ORIGINAL RESEARCH PAPER

Ayurveda

EFFICACY *OF MUNZIJ WA MUS'HIL-E-BALGHAM* AND *ZIMAD-E-SHEETRAJ* ON MOTOR RECOVERY IN *FALIJ-E-NISFI* (HEMIPLEGIA)

KEY WORDS: *Falij; Munzij-e-Balgham; Mushil-e-Balgham;* Barthel Index; MAS

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ABSTRACT

Background and objectives: *Falij* is derived from an Arabic word *Falj* which literally means splitting into halves. It is the paralysis of longitudinal half of the body starting either below the neck, sparing head & face or covering the entire longitudinal half of the body from head to toe. It draws analogy with hemiplegia occurring due to stroke. The estimated age-adjusted prevalence rate for stroke in India is between 84/100,000 and 262/100,000 in rural and between 334/100,000 and 424/100,000 in urban area. Unani physicians have advocated *Tanqia* and *Ta'deel* as treatment of *Falij*. Therefore, a study was designed to evaluate the efficacy of *Munzij wa Mus'hil-e-Balgham* and *Zimad-e-Sheetraj* on Motor Recovery in *Falij-e-Nisfi* (Hemiplegia).

Methods: Present study was an open, single arm, pre and post without control trial, carried out on 29 patients with hemiplegia, secondary to stroke. Patients were given *Munzij-e- Balgham* in *Joshanda* (decoction) form, orally, once daily before breakfast for 14 days; the ingredients of *Mus'hil-e-Balgham* were added in *Munzij-e-Balgham* and given in decoction form on 12th day. From 13th day of treatment, 5 grams of *Safoofe Sheetraj* was applied on spinal column as *Zimad* for 15 minutes, once daily till the 30th day. The assessment was based on Motor Assessment scale (MAS) and Barthel Index. Pre and post treatment values of the scales were analyzed statistically using paired student's t-test.

Results: The difference between the pre and post treatment values obtained for Barthel Index and MAS were found highly significant ($p<0.001$).

Interpretation & Conclusion: On the basis of the above observations and results, it may be concluded that the trial formulations are effective in the treatment of motor recovery in stroke. This treatment regimen may be used to reduce the dependence and improve the quality of life in patients of hemiplegia secondary to stroke.

INTRODUCTION

The word *Falij* is an Arabic word literally meaning "splitting into halves".[1] Since the body is split into paralyzed and unparalyzed halves, therefore the term *Falij* is applied to the equal and paradoxical state of the body. Unani scholars have described *Falij* and *Istirkha* synonymously.[1,2] *Falij* (Hemiplegia) is the commonest manifestation and classical sign of all cerebrovascular diseases or stroke.[3] Stroke is a neurological syndrome of rapidly developing signs and symptoms of focal loss of cerebral function due to sudden death of brain cells caused by disturbance in the blood supply to the brain.[4]

Stroke is one of the leading causes of disability, morbidity and mortality worldwide. World Health Organization (WHO) states that it is the second leading cause of death in people who are aged above 60 years and fifth leading cause in people aged between 15-59 years.[5]. Global burden of stroke depicts that nearly 20 million people suffer from acute stroke every year and among them 5 million die each year It is the the leading cause of disability and functional impairment of which 20% of the stroke survivors require institutional care after 3 months and around15%-30% are permanently disabled.[6] In addition, such disabilities place a significant burden on caregivers of stroke survivors. Initial walking function is impaired in two-thirds of the stroke population and this impairment is the greatest contributor to functional disability after stroke.

Motor recovery remains the major objective in the rehabilitation of stroke patients. By definition, motor recovery refers to a comprehensive program designed to regain as much as function as possible and compensate for the permanent losses.[7,8] In modern medicine, management of acute stroke involves thrombolytic agents, anticoagulants, anti-platelet aggregation agents for effectively controlling and reducing the cerebral damage but long term management of disability and neurorehabilitation is still a challenge.[7,9] Despite perpetual advancement in its treatment, the figures in terms of death and disability grossly suggest the limitation in its management. Considering this unconvincing scenario, Unani medicine on its own merit comes to the fore, as the *Falij* has successfully been treated since ancient times without any significant and obnoxious side effects by eminent Unani physicians.

