



HEMATOLOGICAL EVALUATION OF “SHARBAT UNSUL MURAKKAB” IN SUAL-E-MUZMIN (CHRONIC BRONCHITIS)

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ABSTRACT

The present clinical study was undertaken as a single blind placebo controlled study to revalidate the pharmacological actions of *Sharbat Unsul Murakkab* in the treatment of chronic bronchitis as there is no curative treatment available for chronic bronchitis in modern medicine. The test drug and placebo were given in the two groups of 20 diagnosed patients in each, of chronic bronchitis during winter cough in Unani OPD Majeedia Hospital, New Delhi. The hematological and biochemical changes were observed and recorded accordingly. The pharmacological response of patients of acute exacerbation of chronic bronchitis was assessed through Hemogram and AEC besides clinical assessment as per the study protocol duly approved by institutional ethical committee. The study revealed that the test drug is safe and potent anti-infective drug and significantly reduced the signs and symptoms of chronic bronchitis in comparison to placebo.

KEYWORDS: Sual-e-Muzmin, Cough, Dyspnoea, Sharbat-e-Unsul Murakkab, Chronic bronchitis.

INTRODUCTION

Chronic bronchitis is a common ailment of respiratory system manifested as productive cough, dyspnoea due to mucosal irritation caused by smoking, occupational irritants, bacterial and viral infections [Davidson S.S., Macleod J. (1971)]. In winter there is worsening of patient's condition which is known as acute exacerbation of chronic bronchitis or winter cough [Davidson S.S., Macleod J. (1971)]. It is usually a progressive disease punctuated by exacerbation and remissions. Chronic bronchitis is widely prevalent worldwide and according to WHO/WB prevalence of COPD in 1990 was estimated at 9.34/1000 men, 7.33/1000 women [National Vital Statistics Report (2003)]. Mainly bronchodilators and antibiotics when required treats chronic bronchitis but on each acute exacerbation there is progressive decline in ventilatory function, exercise capacity and health status and increased financial burden on hospitalization. Besides these there is risk of side effects and development of bacterial resistance to antibiotics [Isselbacher K.J et al 1994]. Ventilatory and cardiac failure are the commonest complications leading to death [Haslet C, 1999]. The great Unani physician Hippocrates 460 BC [Husain M. (1272 H), Khan, M.A. (1872), Majoosi A.I.A. (1884), Razi Z. (1991), Samarqandi N. (1924), Sina B.A. (1886), Tabri A.B.M. (1997)] has

described chronic bronchitis as Sual-e- Muzmin in Unani publications. It was proposed for the revalidation of pharmacological actions of one of the Unani compound formulation i.e. Sharbat-e-Unsul Murakkab described in classical books as Laooq-e-Unsul [Arzani, M.A. (1880)], for Chronic bronchitis especially in winter cough, to compare the efficacy of test drug with placebo and to provide potent and safe drug for the treatment of chronic bronchitis. The pharmacological response of patients [Zaidi S.A.R. et al (2010)] was assessed through Hemogram and AEC besides clinical assessment as per the study protocol duly approved by institutional ethical committee.

MATERIALS AND METHODS

The study was conducted on 40 patients of chronic bronchitis in OPD Majeedia Hospital. The patients were selected on the basis of clinical parameters and pulmonary function test, history of chronic cough with expectoration and breathlessness of more than six consecutive weeks in a year for more than two consecutive years, history of exposure to risk factors and suggestive complaints. Test drug was prepared according to classical text in the Ilmul Adviya laboratory FOUN with the constituent drugs (Table 1) after their proper identification as well authorization by National Institute

of Science Communication and Information Resources, New Delhi. The test drug and identically looking syrup were given in the dose of 2 TSF BD to the patients of test drug & placebo groups respectively. The follow up of all the patients was carried out at weekly interval on the basis of history, clinical examination and PFT. All the patients were screened at beginning of treatment and after completion of study of 21 days with investigations i.e. Hemogram, AEC. Statistical analysis was performed on data generated from all patients by using paired 't' test while comparing effects of placebo and test drug before and after treatment and unpaired 't' test was applied while comparing effects of placebo verses test drug after treatment. A value of $P < 0.01$ was considered statistically significant and value of $P < 0.0001$ was considered statistically highly significant. (P denotes probability)

RESULTS AND DISCUSSION

Out of 55 patients enrolled for study 40 patients completed the study i.e. 20 patients in each group.

