

Efficacy of massage with *roghan seer* in motor recovery in hemiplegia secondary to ischaemic stroke

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A randomized placebo controlled study was designed to evaluate the efficacy of massage with *Roghan Seer* (a polyherbal Unani formulation), in motor recovery in Hemiplegia secondary to ischaemic stroke. Forty patients of ischaemic stroke diagnosed radiologically, presenting with hemiplegia (*Falije Nisfi*) were randomly allocated to Group A (test) and Group B (control); comprising 20 patients each. Patients in Group A were massaged with *Roghan Seer* whereas patients in Group B were massaged with white petroleum jelly. The study reveals that there was significant improvement in voluntary movements of lower limb ($p < 0.05$) and basic mobility ($p < 0.05$) in Group A as compared to Group B. There was no significant improvement in voluntary movements of upper limb in both Group A and B ($p > 0.05$).

Keywords: *Falije Nisfi*, Hemiplegia, Stroke, Unani medicine, Motor recovery, Massage

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In Unani system of medicine *Falij* is described as a disease causing loss of movement and sensation in longitudinal half of the body because the penetration of *Roohe Hassas* and *Muharrrik* into the organs may either be arrested or the *Rooh* may penetrate but the organs may not respond due to *Fasaad* in their *Mizaj*¹⁻². A renowned Unani physician has described that *Falij* is caused by an obstruction in any part of the brain³. This description draws analogy with hemiplegia occurring due to cerebrovascular accidents or stroke.

A stroke or cerebrovascular accident is defined by the abrupt onset of neurological deficit that is attributable to a focal vascular cause. In stroke, neurological signs and symptoms last for >24 hrs⁴. Acute focal stroke is characterized by the sudden appearance of a focal deficit of brain functions, most commonly a hemiplegia with or without signs of focal higher cerebral dysfunction, hemisensory loss, visual field defects or brain stem deficit⁵.

Approximately 85% of strokes are caused by sudden onset of inadequacies of blood flow to some part or whole of the brain. The remaining strokes are between haemorrhage into the brain tissue (parenchymatous haemorrhage) and haemorrhage into the spaces surrounding the brain, most frequently the subarachnoid space⁶.

Cerebrovascular diseases are one of the major causes of human mortality and morbidity. It was the second leading cause of death in 2004 accounting to 5.7 million deaths worldwide. Cerebrovascular diseases were the sixth leading cause of burden of diseases and left 12.6 million people moderately to severely disabled worldwide in 2004⁷. Each year millions of stroke survivors have to adapt to a life with restrictions in activities of daily living and become dependant on other people's continuous support to survive mainly due to motor impairments. Thus effective treatment in stroke should primarily aim at motor recovery.

Despite advancements in technology and drug development, the figures in terms of deaths and disability caused by stroke grossly suggest the limitations in its management. Hence, a clinical trial was conducted with the objective of providing safe, effective and economical drug therapy in motor recovery in patients of Hemiplegia. *Roghan Seer*, a pharmacopeial compound formulation of Unani medicine, was selected for the purpose of massage as a test drug. The ingredients of *Roghan Seer* are *Barge suddab* (*Ruta graveolens* leaves), *Aaqarqarha* (*Anacyclus pyrethrum*), *Farfiun* (*Euphorbia antiquorum* juice), *Filfile siyah* (*Piper nigrum*), *Lehsun* (*Allium sativum*) and *Tilon ka tel* (*Sesamum indicum* oil)⁸. The efficacy of this formulation has been evaluated on the anvil of modern parameters and results drawn were found promising.

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Methodology

After ethical clearance, a randomized, placebo controlled study was conducted at National Institute of Unani Medicine (NIUM) hospital. This study stretched from February 2008 to January 2009.

Inclusion criteria: Patients were recruited according to following criteria:

- (1) Hemiplegia secondary to ischaemic stroke.
- (2) Stroke onset between 4 weeks to 5 yrs.
- (3) Stroke confirmed as ischaemic radiologically.
- (4) Both sexes, between 18-70 yrs of age.
- (5) No significant pre- stroke disability.

Exclusion criteria: (1) Stroke onset less than 4 weeks or more than 5 yrs (2) Hemorrhagic stroke (3) Minor stroke with non-disabling deficit (4) Patients with altered sensorium or aphasia serious enough to impair understanding of simple commands (5) Pregnancy and lactation (6) Advanced liver, kidney, cardiac, pulmonary diseases (7) Orthopaedic and/or rheumatological diseases impairing mobility (8) Co-existent major neurological disease (9) Co-existent major psychiatric disease (10) Uncontrolled Diabetes mellitus (11) History of seizures (12) Patients who fail to follow up (13) Patients who fail to give consent (14) Conditions where massage is contraindicated.

