

A Randomized, Open Label Study to Assess the Impact of Electronic Information Technology in Treatment of Obstructive Airway Disease on Inhaler Therapy in Tertiary Care Hospital

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ABSTRACT

Background: Over 300 million people are affected worldwide with asthma. Asthma, COPD and TOPD are respiratory disorders of chronic inflammatory illness causing bronchial hyperactivity. eHealth applications are widely used nowadays in assisting patients with lifelong diseases. **Aim and Objectives:** To assess the medication adherence of Obstructive airway disease patients who are using electronic applications. **Materials and Methods:** A randomized open label trial study was conducted in department of Respiratory medicine, Dhiraj Hospital, Vadodara with the sample of 90 subjects divided into groups A (with application) and B (without application). Patients' medical records and information such as demographics, medical history and smartphone accessibility were checked. **Results:** There was total 90 subjects enrolled, out of them 55.55% were male and 44.45% were female. Mean age of the patients was 43.27 ± 15.54 which shows that majority of our study population were in 4th decade of their age. In this study, Bronchial Asthma was found to be the most prevalent among the study population and which presented in more than 90% of the patients, followed by COPD and TOPD. In Group A, FEV₁, FVC, FEV₁/FVC and PEF_R was significantly improved as compared to Group B at the time of End of Study Visit. Medication Adherence of group A, at interim visit was found to be 68.89%, which later on, at the end of study was found to be significantly increased to 95.56%, using chi square test. Rescue medication was required more in Group B as compared to Group A however results were not statistically significant. Adverse events were noted in both groups however it was seen higher in Group B but results are not significant. **Conclusion:** eHealth application has a wide role in assisting the long-term management diseases medication. Application represents a strategy to increase the medication adherence and helps in providing guidance to patients.

Keywords: Asthma, Ehealth application, Medication adherence, Compliance.

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INTRODUCTION

Advantages of digital technology include flexibility, availability, repeatability, and reach. As it is the most popular and widely accessible technology by all levels of the community, it may quickly reach a large number of needy and suffering patients, especially in circumstances where access to non-digital materials or face-to-face consultations is minimal (Masoli *et al.*, 2004). Recently, digital technology has grown more accessible and trouble-free, such as online platforms, websites, and mobile

phone applications, which may enhance adherence intervention participation (Dayer *et al.*, 2013). Digital interventions can also help people and healthcare professionals communicate better (Eakin and Rand, 2012). Monitoring and tracking medication administration, asthma symptoms, lung function, or all of these can be improved by digital technology. Data may be analysed and communicated to the healthcare provider as important instructions and prescriptions are supplied by the healthcare provider to promote a seamless transfer of health information during chronic illness treatment. Since more than a decade, mobile phones have been employed as a tool to improve chronic illness management, including major health treatments such as smoking cessation for respiratory disorders. Short Message Services (SMS) systems have been introduced to provide appointment reminders, (Da Costa *et al.*, 2010; Vervloet *et al.*,



