IJPSR (2015), Vol. 6, Issue 1 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 02 June 2014; received in revised form, 12 August, 2014; accepted, 16 November, 2014; published 01 January, 2015

EFFICACY OF MUNZIJ WA MUSHIL-E-BALGHAM (POLY HERBAL FORMULATIONS) AND MASSAGE WITH ROGHAN-E-MALKANGANI IN FALIJ NISFI (HEMIPLEGIA): A RANDOMISED CONTROLLED CLINICAL TRIAL

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Keywords:

Falij, Nuskha Munzije Balgham, Nuskha Mushile Balgham, Roghan Malkangani

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ABSTRACT: This study was conducted as a single blind, randomized and standard controlled clinical trial in cases of *Falij Nisfi* (Hemiplegia) due to ischaemic stroke. Forty eligible patients of Hemiplegia were randomized into test and control groups, comprising 20 patients in each. Test group was given *Nuskha munzije balgham* for 12 days, followed by *Nuskha Mushile Balgham*, mixed with *Munzije Balgham* for next two consecutive days in decoction form, orally. Massage was started from 15th day with *Roghan Malkangani* on spinal column and paralyzed limbs for 15 minutes daily till 28th day. Control group was given tablet Piracetam Hydrochloride, 800 mg twice a day. Hypertensive patients in both groups, A and B, also received tablet Aspirin, 75 mg and tablet lisinopril, 2.5 mg, once daily for 28 days. The assessment of efficacy was based on "Stroke Rehabilitation Assessment of Movement (STREAM)". Pre and post treatment values of STREAM were subjected to statistical analysis within and between the groups using Paired't' test, Wilcoxon matched pairs signed rank test, and Kruskal-Wallis test with Dunn's multiple comparison test. There was significant improvement in STREAM scores for voluntary movements of upper limb ($P<0.01$), lower limb ($P<0.01$), Basic mobility ($P<0.01$), and total score ($P<0.01$), in test Group as compared to control Group. The study revealed that test drug has statistically significant response in improving voluntary movements as compared to control drug.

INTRODUCTION: Stroke is the second leading cause of mortality worldwide and third most common cause of death in the developed world.[1] Ischemic stroke accounts for more than 80% of all strokes.[2] it usually results from predisposing conditions that originated years before the ictus.[3] Up to 90% of stroke survivors report one or more disabilities including decreased motor control and movement.[4]

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.6(1).453-58

Article can be accessed online on: www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.6(1).453-58

Modern treatment is aimed at minimizing the volume of the brain that is irreversibly damaged, preventing complications, reducing disability and handicap through rehabilitation, and reducing the risk of recurrent episodes.[1] In Unani medicine, *Falij* has been described elaborately in relation to its predisposing factors, causes and treatment in almost all standard text books of Unani medicine. Unani Physicians, *Buqrat, Jalinoos, Ibne Sina, Razi* and all successors are known to have treated the *Falij Nisfi* on the principles of *Tanqia* and *Tadeel* since centuries.

The combination of *Tanqia* and *Tadeel* makes comprehensive treatment line for *Falij* and mandates to be tested as such to assess the efficacy of employable intervention in its treatment scientifically.

Methodology

The present study was conducted at National Institute of Unani Medicine (NIUM) Hospital. A comprehensive protocol was framed and approval obtained from the Ethical Committee of National Institute of Unani Medicine. After obtaining written voluntary consent from eligible patients, clinical study was started by enrolling them into test and control groups by random allocation, achieved by lottery method. This study spanned from February 2011 to March 2012.

