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RESEARCH ARTICLE

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### A Clinical Study to Assess the Efficacy of Anti Asthamatic Effect of *Sharbat-E-Sadar*

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#### ABSTRACT

Asthma is a chronic inflammatory disease of the airways characterized by reversible airway obstruction, Inflammation and hyper responsiveness of the airways. It is characterized by recurrent episodes of wheezing, breathlessness, chest tightness and cough particularly at night / or in the early morning. It currently affects approximately 300 million people world-wide. It is very well described in Unani literature under headings of *Rabu, Buhar, Zeequn-Nafas, Dama and Intesabun-Nafas*. Unani physicians treated this disease by Unani medicines up to some extent. Sharbat-e-Sadar which is a Unani pharmacopoeial preparation, is one of the drugs which have been used in Unani system of medicine for the desired purpose but its use as a bronchodilator drug is not yet proved scientifically. Therefore, an open label study was designed to evaluate the efficacy of said Unani formulation scientifically on various research parameters like dose of drug, efficacy and any adverse effect of drug.

A total of 30 cases diagnosed with the shortness of breath due to Bronchial Asthma were studied and received the test drug for 90 days. The drug was found safe on hematological and biochemical parameters. The study demonstrated that the test drug is safe and effective in improving the signs & symptoms associated with Bronchial Asthma.

**Key words:** Sharbat-e-Sadar, bronchial asthma, *Rabu Buhar, Zeequn-Nafas, Dama and Intesabun-Nafas*.

## INTRODUCTION

Asthma is a syndrome characterized by airflow obstruction that varies markedly, both spontaneously and with treatment. Asthmatics harbour a special type of inflammation in the airways that makes them more responsive than non-asthmatics to a wide range of triggers, leading to excessive narrowing with consequent reduced airflow and symptomatic wheeze and dyspnoea.<sup>1</sup>

Narrowing of airways is usually reversible but in some patients, there may be an element of irreversible airflow obstruction.

Asthma is one of the most common chronic diseases globally and currently affects approximately 300 million people world-wide. Approximately 10-12% of adults and 15% of children are affected by the disease and is directly proportional to the rate of urbanization. Epidemiological observations suggest that it has most likely a genetic predisposition.<sup>1</sup>

The actual term asthma is a Greek word that has arisen from verb *aezin* meaning to exhale with open mouth or to pant.<sup>2</sup> Ever since the time of Aristotle, it has been a subject to study of medical men of practically all the disciplines especially physiologist, pharmacologist, clinicians, surgeons, psychiatrist, pathologist and geneticist.

Egyptian civilization has left over written records of this disease and possible procedures to treat it. It has been substantiated by discovery of Ebers papyrus in the graves of Thebes (1862 A.D). *Corpus Hippocraticum* has considered it as either clinical entity or a symptom only.<sup>2</sup> Hippocrates described the relationship between the environment and respiratory ailments.<sup>3</sup>

With the passage of time, scientist and physicians of their ages postulated their theories which in most of the cases were by experimental and clinical evidence for the causes and treatment of asthma. Among Arab physicians, Ali *bin Rabban Tabri* (810-895) was the first physician who described different type of asthma in his famous book "*Firdausul-Hikmat*". Thus gave the basis of modern classification.<sup>4</sup> *Razi* was the first to describe status asthmaticus.<sup>4</sup> Bernardino Ramazzini (1633-1714 AD), detected a link between asthma and organic dust and also

