



Received on 04 February 2023; received in revised form, 19 April 2023; accepted, 31 May 2023; published 01 October 2023

EVALUATION OF EFFICACY OF UNANI REGIMEN IN THE REHABILITATION OF POST STROKE HEMIPLEGIC GAIT: AN OPEN INTERVENTIONAL STUDY

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Keywords:

Stroke, Hemiplegic gait, Neuroplasticity, Neuroprotection, Unani Medicine

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ABSTRACT: Background: Stroke is the most frequent clinical manifestation of diseases of the cerebral blood vessels. Up to 90% of post-stroke survivors report one or more disabilities, including impaired walking. Physical rehabilitation and gait training with equipments are essential in the management of post stroke gait disability, however, these techniques are not amenable for hemiplegic patients because of their limitations to actively participate in such training programs. Unani (Greco-Arab) Medicine scholars have been known to treat post-stroke complications on concept of *Tanqiya* (elimination of morbid matter) and *Ta'deel* (revitalization of diseased organ) since centuries. **Methods:** The study was conducted as open, interventional clinical trial, enrolling 30 eligible patients. *Tanqiya* was done by *Mundij* (coctives) and *Mus'hile Balgham* (phlegm purgatives) drugs used in decoction form for 13 days; after *Tanqiya*, full body *Inkibab* (steam bath) with *Advia Harrah* (Hot temperament Drugs) was started from 14th to 28th day of the study for the purpose of *Ta'deel*. Assessment for gait improvement was performed on valid and reliable scale "FAC" at baseline, 14th day and 28th day of the treatment. **Results:** Significant statistical difference was observed in walking patterns between baseline and 14th day scores ($p < 0.01$); and base line and 28th day scores ($p < 0.001$) using Friedman test with Dunn's multiple comparison test. No significant adverse change appeared in safety parameters. **Conclusion:** The test formulations, used in consonance with the concept of *Tanqiya* and *Tadeel*, were found effective and more feasible in the rehabilitation of post-stroke hemiplegic gait.

INTRODUCTION: Stroke is one of the leading causes of mortality and morbidity worldwide. Up to 90% of stroke survivors report one or more disabilities ¹ of which, walking impairment is most commonly reported. ² Gait recovery is a major objective in the rehabilitation of patients of stroke ^{3, 4}.

The approaches used in gait rehabilitation after stroke include neurophysiological and motor learning techniques, robotic devices, FES (Functional Electrical Stimulation) and BCIs (Brain Computer Interfaces) ⁵. But the aforesaid techniques are not fully suited for hemiplegic patients because of their limitations to actively participate in such training programs ^{1, 6}.

According to concept of Unani (Greco-Arab) System of Medicine, *Falij* (Hemiplegia) is considered as a disease due to *Sue Mizaj Balghami* (Disease caused by derangement in phlegm). *Sue Mizaj Maddi* (including *Balghami*) is treated by *Tanqiya* (elimination of causative matter) and

QUICK RESPONSE CODE	DOI: 10.13040/IJPSR.0975-8232.14(10).4871-77
	This article can be accessed online on www.ijpsr.com
DOI link: https://doi.org/10.13040/IJPSR.0975-8232.14(10).4871-77	

Ta'deel (revitalization of temperament). *Tanqiya* or *Istifraghe Mawad* is achieved by using drugs called as *Mundij Advia* which have properties such as *Tahleel*, *Taqtee*, and *Talteef*, followed by another set of drugs called as *Mushil Advia* which have propensity to expel the morbid *Akhlat* from whole body, particularly from vessels and neighboring structures through intestine. *Ta'deel* or *Islahe Mizaj* of affected *Uzw* (organ), which has been disturbed by causative matter is achieved by *Muqawwie* drugs and/or employing various *Tadabeer* (regimens) such as *Dalk* (massage), *Riyazat* (exercise), *Takmeed* (Hot Fomentation), *Hammam* (Hot Bath), *Inkibab* (steam bath) etc^{7, 8, 9, 10, 11}. The combination of *Tanqia* and *Tadeel* constructs a comprehensive treatment line for *Falij* and mandates to be tested as such to evaluate the efficacy of employable intervention in its treatment of stroke related walking disability, scientifically.