Criteria for Selection of Cases:

Inclusion Criteria:

a) Hemiplegia secondary to ischaemic stroke, b) Stroke onset between 4 weeks to 5 years c) Stroke confirmed as ischaemic radiologically, d) Either gender, between 18-70 years of age, e) No significant pre- stroke disability

Exclusion Criteria:

a) Minor stroke with non-disabling deficit, b) Patients with altered sensorium or aphasia serious enough to impair Understanding of simple commands, d) Pregnancy and lactation, e) Advanced uncontrolled systemic illnesses, f) Co-existent major neurological and psychiatric diseases, g) History of seizures, h) Patients who fail to follow up, i) Patients who fail to give consent, j) Conditions, where massage is contraindicated

Investigations: following investigations were done primarily for two purposes- a) To exclude other patients as a part of exclusion criteria; b) To establish the safety of the test drug - Hb%, TLC, DLC, ESR, Blood Sugar-F/PP, Serum Cholesterol, KFT, LFT, X-Ray Chest PA View and ECG

Test drug:

The ingredients of *Munzij Balgham:* [6]

Badyan (Foeniculum vulgare, Bekh Badyan (Foeniculum vulgare root), Maveez Munaqqa (Vitis vinifera), Ustukhuddoos (Lavendula stoechas), Inabussalab (Solanum nigrum), Bekh Kibr (Capparis spiosa), Persiaoshan (Adiantum capillus veneris) 5 gm each.

The ingredients of *Gulqand:*

Gul-e-surkh (*Rosa damascene* Mill) and *Shakar safaid* (Sugar) 25 gm each.

The ingredients of *Mushil Balgham*: [6]

Ustukhuddoos (Lavendula stoechas) 5gm, Barg Sana (Cassia angustifolia) 10gm, Turbud (Ipomoea turpethum) 3gm, Maghz faloos (Cassia fistula) 50 gms, Roghan Zard (Ghee) 5gm

The ingredients of *Roghan Malkangani*: [7]

*Malkangani (Celastrus paniculatus)……*Q. S.

Control drug:

Piracetam, 800 mg, Lisinopril, 2.5 mg, Aspirin 5 mg given orally in tablet form once daily in both groups for the control of hypertension.

Procedure of study:

The study was designed as single blind, randomized, standard controlled clinical trial. A total of 40 patients were randomly allocated into two groups, comprising 20 patients in each of test (Group A) and control (Group B) group, respectively. The treatment period in both, Test and Control groups was ascertained as 28 days.

The ingredients of *Munzij Balgham* [6] were pounded and soaked in 250 ml. of water for whole night. *Joshanda* (decoction) was prepared in the morning on low heat as per the standard procedure. After filtration of *Joshanda*, 25 gm of *Gulqand* was mixed in filtrate and given to drink once in the morning before breakfast for 12 days. On 13th day, the ingredients of *Mushile Balgham* were added in the ingredient of *Munzije Balgham*; *Joshanda* was prepared and given to drink in the morning before breakfast for two consecutive days.

On 15th day, *Dalk Layyan* (massage) was started using 20 ml of warm *Roghan Malkangani* on the spinal column and affected limb for 15 minutes, once a day, for a period of 2 weeks i.e. up to 28th day of the trial treatment. Along with the test drugs, the hypertensive patients were given Lisinopril, 2.5 mg, orally in the tablet form for the management of Hypertension while Aspirin, 75 mg, was given once in a day after meal to avoid the recurrence of ischemia for a whole period of 28 days. The control group received Piracetam, 800 mg, twice a day; Lisinopril, 2.5 mg, once a day; Aspirin 5 mg, once a day in tablet form, orally for a period of 28 days.
The assessment of efficacy of treatment in test and control group 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. Assessment was carried out on zero day and 28th day.

After 28 days of the treatment, Pre and post treatment values of STREAM were subjected to statistical analysis within and between the groups using Paired't' test, Wilcoxon matched pairs signed rank test, and Kruskal-Wallis test with Dunn's multiple comparison test. The effects of test and control drugs on voluntary motor control are discussed in following tables. **(Table 1- 4)**.