Following investigations were done in each and every case before starting the treatment:

Hb%, TLC, DLC, ESR, fasting blood sugar, postprandial blood sugar, serum cholesterol, KFT, LFT, X-Ray chest PA view, and ECG

Forty patients, diagnosed with ischaemic stroke radiologically, who fit in the inclusion criteria were randomly allocated by using lottery method into two groups comprising twenty patients in each of test (Group

A) and control (Group B) groups, respectively. The treatment period in both test and control groups was determined as forty five days. Patients in Group A were massaged on paretic arm and leg, and back with warm *Roghan Seer*. Firm pressure was applied while stroking with hands (*Dalake sulb*). Twenty five ml of *Roghan Seer* was used in a single sitting. Massage was done on alternate days for a duration of ten minutes. Group B was massaged with white petroleum jelly in the identical fashion as performed in Group A. The assessment of efficacy of treatment in test and control groups was carried out on the basis of a reliable and valid scale Stroke Rehabilitation Assessment of Movement (STREAM) especially designed for evaluation of motor functions. STREAM contains 30 items divided among 3 subscales: 10 items for voluntary motor ability of the upper extremity (UE), 10 items for voluntary motor ability of the lower extremity (LE), and 10 items for basic mobility. Each item of STREAM is a definite activity or task which the patient was asked to perform and was scored according to the guidelines provided with the scale. A 3-point ordinal scale (0,1,2) is used for scoring voluntary movement of the limbs, and a 4-point ordinal scale (0,1,2,3) is used for basic mobility. The extra category for basic mobility allows for one of the score choices to be independence in the activity without the help of an aid (e.g., walking aid, splints). The quality of movement for the UE and LE is also scored on a 3-point scale (a,b,c), but it is not reflected in the final score. A total score for each subscale is calculated, out of 20 points for the UE and LE subscales and 30 points for basic mobility.

The items related to voluntary movement of the limb and basic mobility were scored according to the criteria given at Table 1⁹⁻¹¹.

Table 1—STREAM SCORING
VOLUNTARY MOVEMENT OF THE LIMB

- 0. unable to perform the test movement through any appreciable range (includes flicker or slight movement)
- 1a. able to perform only part of the movement, and with marked deviation from normal pattern
- 1b. able to perform only part of the movement, but in a manner that is comparable to the unaffected side
- 1c. able to complete the movement, but only with marked deviation from the normal pattern
- 2. able to complete the movement in a manner that is comparable to the unaffected side
- X. activity not tested (specify reason)

BASIC MOBILITY

- 0. unable to perform test activity through any appreciable range (i.e. minimal active participation)
- 1a. able to perform only part of the activity independently (requires partial assistance or stabilization to complete), with or without an aid, and with marked deviation from the normal pattern
- 1b. able to perform only part of the activity independently (requires partial assistance or stabilization to complete), with or without an aid, but with a grossly normal movement pattern
- 1c. able to complete activity independently, with or without aid, but only with a marked deviation from normal pattern
- 2. able to complete activity independently, with a grossly normal movement pattern, but requires an aid
- 3. able to complete activity independently, with a grossly normal movement pattern, without an aid
- X. activity not tested (specify reason)

Assessment was carried out on 0 day, 15th day, 30th day and 45th day. After 45 days of the treatment, the pre and post treatment scores of STREAM were analyzed both in test and control groups and subjected to comparison and analysis statistically to evaluate the efficacy of the treatment.

Results

The maximum numbers of patients were observed within 61-70 yrs of age group. The highest incidence of 36 (90%) was observed in male patients while 4 (10%) in female patients. The highest incidence of 27 (67.5%) patients presented with left hemiplegia while 13 (32.5%) presented with right hemiplegia. The most prevalent among the risk factors in this study was hypertension present in 12 (30%) patients, followed by Diabetes mellitus in 10 (25%), smoking in 8 (20%), TIA in 3 (7.5%) and alcoholism in 3 (7.5%) patients.

The study assessed the voluntary movements of upper limb and lower limb, and Basic mobility using subscales of STREAM in both Group A (test) and Group B (control). On statistical analysis, the difference between the median STREAM score for voluntary movement of upper limb at 45th day and at 0 day in Group A as well as Group B was not significant ($p>0.05$). Intergroup comparison both at 0 day and 45th day was not significant ($p>0.05$) (Table 2).