METHODOLOGY: The study was conducted at National Institute of Unani Medicine (NIUM) hospital. Before starting the clinical trial, a comprehensive protocol was planned and put forth for ethical clearance from the Institutional Ethical Committee of National Institute of Unani Medicine, Bangalore. After ethical clearance (IEC Reference No: NIUM/IEC/2011-12/004/Moal) clinical study was conducted according to the Declaration of Helsinki and the GCP guidelines by enrolling eligible patients according to inclusion criteria. This study spanned for one year i.e. from February 2012 to January 2013.

The study was designed as open interventional clinical trial. A total of 30 patients were enrolled; 28 completed the trial with 2 drop outs due to unknown reasons. **Fig. 1** the ingredients of *Mundije Balgham*, *Mus'hile Balgham* and *Inkibab* **Table 13** were provided by pharmacy of NIUM. Proper identification of these drugs was done by chief pharmacist, NIUM, to ensure their originality and authenticity.

The ingredients of *Mundije Balgham*^{12, 13} were pounded and soaked in 500 ml. of water for whole night. *Joshanda* (decoction) was prepared in the morning on low flame as per the standard procedure, and given to the patients to drink once in the morning before breakfast for 12 days. On 13th day, the ingredients of *Mus'hile Balgham* were

added in those of *Mundije Balgham*; *Joshanda* was prepared and given to drink in the morning before breakfast for one day only. On 14th day, whole body *Inkibab* was started with *Advia Harrah* (hot temperament drugs), once a day for 20 minutes, for a period of 15 days i.e. up to 28th day of test treatment. The drugs for *Inkibab* were soaked in 1.5 litre of water at night and boiled next morning; the generated steam was passed through a hose into steam chamber for the purpose of *Inkibab* of the patient sitting in the chamber.

Criteria for Selection of Cases:

Inclusion Criteria:

- A. Post stroke gait disability
- B. Patients aged between 18–64 years
- C. Ischemic Stroke having history at least of 3 months
- D. Either gender

Exclusion Criteria:

- A. Patients with terminal medical conditions such as Cancer.
- B. Unstable cardiac diseases.
- C. Uncontrolled hypertension.
- D. Renal insufficiency.
- E. Pregnant and lactating women.
- F. Other significant lower limb impairment e.g. fracture within six months.
- G. Severe arthritis and amputation.
- H. Evidence of fixed contracture.
- I. Other diagnoses which may contribute to gait disorder e.g. bony deformities.
- J. Cerebral palsy.
- K. Patients who fail to give consent.
- L. Medical conditions, where *Inkibab* is contraindicated.

Investigations: Following investigations were done to exclude other patients as a part of exclusion criteria; and to establish the safety of the test drug - Hb%, TLC, DLC, ESR, Blood Sugar-F/PP, RFT, LFT, Urine- R/M and ECG.

Test Drug:

TABLE 1: THE INGREDIENTS OF MUNDIJ BALGHAM

Name of Drugs	Botanical Name	Parts Used
Aslussoos	<i>Glycyrrhiza glabra</i>	Root
Ustukhuddoos	<i>Lavandula stoechas</i>	Flowers
Barge Gaozaban	<i>Borago officinalis</i>	Leaves
Bekhe Izkhir	<i>Andropogon jwarancusa</i>	Root
Ood saleeb	<i>Paeonia emodi</i>	Root
Badyan	<i>Foeniculum vulgare</i>	Seeds
Anisoon	<i>Pimpinella anisum</i>	Seeds
Bekhe Badyan	<i>Foeniculum vulgare</i>	Root
Tukhme Karafs	<i>Apium graveolens</i>	Seeds

Each ingredient has been taken in 4 grams per day dose and used in decoction

TABLE 2: THE INGREDIENTS OF MUS’HILE BALGHAM

Name of Drugs	Botanical Name	Parts used	Dose (per day) to be used in decoction
Ustukhuddoos	<i>Lavandula stoechas</i>	Flowers	5 grams
Barge Sana	<i>Cassia angustifolia</i>	Leaves	10 grams
Turbud	<i>Operculia turpethom</i>	Root	3 grams
Maghze Fuloose Khayar Shambar	<i>Cassia fistula</i>	Fruit pulp	70 gm
Raughane Zard	Ghee		5 grams

TABLE 3: THE INGREDIENTS OF DRUGS FOR INKIBAB

Name of Drugs	Botanical Name	Parts used
Baboona	<i>Matricaria chamomilla</i>	Whole plant
Hulba	<i>Trigonella foenum – graceum</i>	Seeds
Aqarqarha	<i>Anacyclus pyrethrum</i>	Roots
Tukhme Shibbat	<i>Peucedanum graveolus</i>	Seeds