TABLE 1: THE FOLLOWING TABLE DEPICTS EFFECT OF TEST AND CONTROL DRUGS ON UPPER LIMB SCORES. THE SCORES ARE SHOWN IN MEAN ± SEM

Group & (No. of Patients)	Assessment day		P value
	0 day	28th day	
Test (20)	5.05±0.8061	11.15 ± 1.182*, +	p<0.01
Control (20)	4.55±0.27591	5.5± 0.7997**	p<0.01

TABLE 2: THE FOLLOWING TABLE DEPICTS EFFECT OF TEST AND CONTROL DRUGS ON LOWER LIMB SCORES. THE SCORES ARE SHOWN IN MEAN ± SEM

Group & (No. of Patients)	Assessment day 0 day	28th day	P value
Test (20)	6.7 ± 0.8464	12.05 ± 0.8061*,+	p<0.01
Control (20)	7.85 ± 0.8375	8.5 ± 0.7416**	p<0.01

TABLE 3: THE FOLLOWING TABLE DEPICTS EFFECT OF TEST AND CONTROL DRUGS ON BASIC MOBILITY SCORES. THE SCORES ARE SHOWN IN MEAN ± SEM

Group (No. of Patients)	Assessment day		P value
	0 day	28th day	
Test(20)	9.05 ± 8159	15.05 ± 1.055*,+	p<0.01
Control(20)	10.05 ± 0.8318	12.05 ± 0.609**	p<0.01

TABLE 4: THE FOLLOWING TABLE DEPICTS EFFECT OF TEST AND CONTROL DRUGS ON TOTAL SCORES. THE SCORES ARE SHOWN IN MEAN ± SEM

Group (No. of Patients)	Assessment day		P value
	0 day	28th day	
Test (20)	20.08 ± 1.970	38.8 ± 2.448*	p<0.01
Control (20)	22.45 ± 1.975	25.85 ± 1.619*	p<0.01

DISCUSSION AND CONCLUSION: According to the tenets of Unani medicine, health is reflection of equilibrium in four *Akhlat* (humours) with respect to their quantity and quality, conferring *Mizaj Tabai* to the human body, necessary for occurrence of normal functions. Any disturbance in the equilibrium of these four *Akhlat* leads to *Sue Mizaj* (ill temperament), responsible for abnormal bodily functions and a reflection of disease. *Sue Mizaj Maddi* (abnormal temperament) means a derangement in *Mizaj tabai* (normal temperament) coupled with abnormality in *Madda* (material). Correction of *Sue Mizaj Maddi* requires elimination of abnormal *Madda* for restoration of *Mizaj Tabai*.[8, 9]

Since, *Falij* is caused due to *Ghair Tabai Balgham* (abnormal phlegm); it produces *Sue Mizaj Maddi* in the body and needs *Madda* to be eliminated to restore *Mizaj Tabai*. The elimination of abnormal humour/*Madda* is known as *Tanqia* (evacuation/elimination) and restoration of *Mizaj Tabai* is known as Ta'deel (normalization).[10]

Tanqia is the first step in the treatment of *Falij* and is performed by employing *Munzij* (coctives) and *Mushile Balgham* drugs (phlegm purgatives) and *Ta'deel* is the second step which requires employment of various compound drug preparations along with a gamut of regimenal procedures e.g. *Dalak*, *Hijamat*, *Hammam* etc. to restore and potentiate the functions of the involved organs. [5, 10, 11]

Tahleel (dissolution), *Taqtee* and *Talteef* are the properties of *Munzij Balgham* drugs which make the fulcrum of the first phase of *Tanqia* and fairly resemble with the principles of treatment of stroke in modern medicine advocating use of Thrombolytics, Antithrombotic agents and Neuroprotective drugs. [12]

