Clinical Evaluation of Coded Unani Drugs in Lymphatic Filariasis

[1]*Mahboob-us-Salam, [1]Bilal Ahmad, [2]M.I. Alam, [2]S.M.Ahsan, [2]S.S. Ali Khan and [2]N. Sehar

[1]Literary Research Institute of Unani Medicine (CCRUM), Central Library, First Floor, Jamia Hamdard, New Delhi-110062

[2]Regional Research Institute of Unani Medicine (CCRUM), Guru Govind Singh Hospital, Guzri, Patna City, Patna-800008

Abstract

In the present study, clinical efficacy of two coded Unani drug combinations, UNIM-268 and UNIM-269 was evaluated with and without Munzij and Mushil therapy (MMT) on the patients of lymphatic filariasis (*Da'ul Feel)* at Regional Research Institute of Unani Medicine, Patna. Out of all the patients of *Da'ul Feel* registered during 2009-2011, seventy one cases completed the trial. The comparison between clinical and pathological findings of all the four groups before and after the treatment suggested that both the combinations are effective in the treatment of filariasis. However, the effect of UNIM-268 and UNIM-269 on lymphoedema was comparatively pronounced when used after Munzij and Mushil therapy.

Keywords: Lymphatic filariasis, *Da'ul Feel*, *Wuchereria bancrofti, Brugia timori, Brugia malayi, Munzij-Mushil Therapy*

Introduction

Lymphatic filariasis is caused by infection with three nematode worms, *Wuchereria bancrofti*, *Brugia malayi*, *Brugia timori* which are transmitted to man by mosquitoes (Park, 2009). Out of the three nematode worms, *W. bancrofti* has wide distribution, affects about 115 million people and is found all over the tropics and subtropics, including Asia and the Pacific Islands, Africa, areas of South America and the Caribbean basins (Fauci *et al.,* 2008). It is a major public health problem in India and its various states such as Uttar Pradesh, Bihar, Orissa, Jharkhand, Andhra Pradesh, Tamil Nadu, Kerala and Gujrat are heavily infected (Park, 2009). In endemic areas, the disease is a major cause of debilitating and disfiguring manifestations such as lymphoedema, elephantiasis, hydrocele etc. (WHO, 1992).

According to Zakariya Razi and Ibn al-Quff Masihi the disease is caused by the Black Bile (*Sawda'*) (Razi, 1962; Masihi, 1356H.), while, Nuh Qamari has mentioned the abnormal flow of thick matter towards the legs as the causative factor (Qamari, 2008). Some physicians say that the disease, results due to the abnormality of Phlegm (*Balgham*) and Black Bile (Antaki, 2009), while few add pure sanguine to the list (Khan, 1885).

Diethyl carbamazine (DEC) is the only drug available for chemotherapeutic control of filariasis (Park, 2009). However, due to its variable efficacy and serious allergic reactions there is the need of finding out more efficacious and safer drugs to treat the filariasis. As the disease was known to Unani

[1]* Author for correspondence

physicians since ancient times, they have mentioned a large number of effective single and compound formulations, but no clinical data is available to support their claims. Keeping in view the above mentioned facts, the present study was conducted in the O.P.D. and I.P.D. section of Regional Research Institute of Unani Medicine, Patna to evaluate the clinical efficacy of two coded Unani drug combinations, UNIM-268 and UNIM-269 in the cases of lymphatic filariasis (*Da'ul Feel*) with and without *Munzij-Mushil Therapy*.

Materials and Methods

The clinical trial was conducted in the O.P.D. and I.P.D. section of Regional Research Institute of Unani Medicine, Patna. Patients of lymphatic filariasis (*Da'ul Feel*) of either sex aged between 11-60 years having lower limb lymphoedema were selected for the study after thorough clinical examination. After obtaining the informed consent, the patients were subjected to laboratory investigations. The laboratory investigations performed at different stages of trial included haemoglobin (Hb), red blood corpuscles (RBC) count, total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), urine analysis, stool examination, blood smear for detection of microfilaiae (mfs) and absolute eosinophil count (AEC). Safety of trial drugs was monitored through performing liver function tests and kidney function tests periodically. Lymphoedema was measured with the help of measuring tape. Out of all the patients registered for the study during 2009-2011, total 71 cases completed the study. The results obtained at base line and after treatment were compared to evaluate the efficacy of trial drugs. All the registered subjects were randomly divided into following four groups e.g. Group A: 5 patients, Group B: 31 patients, Group C: 23 patients and Group D: 12 patients respectively.