All ingredients have been taken 12 grams per day dose, and used for Vaporization

Assessment: The assessment of efficacy of treatment was carried out on the basis of a valid and reliable scale- “FAC (Functional ambulation category)”, specific for walking¹⁴. After 28 days of the treatment, Pre and post treatment values of FAC were subjected to statistical analysis using Friedman test with Dunn’s multiple comparison tests. Safety parameters were analyzed using paired ‘t’ test to assess statistical differences. Statistical analyses were carried out using Graph Prism 5.03. Difference was considered significant at P<0.05, highly significant at p<0.01.

RESULTS: All patients (n=28) were associated with one or more risk factors of stroke i.e. Smoking, DM, HTN & Alcoholism. Demographic data is depicted by **Table 4 (a) & 4 (b)** and **Fig. 2 & 3**. The study outcome on Functional Ambulatory Categories at baseline, 14th day and 28th day of treatment was assessed using Friedman test with Dunn’s multiple comparison tests. Baseline and 28th day comparisons were statistically significant (p<0.001). Baseline and 14th day comparisons were statistically significant (p<0.01). **Fig. 4** Safety parameters were assessed applying paired ‘t’ test using Graph pad prism 5.03.

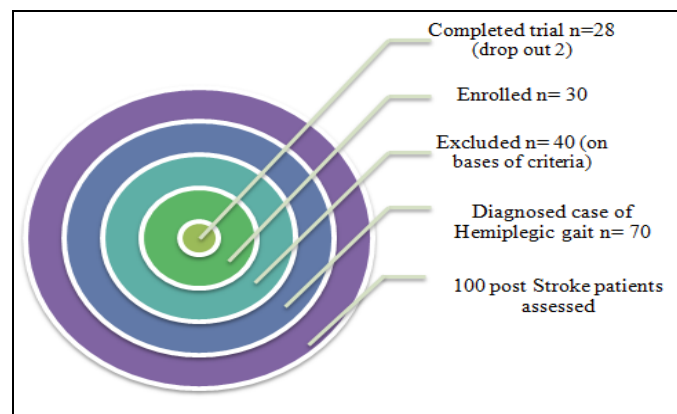


FIG. 1: FLOW CHART OF STUDY PATIENTS

Table 4(A):

Particulars	Values in Mean ± SD
Age (years)	48.96± 9.13
Duration of stroke in months	17.5±2.49

TABLE 4(B):

Particulars	Values in number (N=28)
Religion (Muslim/Hindu)	13/15
Marital status (Married/ un Married)	27/1
Side involved (right/left)	9/19
Gender (female/male)	3/25

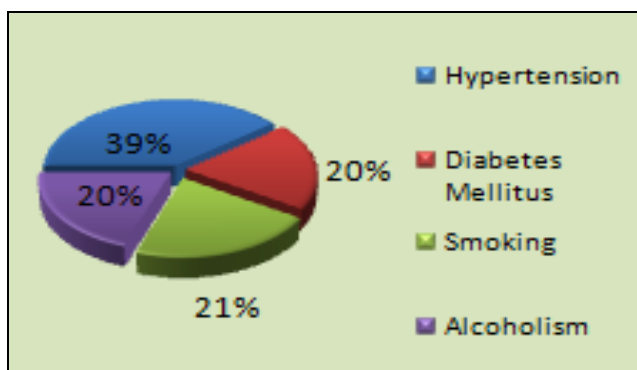


FIG. 2: DISTRIBUTION OF PATIENTS ACCORDING TO INDIVIDUAL RISK FACTORS (N=28)

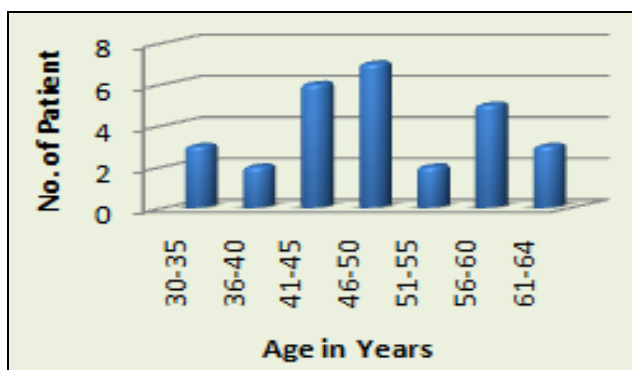


FIG. 3: DISTRIBUTION OF PATIENTS ACCORDING TO AGE (N=22)