recognized exercise-induced asthma whereas Familial aggregation of asthma was first described by Sennertus in 1650.<sup>5</sup> After the discovery of histamines bronchial responsiveness in asthmatics was first reported by Alexander and Paddock.<sup>6</sup> Thereafter in 1938, leukotriene was discovered<sup>7</sup> and was coined as major cause of airway constriction during allergic attack. In 1940 Rackeman differentiated between intrinsic and extrinsic asthma.<sup>8</sup> Dunhill in 1960 reported the mucos obstruction of peripheral airways as an important pathological finding in fatal asthma.<sup>9</sup> In 1966-67 IgE antibodies were tagged with allergic response in asthma.<sup>7</sup> In 2003, FDA approved xolair as the first drug to block the effect of IgE.<sup>7</sup> The inhalation of an allergen results in two phase bronchoconstriction response. The inhaled allergen interacts with mucosal mast cells resulting in the release of histamines and cysteinyl leukotrienes with resulting in bronchoconstriction. In chronic Asthma complex inflammatory response is also present which is characterized by influx of numerous inflammatory cells, transformation of airway structural cells and the secretion of cytokines, chemokines and growth factors.<sup>10</sup>

The present study has been carried out with the following aims and objectives-

To validate the antiasthamatic effect of compound Unani formulation (Sharbat-e-Sadar).

To note the side effect/toxicity of the said drug if any.

## **MATERIAL AND METHODS**

The present study was conducted in the department of Moalajat of Ajmal Khan Tibbiya College, hospital Aligarh Muslim University, Aligarh in the year 2013-2014 on 30 patients suffering from Bronchial Asthma after obtaining their informed written consent and approval of the topic from Ethical committee of faculty of Unani Medicine. The definitive diagnosis was made by nebulizing the patients with salbutamol 4 mg and patients were evaluated for peak expiratory flow rate (PEFR) after 15-20 minutes, a 20% increase in PEFR was considered as reversibility airflow obstruction.<sup>11</sup> The herbal drug formulation whose composition is given below was administered orally 20 ml twice a day for three months and the effects on symptoms and signs were evaluated periodically after every 15 days.

### **Adverse events**

All adverse events, either reported or observed by subjects/parents/guardians, were recorded in the CRF with information about severity, onset, duration and action regarding the study drug.

The subjects were allowed to voluntarily withdraw from the study if they experienced serious discomfort during the study or sustained serious clinical problem requiring specific treatment.

### Statistical analysis

The result were analyzed statistically using Student 't' test wherever applicable.

### Ingredients of Sharbat-e-Sadar<sup>12</sup>

1. Abresham muqarraz (*Bombax mori*)
2. Ajwain desi (*Ptycotis ajowan*)
3. Aslussoos neem kofta (*Glycerrhiza glabra*)
4. Badiyan (*Foeniculum vulgare*)
5. Anjir zard (*Ficus carica*)
6. Alsi (*Linum ussitatissimum*)
7. Barg-e-bansa (*Adhatoda vesica*)
8. Barg-e-gaozaban (*Borage officinalis*)
9. Parsiyaon shan (*Adiantum capillus*)
10. Tukhm-e-khubbazi (*Malva sylvestris*)
11. Zoofae khushk (*Hyssopus officinalis*)
12. Sapistan (*Cordia latifolia*)
13. Unnab (*Zizyphus sativus*)
14. Koknar (*Papaver somniferum*)
15. Gul-e-gaozaban (*Borage officinalis*)
16. Shakar safaid (*Saccharum officinarum*)
17. Sat-e-lemon (*Citrullus lemon*)
18. Boorae armani