The drugs having power of *Tahleel* are known as *Muhallil* and may be defined as the drugs which act on a *Ghaleez Khilt* (viscid humour) to make it dissoluble and detachable from its site of attachment.[10] *Dawae Lateef* is inherent with the property of *Talteef* and interacts with body's *Quwwat Tabiya* to divide the morbid matter into smaller parts.[10] *Muqatti advia* are those drugs,

which owing to property of *Taqtee,* penetrate into the interstitial spaces of the organs due to their lightness and remove the adhered *khilt* from the organ.[10]

It is vital to dissolve and disintegrate the *Balghami Sudda* first, and purgate it out later from the body. The first part, in this study, was achieved by using *Nuskha Munzij Balgham* for twelve days. All the drugs of *Munzije Balgham*, especially, *Ustukhuddoos, Persiaoshan, Mako Khushk, Bekh kibr*, *Badyan* and *Maveez Munaqqa* possess the properties such as *Muhallil*, *Mulattif*, *Mufatteh Sudad*, *Munaqqie Dimagh*, *Muqawwie Asab*, *Qate Balgham, Munaqqie Akhlate Ghaleeza*, *Jali* etc. and are; therefore, used in diseases such as *Falij* (hemiplegia), *Isterkha* (paresis), *Rasha* (tremors), *Zofe Asab* (weakness of nerves), *Sara* (epilepsy), *Laqwa* (facial palsy), *Suda* (headache) and other *Balghami Amraz* etc. [13, 14, 15, 16, 17, 18, 19, 20, 21]

Once the *Balghami madda* (Phlegmatic material) is dissolved, detached and disintegrated by the action of *Munzije Balgham* (phlegm coctives) drugs, it is purgated out by *Mushlie Balgham* (phlegm purgatives) drugs. *Mushil* drugs have property to expel the *Akhlat raddiya* (Morbid humours) from the vessels, neighboring structures and from whole body through intestine.

Majority of the Unani physicians opine about the action of *Mushil* drugs that they expel both *Raqeeq* (thin) and *Ghaleez* (viscid) constituents of *Akhlat*, [10, 22] which they have affinity with. The ingredients of *Nuskha Mushile Balgham* have affinity with *Balgham* and, therefore, purgate it out. The *Nuskha Mushile Balgham* contains the following drugs: *Turbud*, *Barg sana*, *Khayar shambar*, *Roghan Zard*, *Ustukhuddoos*.

These drugs are endowed with the properties such as *Mushile Akhlate Salasa*, *Mushile Balgham*, *Munaqqie Diamgh*, *Mukhrije Balgham, Qate Balgham*, *Mulattif*, *Jali* and *Mufattehe Sudad* etc. and, thus, are frequently used in diseases such as *Amraze Asab e.g. Falij*, *Laqwa* and *Rasha*. [17, 16, 18, 19, 20, 23] After purgation of *Ghaleez Ghair Tabai Balgham,* which produces *Sudda* (obstruction) to cause *Falij*, the nervous structures become receptive to regain lost vigor, vitality and normal functions. This phase of recuperation and rejuvenation is known as *Ta'deel* (Normalization) and is accomplished by using various regimenal procedures such as massage, cupping, exercises etc. [9, 10, 22]

Ta'deel generally means normalization, restoration and potentiation of physiological functions of an organ and is achieved by restoring the *Mizaj moatadil*. After a course of *Mushil*, The remnant *Baroodat* (coldness), diffused in *Asab,* is removed by massaging oils having *Har advia* (hot natured drugs). *Roghan Malkangani* was used for this purpose. *Malkangani* has properties such as *Dafae Amraze Barida wa Balghamia, Muqavvie Asab (neurotonic), Muqavvie Dimagh wa Hafiza* (brain tonic and memory enhancer) etc. and, therefore, is used in diseases such as *Falij*, *Laqwa*, *Rasha* etc. [15, 18, 24]

Tadeel is the last phase of treatment of *Falij* (paralysis) and is used for a variable period of time depending upon the severity of the disease and loss of functions.[22] Massage with *Roghan Malkangani* was done for 14 days in test group to regain the motor power in the limbs.