Hippocrates (*Buqrat* 460-370 BC) was the first to describe the phenomenon of sudden paralysis that is often associated with ischemia of brain. Among others, *Ibne Sina, Jalinoos, Ali Ibn Majoosi, Rabban Tabri, Sabit Bin Qurrah, Hakim Azam Khan* have described *Falij* in detail. They clearly mentioned the risk factors, aetiology, pathogenesis, clinical features and the treatment of the disease in detail in their respective treatises. *Falij* is considered a disease caused by *Sue Mizaj Maddi* (including *Balgham*)[10,11] and is treated by *Tanqiya* and *Ta'deel* (evacuation and normalization of temperament). *Tanqiya* or *Istifraghe Mawad* (elimination of causative matter) is brought about by *Munzij Advia* which have properties such as *Tahleel*, *Taqtee* and *Talteef*. The *Munzij* is followed by *Mus'hil Advia* having properties to expel the morbid *Akhlat* from whole body, particularly from vessels and structures neighbouring intestine. *Ta'deel* or *Islahe Mizaj* (rejuvenation) of affected organ is achieved after *Tanqiya* by judicious employment of various *Tadabeer* such as *Dalk, Hammam, Riyazat, Takmeed, Nutool, Zimad* etc.[10,11,12]

In light of the above facts, Unani formulations, consisting of *Joshanda Munzij-e-Balgham*, *Joshanda Mus'hil-e-Balgham* and *Zimad-e-Sheetraj* were selected from the reputed Unani pharmacopeia to evaluate the efficacy of this whole regimen in *Falij-e- Nisfi* in present study.

MATERIALS AND METHODS

An open, single arm, pre and post without control clinical trial was conducted at National Institute of Unani Medicine (NIUM) Hospital Bengaluru, which spanned from April 2016 to March 2017. A comprehensive protocol was framed and put forward to Ethical Committee of National Institute of Unani Medicine which approved it with the no. (NIUM/IEC/2014-15/022/IBT/02 Dated: 16/04/14). After the approval patients were screened for the eligibility criteria from both IPD/OPD of the hospital. During the selection procedure, complete history including general physical

and systemic examination was carried out and recorded on a prescribed proforma which was designed according to the objectives of the study. Written consent was taken from all the subjects who were enrolled for the study. Radiologically and clinically diagnosed cases of *Falij-e-Nisfi* (Hemiplegia) secondary to stroke, or having history of stroke (at least more than 15 days) of either gender and between 30-70 years were enrolled in present study. Subjects with minor stroke with non-disabling deficit, altered sensorium, aphasia, serious enough to impair understanding of simple commands, having Orthopaedic or Rheumatologic diseases impairing mobility, evidence of fixed contracture, and those with liver, kidney, cardiac, uncontrolled diabetes mellitus, severe hypertension and other co- morbidities were excluded from the study. Pregnant and lactating women were also excluded.

INVESTIGATIONS

Certain laboratory investigations were carried out in present study aiming at two important objectives: a) Exclusion of the patients as per study protocol and b) Establishing the safety of the test drug.

Investigations done before and after the treatment were Hb%, TLC, DLC, ESR, Urine- Routine & Microscopic, Blood Sugar-F/PP, Blood Urea & Serum Creatinine, AST, ALT, Serum Bilirubin and ECG

INTERVENTION

Study subjects were given *Munzij-e- Balgham* in *Joshanda* (decoction) form, orally, once daily before breakfast for 14 days which contains *Aslussoos, Badyan, Bekhe Badyan, Ustukhuddoos, Anisoon, Tukhme Karafs, Ood Saleeb, Bekhe Izkhir* and *Barge Gauzaban* 4 gm each. *Mus'hil Balgham* also in *Joshanda* (decoction) form containing *Ustukhuddoos* 5 gm*, Barge Sana* 10 gm*, Turbud* 3 gm*, Maghze Fuloos Khayar Shambar 7 gm* and *Raughane Zard* 5 gm were added in *Munzij-e-Balgham* on 12th day. From 13th day of treatment *Safoofe Sheetraj* was applied on spinal column as *Zimad*.[10] *Zimad-e-Sheetraj* consists of *Sheetraj* only[10, 11].