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2012) improve medication adherence, (Britto *et al.*, 2017) and help asthma treatment. Similarly, web-based eHealth treatments promote chronic illness management and patient empowerment (Gustafson *et al.*, 2012; Kuijpers *et al.*, 2013). Asthma is one of the most common causes of chronic disease among adolescents in advanced countries (Asher and Pearce, 2014). The World Allergy Organization (Taylor *et al.*, 2014) has shown a steady increase in asthma prevalence worldwide, particularly in nations such as India, Australia, the United Kingdom, and the United States. Asthma is estimated to impact approximately 300 million people worldwide (Mansouri *et al.*, 2017). The day-to-day management of asthma presents significant hurdles, including medication adherence and management of symptoms. Self-management of Asthma is an important aspect of health treatment because it is a chronic condition. Self-management refers to the actions that people must perform in order to live with a chronic disease, such as medical management, role management, and emotional management. Self-management and interventions encourage patients to actively participate in their care and enhance their responsibility for controlling their disease, symptoms and complications (McClure *et al.*, 2018; Tinschert *et al.*, 2017). Education, empowerment, self-judgment, and commitment to preventative actions are key strategies. The most common, though underutilized, self-management strategy in asthmatic children and adolescence is an Asthma Action Plan (Foster *et al.*, 2014). Self-efficacy, or the confidence in one's abilities to self-manage, is another important component in the management of long-term chronic disease (McClure *et al.*, 2018). COPD is one of the major health problems associated with airway and breathing difficulty with one or more exacerbation each year. Mostly the treatment includes inhalers and bronchodilators. The tolerance is associated with inhaled medications over long term usage which results that when the need arises during exacerbation the medication would be less effective. So, assessing adherence remain mainstay with electronic monitoring. Much data is to be needed regarding the feasibility of adherence intervention using electronic monitoring (Lareau and Yawn, 2010). TOPD (Tuberculosis-associated obstructive pulmonary disease) is associated with people of young age i.e. <40 years in which there is a tuberculosis associated lung damage which develops in later stages. Risk factors associated with TOPD are smoking, low socio-economic status, vitamin-D deficiency, and biomass fuel exposure. Mostly the treatment of TOPD is same as COPD, which includes bronchodilator and inhaler therapy (Sarkar *et al.*, 2017). The growing use of mobile technologies by consumers all the world gives opportunities and solutions for solving difficulties within the healthcare systems. A wide range of technologies have been used in Asthma and COPD treatment, ranging from management systems to self-monitoring devices (Ahmed *et al.*, 2018). Apps are taking up more and more place in our daily lives in today's technology-driven environment. Mobile applications appear to be a potentially useful technique of improving medication adherence in patients with chronic

conditions due to their simplicity of use, diversity, and lower prices. Still, there is opportunity for development. Future study will need to not just determine the best app features and pricing for providers, but also to develop the apps to make them more user-friendly and safer, as well as to ensure that they remain useful based on patient-centred theory (Blakey *et al.*, 2018).

MATERIALS AND METHODS

This was a prospective study carried out at Respiratory Medicine Department, Dhiraj Hospital, SVDU during the period of December 2021 to April 2022. During this period, 90 patients with past history of bronchial asthma, COPD and TOPD or newly diagnosed patients were included in the study after checking the fulfilment of the study selection criteria. Diagnosis of obstructive airway disease was made based on the clinical history and Spirometry. Before initiating the study, Sumandeep Vidyapeeth Institutional Ethics Committee approval was taken and before enrolling subjects into the study, the pulmonologist had explained the details about the study and study procedures including aims and objectives of the study to the patient in his/her vernacular language, and gave sufficient time to ask the queries, which were answered by the pulmonologist. After patient had understood and participated voluntarily consent was filled. In this study, patients were divided into two groups i.e., Group A & Group B. The allocation of the group was done by predefined computer-generated algorithm. As per the randomization procedure subjects who were enrolled in Group A received the mobile application whereas Group B did not receive the mobile application. Patient's demographic data, detailed clinical & medical history, data regarding physical examination, vitals, Spirometry, peak expiratory flow rate, laboratory investigation if any and Medication (as per GINA & GOLD guideline and based on severity of Asthma) related information were transcribed in pre-defined study proforma. Asthma, COPD & TOPD medications were prescribed as per the pulmonology discretion and the severity of asthma. Rescue medication was provided additionally in the form of SOS along with supportive medications if needed. Peak- expiratory flow rate and Spirometry pre and post bronchodilator were performed. Principal Investigator set digital medication reminder notification timings in software for each patient of Group A. Link of application was sent to Mobile User through voluntarily, written and informed consent was obtained from the patient. software via text message and subsequently was taught about the usefulness of the mobile application in the treatment of his/her chronic Asthma, COPD and TOPD. Group A Patient were able to see all his/her demographic data, detailed clinical, medical history, data regarding physical examination, vitals, Spirometry, peak expiratory flow rate, laboratory investigation and Medication related information in the given mobile application. Everyday Group A patient got reminder notification about his/her prescribed medication as per pre-defined time at the time of enrolment. Group A Patient