## OBSERVATIONS, RESULTS AND DISCUSSION

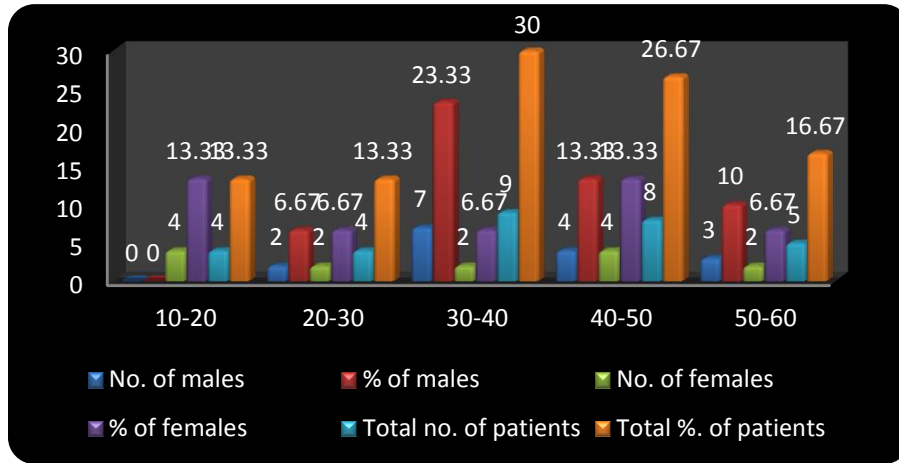
**Table no.1**

### **Distribution of patient according to age and sex**

<b>Age group (in years)</b>	<b>No. and % of males</b>	<b>No. and % of Females</b>	<b>Total no. and %</b>
10-20	0 (0)	4 (13.33)	4(13.33)
20-30	2( 6.67)	2 ( 6.67)	4(13.34)
30-40	7(23.33)	2 ( 6.67)	9 (30.00)
40-50	4 (13.33)	4 (13.33)	8 (26.66)
50-60	3(10.00)	2 ( 6.67)	5 (16.67)
Total	16 (53.33)	14 (46.67)	30 (100)

The patients selected for the study were divided into 5 age groups. It was observed that maximum number of patients i.e. 9 cases belonged to age group of 30-40 years. 8 cases were recorded in the age group of 40-50 years and 4 cases lies in the age group of both 10-20 years and in 20-30 years and there were 5 cases in 50-60 years group. Out of 30 cases 14 (46.67%) were female while 16 (53.33%) were male. (Table No. 1 and Graph No. 1)

**Figure 1 Distribution of patients according to age and sex**



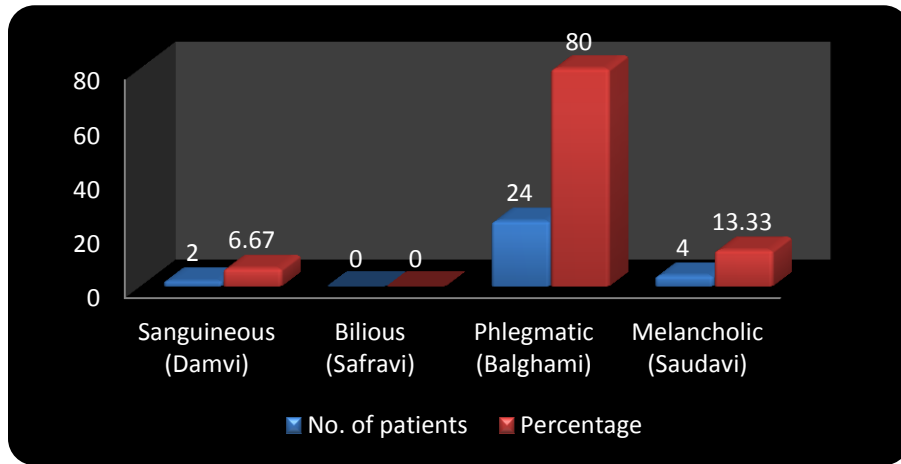
**Table No. 2**

**Distribution of Patients According to Mizaj**

Types of temperament	No. of patients	Percentage
Sanguineous ( <i>Damvi</i> )	2	6.67
Bilious ( <i>Safravi</i> )	0	0
Phlegmatic ( <i>Balghami</i> )	24	80.00
Melancholic ( <i>Saudavi</i> )	4	13.33

During the study, patients were divided into 4 groups on the basis of their temperament. The temperaments of patient were assessed on the basis of *Ajnas e ashra*. As depicted in the above tables it was seen that most of the patients i.e. 24 were of phlegmatic temperament in Test group followed by 4 cases of Melancholic (*Saudavi*) temperament. There was no case of Bilious (*Safravi*) temperament and only 2 cases of Sanguineous (*Damvi*) temperament were found. (Table No. 2 and Graph No. 2)