Group A: UNIM-268 two tablets of 500 mg twice daily
UNIM-270 five grams powder
UNIM-272 twenty grams oil
UNIM-270 and UNIM-272 were mixed together and applied locally on the affected part
UNIM-271, twenty grams coarse powder of crude drugs, used as Nutool (Irrigation). Nutool is a mode of treatment in which luke warm decoction of crude drugs is poured on the affected part.

Group B: UNIM-269 two tablets of 500 mg twice daily
UNIM-270 five grams powder
UNIM-272 twenty grams oil

UNIM-270 and UNIM-272 were mixed together and applied locally on the affected part

UNIM-271 twenty grams coarse powder of crude drugs used as Nutool (Irrigation).

Group C: UNIM-MUNB (*Munzij*)

Decoction of UNIM-MUNB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning per day till the *Nuzj* appeared in the urine of patients

UNIM-MUSB (*Mushil*)

Decoction of UNIM-MUSB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning on alternate days for 5 days

UNIM-TAB (*Tabreed*)

Infusion of UNIM-TAB (crude drugs) in the dose of 50 ml was given orally on empty stomach early in the morning on alternate day to UNIM-MUSB administration for 5 days

After UNIM-MUNB, UNIM-MUSB and UNIM-TAB the patients of this group were given the same treatment as mentioned in group A.

Group D: UNIM-MUNB (*Munzij*)

Decoction of UNIM-MUNB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning per day till the *Nuzj* appeared in the urine of patients

UNIM-MUSB (*Mushil*)

Decoction of UNIM-MUSB (crude drugs) in the dose of 125 ml was given orally on empty stomach early in the morning on alternate days for 5 days

UNIM-TAB (*Tabreed*)

Infusion of UNIM-TAB (crude drugs) in the dose of 50 ml was given orally on empty stomach early in the morning on alternate day to UNIM-MUSB administration for 5 days.

After UNIM-MUNB, UNIM-MUSB and UNIM-TAB the patients of this group were given the same treatment as mentioned in group B.

Elastocrape bandage was used in all four groups. The duration of treatment was 120 days in group A and B, while in group C and D this duration was MMT+120 days. The clinical follow-up was done at regular interval of 30 days. The laboratory investigations were performed at baseline, after MM therapy (group C and D) and at the interval of 30 days in all the groups.

Statistical analysis

All the data were expressed as mean ± S.E.M. and analyzed by One-way analysis of variance (ANOVA) followed by Dunnett's 't' test. Probability level of less than 5% was considered as statistically significant.

Table 1 : Age-wise distribution of the patients

Age Group (Years)	Number of cases	Percentage (%)
11-20	11	15.49
20-30	12	16.9
30-40	24	33.8
40-50	09	12.67
50-60	15	21.12
Total	71	100

Table 2 : Sex-wise distribution of the patients

Sex	Number of cases	Percentage (%)
Male	30	42.25
Female	41	57.74
Total	71	100

Table 3 : Socio-economic status of the patients

Socio-economic status	Number of cases	Percentage
Poor	48	67.6
Average	16	22.53
Good	07	09.85
Total	71	100

Table 4 : Chronicity status of disease

Chronicity in years	Groups			
	A	B	C	D
Up to 1 year	01	12	08	02
1 Year-5 Years	04	17	14	09
5 Years-10 Years	Nil	02	01	01
Above 10 Years	Nil	Nil	Nil	Nil

Table 5 : Clinical Parameters Before and After Treatment

S. No.	Group	No. of Patients	Lymphadenitis		Lymphangitis		Fever	
			Base Line	After Treatment	Base Line	After Treatment	Base Line	After Treatment
1	A	05	05	00	05	01	05	00
2	B	31	28	02	28	03	06	02
3	C	23	23	00	23	00	20	00
4	D	12	11	00	12	02	11	00

Table 6 : Filarial Oedema in Millimeters, Before and After Treatment

Day of Measurement	Mean + S.E.M. (in mm.)			
	Group A	Group B	Group C	Group D
Base Line	878.6 + 3.34	1029.5 + 8.60	953.56 + 1.17	1173.25 + 1.82
After Treatment	829 + 2.23*	971.63 + 3.80**	863 + 2.66**	1023 + 12.24**
% of reduction	5.58%	5.63%	9.44%	12.78%

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
*P<0.05, **P<0.01 as compared to baseline.