Effect of placebo and test drug on hemoglobin in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 14 patients and after treatment the figure was of 15 patients. In Grade II before treatment there were 06 patients and after treatment the figure was of 05 patients. In Grade III before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No. 1)

Out of 20 patients in test drug group, in Grade I before treatment there were 15 patients and after treatment the figure was of 14 patients. In Grade II before treatment there were 05 patients and after treatment the figure was of 06 patients. In Grade III before treatment there were 00 patients and after treatment the figure was of 0 patients. (Table No.2).

Table 1-Constituent of Sharbat Unsul Murakkab

S.No.	Unani Name	Botanical Name	Part Used	Ratio
1	Unsul	Urgenia indica Kunth	Bulb	3 Parts
2	Irsa	Iris ensata Thunb	Rhizome & Root	2 Parts
3	Zufa Khushk	Agastache urticifolia (Benth) Kuntze	Whole plant without leaves	1 Part
4	Farasiyoon	Valleriana walchii DC	Rhizome	1 Part

Table No.2: Response on Lab Investigation before treatment and after 21 days of treatment in chronic bronchitis (Placebo Group)

Grades	Hemoglobin		TLC		Neutrophils		Lymphocytes		Mono/Basophil		ESR	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Grade I	14	15	17	16	16	16	20	20	16	12	06	02
Grade II	06	05	03	04	03	03	00	00	00	01	06	08
Grade III	00	00	00	00	01	01	00	00	04	07	02	04
Grade IV	--	--	00	00	--	--	--	--	00	00	06	06
Grade V	--	--	--	--	--	--	--	--	00	00	--	--

Hemoglobin Gr. I- 13.0-18.0, Gr. II-08-12Gr. III-4-7 %

TLC Gr. I- 4000-11000, Gr. II-11001-15000, Gr. III-15001-20,000

Neutrophils Gr. I- 45-70, Gr. II-71-75, Gr. III-76-80 %

Lymphocytes Gr. I- 20-45, Gr. II-46-50, Gr. III-51-60%

Monocytes/Basophils Gr. I- 00, Gr. II-01, Gr. III-02, Gr. IV-03, Gr. V-04 %

ESR Gr. I- 0.4-09, Gr. II-10-18, Gr. III-19-28, Grade IV-29 & above

Table No.3: Response on Lab Investigation before treatment and after 21 days of treatment in chronic bronchitis (Test Drug Group)

Grades	Hemoglobin		TLC		Neutrophils		Lymphocytes		Mono/Basophil		ESR	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Grade I	15	14	16	18	17	19	18	19	10	14	07	07
Grade II	05	06	03	02	01	01	02	01	00	01	05	06
Grade III	00	00	01	00	02	00	00	00	08	05	06	06
Grade IV	--	--	00	00	--	--	--	--	00	00	02	01
Grade V	--	--	--	--	--	--	--	--	02	00	--	--

Hemoglobin Gr. I- 13.0-18.0, Gr. II-08-12Gr. III-04-07 %

TLC Gr. I- 4000-11000, Gr. II-11001-15000, Gr. III-15001-20,000

Neutrophils Gr. I- 45-70, Gr. II-71-75, Gr. III-76-80 %

Lymphocytes Gr. I- 20-45, Gr. II-46-50, Gr. III-51-60%

Monocytes/Basophils Gr. I- 00, Gr. II-01, Gr. III-02, Gr. IV-03, Gr. V-04 %

ESR Gr. I- 0.4-0.9, Gr. II-10-18, Gr. III-19-28, Grade IV-29 & above

Table No.4: Response of Placebo & Test Drug on Hemogram of the patients of chronic bronchitis before and after treatment

Parameters	Group	BT	AT	Placebo versus Test Drug
Hemoglobin	Placebo	13.46 ± 0.36	13.55 ± 0.29 ns	13.55 ± 0.29 ns
	Test Drug	13.62 ± 0.41	13.62 ± 0.40 ns	13.62 ± 0.40 ns
TLC	Placebo	7990 ± 492.78	9179 ± 449.16 ns	9179 ± 449.16 ns
	Test Drug	8355 ± 835.92	7225.5 ± 402.85 ns	7225.5 ± 402.85***
Neutrophils	Placebo	62.9 ± 1.175	62.65 ± 1.54 ns	62.65 ± 1.54 ns
	Test Drug	58.45 ± 3.9	58.7 ± 2.15 ns	58.7 ± 2.15 ns
Lymphocytes	Placebo	29.65 ± 1.75	29.3 ± 2.59 ns	28.75 ± 1.49 ns
	Test Drug	58.45 ± 3.9	32.85 ± 1.58 ns	32.85 ± 1.58 ns
Eosinophils	Placebo	7.05 ± 0.46	7.8 ± 0.40 ns	7.8 ± 0.40 ns
	Test Drug	10.5 ± 2.74	6.7 ± 1.06 ns	6.7 ± 1.06 ns
AEC	Placebo	532.5 ± 49.85	665.15 ± 0.40 ns	665.15 ± 0.40 ns
	Test Drug	29.3 ± 2.59	540.75 ± 55.91 ns	540.75 ± 55.91 ns
Basophils	Placebo	0.4 ± 0.18	0.8 ± 0.21 ns	0.8 ± 0.21 ns
	Test Drug	1.5 ± 0.27	0.55 ± 0.19 ns	0.55 ± 0.19 ns
ESR	Placebo	20.95 ± 3.55	22.7 ± 3.45 ns	22.7 ± 3.45 ns
	Test Drug	14.55 ± 2.12	13.6 ± 1.64 ns	13.6 ± 1.64**