**Figure 2 Distribution of patients according to Mizaj**



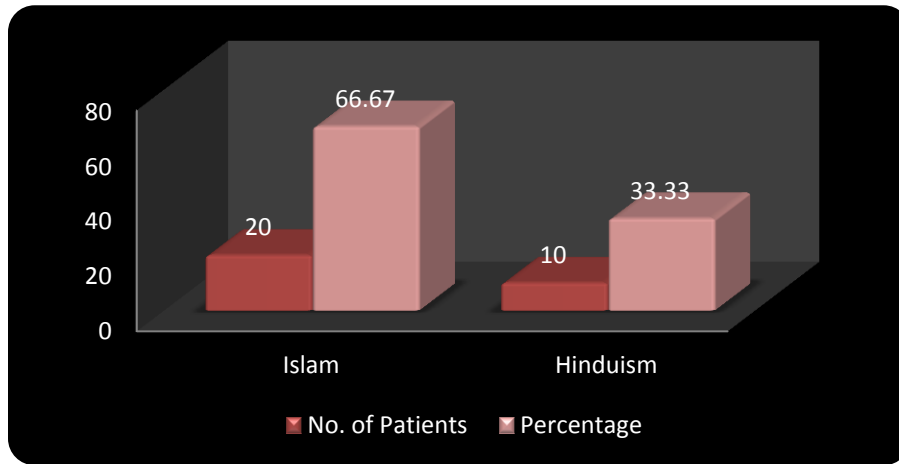
**Table no.3**

**Distribution of patient according to Religion**

Religion	No. of Patients	Percentage
Islam	20	66.67
Hindu	10	33.33
Total	30	100

The cases selected for the study belongs to two religions. It has been found that 20 cases (66.67%) were Muslims while 10 (33.33%) were Hindus and it is due to the situation of hospital in Muslim dominated area. (Table No. 3 and Graph No. 3)

**Figure 3 Distribution of patients according to Religion**



**Table No. 4**

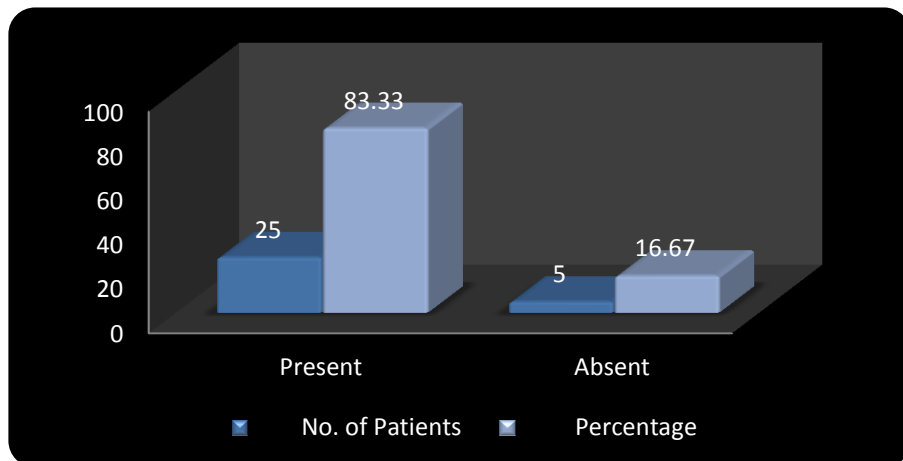
**Distribution of Patient According to Seasonal variation**

H/o Seasonal variation	No. of Patients	Percentage
Present	25	83.33
Absent	5	16.67
Total	30	100

In the present study patients were divided into two groups on the basis of seasonal variation in their symptoms and it was recorded that in most of the patients i.e.25 (83.33%) in number, seasonal variation was present while it was not present in 5 (16.67%) cases. It was more in spring and autumn season and it may be because of harvesting and pollination. (Table No. 4 and Graph No. 4)