also got follow up visit reminder before 3 days of his/her next visit to hospital. Both groups of patients were followed-up after 15 days (via mobile communication) and 1 month (OPD) from the date of commencement of the study. On first follow-up after 15 days the assessment of patient's clinical status was done by mobile communication and related data were recorded (MMA Scale). On second visit after 1 month, again peak-expiratory flow rate and Spirometry pre and post bronchodilator was measured and recorded after clinical assessment. Both groups were compared for the level of control of asthma, use of rescue medications and adherence to treatment and follow-up. After the data collection, all the data was exported to statistical software for statistical analysis. P value Frequencies of drug compliance was described. Medication Compliance of different persons according to demographic characteristics was compared with independent-samples *t* test, One-Way Analysis of Variance (ANOVA), or Chi-square test as appropriate. Unstandardized regression coefficients (β) and Odds Ratios (ORs) and their 95% Confidence Intervals (CIs) was used to quantify the associations between variables. Data analyses was conducted with SPSS version 20.0 The statistical significance level was set at *p* 0.05 (two-sided). *e* ≤ 0.05 was considered as significant. Graphical representation was used for better understanding of data.

RESULTS

This study was carried out at Department of Respiratory Medicine, Dhiraj Hospital, SVDU, Vadodara. A total of 90 patients were screened for respiratory illness and included in our study. Randomization of patients was done in Group-A and Group-B,

to access medication adherence. Group-A included patients with application and Group-B without application. In present study we have enrolled 90 patients. Majority of the study population were in 5th decade of their age. In group A mean age was 44.89 ± 16.44 and mean age in group B was 41.64 ± 14.58 . It was found that there was no statistical mean age difference between the groups. *p*-Value was 0.325. In group A, 57.78% subjects were female and 42.22% subjects were male. Similarly in group B, 63.33% subjects were female and 46.67% subjects were male. It was found that there was no gender dominant group found. *p*-Value was 0.832. It was observed that 91.11% of group A subjects and 88.89% of group B subjects had Bronchial Asthma, followed by 8.89% subjects of both the groups had TOPD and 2.22% subjects of group B had COPD. We have found that in both the group the most common diagnosis was bronchial Asthma with the *p*-Value 0.603 (Table 1). In the above table, spirometry examination determines the baseline and end of the study visit spirometry data. Looking at the baseline visit data (first five parameters), % change was determined which was relatively 20.91% for group A and 19.50% for group B. Similarly, at the end of the study visit data (other five parameters), % change was 25.38% for group A and 20.05% for group B. The final change obtained was 4.47% and 0.71% relatively and *p*-value 0.001 which is significant. In conclusion, group A data showed relative improvement of 3.76% than group B (Table 2).

In Mentioned figure determines the FEV1 (Pre), FVC (Pre), FEV1 (Post) and FVC (Post) of the baseline and end of the study visit data of group A. The relavent increase in the end of the study visit data showed relative improvement in the spirometry

Table 1a: Demographic details of study population as per Mean age, Gender and Diagnosis.

Group	N	Mean Age	Std. Deviation	<i>p</i> value
A	45	44.89	16.443	0.325
B	45	41.64	14.575	
Total	90	43.27	15.540	

Table 1b:

Gender	Group				Total	<i>p</i> value
	A	%	B	%		
Female	26	57.78%	24	53.33%	50	0.832
Male	19	42.22%	21	46.67%	40	
Total	45	100.00%	45	100.00%	90	

Table 1c:

Diagnosis	Group				Total	<i>p</i> value
	A	%	B	%		
Bronchial Asthma	41	91.11%	40	88.89%	81	0.603
COPD	0	0.00%	1	2.22%	1	
TOPD	4	8.89%	4	8.89%	8	
Total	45	100.00%	45	100.00%	90	

analysis. All the parameters were significantly improved. The above graph determines the FEV1 (Pre), FVC (Pre), FEV1 (Post) and FVC(Post) of the baseline and end of the study visit data of group B. Significant decrease in the spirometry data was seen at the end of the study visit which determined that medication adherence was deteriorating (Figure 1). % Change was calculated and obtained 20.91% for group A and 19.50% for group B of baseline visit. While on the other hand, at the end of the study % change obtained was 25.38% for group A and 19.50% for group B which relatively determined the final % change difference as 4.47% and 0.71%. Relative difference of 3.76% was observed in group A (Figure 2).

