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Research Article

EFFICACY OF MĀ-UL-ŪSOOL, MUS'HIL-E-BALGHAM AND INKIBĀB WITH MARZANJOSH IN MANAGEMENT OF POST- STROKE DISABILITY WITH RESPECT TO ADL: A BLACK BOX STUDY

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ABSTRACT

Falij-e-Nisfi (hemiplegia) is a disease characterized by loss of motor and sensory functions in longitudinal half of the body. The present study was conducted to evaluate the efficacy of Ma-ul-Usool (root extracts), Mus'hil-e-Balgham (phlegm purgative) and Inkibab (steam inhalation) with Marzanjosh in management of post- stroke disability with respect to Activities of Daily Living (ADL) on scientific parameters. It was an open label, pre and post without control clinical trial for the period of 30 days conducted on 29 eligible cases of hemiplegia due to stroke. Nuskha Ma-ul-Usool was administered in form of decoction once in morning on an empty stomach for 15 days; then Nuskha Mus'hil-e-Balgham was added with Ma-ul-Usool and given on 13th and 15th day of treatment in order to induce purgation. From 16th day onwards, Inkibab (steam inhalation) was started with 20 gm of Marzanjosh once a day daily till the end of the study. The pre and post treatment values of Barthel Index Scale were analyzed by paired *t* test to assess ADL in the participants. Significant improvement ($P<0.05$) was observed in ADL of participants at the end of treatment. No side effect was observed during and after the study; overall compliance to the treatment was satisfactory. The study concluded that trial formulations have statistically significant effect in improving the ADL of post stroke disability cases.

KEY WORDS: Falij, Hemiplegia, Unani, Inkibab

INTRODUCTION

Stroke is the most prevalent disease of the cerebral blood vessels.[1] The WHO has defined stroke as "rapidly developing clinical signs of focal (or global) disturbances of cerebral function, with symptoms lasting more than 24 hours or longer, leading to death, with no apparent cause other than of vascular origin.[2] It is a leading cause of functional impairments, with 20% of survivors requiring institutional care after 3 months and 15% - 30% being permanently disabled. According to the American Stroke Association, approximately 700,000 individuals are diagnosed with a stroke each year; of these 90% survivors report one or more disabilities.[3] In India, the stroke has contributed 41% of deaths and 72% of disability adjusted life years amongst the non-communicable diseases.[4] Pathologically, hemiplegia is the commonest manifestation of stroke leading to disability representing the social and societal consequences of functional limitations defined by a patient's inability to perform Activities of Daily Living (ADL) and maintain social and family relationships, to continue in a vocation, or to pursue leisure activities.[5]

In Unani medicine, hemiplegia is the loss of motor and sensory functions in the longitudinal half of the body sparing the face. [6, 7, 8] It is caused due to the occlusion in dissemination of Ruh-e-Haiwani (vital pneuma), which in turn obstructs pathway of Ruh-e-Hissi (psychic pneuma). [6, 7, 8] It develops due to accumulation of thick morbid phlegm or abnormal blood in ventricles of brain. [9] The severity and intensity of hemiplegia may vary based on the quality and quantity of morbid humour, and site of deposition in brain. [7]

The primary goal of rehabilitation in post stroke disability is to make the diseased able to perform daily activities and to walk independently.[10] In conventional medicine, physiotherapy has been the most preferred approach for post stroke disability management; but despite intensive therapy, a large number of stroke survivors are left with significant disabilities.[5] Hence, prevention or reduction in post-stroke disability is the most useful approach to minimize the costs both to society and the family. [11]

Falij is predominantly caused by deposition of abnormal phlegmatic humour in the neural pathways and the brain. It is treated by phlegmatic concoctive drugs followed by phlegmatic purgatives based on the principle of elimination of morbid humour out of the body as these class of drugs the resolvent, morcellator, attenuant actions with higher potency to expel the morbid matter. [6, 8, 9, 12] After morbific elimination, Ta'deel Mizaj (restoration of impaired temperament) is achieved through Muqawwi (tonic) drugs and/or employing various regimens including Dalk (massage), Riyazat (exercise), Nutool (irrigation), Takmeed (fomentation), Hammam (bathing), Inkibab (steam inhalation) etc. [6, 7, 8, 9, 12] In recent years, various clinical studies have been conducted on Falij-e-Nisfi employing phlegmatic concoctive and purgative drugs along with regimenal therapies in post stroke disability to validate lines of treatment.