Table 7 : Total Eosinophil percentage, Before and After Treatment

Day of Measurement	Mean + S.E.M.			
	Group A	Group B	Group C	Group D
Base Line	6.2 + 0.37	6 + 0.15	4.65 + 0.10	5.33 + 0.14
After Treatment	4.4 + 0.24**	4 + 0.15**	3.34 + 0.10**	4.33 + 0.14**
% of reduction	29.03%	33.33%	28.17%	18.76%

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
**P<0.01 as compared to baseline.

Table 8: Absolute Eosinophil count (AEC), Before and After Treatment

Day of Measurement	Mean ± S.E.M.			
	Group A	Group B	Group C	Group D
Base Line	485.8 ± 2.01	425.4 ± 0.83	381.78 ± 1.22	358.58 ± 1.70
After Treatment	276.8 ± 2.15**	246.8 ± 0.71**	256.95 ± 1.23**	256.5 ± 2.06**
% of reduction	43.09%	42.11%	32.80%	28.49%

One-way analysis of variance (ANOVA) followed by Dunnett's 't' test.
**P<0.01 as compared to baseline.

Results and Discussion

The maximum number of patients belonged to the age group of 30-40 years (Table-1). It shows that persons belonging to this age group (young working adults) are mostly affected, which may have serious economic and social implications as indicated by World Health Organization in its report (WHO, 1992).

Out of total 71 cases, 48 (67.6%) belonged to poor class of society (Table-3). This may be due to poor hygienic conditions in localities inhabited by them.

Clinical efficacy of two coded drug combinations was assessed on the basis of clinical observations and laboratory findings at baseline and after treatment which are shown in tables 05 to 08. The clinical parameters including fever, lymphadenitis and lymphangitis which were observed at baseline in most of the cases subsided after treatment with the trial drugs in majority of them but the response of trial drug used in group C was comparatively better (Table-5).

Percentage reduction in lymphoedema was observed to be 5.58%, 5.63%, 9.44% and 12.78% in group A, B, C and D respectively which is also found statistically significant ($P<0.05$) in Group A and highly significant ($P<0.01$) in Group B, C and D respectively as compared to baseline (Table-6). These results indicate that UNIM-268 and UNIM-269 are more effective in reducing the filarial oedema when used after MM therapy. This finding authenticates the observations made by Razi when he says that a decrease in the volume of affected leg can be achieved through purgation in early stage of the disease (Razi, 1962).

The decrease in eosinophil percent was observed to be 29.03%, 33.33%, 28.17% and 18.76% in group A, B, C and D respectively and also found highly significant ($P<0.01$) in Group A, B, C and D respectively as compared to baseline (Table-7). Percentage reduction in absolute eosinophil count was found to be 43.09%, 42.11%, 32.80% and 28.49% in group A, B, C and D respectively and also found highly significant ($P<0.01$) in Group A, B, C and D respectively as compared to baseline (Table-8).

During the course of the trial no adverse effects were reported. Biochemical parameters to evaluate the safety of trial drugs were found to be within normal range.

Conclusion

On the basis of our observations, it can be concluded that both the trial drugs viz., UNIM-268, UNIM-269 are effective in the cases of lymphatic filariasis

(*Da'ul Feel)*. The lymphoedema, which is the most prominent feature of the disease and is responsible for social suffering, is markedly reduced only when the trial drugs are used after MM therapy. This reduction in filarial oedema becomes negligible when used without MM therapy as can be observed through the results obtained in group A and B. As there were no reports of any adverse effect and laboratory test for safety evaluation were within normal range, it can be suggested that the trial drugs are well tolerated and have no adverse effect and can be propagated as an alternate to diethyl carbamazine for the treatment of lymphatic filariasis.

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