: Distribution of cases according to Type of Error while using DPI inhaler.

S.N.	Type of Error	Frequency of error	%	χ^2	P
1	Dirty/Clogged device	83	27.3	21.939	<0.001
2	Failure to remove cover	0	-	-	-
3	Incorrect dose loading	26	8.6	5.463	0.019
4	Failure to pierce/break capsule	17	5.6	3.460	0.063
5	No exhalation/incomplete exhalation	134	44.1	46.045	<0.001
6	Breathing out into device	7	2.3	1.377	0.241
7	Poor seal around mouth piece	25	8.2	5.234	0.022
8	Not inhaling quickly enough	79	26.0	20.510	<0.001
9	Insufficient acceleration	61	20.1	14.664	<0.001
10	No/Short breath hold	91	29.9	24.957	<0.001
11	Inappropriate storage	28	9.2	5.926	0.015
12	Failure to maintain oral hygiene after each dose (rinsing, gargle and spit)	87	28.6	23.420	<0.001
13	Not cleaning the device timely and properly and using before air dry	69	22.7	17.152	<0.001
	Total no of errors in 185 patients	707			

Total number of patients using DPI-183.

Dirty/Clogged device error was found in 83 patients, incorrect dose loading error was found in 26 patients, failure to pierce/break capsule error was found in 17 patients, no exhalation/incomplete exhalation was found 134 patients, breathing out into device was found in 7 patients, poor seal around mouth piece was found in 25 patients, not inhaling quickly enough was found 79 patients, insufficient acceleration was found in 61 patients, no/short breath hold was found in 91 patients, inappropriate storage was found in 28 patients,

failure to maintain oral hygiene after each dose was found in 87 patients while not cleaning the device timely and properly and using before air dry was present in 69 patients.

CONLUSIONS

83.9% patients had errors in techniques while using inhalational devices, highest error with age group 41 to 60 year, more in males than females, more in rural than urban, illiterate & primary literate made more error then secondary, higher secondary & graduate. COPD patients conducted more errors then bronchial asthma patients.

Error was higher with MDI without spacer than with spacer and least with DPI; patients who were using devices more times (>6 times/day) having less error and patients educated by doctors conducted least error & highest with self educator.

Error with MDI without spacer were inhaling fast, not shaking inhalational devices before use, failing to maintain oral hygiene, and incomplete exhalation. Thus, at every visit the techniques of inhalational should be checked and practical demonstration is needed to improve the patient ability to use the inhalation with correct techniques.

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