Most prevalent symptoms were cough, followed by wheezing, chest tightness and headache. All the subjects of group A had cough at the time of baseline visit, which reduced to 4.44% at the end of the study. 68.89%, 88.89% and 84.44% subjects experienced headache, wheezing and chest tightness which significantly reduced to 4.44%, 40.00% and 84.44% respectively at the end of study. The *p*-value was found to be relatively significant and improvement in the symptoms were seen at the end of the study visit. At the baseline visit, 97.78% subjects of group B experienced cough. Similarly, 77.78%, 97.78% and 75.56% subjects had headache, wheezing and chest tightness. At the end of the study visit, these rates were reduced to 22.22%, 53.33% and 24.44% respectively. Improvement in the symptoms were seen from the baseline visit but not as significant as group A. In present study, we have used MMAS score to evaluate medication adherence in patients of both the groups the end of baseline visit and at the end of study visit. It was found that in group A patients at end of the study visit MMAS score was found 0 which is 26.67% higher than baseline visit, it was also seen that subjects with MMAS score more than 2 were 6.67% at baseline visit however at the end of the study, none of the subjects had score more than 2. This improvement rate is found statistically significant by using chi-square test. As shown in the table, the significant value observed was 0.0068. In this group number of patients with high

medication adherence was increased 13.33% as compared to that observed at baseline visit although it was also seen that at the end of the study as compared to baseline medication adherence rate of subjects was found deteriorating by 2.22%. We have applied chi square test to find significant value and it was found to be 0.469 (Table 3).

As shown in above Table, 9 subjects experienced episode(s) of breathlessness. And out of these 9 subjects, 2 subjects were from group A and 7 were from group B. Group A subjects comparatively required less rescue medication than group B subjects. As shown above, there were no patients who were loss to follow-up or discontinued the study. All the subjects have completed the study (Table 4).

DISCUSSION

Health applications are nowadays most widely used in assisting patients with life-long diseases. Smartphone technology helps in increasing patient compliance and provides essential guidance to the patient's health. The main objective of using smartphone is Asthma is the most common respiratory disorder affecting 300 million people worldwide. It is a chronic inflammatory disease of airways causing bronchial hyperactivity, shortness of breath, wheezing, headache, mucus production and chest tightness. nowadays all the individuals are derived towards using it and its feasibility (Risso *et al.*, 2016). COPD is developed by inflammation, causing constriction of airway leading to shortness of breath due to inflammatory mediators in the circulation causing various symptoms such as skeletal muscle wasting and cachexia COPD morbidity is amplified by comorbid conditions, resulting in hospitalization (Haze and Lynaugh, 2013). TOPD mainly occur in individual with previous history of TB. This type of obstructive pulmonary disease is known as post tubercular obstructive airway disease or TB-associated Chronic Obstructive Pulmonary Disease. The prevalence found in our study was very minimal i.e. A and B both groups have 8.89% (Lambrecht and Hammad, 2015). TOPD mainly occur in individual with

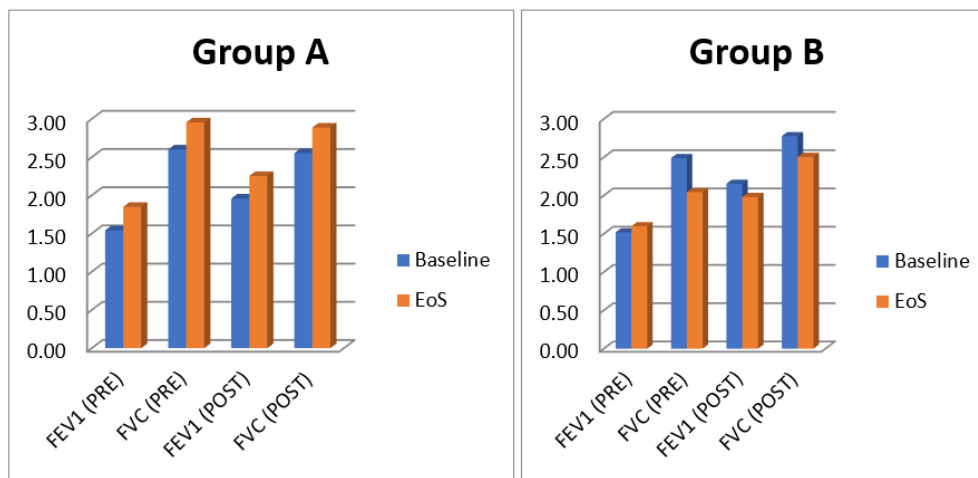


Figure 1: Spirometry Data of Group A and B.