PROCEDURE OF THE STUDY

The ingredients of *Munzij*-e-*Balgham* wa *Mus'hil-e-Balgham*, and *Zimad-e-Sheetraj* were provided by NIUM pharmacy. The ingredients of *Munzij-e-Balgham*, *Mus'hil-e-Balgham*, and *Zimad-e-Sheetraj* were cleaned of any unwanted material or wild plants, pounded and placed in separate airtight containers. Later, these drugs were given to the patients to follow the treatment as given under;

The ingredients of *Munzij*-e-*Balgham* were soaked in 250 ml of water and left for whole night. Next morning they were boiled on low flame to prepare *Joshanda* (decoction). After filtration of *Joshanda* (decoction), the filtrate was given to patients to drink it before breakfast in the morning once a day for 14 consecutive days. On the 12th day, the ingredients of *Mus'hil-e-Balgham* were mixed with those of *Munzij-e-Balgham;* The *Joshanda* was prepared and given to drink before breakfast in the morning for 1 day only. From 13th day of treatment, 5 grams of *Zimad-e-Sheetraj* was applied on spinal column for not more than 15 minutes, once daily till the 30th day.

ASSESSMENT

The assessment was based on reliable, specific and valid scales- Motor Assessment scale (MAS) and Barthel Index. Assessment was carried on 0th day, 15th day and 30th day.

Motor Assessment Scale; The Motor Assessment Scale (MAS) is a performance-based scale that was developed as a means of assessing every day motor function in patients with stroke. The MAS is based on a task-oriented approach that assesses performance of functional tasks rather than isolated patterns of movement.[13]

Barthel Index;[1]The Barthel scale or Barthel ADL index is an ordinal scale used to measure performance in activities of daily living (ADL). Each performance item is rated on this scale with a given number of points assigned to each level or ranking. It uses ten variables describing ADL and mobility.[14]

STATISTICAL ANALYSIS

Descriptive and inferential statistical analysis has been carried out in the present study to evaluate the efficacy of the drugs. Results on continuous measurements are presented on Mean SD (Min-Max). Significance is assessed at 5 % level of significance. Student's t-test (two tailed, dependent) has been used to find the significance of mean difference of study parameters on continuous scale within group. The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

A total of 50 patients were screened, out of which 40 cases fulfilled the inclusion criteria, hence; were subjected to clinical & laboratory investigations. Four patients had abnormal values of investigative parameters and therefore excluded. Finally 36 cases were enrolled. A total of 29 cases completed the study as 7 cases lost to follow up.

Table no 1; Sociodemographic characteristic of the studied subjects

Age Group		No. Of subjects	% age
	30-40	13	44.8
	41-50	7	24.1
	51-60	7	24.1
	>60	2	6.9
Gender	Male	26	89.7
	Female	3	10.3
Marital status	Married	27	93.1
	Unmarried	2	6.9
Religion	Hindus	20	69
	Muslims	8	27.6
	Christians	1	3.4
Socioeconomic Status	Lower	17	58.6
	Lower middle	7	24.1
	Upper middle	5	17.2

In present study, the highest incidence of 19 (65.5%) patients presented with left hemiplegia; while, 10 (34.5%) with right hemiplegia. (Figure no. 21) Our study suggested a preponderance of left sided hemiplegia. This trend coincides with the findings of Almani SA *et al.* and Maimadi P *et al*.[15,16]

In present study, distribution of subjects with respect to occurrence of stroke includes 4 patients (13.8%) of less than 6 months duration, 10 (34.0%) of 6 months to 1 year duration, 6 (20.7%) of 1-2 year duration, 7 (24.1%) of 3-5 year duration and 2 (6.9%) with more than 5 years duration.

