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Research Article

Comparative therapeutic evaluation of two Unani formulations in the management of Chronic Tonsillitis

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Abstract

Chronic tonsillitis is a common disease found worldwide mostly in school going children. There are many challenges in the management of chronic tonsillitis especially in refractory cases. There are many single as well compound drugs for the management of tonsillitis which are being used for a longer duration without any known side effect. A randomized open comparative study was designed to validate the efficacy of two very commonly prescribed formulations in the patients of chronic tonsillitis viz. *Laoq Sapistan Khyar Shambari* and *Sharbat Toot Siyah*.

Laoq Sapistan Khyar Shambari 6 gm and *Sharbat Toot Siyah* 20 ml were given orally twice a day to the patients of Group A & Group B respectively for 6 weeks continuously. The data was compiled and statistically analyzed using chi square test and paired t-test.

In test group A, maximum benefit was seen in Sore throat ($p<0.0001$, $\chi^2=48.81$), followed by Irritation in throat ($p<0.0001$, $\chi^2=17.23$), Pain in throat ($p<0.0001$, $\chi^2=17.23$), dry cough ($p=0.0002$, $\chi^2=14.35$) and dysphagia ($p=0.0076$, $\chi^2=7.12$). In test group B, maximum benefit was observed in sore throat ($p=0.0076$, $\chi^2=7.12$), followed by notable improvement in irritation in throat ($p=0.0014$, $\chi^2=10.15$), and pain in throat ($p=0.0098$, $\chi^2=6.67$).

Although both *Laoq Sapistan Khyar Shambari* and *Sharbat Toot Siyah* are effective, but *Laoq Sapistan Khyar Shambari* is a better option for the management of chronic tonsillitis; as it relives most of the symptoms & signs very effectively and safely.

Keywords: Chronic tonsillitis, Unani formulation, *Laoq Sapistan Khyar Shambari*, *Sharbat Toot Siyah*

INTRODUCTION

Background: Chronic tonsillitis is a common disease found worldwide mostly in school going children. There are many challenges in the management of chronic tonsillitis especially in refractory cases.^{1,2,3}

Chronic tonsillitis is manifested by pain in throat, irritation in throat, dry cough, dysphagia, foul breath and sometimes earache. On examination, enlarged tonsils along with palpable jugulodigastric lymph nodes are usually found.^{1,2,3}

Ikne Habal Albaghadi says that "Due to *Warame Lauzatain* (tonsillitis) there will be severe pain in the throat and difficulty in swallowing and breathing and it may lead to complication similar to diphtheria.⁴

Allopathic medical treatment includes use of antibiotics, anti-inflammatory, antihistaminic, decongestant and in very few cases oral steroid. Continuous use of these drugs for a longer duration always leads to number of hazardous side effects. At last, the patient is advised to go through surgical

procedure. Surgical interventions include Electrocautery Tonsillectomy, Bipolar Radiofrequency Tonsillectomy, Cold Knife Tonsillectomy, Powered Intra-capsular Tonsillectomy, and Ultrasonic Dissection Tonsillectomy.^{1,2,3}

There are many single as well compound drugs for the management of tonsillitis which are being used for a longer duration without any known side effect. For example *Khyar-e-shambar* (*Cassia fistula* Linn.),^{5,6} *Banafsha* (*Viola odorata* Linn.),^{6,7} the milk of fig, *tukhm-e-hulba* (*Trigonella foenum-graecum*), *tukhm-e-katan* (*Linum usitatissimum* Linn.)^{7,8} etc. are indicated for the medical treatment of *waram-e-lauztain* (tonsillitis). Gargle of *Shibb-e-yamani* (alum)^{6,8} and *Rubbutoot* (*Morus nigra* Linn. extract)⁸ are also beneficial in *waram-e-lauztain*.

Keeping in view that, holistic approach of Unani system of medicine may be much beneficial in the management of chronic tonsillitis; a randomized, open, and comparative study was designed to evaluate the efficacy and safety of two very commonly prescribed and used Unani pharmacopeial

compound formulations viz. *Laoq Sapistan Khyar Shambari* and *Sharbat Toot Siyah* in chronic tonsillitis.