Table 2: Baseline and end of study visit Spirometry Examination comparison.

Spirometry Examination	Group	N	Mean	Std. Deviation	p value
FEV1 (PRE)	A	45	1.54	0.46	0.569
	B	45	1.52	0.57	
FVC (PRE)	A	45	2.60	0.83	0.078
	B	45	2.49	0.89	
FEV1 (POST)	A	45	1.96	0.59	0.123
	B	45	2.16	0.60	
FVC (POST)	A	45	2.55	0.83	0.187
	B	45	2.78	0.77	
% Change	A	45	20.91%	4.07%	0.096
	B	45	19.50%	3.85%	
FEV1(PRE)	A	45	1.85	0.52	0.024
	B	45	1.60	0.50	
FVC(PRE)	A	45	2.96	0.94	0.001
	B	45	2.04	0.73	
FEV1 (POST)	A	45	2.25	0.62	0.025
	B	43	1.98	0.53	
FVC (POST)	A	45	2.89	0.94	0.001
	B	45	2.51	0.60	
% Change	A	45	25.38%	3.38%	0.001
	B	45	20.05%	4.15%	
Final Change	A	45	4.47%	2.37%	0.001
	B	45	0.71%	1.59%	

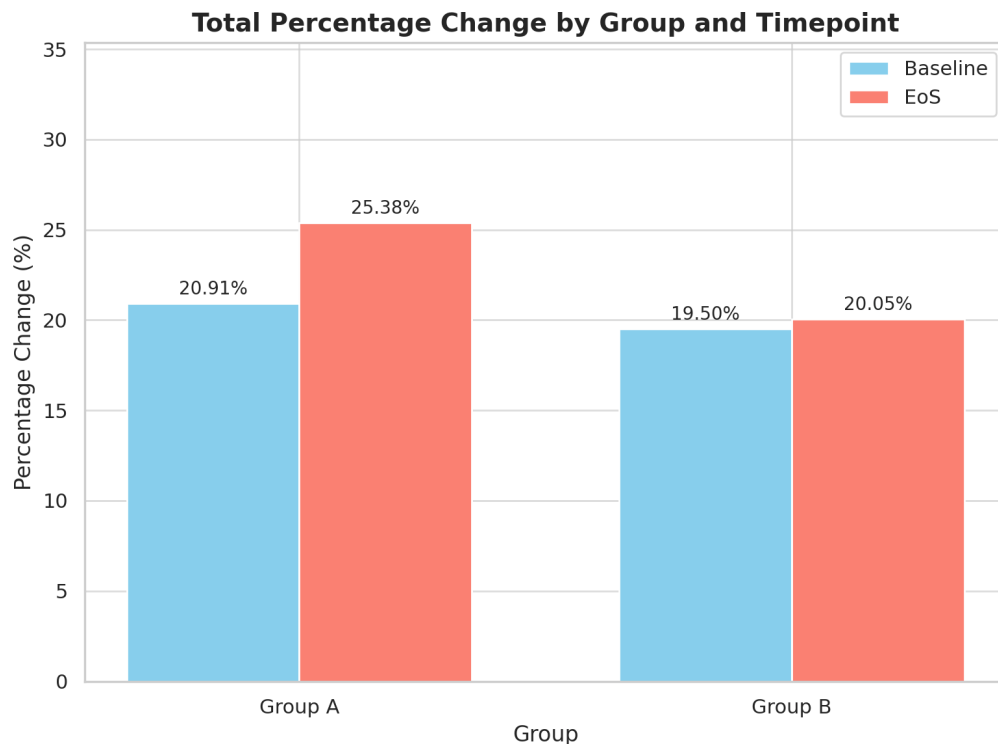

Figure 2: Total Percentage change.

Table 3a: Symptomatology (Group A) and (Group B) and MMAS Adherence percentage (Group A) and (Group B).