The ingredients of the trial formulations possess pharmacological actions such as resolvent, morcellator, deobstruent and attenuant which play important role in restoration of motor and sensory functions in post stroke

disability substantiated with various studies conducted on these ingredients. Hence, an open label, pre and post interventional study was conducted to estimate the hypothesis in order to assess the efficacy of these formulations in cases with post-stroke disability.

MATERIALS AND METHODS

The study was conducted at National Institute of Unani Medicine Hospital, Bengaluru during January, 2014 to October, 2014. It was an open label, pre and post interventional study conducted on 30 completed cases with post stroke disability, out of which one participant was dropped out due to failure to follow the protocol without any obvious reason; duration of protocol was 30 days. A total of 30 participants were enrolled in the study,

Before starting the trial, approval from Institutional Ethical Committee was taken (IEC No. NIUM/IEC/2012-13/Moal/08); participants with diagnosis of stroke and fulfilling the inclusion criteria were enrolled in the study. Inclusion criteria was participants of either gender aged between 18–70 years having post stroke disability with less than 50% score on Barthel index with history of stroke not less than 3 months. Participants who agreed to give the written informed consent as well as follow-up the protocol were enrolled in the study. Exclusion criteria included participants below 18 years and above 70 years of their age having cardiac, pulmonary, hepatic and renal diseases, uncontrolled hypertension and diabetes mellitus; pregnant and lactating women; cognitive impairment, evidence of fixed contracture; orthopedic or rheumatologic diseases impairing mobility; minor stroke with non-disabling deficit, and those who fail to give written informed consent [Fig-1 CONSORT Flow Chart].

Then, participants were subjected to routine investigations such as Hb%, TLC, DLC, ESR, urine routine & microscopic, blood sugar-fasting & post prandial, blood urea & serum creatinine, SGOT, SGPT, serum billirubin and ECG in order to exclude the pathological conditions described under exclusion criteria. All the patients were admitted in IPD, kept under observation and followed at 15 days intervals for the assessment of disease till the completion of the study. No concomitant medication was allowed except those of diabetes mellitus and hypertension during the study. No adverse event was observed during the trial.

TEST FORMULATIONS

The ingredients of Ma-ul-Usool were Beekh-e-Karafs (*Apium graveolens*) 4 gm; Beekh-e-Izkhar (*Andropogon jwarancusa*) 4 gram; Beekh-e-Badyan (*Foeniculum vulgare*) 4 gm; Beekh-e-Kibr (*Capparis spinosa*) 4 gm; Aslus'soos (*Glycyrrhiza glabra*) 4 gm and Khardal (*Brassica nigra*) 4 gm. The ingredients of Mus'hil-e-Balgham were Ustukhudoos (*Lavandula stoechas*) 5 gm/day; Barg-e-Sana (*Cassia angustifolia*) 10 gm; Turbud (*Operculia turpethum*) 3 gm; Maghz-e-Fuloos Khayar Shambar (*Cassia fistula*) 70 gm and Roghan-e-Zard 5 gm. The ingredient of Inkibab (steam inhalation) [7] was Marzanjosh (*Origanum vulgare*) 24 gm.