Significant improvement was found in median STREAM score for voluntary movement of lower limb of Group A at 45th day in comparison with the median score at 0 day ($p<0.01$), whereas there was no significant difference between median score of Group B at 45th day and 0 day ($p>0.05$). Intergroup comparison of median scores at 0 day was not significant ($p>0.05$) while at 45th day it was significant ($p<0.05$) (Table 3).

Table 2—Effect of massage with test drug vs. placebo on STREAM Scores for voluntary movements of upper limb

(Median with Range in brackets)

Assessment time		0 day	15 th day	30 th day	45 th day
Groups					
Group A (Test)		5.5 (0/15)	5.5 (0/16)	7 (2/16)	8.5 (2/18)
Group B (Control)		7 (0/16)	7 (0/16)	7 (0/16)	7.5 (0/16)

Test used: Kruskal-wallis test with Dunn's multiple comparison test.
 Kruskal-wallis statistic KW= 6.788 (corrected for ties), n=20 in each group.
 $p>0.05$

Moreover, significant improvement was found in median STREAM score for Basic mobility of Group A at 45th day in comparison with the median score at 0 day ($p<0.01$), whereas there was no significant difference between median score of Group B at 45th day and 0 day ($p>0.05$). Intergroup comparison of median scores at 0 day was not significant ($p>0.05$) while at 45th day it was significant ($p<0.05$) (Table 4).

The study also assessed the total STREAM score in both Groups. When the median total STREAM scores in both Groups were analyzed statistically, significant improvement was found in median total score of Group A at 45th day in comparison with the median total score at 0 day ($p<0.01$). It was also found that there was no significant difference in the median total scores of Group B at 45th day and 0 day ($p>0.05$). Intergroup comparison of median total scores both at 0 day and 45th day was not significant ($p>0.05$) (Table 5).

Discussion

In Unani system of medicine, *Faliye Nisfi* is described as a disease causing loss of sensation and movement in longitudinal half of the body as the

Table 3—Effect of massage with test drug vs. placebo on STREAM Scores for voluntary movements of lower limb

(Median with Range in brackets)

Assessment time		0 day	15 th day	30 th day	45 th day
Groups					
Group A (Test)		8.5 (4/17)	9.5 (4/17)	13 (7/19)	14 ^{**} (8/19)
Group B (Control)		8 (4/17)	8.5 (4/17)	9 (4/17)	9 (4/17)

Test used: Kruskal-wallis test with Dunn's multiple comparison test.
 Kruskal-wallis statistic KW= 27.065 (corrected for ties), n=20 in each group
 ** Significant difference on comparison with baseline value within the group with $p<0.01$
 + Significant difference on comparison with the corresponding value in the other group with $p<0.05$

Table 4—Effect of massage with test drug vs. placebo on STREAM Scores for Basic mobility

(Median with range in brackets)

Assessment time		0 day	15 th day	30 th day	45 th day
Groups					
Group A		17.5 (11/27)	20 (11/27)	22.5 (15/27)	24 ^{**} (19/29)
Group B		18.5 (10/26)	18.5 (11/26)	19.5 (11/26)	20 (11/26)

Test used: Kruskal-wallis test with Dunn's multiple comparison test.
 Kruskal-wallis statistic KW= 27.474 (corrected for ties), n=20 in each group
 ** Significant difference on comparison with baseline value within the group with $p<0.01$
 + Significant difference on comparison with the corresponding value in the other group with $p<0.05$

Table 5—Effect of massage with test drug vs. placebo on total STREAM Scores

(Median with range in brackets)

Assessment time	0 day	15 th day	30 th day	45 th day
Group A	31 (15-56)	34 (15-56)	40.5 (25-60)	47.5** (32-63)
Group B	33.5 (17-57)	35 (17-57)	35.5 (19-58)	36 (19-57)

Test used: Kruskal-wallis test with Dunn's multiple comparison test.
Kruskal-wallis statistic KW= 22.084 (corrected for ties), n=20 in each group
** Significant difference on comparison with baseline value within the group with p<0.01

penetration of *Roohe hassas* and *muharrik* into the organs may either be arrested or, if penetrated, may fail to elicit a response in the organs due to *Fasaad* (derangement) in their *Mizaj*. The prime pathology behind loss of movement and sensation is obstruction in supply and penetration of *Rooh* into the organs due to *Intilae madda* in the pores and passages through which *Rooh* normally reaches the organs¹⁻². This pathogenic *madda*, responsible for *Falije Nisfi*, first accumulates in *Dimagh* (brain) and then descends and absorbs into the *Nukha* (spinal cord) and *Aasab* (nerves), blocking the routes of *Roohe hassas* and *muharrik*³. The principles of treatment of *Falije Nisfi* in Unani medicine mandates the detoxification and removal of the causative material; followed by normalization and potentiation of physiological functions of the diseased organ. The causative material responsible for *Falije Nisfi* is predominately a *Balghami madda* which produces *Sue mizaj barid ratab* in the body. Hence, *Falije Nisfi* is regarded as a *Balghami marz*.