In relation to the risk factors of stroke, 11 (38%) subjects were hypertensive followed by 3 (10%) as alcoholics, 2 (7%) each of the subjects as smokers and diabetic. Subjects with both hypertension and alcoholism were 4 (14 %), with hypertension and DM were 3 (10%) and with smoking and alcoholism were 1 (3%). 1(3%) subject had hypertension and smoking; While, 2 (7%) were without any risk factor as shown in table no. 2.

Table no. 2; Risk factors of the studied subjects

Risk Factors	No. of patients (n=29)	%
No	2	6.9
HTN only	11	37.9
Alcoholism only	3	10.3
Smoking only	2	6.9
DM only	2	6.9
HTN+DM	3	10.3
HTN+Alcohol	4	13.8
HTN+Smoking	1	3.4

In the present study, Mean ± SD of Barthel Index Scores at 0 day, 15th day and 30th day were 34.14 ± 8.03, 42.24 ± 8.41 and 49.14 ± 8.25, respectively. The pre and post treatment values obtained for

Barthel Index were subjected to statistical analysis using student's t- test (dependent). The difference between the Mean ± SD score from baseline and 15th day was found highly significant (p<0.001). Statistical difference was also significant (p<0.001) between 15th day and 30th day score as well as between baseline and 30th day.

Table no. 3. Barthel Index Score of the subjects

Barthel Index Score	Min-Max	Mean ± SD	Comparison	difference	t value	p value
0 Day	20.00-55.00	34.14±8.03	0 day-15th day	8.103	9.666	<0.001**
15th Day	25.00-55.00	42.24±8.41	0 day-30th day	15.000	15.608	<0.001**
30th day	30.00-65.00	49.14±8.25	15th day-30th day	6.896	10.974	<0.001**

In this study, Mean ± SD of Motor Assessment Scale scores at 0 day, 15th day and 30th day were 15.07 ± 5.35, 17.79 ± 4.85 and 19.38 ± 4.55, respectively as shown in the table no. 4.. The difference between Means scores from baseline and 15th day was found highly significant (p<0.001). Statistical difference was also significant (p<0.001) between 15th day and 30th day score as well as between baseline and 30th day.

Table no. 4. Motor Assessment Scale scores of the subjects

MAS Score	Min-Max	Mean ± SD	Comparison	difference	t value	p value
0 Day	6.00-28.00	15.07±5.35	0 day-15th day	2.724	12.975	<0.001**
15th Day	9.00-29.00	17.79±4.85	0 day-30th day	4.310	18.069	<0.001**
30th Day	11.00-29.00	19.38±4.55	15th day-30th day	1.586	9.418	<0.001**

In order to determine the adverse effects of the test drug, safety parameters like Hematological investigations, ECG, urine (routine & microscopy), blood glucose, LFT and RFT were carried out at the baseline and at the end of the treatment. (Table no.5) It was found that all the safety parameters were within the normal range after the completion of the trial. This suggests that the test formulation can be used safely at mentioned therapeutic dose.