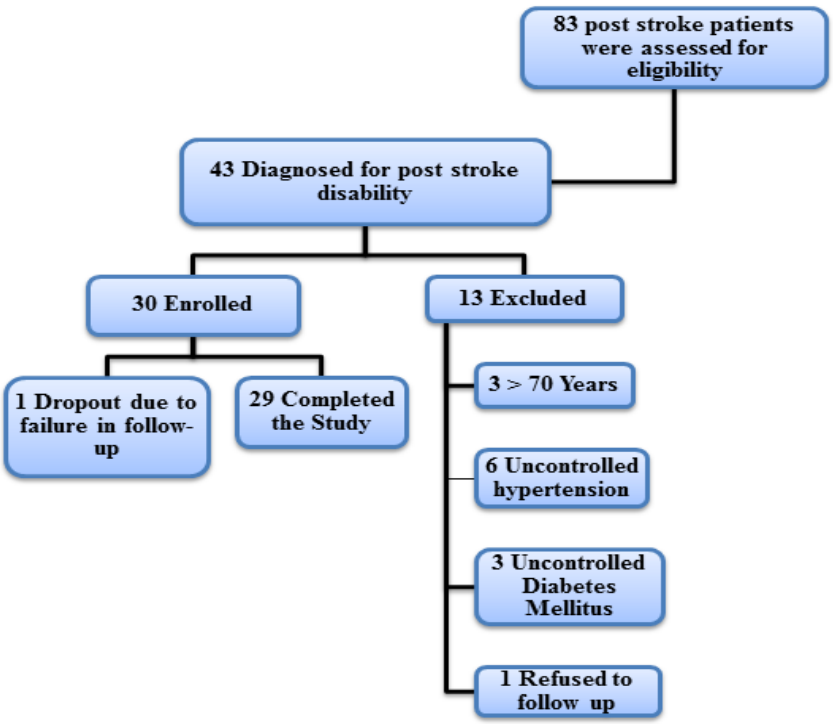

Figure 1: CONSORT Flow Chart

Table 1: Gender, age and chronicity (mean ±SD, range) of participants

S. No.	Patients	No. of cases (%)
1.	Male	25 (86.2%)
	Female	4 (13.8%)
	Total	29
2.	Age – Mean ± S.D.	51.6 ± 13.1 years
	Range	18 – 70 years
3.	Chronicity – Mean ± S.D.	14.3 ± 13.7 months
	Range	3 to 60 months

Table 2: Age and sex wise distribution of the patients

Age (years)	Male	Female	Total	Percentage
18 – 27	1	-	1	3.5
28 – 37	2	-	2	6.9
38 – 47	3	-	3	27.6
48 – 57	5	-	5	17.2
58 – 67	6	4	10	34.5
68 – 77	3	-	3	10.3
Total	25	4	29	100.0

Table 3: Distribution of patients according to chronicity of the disease

Chronicity of disease	Male	Female	Total	Percentage
1 – 12 m	18	2	20	69.4
13 – 24 m	5	1	6	20.7
25 – 36 m	-	1	1	3.4
37 – 48 m	1	-	1	3.4
49 – 60 m	1	-	1	3.4
Total	25	4	29	99.9

Table 4: Barthel Index at baseline and after treatment (n=29)

Parameter	Base-line	16th day	30th day	P<0.05
Barthel Index	34.67±9.44	57.41±7.75	75.69 9.04	Significant

Student *t* test (paired)

Table 5: Showing changes in pathological investigations after treatment (n=29)

S. No.	Parameter	Baseline (Mean ± SD)	After treatment (Mean ± SD)	P<0.05
1	Hb gm%	13.29±2.39	13.33±2.26	NS
2	TLC m/cu.mm	7562 ±1527	7312 ±1920	NS
3	DC (neutrophils)	60.2 ±7.3	60.1 ±6.6	NS
	DC (lymphocytes)	30.5 ±6.0	31.8 ±5.6	NS
	DC (Eosinophils)	5.1 ±1.2	4.4 ±1.4	NS
	DC (Monocytes)	4.0 ±1.3	3.6 ±1.5	NS
	DC (Basophils)	0.2 ±0.4	0.1 ±0.4	NS
4	ESR	35.6 ±20.6	29.7 ±20.4	NS

NS= Not Significant; Student *t* test (paired)

Table 6: Showing changes in biochemical investigations after treatment (n=29)

S. No.	Parameters	Baseline (Mean ± SD)	After treatment (Mean ± SD)	P<0.05
1	FBS	102.6 ±57.3	101.0 ±59.4	NS
2	PPBS	154.2 ±93.4	157.8 ±83.3	NS
3	Blood Urea	31.4 ±9.2	30.2 ±7.7	NS
4	Sr. Creatinine	0.9 ±0.1	0.9 ±0.1	NS
5	Sr. Uric acid	5.2 ±0.9	5.2 ±1.3	NS
6	SGOT	20.2 ±13.1	17.2 ±3.9	NS
7	SGPT	24.6 ±13.6	20.3 ±7.3	NS
8	A Phosphatase	125.8 ±34.0	114.9 ±30.0	Significant
9	Total Bilirubin	0.68 ±0.24	0.63 ±0.23	NS