Objective: Primary objective of this clinical study was "to validate" the efficacy and safety of two most used Unani compound formulations in the management of chronic tonsillitis. Secondary objective was to find out superior formulation and better option out of these two.

MATERIAL AND METHOD

Study design: It was an open, randomized, parallel design, and comparative study clinical study. 60 patients of chronic tonsillitis were allocated into two groups viz. group A and group B having 30 patients in each. A total of 75 patients were enrolled in the study but, 15 patients did not complete the study.

Participants: Participants were selected on the basis of inclusion and exclusion criteria as finalized in the protocol and approved by the Institutional ethical committee.

Inclusion criteria: Clinically diagnosed patients of chronic tonsillitis with constitutional symptoms viz. Recurrent episodes of sore throat, Chronic irritation in the throat, Difficulty in swallowing, Dry cough, Earache, Foul breath, Follicles on tonsils, Post nasal dribbling, Enlarged tonsil and Palpable Jugulodigastric lymph nodes. Patients of either sex aged between 5-45 years.

Exclusion Criteria: Patients with severe acute presentation or with gross enlargement of tonsils associated with choking spells. Mentally retarded, Congenital/ acquired structural abnormality of oral cavity, patients suffering from Diabetes Mellitus or any severe systemic illness. Patients who failed to give written consent.

Location and setting: The present study was carried out in the department of Moalajat, Faculty of Unani Medicine, AMU, Aligarh, India during the period 2015-2017. The study was started after getting approval from Institutional Ethical Committee (IEC) in the meeting held on 13th July 2015. Recruitment of participating patients was done from the OPD of ENT and OPD/ IPD of Moalajat (general medicine) of A.K. Tibbiya College Hospital, AMU, Aligarh.

Intervention: In Group A, patients were given *Laoq Sapistan Khyar Shambari* 6 gram orally twice a day before one hour of meals with lukewarm water, whereas, in Group B, patients were given *Sharbat Toot Siyah* 20 ml orally twice a day before one hour of meals, for 6 weeks continuously. Study formulations were given without any label on the container, on weekly basis. Medicine for next week was only provided after getting empty container from the patient.

For the purpose of the clinical study, the test drugs viz. *Laoq Sapistan Khyar Shambari* and *Sharbat Toot Siyah* were procured from the production unit of Unani medicine of AMU, Dawakhana Tibbiya College, Muslim University, Aligarh.

Drugs Used

Laoq Sapistan Khyar Shambari: This is a polyherbal formulation, prepared as thick semisolid linctus. The formulation has following ingredients:

1. *Sapistan* (*Cordia latifolia* Roxb.)
2. *Amaltas* (*Cassia fistula* Linn.)
3. *Unnab* (*Zizyphus vulgaris* Linn.)
4. *Khatmi* (*Althaea officinalis* Linn.)
5. *Barg-e-sana* (*Cassia angustifolia* Vahl.)
6. *Katan* (*Linum usitatissimum* Linn.)
7. *Banafsha* (*Viola odorata* Linn.)
8. *Leemu* (*Citrus lemon* Linn.)
9. *Shakkr surkh* (jaggery)

Sharbat Toot Siyah: This is a single drug formulation, prepared from decoction of *Toot Siyah* (*Morus nigra* L.) into sugar based syrup.

Follow-up and Assessment: The patients were evaluated clinically every week on a regular basis for the improvement in sign and symptoms and recorded in the case report form (CRF). Laboratory investigations for the assessment of efficacy and safety evaluation were carried out at the beginning and completion of the clinical study, at Post Graduate Laboratory of department of Moalajat, Faculty of Unani Medicine, AMU, Aligarh.

Evaluation: After completion of the study, the data was compiled and statistically analyzed. Since most of the clinical features of chronic tonsillitis are subjective in nature, therefore, for the assessment of efficacy of drugs on these subjective parameters chi-square (χ^2) test was applied within the group, as well as between the group. The effect of drugs on differential eosinophil count (DEC) and Absolute eosinophil count (AEC) was assessed by Student's pair t-test. Student's pair t-test was also applied while assessing effect of drugs on Hb%, ESR, TLC, Neutrophils, Lymphocytes, LFT & KFT (biochemical parameters) and random blood sugar (RBS).