**Figure 4 Distribution of Patient According to Seasonal variation**





**Table No. 5**

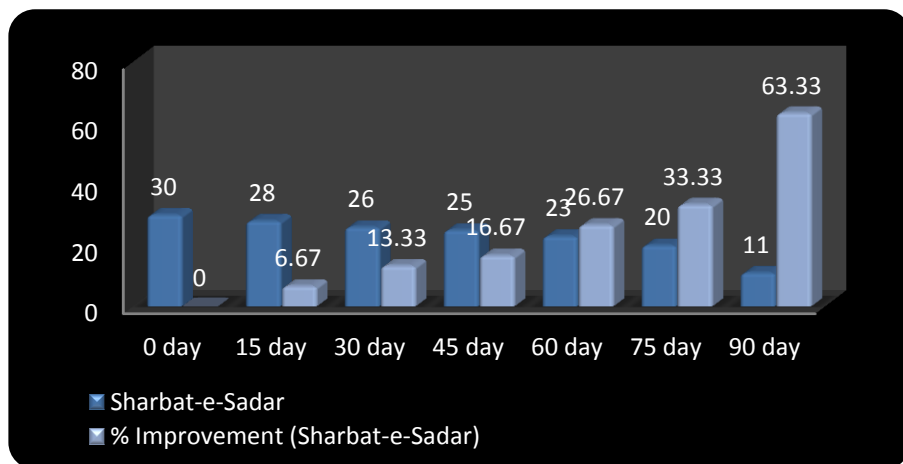
**Effect of Drugs on Shortness of Breath**

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
<b>Shortness of breath</b>	30	28	26	25	23	20	11
<b>Improvement</b>	-	2	4	5	8	10	19
<b>% Improvement</b>	-	6.67	13.33	16.67	26.67	33.33	63.33

As evident from the above table, out of 30 patients, there was improvement in the shortness of breath in 63.33%. The effect was found to be because of our drug combination contains Arusa, Zoofa, Sapistan, Gul –e-Gaozaban, Aslussoos and Koknar having *Mulattif*<sup>13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29</sup>, *Munaffisse Balgham*<sup>14,15,16,17,18,19,20,22,24,27,30,31,32,33,34,35,36,37</sup> and *Munzije balgham*<sup>15,26,30,31,34,38,39</sup> actions thereby facilitating the expectoration and resulting in improvement in shortness of breath . Among the said drugs, Aslussoos which has glycyrrhizin<sup>15,16,17,20,28,29,32,40,41,42</sup>, a potent antispasmodic and Arusa which has vasicinine<sup>17,30,31,34,36,43,44,45,46,47,48</sup> and vasicinone<sup>31,34,40,43,44,45,46,47,48,49</sup> that are potent

bronchodilator and Koknar which has Papaverine<sup>17,33,40, 43,44,49, 50,51</sup> and Laudanosine<sup>33,43,49</sup> that are potent antispasmodic.