Following the line of treatment, the detoxification and elimination of *Balghami madda* (morbid material) necessitates the *Nuzj* (concoction) to modify its consistency in such a way which enables it to eliminate easily from the body by various routes. Once this *madda* is cleared off, the organs start regaining the previous vigour and vitality which is enhanced by drugs endowed with *Muqawwi* and *Muharrike aasab* properties. On one hand, where *Balghami madda* from brain is eliminated through *Munzij-Mushil* therapy, the *madda* permeated in the extremities on the other hand is affected by massage with medicated oil. *Ilaj bil zid* is among the fundamentals of Unani treatment especially when the *Sue mizaj* is the underlying cause. This rule, in case of *Balghami amraz*, can be translated as the use of those drugs having temperamental properties opposite to

that of *Balgham*. As the *Mizaj* of the disease is *Barid Ratab*, the drugs must possess *Haar Yabis* properties. The ingredients of *Roghan Seer*, viz. *Aaqarqarha*, *Farfiun*, *Lehsun*, *Filfile siyah*, *Barge Suddab* used in the base of *Roghan kunjad*, owing to their temperament, are endowed with therapeutic properties of *Mulattif*, *Mufatteh sudad*, *Muhallil*, *Musakhkhin*, *Muhammir* and *Muqawwie* and thus can be used in the derangement of *Balghami amraz*.

Since, the *Balghami madda* is ingrained in the *Aasab* of extremities, it may be rooted out by following the rule of *Tanqiya* and *Ta'deel*. Among other methods, *Dalak* (massage) is one of the preferred and time tested methods of eliminating the morbid material and achieving the goal of therapy^{1,12}.

The *Balghami madda*, first needs to be modified in consistency, dissolved and then dislodged from the site of the disease. *Aaqarqarha*, *Lehsun* and *Barge Suddab* are *Mulattif*¹³⁻¹⁴, *Kunjad*, *Lehsun* and *Filfile siyah*, *Muhallil*¹⁵⁻¹⁸ and *Aaqarqarha*, *Barge Suddab* and *Farfiun*, *Mufatteh Sudad*^{15-17,19}. It seems all these drugs, by virtue of different pharmacological actions modify, dissolve and dislodge the *Balghami madda*.

Once the *Tanqiya* is achieved and the *Balghami madda* dispersed, the diseased organ needs to be restored to normalcy by *Ta'deel*. *Ta'deel* means restoration, normalization and potentiation of physiological function of an organ. This is achieved by the *Musakhkhin*, *Muhammir* and *Muqawwie aasab* properties inherent in *Aaqarqarha*, *Filfile siyah*, *Lehsun* and *Barge Suddab*^{13,15-19}.

As the oil is rubbed on the paralyzed part, the *Musakhkhin* and *Muhammir* drugs, due to their hot and irritative nature, induce vasodilatation, and increase blood circulation. The tissues receive more than usual amount of blood which supply the necessary elements to rejuvenate the paralyzed part. *Farfiun* and *Filfile siyah* are *Muqawwie aasab* and thus potentiate the function of the nerves enabling them to provide activity and strength in the paralyzed extremities^{16,18,20}.

Hence, the overall motor recovery by massage with test drug in patients of hemiplegia as evident by the results of the present study may be attributed to the cumulative effects of its ingredients exhibiting *Mulattif*, *Mufatteh sudad*, *Muhallil*, *Muhammir*, *Muqawwie aasab* and *Musakhkhin* properties. However massage with test drug showed no improvement in the voluntary movements of upper limb as evident by the results of the present

study. There is a general belief among rehabilitation professionals that the motor recovery in leg occurs earlier, and is more complete than in the arm as reported by Twitchell²¹. According to Kwakkel *et al.* most stroke survivors regain the ability to walk, whereas only between 30 and 66 percent of stroke survivors are able to use their affected arm²².

Conclusion

The overall effect of the test drug was found encouraging in the motor recovery in hemiplegia. Significant improvement was observed in voluntary movements of lower limb and basic mobility in test group in comparison to control group. No clinically significant side effects were observed in test group and overall compliance to the treatment was found good. These results conclude that the test drug is safe, effective and better than the placebo (white petroleum jelly) in motor recovery in hemiplegia and also validate the use of the massage with the test drug in improving the quality of life of patients of hemiplegia.

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