Test group showed statistically significant improvement in motor recovery in all parameters in comparison to the control group and may be due to institution of a complete regimen of therapy based on principles of Unani medicine.

Motor recovery in stroke and possible role of test formulation:

There are a number of processes that may contribute to the recovery of motor function after stroke:

- Resolution of pathological changes allowing for recovery at the cellular level.
- Development of compensatory movement strategies enabling 'recovery' of certain motor functions.
- Taking over the function of damaged or disconnected area by undamaged regions in the sensory-motor make over.[25]

Resolution of Pathology and hypothetical role of test drug:

In acute stages after stroke, recanalisation of occluded vessels, establishment of collateral flow and reduction in inflammation, all contribute to salvaging partially spared tissue. Potentially resolvable pathological results of stroke are particularly relevant to the ischemic penumbra. Limiting neuronal damage in the surrounding penumbra is a major goal for acute therapeutic interventions as neurons they are initially structurally intact.[26]

The above mentioned pathological changes in and around the infracted zone provide a premise for the possible mechanism of action of the ingredients of test formulation. As described earlier, test formulations possess *Muhallil*, *Mulattif*, *Munaqqie Dimagh*, *Mufatteh Sudad*, *Muhallile Auram* and *Jali* properties which, by the definition of Unani medicine, [13, 16, 18, 19, 20, 21, 27] tend to open the obstruction and recanalise the vessels; reduce the inflammatory reaction and edema; scale down the damage of ischemic penumbra, and ultimately limiting the neuronal damage by cumulative action of ingredients of test formulation. The presenting rational correlation between the developed pathology in stroke and counteracting properties of the test drugs seem to have a significant effect in improving the motor power in the hemiplegic patients.

Enhancement in brain plasticity

In recent years, it has become increasingly evident that representational networks in the adult brain are capable of extensive reorganization after damage of a specific area of the brain. Recovery of motor functions after stroke is also associated with changes in motor cortical representation.[28]

It is thought that undamaged areas and pathways in the brain 'take over' the functions of the damaged regions. The plasticity of brain seems to have been enhanced by the *Muqavvie Dimagh* (brain tonics) and *Munaqqie Asab* (nerve cleanser) [13, 14, 15, 18] properties of the ingredients of the test formulations. These drugs, owing to their properties, seem to be capable of up regulating the function of the undamaged area to help them take over the function of the damaged areas easily.

Sprouting of new connections:

Local growth of axons and synapses could provide a mechanism for intracortical remapping of sensory motor representation. Sprouting can also occur remotely from the site of damage as well as around the lesion rim. Increased expression of synaptophysic has been detected in the contralesional hemisphere 14 to 16 days after experimental stroke [25] and dendritic sprouting has been found in pyramidal cells in the intact hemisphere after cortical lesion in rats.[25] *Muqavvie Dimagh*, *Munaqqie Dimagh*, *Muqavvie Asab* properties of the test formulations might have a significant role in stimulation of sprouting of new connection in and around the damaged area to restore the lost functions.

Thus, it may be concluded from the above discussion that the test drugs formulations used in *Tanqia* and *Tadeel* have all the potential properties which seem to have positive effects not only in controlling the pathological changes but reverting them to normal state to restore the motor functions.

ACKNOWLEDGEMENTS: The authors are thankful to Director, NIUM, Bangalore and hospital staff for providing necessary facilities needed for research work.

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How to cite this article:
Ahmed A Ansari AN Ali SJ and Mohd Y: Efficacy of Munzij Wa Mushil-E-Balgham (Poly Herbal Formulations) And Massage With Roghan-E-Malkangani In Falij Nisfi (Hemiplegia): A Randomised Controlled Clinical Trial. Int J Pharm Sci Res 2015; 6(1): 453-58.doi: 10.13040/IJPSR.0975-8232.6 (1).453-58.

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