**Figure 5 Effect of Drug on Shortness of Breath**



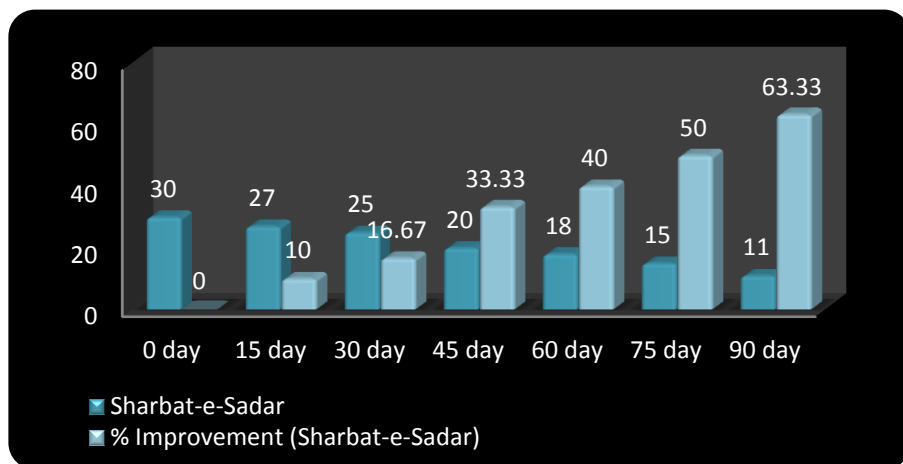
**Table No. 6**

**Effect of Drug on Cough**

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
<b>Cough</b>	30	27	25	20	18	15	11
<b>Improvement</b>	-	3	5	10	12	15	19
<b>% Improvement</b>	-	10.00	16.67	33.33	40.00	50.00	63.33

Before starting the therapy, all the patients had cough, the incidence of which gradually fell to 11 showing an improvement of 63.33%. The most probable cause of improvement in the test group may be due to the expectorant (*Munaffisse Balgham*)<sup>14,15,17,18,19,20,23,30,31,35,36,38,50,51,52,53,54</sup> and

**Figure 6 Effect of Drug on Cough**



**Table No. 7**

**Effect of Drugs on Chest Tightness**

Test group (Sharbat-e-Sadar)

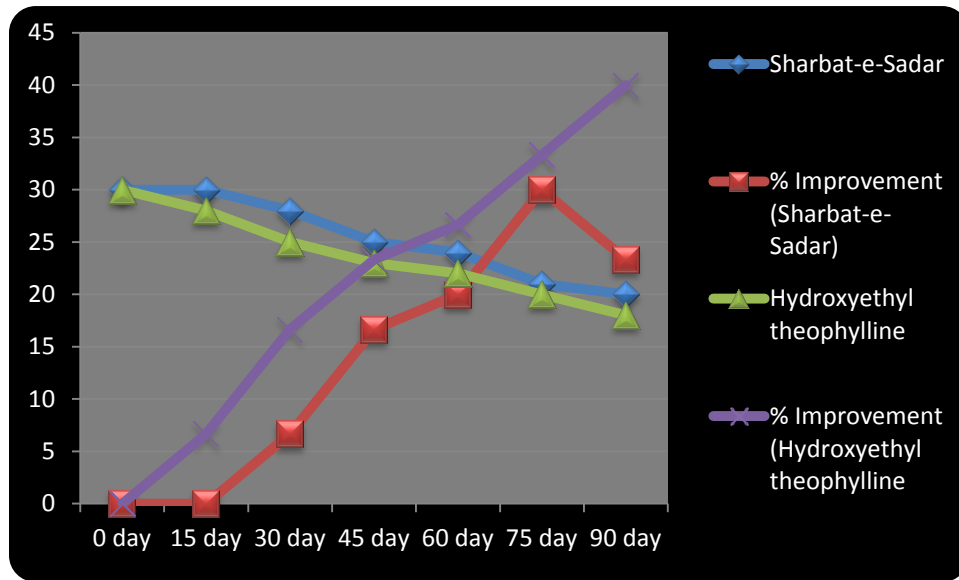
sample size: 30

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
chest tightness	30	30	28	25	24	21	20
Improvement	-	-	2	5	6	9	10
% Improvement	-	-	6.67	16.67	20	30	33.33

The relief in the chest tightness in Test group was observed significantly from 60<sup>th</sup> day onwards and overall improvement of 33.33% observed at the end of therapy. as the chest tightness in Bronchial asthma is mainly because of spasm of smooth muscle of respiratory tract which was reversed by our Test drug combination mainly containing Zoofa-e-khushk, Khubbazi, Sapistan, Anjir, barg-e-Gaozaban, Ajwain desi and Abresham having *Munaqqi sadar*<sup>22,23,30,55</sup> and *Mulayyine sadar*<sup>14,17,20,21,22,26,28,30,32,36,38</sup> actions. Out of them Arusa which has alkaloid vasicine<sup>17,30,31,34,36,43,44,45,46,47,48</sup> and vasicinone<sup>31,34,40,43,44,45,46,47,48,49</sup> having potent bronchodilator effect thereby resulting in the improvement in chest tightness.