Symptomatology	Group A				p value
	Baseline	%	Eos	%	
Headache	31	68.89%	2	4.44%	0.001
Wheezing	40	88.89%	18	40.00%	0.004
Cough	45	100.00%	21	46.67%	0.003
Chest Tightness	38	84.44%	8	17.78%	0.001
Symptomatology	Group B				p value
	Baseline	%	Eos	%	
Headache	35	77.78%	10	22.22%	0.002
Wheezing	44	97.78%	24	53.33%	0.015
Cough	44	97.78%	28	62.22%	0.059
Chest Tightness	34	75.56%	11	24.44%	0.006

Table 3b:

Adherence	Group A				p value
	Pre	Pre	Pre	Pre	
High Adherence	31	68.89%	43	95.56%	0.0068
Medium Adherence	11	24.44%	2	4.44%	
Low Adherence	3	6.67%	0	0.00%	
Total	45	100.00%	45	100.00%	
Adherence	Group B				p value
	Pre	Pre	Pre	Pre	
High Adherence	21	46.67%	27	60.00%	0.469
Medium Adherence	17	37.78%	10	22.22%	
Low Adherence	7	15.56%	8	17.78%	
Total	45	100.00%	45	100.00%	

previous history of TB. This type of obstructive pulmonary disease is known as post tubercular obstructive airway disease or TB-associated Chronic Obstructive Pulmonary Disease. The prevalence found in our study was very minimal i.e. A and B both groups have 8.89% (Taylor, S *et al.*, 2014). Diagnosis of 90 patients evaluated that bronchial asthma was the most prevalent, i.e., 91.11% and 8.89% had TOPD. Similarly in group B, 8.89% has asthma and 2.22% had COPD and 8.89% had TOPD. Bronchial Asthma was the most common diagnosis and *p*-value found is 0.603. Most common symptoms found were cough, headache, chest tightness and wheezing. It was found out that out of 90 patients, all the subjects had cough. Headache was in 68.89% of group A subjects and 77.78% of group B subjects. 88.89% of group A subjects and 97.78% of group B subjects had complaints of wheezing and 84.44% of group A subjects and 75.78% of group B subjects experienced chest tightness. Similar study by Teufel li RJ and Patel SK determined to design and test feasibility of smartphone app in youth with high-risk asthma. Factors such as coughing, wheezing, chest tightness and boredom were derived and check up on the next follow up. It evaluated the improvement in the symptoms. Similarly, in our study wheezing,

cough, chest tightness and headache were evaluated. Group A had least occurrence of symptoms compared to group B in end of study visit. Thus, it helped in evaluating the comparison of adherence of both the groups (Teufel II *et al.*, 2018). Diagnosis of 90 patients evaluated that bronchial asthma was the most prevalent, i.e., 91.11% and 8.89% had TOPD. Similarly, in group B, 8.89% has asthma and 2.22% had COPD and 8.89% had TOPD. Bronchial Asthma was the most common diagnosis and *p*-value found is 0.603. Most common symptoms found were cough, headache, chest tightness and wheezing. It was found out that out of 90 patients, all the subjects had cough. Headache was 68.89% of group A subjects and 77.78% of group B subjects. 88.89% of group A subjects and 97.78% of group B subjects had complaints of wheezing and 84.44% of group A subjects and 75.78% of group B subjects experienced chest tightness. Similar study by Teufel li RJ and Patel SK determined to design and test feasibility of smartphone app in youth with high-risk asthma. Factors such as coughing, wheezing, chest tightness and boredom were derived and check up on the next follow up. It evaluated the improvement in the symptoms. Similarly, in our study wheezing, cough, chest tightness and headache were evaluated. Group A had least

Table 4a: Rescue medication and Status of Patients Status of Patients.