OBSERVATIONS AND RESULT

After enrolment of the patients for the clinical study, patients were assessed on the basis of the clinical presentation of the chronic tonsillitis viz. Sore throat, Irritation in the throat, Pain in throat, Dysphagia, Cough, Earache, Halitosis, Follicles on tonsils, Post-nasal dribbling, Enlarged tonsils, Palpable Jugulodigastric lymph nodes. The detailed observations and results are summarized in table 1. Table 2 shows the efficacy of both formulations on reduction on Eosinophil counts, AEC & DEC. For the safety assurance, the effect was noted on haemogram parameters (table 3) as well as on biochemical parameters viz. KFT, LFT and Random blood sugar (RBS) as shown in table 4.

Table 1: Effect of test formulations on clinical parameters

Symptoms	Number of Patients in Group A (n=30)							Number of patients in Group B (n=30)							Stats between Group A & B	
	0 week	1 week	2 week	3 week	4 week	5 week	6 week	Stats at before & after treatment	0 week	1 week	2 week	3 week	4 week	5 week	6 week	
Sore throat	30	25	21	15	13	9	2	p<0.001, $\chi^2 = 48.81$	28	26	25	22	20	19	15	p<0.001, $\chi^2 = 11.82$
Irritation in throat	22	15	12	8	7	7	5	p<0.001, $\chi^2 = 17.23$	25	19	16	16	15	13	12	p=0.0014, $\chi^2 = 10.15$
Pain in throat	22	14	12	10	10	6	5	p<0.001, $\chi^2 = 17.23$	20	18	15	15	14	13	9	p=0.0098, $\chi^2 = 6.67$
Dysphagia	10	6	5	5	4	3	1	p=0.0076, $\chi^2 = 7.12$	12	11	11	9	9	8	8	p=0.4113, $\chi^2 = 0.675$
Dry cough	18	8	7	7	6	4	3	p=0.0002, $\chi^2 = 14.35$	14	14	13	13	11	10	10	p=0.429, $\chi^2 = 0.625$
Earache	12	11	6	4	4	4	4	p=0.041, $\chi^2 = 4.17$	8	8	7	7	6	5	5	p=0.530, $\chi^2 = 0.392$
Halitosis	6	6	6	4	4	1	1	p=0.107, $\chi^2 = 2.59$	6	6	6	6	5	5	4	p=0.729, $\chi^2 = 0.120$
Follicles on tonsils	8	7	3	3	2	2	2	p=0.083, $\chi^2 = 3.00$	8	8	7	6	6	6	6	p=0.760, $\chi^2 = 0.093$
Post nasal dribbling	8	7	7	7	5	5	5	p=0.530, $\chi^2 = 0.392$	9	9	9	9	8	8	8	p=0.774, $\chi^2 = 0.082$
Enlarged tonsils	18	18	18	13	13	13	12	p=0.196, $\chi^2 = 1.667$	17	17	17	17	16	16	16	p=0.795, $\chi^2 = 0.067$
Palpable Jugulodigastric lymph nodes	10	10	10	10	9	8	6	p=0.381, $\chi^2 = 0.767$	12	12	12	12	11	11	11	p=0.790, $\chi^2 = 0.070$

Table 2: Effect of test formulations on AEC & DEC

S. No.	Investigation	Test Group A (n=30)				Test Group B (n=30)			
		Mean \pm SEM		p value	t value	Mean \pm SEM		p value	t value
		BT	AT			BT	AT		
1.	AEC	675.2 \pm 14.91	564.2 \pm 13.5	<0.0001	5.51	655 \pm 10.42	653 \pm 10.20	0.11	1.61
2.	DEC	12.1 \pm 4.6	5.64 \pm 0.39	<0.0001	11.88	5.24 \pm 0.29	5.98 \pm 0.39	0.16	1.44