**Graph No. 7**

**Effect of Drugs on Chest Tightness**



**Table No. 8**

**Effect of Drugs on Sputum Production**

Test group (Sharbat-e-Sadar)

sample size: 25

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
<b>Sputum production</b>	25	24	22	19	17	16	12
<b>Improvement</b>	-	1	3	6	8	9	13
<b>% Improvement</b>	-	4	12	24	32	36	52.00

Out of 30 patients, 25 had productive cough. In Test group 13 patients showed marked improvement in the sense that sputum production became negligible, while in Control group, it was seen in 9 patients only. The better response in the Test group is due to the expectorant (*Munaffisse Balgham*)<sup>14,15,17,18,19,20,23,30,31,35,35,50,51,52,53,54</sup> and Demulcent effect

(*Mulattif*)<sup>31,32,15,16,17,19,23,25,34,35,36,38,50,53,55,56</sup> of Arusa, Aslussoos, Khubbazi, Parsiyaoshan, Zoofa-e-khushk ,Unnab, Sapisataan, Alsi and Gaozaban. The role of theophylline has been explained earlier. On comparing both the group

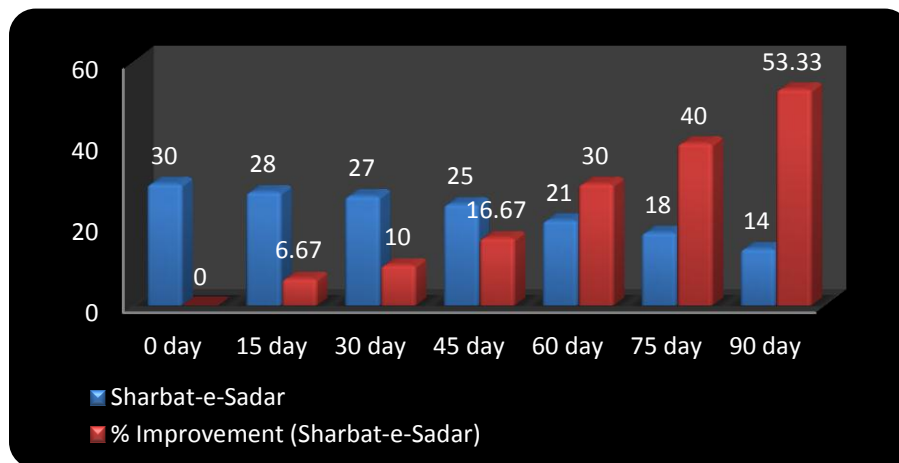
**Table No. 7**

**Effect of Drug on Prolonged Expiration**

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
<b>prolonged expiration</b>	30	28	27	25	21	18	14
<b>Improvement</b>	-	2	3	5	9	12	16
<b>% Improvement</b>	-	6.67	10.00	16.67	30.00	40.00	53.33

By bedside spirometry, prolonged expiratory time of 6 seconds or more was observed in all patients. After the administration of drug, it was observed that expiratory time decreased in 16 patients. These observation reflect the direct bronchodilator effect in Test group Sharbat-e-sadar containing Arusa<sup>17, 30,31,34,36, 43,44,45,46,47,48</sup>, Ajwain desi<sup>15,17,24,32,35,36,38,53,57,58</sup>, Koknar<sup>17, 28,33,36,43,49,50</sup>, Aslussoos<sup>28,29,40,41,42,45,48,49</sup> and Badyan<sup>28</sup> which has bronchodilator effect.