On statistical analysis the effect of placebo was non significant and the effect of drug is non significant. On comparison of the hematinic effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug is non significant. (Table No.3)

Effect of placebo and test drug on TLC in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 17 patients and after treatment the figure was of 16 patients. In Grade II before treatment there were 03 patients and after treatment the figure was of 04 patients. In Grade III before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 16 patients and after treatment the figure was of 18 patients. In Grade II before treatment there were 03 patients and after treatment the figure was of 02 patients. In Grade III before treatment there were 01 patient and after treatment the figure was of 0 patients. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug is also non significant.

On comparison of anti leucocytic effect of placebo verses test drug the efficacy of placebo is non significant while the efficacy of the test drug is highly significant. (Table No.3)

Effect of placebo and test drug on neutrophils in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 16 patients and after treatment the

figure was of 16 patients. In Grade II before treatment there were 03 patients and after treatment the figure was of 03 patients. In Grade III before treatment there were 01 patient and after treatment the figure was of 01 patient. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 17 patients and after treatment the figure was of 19 patients. In Grade II before treatment there were 01 patient and after treatment the figure was of 01 patient. In Grade III before treatment there were 02 patients and after treatment the figure was of 0 patients. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug is non significant.

On comparison of the anti-neutrophilic effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug is non significant. (Table No.3)

Effect of placebo and test drug on lymphocytes in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 20 patients and after treatment the figure was of 20 patients. In Grade II before treatment there were 00 patients and after treatment the figure was of 00 patients. In Grade III before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 18 patients and after treatment the figure was of 19 patients. In Grade II before treatment there were 02 patients and after treatment the figure was of 01 patient. In Grade III before treatment there were 00

patients and after treatment the figure was of 00 patients. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug is non significant. On comparison of the efficacy of anti-lymphocytic effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug is non significant. (Table No.3)

Effect of placebo and test drug on eosinophils in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 07 patients and after treatment the figure was of 02 patients. In Grade II before treatment there were 13 patients and after treatment the figure was of 18 patients. In Grade III before treatment there were 00 patients and after treatment the figure was of 00 patients. In Grade IV before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 07 patients and after treatment the figure was of 13 patients. In Grade II before treatment there were 10 patients and after treatment the figure was of 05 patients. In Grade III before treatment there were 01 patient and after treatment the figure was of 01 patient. In Grade IV before treatment there were 02 patients and after treatment the figure was of 01 patient. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug is non significant. On comparison of the anti-eosinophilic (anti-histaminic) effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug is non significant. (Table No.3)

Effect of placebo and test drug on absolute eosinophils count in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 08 patients and after treatment the figure was of 02 patients. In Grade II before treatment there were 11 patients and after treatment the figure was of 14 patients. In Grade III before treatment there were 01 patient and after treatment the figure was of 04 patients. In Grade IV before treatment there were 00 patients and after treatment the figure was of 00 patients. In Grade V before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 06 patients and after treatment the figure was of 07 patients. In Grade II before treatment there were 09 patients and after treatment the figure was of 12 patients. In Grade III before treatment there were 03 patients and after treatment the figure was of 00 patients. In Grade IV before treatment there were 00

patients and after treatment the figure was of 01 patient. In Grade V before treatment there were 02 patients and after treatment the figure was of 00 patients. (Table No.2)

On Statistical analysis the effect of placebo was non significant and the effect of test drug is non significant. On comparison of the anti-eosinophilic (anti-histaminic) effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug is non significant. (Table No.3)

Moreover there were five patients whose Eosinophils Count and Absolute Eosinophils Count show drastic reduction in test drug group after treatment.