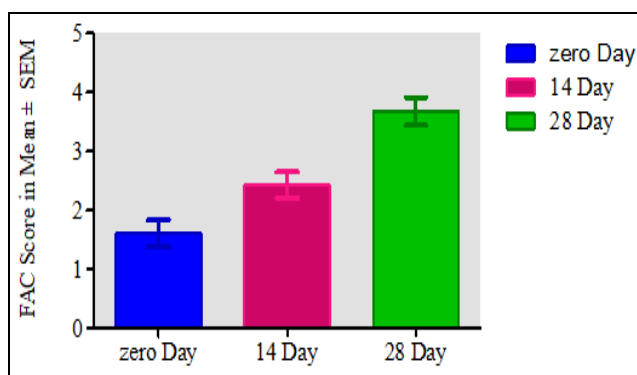


FIG. 4: SAFETY PARAMETERS

DISCUSSION: According to tenets of Unani Medicine, *Falij* is considered as a disease due to *Sue Mizaj Balghami* (Disease caused by derangement in phlegmatic humour). *Sue Mizaj Balghami* is managed by *Tanqiya* (elimination of causative matter) and *Ta'deel* (restoration of temperament). *Mundij Advia* are endowed with properties such as *Tahleel* (dissolution), *Taqtee* (remotion) and *Talteef*, (demulcent), *Mufattih* (deobstruent)^{9, 10} making the pivot for the first phase of *Tanqia*, which largely resembles with the current principle of treatment of stroke in modern medicine, advocating the use of thrombolytics, antithrombotic agents and neuroprotective drugs¹⁵.

The drugs having property of *Tahleel* (dissolution) are known as *Muhallil*. They act on viscid humour to make it dissoluble and detachable from its site of pathology⁹. *Dawae Lateef* has the property of *Talteef* and interacts with body's *Quwa Tabi'iyya* (natural faculties.) to divide the morbid matter into smaller parts⁹. *Muqatte advia* are the drugs, which owing to property of *Taqtee* (remotion), penetrate into the interstitial spaces of the organs due to their lightness and remove the adhered *khilt* (humour) from the organ⁹. The ingredients of the *Mundije Balgham* possess the above mentioned properties

along with other synergistic properties such as *Mufattih Sudad* (deobstruent for blockages), *Muharrik Dimagh* (brain stimulants), *Muqawwie Aa'saab* (Nervine tonic), *Muharrik-i-A'sab* (nervine stimulants), *Jali* (detergent) etc. and are; therefore, used in diseases such as *Falij* (Hemiplegia), *Laqwa* (Facial Palsy), and other *Balghami Amraz* (phlegmatic Disease) of nervous System^{9, 16}. Once, the *Ghair Mo'tadil Balghami madda* (morbid phlegmatic material) is dissolved and broken down by the action of *Mundije Balgham*, it is purgated out by *Mus'hilie Balgham*. *Mus'hil* drugs have properties to expel the morbid *Akhlat* from the vessels, neighbouring structures and from whole body through intestine.

Majority of the Unani physicians believe that *Mus'hil* drugs expel both *Raqeeq* (thin) and *Ghaleez* (Viscous) constituents of *Ghair Mo'tadil Akhlat* (morbid humour),¹⁷ which they have affinity with. The ingredients of *Mus'hile Balgham* have affinity with *Balgham* and; therefore, purge it out. After a course of *Mus'hil*, the remnant *Buroodat* (Coldness) diffused in *Aa'saab* is removed by *Inkibab*, using *Haar Advia* (hot temperament drugs). *Inkibab* (steam bath) itself produces *Hararat* (Hotness) and thereby used as

Mufattih Sudad (deobstruent of blockages), *Musakhkhin* (calorific), and *Muhallil* (resolvent)¹⁸. *Inkibab* with *Haar Advia* further helps to remove *Buroodat* caused by *Balgham*. The drugs used for *Inkibab* in this study possess properties such as *Musakhkhin* (calorific), *Qaate wa mukhrije balgham* (phlegm removal), *Mu'arriq Muqawwie asab* (Nervine Tonic), *Musakkin* (Pain removal), *Mulattif* (demulcent), *Mufattih* (deobstruent), *Muqawwie Dimagh* (Brain Tonic)^{12, 16, 19, 20} and therefore, are used in *Falij* and other *Barid amraze asab*^{12, 16, 19, 20}.