**Figure 7 Effect of Drug on Prolonged Expiration**



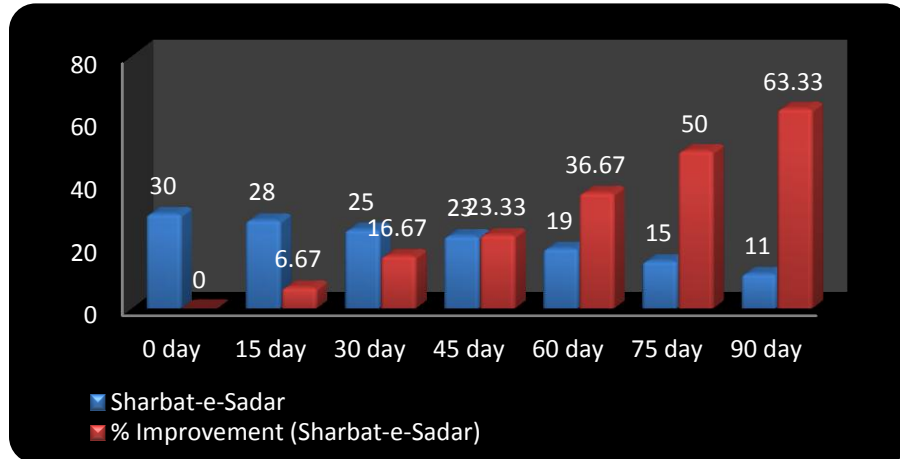
**Table No. 8**

**Effect of Drug on Wheezing/Rhonchi**

No. of days	0 day	15 day	30 day	45 day	60 day	75 day	90 day
wheezing/rhonchi	30	28	25	23	19	15	11
Improvement	-	2	5	7	11	15	19
% Improvement	-	6.67	16.67	23.33	36.67	50.00	63.33

As depicted in the above table, rhonchi disappeared in 19 patients at the termination of therapy i.e. showing an overall improvement of 63.33% . This effect is because of Arusa, Koknar Aslussoos and Zoofa, which has alkaloid vasicinine<sup>17,30,31,34,36,43,44,45,46,47,48</sup> and vasicinone<sup>31,34,40,43,44,45,46,47,48,49</sup>, Papaverine<sup>17,33,40, 43,44,49, 50,51</sup> and Laudanosine<sup>33,43,49</sup> and glycyrrhizin<sup>15,16,17,20,28,29,32,40,41,42</sup> having bronchodilator effect due to smooth muscle relaxation and thereby expelling the mucus. Furthermore Ajwain desi<sup>59</sup> and Unnab<sup>60</sup> also exhibit anticholinergic activity (M<sub>3</sub> receptors blocker) resulting in blockade of constrictor neurotransmitter thereby causing bronchodilation.

**Figure 8 Effect of Drug on Wheezing/Rhonchi**



## CONCLUSIONS

From the above study, following inferences were drawn.

Age and sex- In our study maximum number of patients belong to age group of 30-40 years and were 9 in number followed by 8 patients in the age group of 40-50 years. Number of female patients were 14 (46.67%) while 16 (53.33%) were male.

Temperament-80 % patients belonged to Phlegmatic (*Balghami*) temperament.

Religion - Although on most of the instances disease recognizes no religion. However, from statistical point of view 20 (66.67%) were Muslims and 10 (33.33%) were non muslims.

Seasonal variation - Out of 30 patients of test group 25 i.e. 83.33 % had history of allergy whereas 21 i.e.16.67 % had no history of seasonal variation.

Dyspnoea on exertion or rest was reduced by 63.33% in Test group.

Cough - The improvement was 63.33% in Test group.

Prolonged expiration - During bedside respirometry, prolonged expiration beyond normal i.e. 4 seconds was seen in all the patients. After the treatment expiratory time was decreased by 53.33% in Test group.

Rhonchi - The hallmark of clinical sign i.e. rhonchi was present in all the patients. It decreased by 63.33% in Test group.

Finally it is concluded that Sharbat-e-Sadar is very much effective in the management of bronchial asthma as there was much improvement in the signs and symptoms and also no adverse event was noted during the trial.

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