Table 3: Effect of test formulations on Haemogram

S. No.	Investigation	Test group A				Test Group B			
		Mean \pm SEM		t value	p value	Mean \pm SEM		t value	p value
		BT	AT			BT	AT		
1	Hb gm/dl	11.99 \pm 0.22	11.99 \pm 0.23	0.05	>0.05	12.38 \pm 0.24	12.46 \pm 0.23	0.30	>0.05
2	ESR mm/hr	17.18 \pm 1.61	16.92 \pm 1.62	0.11	>0.05	15.84 \pm 1.14	17.1 \pm 0.53	0.67	>0.05
3	TLC/cumm	7444 \pm 195	7491 \pm 190	1.16	>0.05	7584 \pm 275	7530 \pm 184	0.23	>0.05
4	N/cumm	61.82 \pm 1.28	61.24 \pm 1.43	0.57	>0.05	59.26 \pm 1.01	58.06 \pm 1.06	1.29	>0.05
5	L/cumm	30.34 \pm 1.12	32.1 \pm 0.98	1.70	>0.05	31.2 \pm 1.71	33.4 \pm 1.23	1.54	>0.05

Table 4: Effect of test formulations on KFT, LFT & Random Blood Sugar

S. No	Investigation	Test Group A				Test Group B			
		Mean \pm SEM		t value	p value	Mean \pm SEM		t value	p value
		BT	AT			BT	AT		
1	BU mg/dl	24.48 \pm 0.76	24.58 \pm 0.78	0.09	>0.05	22.46 \pm 0.86	23.78 \pm 0.70	1.20	>0.05
2	SC mg/dl	0.91 \pm 0.01	0.91 \pm 0.01	0.34	>0.05	0.91 \pm 0.12	0.90 \pm 0.01	0.58	>0.05
3	SB mg/dl	0.93 \pm 0.02	0.89 \pm 0.02	1.38	>0.05	0.83 \pm 0.04	0.82 \pm 0.03	0.18	>0.05
4	AST IU/L	23.62 \pm 0.54	22.66 \pm 0.53	1.34	>0.05	23.52 \pm 0.52	23.12 \pm 0.41	0.60	>0.05
5	ALT IU/L	22.62 \pm 1.08	20.54 \pm 1.05	1.27	>0.05	18.8 \pm 1.24	20.98 \pm 0.49	1.55	>0.05
6	SAP IU/L	121.32 \pm 1.12	120.18 \pm 0.90	1.54	>0.05	113.32 \pm 1.02	113.88 \pm 1.07	1.30	>0.05
7	RBS mg/dl	79.42 \pm 1.22	79.78 \pm 1.35	0.19	>0.05	80.56 \pm 1.16	79.48 \pm 1.16	0.72	>0.05

DISCUSSION

In this study, 60 clinically diagnosed patients of chronic tonsillitis belonging to both sex and different age were treated with the aim to provide safe and effective treatment in the management of chronic tonsillitis.

The commonest type of chronic tonsillitis observed in the current study was chronic parenchymatous tonsillitis; it comprised 63.33% of all cases. Chronic follicular tonsillitis was found in 26.67% of cases followed by chronic fibroid tonsillitis that is 6% of all cases. The finding of prevalence of different types of tonsillitis is in accordance to the existing current text.

In test group A, maximum benefit was seen in Sore throat ($p<0.0001$, $\chi^2= 48.81$), followed by Irritation in throat ($p<0.0001$, $\chi^2= 17.23$), Pain in throat ($p<0.0001$, $\chi^2= 17.23$), dry cough ($p=0.0002$, $\chi^2= 14.35$) and dysphagia ($p=0.0076$, $\chi^2= 7.12$). However, rest of the signs and symptoms were also reduced but statistically insignificant ($p>0.05$). These clinical improvement may be attributed to different medicinal properties like *Mulattif* (demulcent), *Qabiz* (astringent), *Musakkin* (sedative), *Dafe suaal* (cough relieving), *Muhallil-e-Auaram* (anti-inflammatory), *Daaf-e-Alam* (analgesic) present in different ingredients of *Laoq Sapistan Khyar Shambari*, or by some of its identified chemical constituents viz. *Sapistan*^{9,10,11,12,13,14,15} (*Sitosterol*¹⁶, *Oleic acid*¹⁷), *Banafsha*^{12,14,15,18,19,20} (*Violin*¹³,