Table No.5 Showing Response of

S.No.	EOSINOPHIL COUNT		ABSOLUTE EOSINOPHIL COUNT	
	BT	AT	BT	AT
1.	20%	05%	25000	0500
2.	16%	06%	01088	0380
3.	60%	20%	11220	1260
4.	10%	05%	00910	0580
5.	10%	05%	00550	0295

From these observations it is clear that the test drug may have potent anti-histaminic action though this action is statistically non significant. This variation can be due to non existence of standard methods of preparation of syrup as two lots of syrup were prepared during the study.

Effect of placebo and test drug on basophils/monocytes in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 16 patients and after treatment the figure was of 12 patients. In Grade II before treatment there were 00 patients and after treatment the figure was of 01 patient. In Grade III before treatment there were 04 patients and after treatment the figure was of 07 patients. In Grade IV before treatment there were 00 patients and after treatment the figure was of 00 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 10 patients and after treatment the figure was of 14 patients. In Grade II before treatment there were 00 patients and after treatment the figure was of 01 patient. In Grade III before treatment there were 08 patients and after treatment the figure was of 05 patients. In Grade IV before treatment there were 00 patients and after treatment the figure was of 00 patients. In Grade V before treatment there were 02 patients and after treatment the figure was 00 patients. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug is non significant. On comparison of the anti basophil effect of placebo verses test drug the efficacy of placebo was non

significant while the efficacy of the test drug is non significant. (Table No.3)

Effect of placebo and drug on ESR in chronic bronchitis

Out of 20 patients in placebo group, in Grade I before treatment there were 06 patients and after treatment the figure was of 02 patients. In Grade II before treatment there were 06 patients and after treatment the figure was of 08 patients. In Grade III before treatment there were 02 patients and after treatment the figure was of 04 patients. In Grade IV before treatment there were 06 patients and after treatment the figure was of 06 patients. (Table No.1)

Out of 20 patients in test drug group, in Grade I before treatment there were 07 patients and after treatment the figure was of 07 patients. In Grade II before treatment there were 05 patients and after treatment the figure was of 06 patients. In Grade III before treatment there were 06 patients and after treatment the figure was of 06 patients. In Grade IV before treatment there were 02 patients and after treatment the figure was of 01 patient. (Table No.2)

On statistical analysis the effect of placebo was non significant and the effect of test drug was non significant. On comparison of the anti ESR effect of placebo verses test drug the efficacy of placebo was non significant while the efficacy of the test drug was significant. (Table No.3)

From the above results it is concluded that the test drug is a potent anti-infective drug. As the test drug is an effective anti-tussive, effective mucolytic, bronchodilator, anti-catarhal drug useful for chronic bronchitis patients. Zaidi S.A.R. et al (2010) Unsul, Irsa, Farasiyoon and Zufa Khushk are *Mohallil-e-Auram*, *Mufatteh*, *Mulattif*, *Munaffis* - e- *Balgham* [Attar Z. (1888), Baghdadi I.H. (1369 H), Baitar Z.I. (1197-1248) Ghani, N. (1920), Hakim M.A. (1311 H.), Husain M. (1272 H), Kabiruddin, M. (1951), Khan, M.A. (1872), Momin M.M. (1272 H.), Nafis B.I. (1924), Sina B.A. (1886)]. The test drug through its *Mohallil-e-Auram* (Anti-inflammatory) action resolved the bronchial inflammation and decreases the excessive secretion of mucopurulent sputum, by *Mulattif* (Demulcent) action it makes the sputum less viscous, by *Mufatteh* (De-obstruent) action it dilates the bronchioles and by *Munaffis-e-Balgham* (Expectorant) action it expectorates the less viscid sputum easily thus improving the pulmonary function.

CONCLUSION

Keeping in view the highly significant antileucocytic response of the test drug in comparison of the placebo and concomitant relief in sign and symptoms observed in patients it is stated that the claims of Unani physicians regarding the pharmacological actions i.e. *Mohallil-e-Auram* (Anti-inflammatory action), *Mulattif* (Demulcent), *Mufatteh* (De-obstruent) *Munaffis-e-*

Balgham (Expectorant) of the constituents of the formulation tally with the results of the study drug. The present study validates the utility of the formulation in the treatment of Sual-e-Muzmin (Chronic bronchitis) as per the claims of classical Unani literature and the formulation has potent and prompt action in respiratory ailments as mentioned earlier. The test drug may prove cost effective, potent and safe drug for the treatment of chronic bronchitis and it may be used as an alternative remedy for the better management of chronic bronchitis if studied further on larger sample size.

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