Table no 5. Safety parameters of the subjects

Variables	BT	AT	Difference	t value	P value
Hemoglobin gm%	13.76±1.61	13.11±1.56	0.645	2.037	0.051
TLC cells/cu mm	7568.97±1539.50	7251.72±1533.35	317.241	1.563	0.129
DLC%: P	60.59±6.73	61.07±8.82	-0.483	-0.333	0.741
L	30.66±6.01	30.38±8.02	0.276	0.241	0.811
E	4.45±1.18	4.52±1.09	-0.069	-0.235	0.816
MO	3.93±1.25	4.03±1.12	-0.103	-0.422	0.676
ESR mm/hr	**Min-Max**	**Mean ± SD**	**Difference**	**t value**	**P value**
BT	1.00-80.00	23.21±20.96	-	-	-
AT	2.00-90.00	19.14±20.31	4.069	1.247	0.223
Variables	**BT**	**AT**	**Difference**	**t value**	**P value**
FBS mg/dl	96.31±18.47	100.69±21.94	-4.379	-1.094	0.283
PPBS mg/dl	135.66±45.82	138.17±43.27	-2.517	-0.288	0.776
Blood Urea mg/dl	31.05±12.28	31.76±13.81	-0.707	-0.211	0.835
Serum Creatinine mg/dl	1.00±0.61	0.89±0.23	0.106	0.892	0.380
SGOT IU/L	36.93±37.20	26.58±11.33	10.348	1.446	0.159
SGPT IU/L	37.57±36.84	23.37±9.25	14.200	1.963	0.060+
Total Bilirubin. mg/dl	0.90±0.40	1.01±0.43	-0.114	-1.431	0.163

DISCUSSION

According to Unani medicine, the *Mizaj* (temperament) of a person, in *Falij-e-Nisfi,* from normal, changes into abnormal character, known as *Sue-Mizaj* (ill-temperament). This *Sue Mizaj* alters the normal physiology into morbidity, leading to malfunction or non-functioning of the organs or whole body. *Sue Mizaj* is divided into two types, *Sue Mizaj Sada and Sue Mizaj Maddi. Sue Mizaj Sada* is treated by reverting the *Sue Mizaj* to *Mizaj Moatadil* only by using drugs and specific regimen. It is known as *Ta'deel-e-Mizaj* (normalization of temperament). *Sue Mizaj Maddi* involves a derangement in normal *Mizaj* coupled with abnormality in *Madda* (material). Correction of *Sue Mizaj Maddi* requires elimination of abnormal *Madda* resulting in restoration and potentiation of *Mizaj Tabayi*.[12]

Falij-e-Nisfi is considered a *Balghami Marz* because of involvement of *Balghame Ghair Tabayi* in its causation and thus, produces *Sue Mizaj Maddi*. The treatment of *Falij-e-Nisfi-e-Nisfi* in *Unani* medicine comprises detoxification and removal of the causative material, followed by reinvigoration of physiological functions of the diseased organ. The removal of vitiated matter is in order to bring back *Mizaj Tabayi* is known as *Tanqiya* (Evacuation) and invigoration of normal functions is termed as *Ta'deel* (rejuvenation).[10]

Tanqiya is considered as the basic step in the treatment of *Falij-e-Nisfi* and is performed by employing *Munzij* and *Mus'hil-e-Balgham* drugs and *Tad'eel* is the next step which is achieved by institution of various compounds drugs along with a range of a regimenal procedures like *Dalk, Hijamah, Inkebab, Hammam, Zimad* etc.[10,17]

The properties of *Munzij Advia* include *Tahleel, Taqtee* and *Talteef,* making the premise of *Tanqiya* which possibly resembles with the current treatment of stroke in modern medicine comprising anti inflammatory, antithrombotic agents, thrombolytics and neuroprotective drugs.

Munzij-e-*Balgham Advia* possess some synergistic properties like *Mufatteh Sudud, Muqavvie Asaab, Munaqqie Dimagh, Munaqqie Akhlat-e-Ghaleeza, Jali* etc.[10,18,19]

Ancient Unani physicians had a strong belief that *Mus'hil* drugs expel out both *Raqeeq* as well as *Ghaleez* constituents of *Ghair Moatadil Akhlat* to which they have affinity with due to their inherent properties like *Mus'hile Akhlat Salasa, Mus'hile balgham, Mukhrije Balgham, Qate Balgham, Munaqqie Dimagh, Mulattif, Mufatteh Sudud* and *Jali* etc.[10]

In present study *Ta'deel* was achieved by *Zimad-e-Sheetraj* to restore *Mizaj Moatadil* of the affected organ. The *Baroodat,* which remains diffused in *Asaab* after the *Tanqiya*, is removed by the local application of *Zimad-e-Sheetraj* having *Har Yabis Mizaj* (Hot and dry temperament).