Rescue Medication	Group				Total	p value
	A	%	B	%		
Required	2	4.44%	7	15.56%	9	0.0780
Not required	43	95.56%	38	84.44%	81	
Total	45	100.00%	45	100.00%	90	

Table 4b:

Status of patient	Group				Total
	A	%	B	%	
Baseline Visit Completed	45	100.00%	45	100.00%	90
Interim Visit 1 Completed	45	100.00%	45	100.00%	90
End of Study Visit Completed	45	100.00%	45	100.00%	90
No. of Withdrawn subjects	0	0.00%	0	0.00%	0
Discontinue Subject	0	0.00%	0	0.00%	0
No. of Adverse events	2	4.44%	9	20.00%	11
No. of serious adverse events	0	0.00%	0	0.00%	0
Total Drop outs	0	0.00%	0	0.00%	0

occurrence of symptoms compared to group B in end of study visit. Thus, it helped in evaluating the comparison of adherence of both the groups (Teufel II *et al.*, 2018). The Morisky Medication Adherence Scale (MMAS) 8-questionnaire scale is used as a diagnostic tool to measure medication adherence (Jácome *et al.*, 2021). MMAS score comparison was done at every 15 days to examine medication adherence via telephonic communication. Group A subject has shown significant improvement and relatively high medication adherence. 1st Visit MMAS was done verbally when patient appeared for evaluation of spirometry analysis. Group B suggested poor medication adherence, through scoring. MMAS score was used to evaluate medication adherence in patients of both the groups and end of baseline visit and end of the study visit. Group A patients at the end of study visit MMAS score was found 0 which is 26.67% higher than baseline visit, it was also seen that subjects with MMAS score more than 2 were 6.67% at baseline visit however at the end of the study, none of the subjects had score more than 2. The improvement rate is found significant in both the groups. Similarly, for group B patients medication adherence was increased by 13.33% which was not prominent in compared to group A. Both the group has shown improvement but group A has more rate of significance. Rescue medication is used during the acute exacerbation of asthma attack. Patients were evaluated out on the basis of comparison while the study period during the treatment course. In group A, 2 patients required Rescue medication and in group B 7 patients needed 4.44% and 15.56% were found to be in need and p-value was found out to be 0.0780. Study carried out by Kevin B Johnson and Baron Patterson in UK enrolled 98 adolescents to study medication adherence using text messages and reminders called MyMediHealth (MMH). It is a system used to be in

charge of medications and dosing through reminder systems. It has relatively showed up rage adherence to medication, good quality of life and self-perception. On the other hand, our study suggested significant improvement in one medication adherence and compliance (Kosse *et al.*, 2019). From the study, it was observed that comparison of group A and B patients data suggested increase in medication adherence and compliance. It shows that application has led to increase medication adherence through reminders. Study relatively shows that ehealth application generation has led to many healthcare benefits respect to meet the healthcare needs of long-term disease patients.

CONCLUSION

This study makes an important contribution to research and e-Health Technology in assisting management of long-term diseases, i.e., Asthma, COPD and TOPD patients in both groups where enrolled in which there was no significant gender bias. The most prevalent respiratory illness found was asthma followed by TOPD and COPD. MMAS (Morisky Medication Adherence Scale) is a scoring scale used to identify the medication adherence. At the end of the study, we found that in Group A, where we have given mobile applications it has shown increased medication adherence by more than 20%. However, in Group B a slight medication adherence was found from the baseline visit but in comparison to Group-A it was not significant. Here we conclude that for chronic disease use of mobile applications is beneficial for better patient compliance. It is useful in monitoring side effects, decreased exacerbations, improvement in spirometry values, decreased requirement of rescue medication and reminding patients for timely medications.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL

This study was approved by the Sumandeep Vidyapeeth Institutional Ethics Committee (SVIEC), Approval Number: SVIEC/ON/Phar/BNPG20/D21036, dated 1st December 2021.

ABBREVIATIONS

COPD: Chronic Obstructive Pulmonary Disease; **TOPD:** Tuberculosis-associated Obstructive Pulmonary Disease; **eHealth:** Electronic Health; **FEV1:** Forced Expiratory Volume in 1 Second; **FVC:** Forced Vital Capacity; **PEFR:** Peak Expiratory Flow Rate; **GINA:** Global Initiative for Asthma; **GOLD:** Global Initiative for Chronic Obstructive Lung Disease; **OPD:** Outpatient Department; **MMA:** Morisky Medication Adherence; **ORs:** Odds Ratios; **CI:** Confidence Intervals; **SPSS:** Statistical Package for the Social Sciences; **TB:** Tuberculosis; **MMAS:** Morisky Medication Adherence Scale; **MMH:** MyMediHealth.

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