Rutin¹³, Methylsalicylate¹³), *Amaltas*^{9,13,21,22} (Tartaric acid, Melic acid, Oxalic acid and Cathartic acid³²), *Unnab*^{2,13,24,25,26} (Tannin^{13,14}, Zizyphus saponin I, II, III and Jujuboside B^{14,15}), *Khatmi*^{12,13,14,21} (Althein or Apragin, Tannin^{27,28,29}), *Barg-e-sana*^{9,13,22,24,30} (Anthraquinone, Sennidin A & B¹³), *Alsi*^{9,13,14,31} (Secoisolarici-resinoldiglycosides⁸).

Some ingredients of *Laoq Sapistan Khyar Shambari* possess antiviral and antibacterial effects also, that might help to cure chronic tonsillitis due to such infections, viz. *Sapistan* (50% extract of *Cordia latifolia* showed a significant activity only against *H. influenzae*²⁵), *Amaltas* (Anti-fungal, Anti-bacterial¹⁵) and *Barg-e-sana* (Anti-bacterial^{13,32}).

In test group B, maximum benefit was observed in sore throat ($p=0.0076$, $\chi^2= 7.12$), followed by notable improvement in irritation in throat ($p=0.0014$, $\chi^2 =10.15$), and pain in throat ($p=0.0098$, $\chi^2= 6.67$). However, a little improvement in other clinical manifestations was also noted, but statistically insignificant ($p>0.05$). The improvement in signs and symptoms of chronic tonsillitis may be attributed to the *Muhallil-e-auram* (anti-inflammatory), *Musakkin* (sedative), *Dafa-e-alam* (analgesic), and *Mulattif* (demulcent) effects of *Toot siyah*.^{11,23,33,34}

For the purpose of comparison, chi square test between the groups was applied. At the base line we found $p>0.05$, depicting therefore, the distribution of patients in two groups was non-biased and randomization was good.

At the end of the study we found significant difference between the groups ($p<0.05$) for Sore throat, irritation in throat, dysphagia and dry cough. Since within the group for these symptoms chi square value is greater in group A, we can say result of group A is better. For rest of the symptoms and signs statistics shows insignificant difference between the groups ($p>0.05$).

Therefore, suggesting *Laoq Sapistan Khyar Shambari* as a better and superior drug than *Sharbat Toot Siyah* for the treatment of chronic tonsillitis.

The effect of drugs on eosinophil count was also assessed. Reduction in differential eosinophil count (DEC) and absolute eosinophil count (AEC) was highly significant in group A patients, while insignificant in group B patients. Therefore, *Laoq Sapistan Khyar Shambari* has promising results in decreasing eosinophil count and *Sharbat Toot Siyah* doesn't, depicting therefore, *Laoq Sapistan Khyar Shambari* also has significant anti-allergic effect.

Hb%, ESR, TLC, Neutrophil (N) and Lymphocytes (L) as well as safety Biochemical parameters show insignificant difference before and after the treatment in both the groups, hence both the formulations are safe to be used.

CONCLUSION

After thorough discussion it can be concluded that, Chronic tonsillitis most of the time is caused by allergic susceptibility, therefore, prevention can play important role in its management.

Although both *Laoq Sapistan Khyar Shambari* and *Sharbat Toot Siyah* are effective, but *Laoq Sapistan Khyar Shambari* is better for this illness; as it relives the majority of the symptoms clinically effectively and statistically significantly. *Laoq Sapistan Khyar Shambari* also posses enough anti-allergic property, as suggested by significant decrease in eosinophil count (DEC & AEC).

For more authentic results, further clinical study on larger sample size with advanced laboratory parameters is needed.

Conflict of interest

The authors declare no conflict of interest.

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