Processes mediating motor recovery:

Number of processes has been mentioned in literature that may contribute to the recovery of motor functions after an attack of stroke summaned up below:

(i)Hypothetical role of test formulation in resolution of the pathology of stroke:

In acute stages after stroke, recanalisation of occluded vessels, establishment of collateral flow and reduction in inflammation, all contribute to salvaging partially spared tissue. The major goal for therapeutic intervention in *Falij-e-Nisfi* patients is to limit neuronal

damage in the surrounding penumbra and removal of local inhibition. In conventional system, specific drugs like antiplatelets, anticoagulants, thrombolytic therapy, neuroprotective agents, and surgical interventions are employed during initial stage of stroke management. The pathological changes in and around the infracted zone provide a hypothesis for the probable mechanism of action of the ingredient of test formulation. Our test drug formulations possess properties such as *Muhallil* (dissolvent), *Mulattif* (attenuant), *Mufattehe Sudad* (deobstruent), *Munaqqie Dimagh* (brain purifier), *Muqawwie Aa'saab* (neurotonic), *Muqatte*, *Jali* (cleanser) etc. Test formulation drugs such as *Asalussoos* is reported to possess Glycyrrhizin and aglycone- an important compounds which exhibit anti-inflammatory, antiallergic, antioxidant, antiviral, antithrombotic properties.[20] Further Studies suggest that glabridin, a major flavonoid of it, significantly decreases the cerebral histological damage, focal infarct volume as well as apoptosis. Similarly *Badiyan (Foeniculum vulgare)* possesses a vital chemical constituent transanethole, which has been reported for its anti-inflammatory effect, blocking LsPS-induced inflammation, regulating pro-inflammatory cytokines, transcription factors, and Nitrous oxide. Also, essential oils derived from it showed antithrombotic activity.[21] Further, *Anisoon (Pimpenella anisum)* one of the ingredient drug of test formulations has been reported to have a significant relaxant e ect due to inhibitory e ect on muscarinic receptors and anti-inflammatory action by inhibitory effect on prostaglandin synthesis.[22,23] It also possesses neuroprotective activity and also contains constituents having COX inhibitory activity which may significantly reduce the inflammatory process. *Ood saleeb (Paeonia emodi)* has been proven to exhibit anti-inflammatory, anti coagulant and spasmolytic activities; therefore, used for blocking effect on neuromuscular junctions. Similarly, *Turbud* is endowed with important chemical constituents such as lupeol, betulin and sitosterol which exhibit hepatoprotective, anticancer and anti-inflammatory effects.[24]

Thus, from the scientific reports of test formulation, it can be inferred that the trial drugs act as antiinflammatory, antithrombotic, anticoagulant and neuroprotective agents which tend to open the obstruction of vessels and recanalise them, reduce the inflammation as well as edema along with reduction in the damage of ischemic penumbra and, thereby, limiting the neuronal damage.

(ii)Development of compensatory movement strategies enabling recovery of certain motor functions:

Oral antispasmodic agents such as baclofen, diazepam, dantrolene sodium, clonidine, and tizanidine are used to relieve spasticity.[25] Experimental studies revealed that antispasmodic or spasmolytic activities were present in Ustukhudoos i.e *Lavandula stoechas,* mediated through calcium channel blockade,[26]*Anisoon (Pimpinella anisum*), through inhibition of acetylcholine,[22] and *Karafs* (*Apium graveolens)* mainly by suppressing the Ca2+ influx.[27] Another study done by Karimzadah F *et al.* shows anise oil having anti- convulsant and neuroprotective effect and suggested a mechanism of inhibition of synaptic plasticity. Study done by Ghahremanitamadon F *et al.* suggested that *Gauzaban (Borago officinalis)* could improve the learning impairment and oxidative damage in the hippocampal tissue and may lead to an improvement of cognitive dysfunction.[28] Aglycone and glabridin from *Aslassoos* inherit properties like memory enhancer, spatial learning improver and neuroprotective properties.[20] The mode of action as mentioned above is similar to botulinum toxin which is commonly used in spasticity management and, hence, gives an idea about the recovery of motor functions.