NS= Not Significant; Student *t* test (paired)

METHOD OF PREPARATION, STORAGE AND MODE OF ADMINISTRATION OF TEST DRUG

The ingredients of Ma-ul-Usool, Mus'hil-e-Balgham and Inkibab (steam inhalation) were provided by pharmacy of NIUM and proper identification of these drugs was done by chief pharmacist, NIUM to ensure their authenticity. [13] The ingredients of Ma-ul-Usool [9] were pounded and soaked in 500 ml. of water overnight and decoction was prepared in the morning on low flame; the filtrate was given to the participants to drink once in the morning before breakfast for 15 days. The ingredients of Mus'hil-e-Balgham were added to those of Ma-ul-Usool [9] to be taken before breakfast on 13th and 15th day. On 16th day, whole body Inkibab was started with Marzanjosh daily

once for 20 minutes up to 30th day of treatment. Marzanjosh was soaked in 1.5 liter of water overnight and boiled next morning in a steam generator. The generated steam was let in through a connecting tube into a closed chamber devised for seating a participant while his neck exposed out of it.

ASSESSMENT OF EFFICACY: The efficacy of trial formulations was assessed using Barthel Index Scale [14, 15, 16, 17] consisting of 10 items scored on the arbitrary scale. Feeding is scored as 0 for unable and 5 for needs help in cutting, spreading butter, etc., or requires modified diet and 10 for independent feeding; bathing is graded as 0 for dependent and 5 for independent or in shower bath; in grooming, 0 stand for help with personal care, 5 for independent face/hair/teeth/shaving (implements provided); dressing as 0 for dependent, 5 for help but can do about half unaided and 10 for independent (including buttons, zips, laces, etc.) dressing; bowel is graded as 0 for incontinent (or needs to be given enemas), 5 for occasional accident and 10 for continent bowel; bladder is scored as 0 for incontinent or catheterized and unable to manage alone, 5 for occasional accident and 10 for continent bladder; toilet use is marked as 0 for dependent, 5 for some help but can do something alone and 10 for independent (on and off, dressing, wiping) use; transfers (bed to chair, and back) 0 for unable or no sitting balance, 5 for major help (one or two people, physical) can sit, 10 for minor help (verbal or physical) and 15 for independent transfer; mobility (on level surfaces): 0 for immobile or < 50 yards, 5 for wheelchair independent, including corners, > 50 yards, 10 for walks with help of one person (verbal or physical) > 50 yards and 15 = independent (but may use any aid; for example, stick) > 50 yards; stairs: 0 for unable, 5 for help (verbal, physical, carrying aid) and 10 for independent stair climbing.

STATISTICAL ANALYSIS: Baseline demographic data was insignificant. The statistical calculation was done on 29 cases. Baseline and post treatment values of BI were subjected to statistical analysis using paired *t* test. Safety parameters were also analyzed using paired *t* test to assess statistical differences. Difference was considered significant at $P<0.05$ and highly significant at $p<0.01$.

RESULTS

The baseline demographic data has been depicted in Table 1-3. Significant improvement ($p<0.001$) was noted in parameters of Barthel Index (Table 4.). Safety parameters were in their normal range (Table 5-6).

DISCUSSION

Stroke is one of the leading causes of mortality and morbidity worldwide. [5] The study was conducted to evaluate the efficacy of Ma-ul-Usool, Mus'hil-e-Balgham and Inkibab (steam inhalation) with Marzanjosh in the management of post- stroke disability with respect to ADL on scientific parameters. Of 29 patients, 10 (35%) were in age group 31-45 years followed by 10 (34%) in 46-60, and 8 (28%) in age group of 61-70. The observed data did not coincide with previous studies [18, 19] but the average age of cases with stroke in developing countries is 15 years younger than that of developed countries [4] By gender, there were 86% male compared to female participants as confirmed by Sethi, suggesting that India men are more susceptible to stroke than women in a ratio of 7:1 [20] attributed to the differences in risk factors such as smoking and drinking being more prevalent in men than women [21] Socio-economically, 11 (38%) were from lower middle class in conformity with observations made by Tripathi et al [4] Going by risk factors of stroke, out of 30 participants, 15 (52%) had history of stroke between 3-9 months, 5 (17%) between 10-15 months, 4 (14%) between 22-36 months of illness duration. This prolonged period of illness allows for accommodation of soft tissue changes while patient becoming customary to do his daily activities keeping the spastic limbs in fixed position. As a result, set of neural patterns are changed with rearrangement of underlying neural circuits [22, 23] Risk factors such as alcoholism, smoking, diabetes mellitus and TIA were found as 24%, 17%, 14% and 10% respectively. The observed data strengthens the causal associations of these major risk factors with stroke [1, 18] which is in coincidence with the findings of Feigin et al [24] and Almani et al. [25]