Study by Nakayama H. suggested that maximum recovery was achieved by 95% of patients within 9 weeks of post stroke attack. The extent of recovery is highly dependent on the severity of initial deficit²¹. The rehabilitation programs for post stroke individuals mainly focus on gait training²². The techniques are aimed to generate adaptive reversibility in functions and structures of the undamaged brain and training is accomplished with that as the main objective. However, there are limitations to the ability of hemiplegic patients with damaged mobility to actively participate in such training programs, and it is not easy to activate the brain through sensory and kinesthetic stimulation to revive the neuroplasticity^{6, 23}.

It is considered that the chief pattern of retrieval after stroke is decided by certain obscure biological processes, called as 'spontaneous neurological recovery'²⁴. But till present-day the nature of this neurological recovery is not understood clearly²⁵. Neuroplasticity has been reported as the ability of the brain to reorganize itself and form fresh neuronal connections throughout life²⁶ and Neuroprotection is a concept of providing a treatment that sustains brain tissue tolerance to defy ischemia¹⁵. It is achieved by prevention of oxidative stress, dysfunction in mitochondria, inflammation and cellular apoptosis in brain tissue²⁷. Confining neuronal damage in the surrounding penumbra is a major goal for acute therapeutic interventions in post stroke patients. As described earlier, test formulations possess *Muhallil*, *Mulattif*, *Mufatteh Sudad*, *Munaqqie Dimagh*, *Jali* and *Muhallile Auram* properties, which^{9, 12, 16} tend to open the obstruction and recanalise the vessels, scale down the inflammatory reaction and edema, reduce the damage of ischemic penumbra, and

ultimately limit the neuronal damage by cumulative action of all the properties of test drugs. Recent studies also suggest that the *Glycyrrhiza glabra*²⁸ and *Pimpinella anisum*²⁹, used in this study are known to have neuroprotective activities and useful in decreasing infarct volume while others have antioxidant activities viz. *Glycyrrhiza glabra*,³⁰ *Paeonia emodi*,³¹ *Trigonella foenumgraecum*,³² *Rosa damascene*,³³ *Operculia turpethom*³⁴ and *Cassia fistula*³⁵. In the same manner antithrombotic activities were found in Essential oil of *Foeniculum vulgare*⁵⁵ and anti-inflammatory activities in *Paeonia emodi*³¹. Experimental studies also revealed that spasmolytic or antispasmodic activities are present in *Lavandula stoechas*, *Pimpinella anisum*, *Trigonella foenum-graecum*, *Matricaria chamomilla*, *Apium graveolens*, *Peucedanum graveolus*, *Paeonia emodi* and *Borago officinalis*^{32, 37, 38, 39, 40, 41, 42, 43}.

No major adverse effect was observed in any patient; only 2 patients complained of mild pain in abdomen after *Mus'hil* drugs, which were relieved by it after few hours. No adverse reaction was observed in any patient after *Mundij* and *Inkibab* therapy.

Further, it has been observed in the study that almost all patients observed improvement in motor power and ADLs, relaxation in spasticity of limbs which further revalidates the observations of Ahmed *et al* (2015)⁴⁴ and Yasir *et al* (2013)⁴⁵. All patients were satisfied by unani regimen and were willing to enroll again in the study if needed.

CONCLUSION: It may be concluded from the above discussion that this study regimen is more feasible, safer and less expensive in comparison to modern techniques of hemiplegic gait improvement in post- stroke survivors. However large scale clinical trials with standard control are needed to infer more accurately.

ACKNOWLEDGEMENT: Authors are thankful to Physiotherapist, Nursing and IBT staff of NIUM hospital, Bangalore.

CONFLICT OF INTEREST: None

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How to cite this article:

Ali SJ and Ansari AN: Evaluation of efficacy of Unani regimen in the rehabilitation of post stroke hemiplegic gait: an open interventional study. Int J Pharm Sci & Res 2023; 14(10): 4871-77. doi: 10.13040/IJPSR.0975-8232.14(10).4871-77.

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