(iii)Enhancement of brain plasticity:

Neural plasticity can be defined as "the ability of brain to change and repair itself". Experimental study done by Yang *et al.* on *Anisoon* mentions that a compound named *L-3-n-butylphthalide* promotes neurogenesis and neuroplasticity in cerebral ischemic rats.[29]Another study done by Murlidharan P *et al.* on hypoxic rat showed cerebroprotective activity of *Aslussoos*,[30] Similarly a review by Pieszak M *et al.* on Gauzaban mentioned its cerebroprotective activity. In our test formulation drugs like *Ustukhuddoos* and *Badyan* possess *Muqavvie dimagh* properties. Similarly *Muqavvie Asaab, Munaqqie Asaab* and *Muharikke Asaab* properties were found in *Ustukhuddoos, Badyan, Maghz Faloos Khayar Shambar* and *Aslussoos.* Thus, the properties of the test drugs used in present trial seem to have enhanced the plasticity of the brain and are further, capable of upregulating the functions of the undamaged area and help them take over the function of the affected part/areas.

(iv)Sprouting of new connections:

It takes place by two processes, firstly, regenerative synaptogenesis, which refers to sprouting of the injured axons to innervate previously innervated synapses, secondly, reactive synaptogenesis, (collateral sprouting) which refers to reclaiming of synaptic sites of the injured axon by dendritic fibers from neighbouring axons.[7] In a study on *Aslussoos,* it has been shown that the aqueous root extract possesses neuronal dendritic growth stimulating properties. According to Ganesan K *et al. Sheetraj* possesses neuroprotective and central nervous system stimulating properties due to plambogin.[7] *Munaqqie Dimagh, Muqavvie Dimagh, Muqavvie Aasab* properties of the drugs in our test formulation might have a significant role in stimulation of sprouting of new connection in and around the damaged area so as to restore the lost functions.

In present study, almost all patients reported improvement in motor power of paralyzed limbs as well as improvement in Activities of Daily Living (ADL) e.g, dressing and personal hygiene which are considered to be an important goal of management in such patients. This improvement is expected to reduce the dependence on caregivers as well as burden for patient's family. Three patients complained of increased frequency of urination and two patients complained of loose motions during the trial period. The possible reason for these side effects may be the *Haar Mizaj* of the test formulation as well as its *Mudir* properties. Itching was also complained by two patients over the application region of *Zimad* i.e spinal region. This may be due to local irritation or hypersensitivity.

LIMITATIONS

Some of the potential limitations inherent in this study include small sample size, short duration of the study and limited parameters of assessment. Thus, it is recommended that clinical trial of this type should be done on larger sample size, for longer duration with other assessment scales including Barthal Index scale and MAS scale. Further studies are recommended with improved methodology to limit these inadequacies for better reliability and acceptability of such clinical trials.

CONCLUSION

The primary aim of treatment in stroke survivors emphasizes on motor recovery so as to reduce the dependency on caregivers as well as burden on patient's family. Unani medicine is one among the alternative pathies which is still capable in the treatment of such disorders. Thus, from the above discussion the conclusion may be drawn that that the trial formulations are effective in the treatment of motor recovery in patients secondary to stroke. This treatment regimen may be used to reduce the dependence and improve the quality of life in patient of *Falij-e-Nisfi*.

ACKNOWLEDGEMENT

The authors are thankful to the authorities of National Institute of Unani Medicine, Bangalore for providing financial assistance and ample facilities for clinical trial, and are also thankful to the patients who participated in the study. We also thank Dr. K.P Suresh (Biostatician) for the statistical analysis of our data.

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