Ingredients of Ma-ul-Usool, especially Beekh-e-Karafs, Beekh-e-Izkhar, Badyan, Beekh-e-Badyan, Beekh-e-Kibr, Aslas'soos and Khardal possess pharmacological actions like resolvent, morcellator, attenuant, phlegmatic concoctive, deobstruent, phlegmatic purgative, brain and nerve tonic. The Nuskha Mus'hil-e-Balgham contains Turbud, Barg-e-Sana, Khayar Shambar, Roghan Zard, and Ustukhudoos. These drugs are endowed with the properties like phlegmatic purgative, brain evacuant, attenuant, and deobstruent. [6, 13, 26, 27, 28, 29] After purgation, the nervous structures become receptive to rejuvenation and restoration of normal functions. This phase of recuperation and rejuvenation is known as Ta'deel and is accomplished by using various regimenal procedures such as Inkibab (steam inhalation). [1, 12, 30] The remnant coldness diffused in nerves was eliminated through Inkibab (steam inhalation) with Marzanjosh. Marzanjosh possesses absorbent, deobstruent, desiccant, sedative, and resolvent properties and therefore used in paralysis. [13, 26]

Various studies conducted on these ingredients have proved that most of these test drugs possess important neuroprotective, anti-oxidant and anti-inflammatory actions. The flavonoid glabridin derived from *Glycyrrhiza glabra* (Aslus'soos) significantly decreases the volume of focal infarct, apoptosis [31] and cerebral histological damage [32] as well as antioxidant activity is also reported in *Glycyrrhiza glabra* has the neuroprotective effect through alteration of multiple pathways link with apoptosis [33] Essential oil from seeds of *Foeniculum vulgare* (Badyan) showed antithrombotic activity, thus preventing the paralysis induced by collagen-epinephrine intravenous injection [34] Another study on Badyan (*Foeniculum vulgare*) has been found to dissolve the blood clot after hemorrhagic stroke [35] which may be attributed to its monoamine inhibitor activity that upregulates the level of serotonin, nor-epinephrine, and dopamine in brain and thus brain plasticity is accomplished [36] *Operculia turpethum* [37]*Cassia fistula.* [38] Experimental studies concluded that *Lavandula stoechas* i.e. Ustukhudoos has spasmolytic or antispasmodic activities mediated through blockade of calcium channel [39] and its oil exerts its action through cAMP [40] which is useful in recovery of motor functions. *Apium graveolens* i.e. Karafs exerts its action in recovery of motor functions mainly by suppressing the Ca^{2+} influx in the muscle cells. [41]

The pattern of motor function recovery: till date, neurological recovery after stroke is not fully understood. [42, 43] Although, various mechanisms have been propounded like vicariation of function theory suggesting that the lesion area retrieves by tissue repair and its function is taken over by other cortical and sub-cortical structures, either adjacent to or remote from the discredited area, and this process is known as resolution of diaschisis. [44, 45] Thus, it may be inferred that diaschisis and vicariation of function was initiated due to the inherent actions of the trial drugs such as resolvent, morcellator, attenuant, brain

and nerve tonic and stimulant, and as a result, the improvement in ADL of participants with post stroke disability was observed.

CONCLUSION

The study infers that the trial formulations are effective in improving the post stroke disability that should to be attributed to the resolvent, morcellator, attenuant and nervine tonic actions inherent in the ingredients of the trial formulations. As this study has been conducted on a small sample size, it is recommended that randomized clinical trials should be conducted with large sample size in order to prove the efficacy in more scientific way.

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