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## Management of post- stroke disability in Unani Medicine – An open interventional clinical trial

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### ABSTRACT

An open, before and post without control, interventional clinical trial was used to conduct the investigation. The length of the study was set at 30 days. *Nuskha Maulusool* was administered in decoction form once per morning (empty stomach) for 15 days to thirty qualified patients with hemiplegia brought on by a stroke. On the 13<sup>th</sup> and 15<sup>th</sup> days, *Nuskha Mushile Balgham* was combined with *Maulusool* and administered orally to induce purgation. Inkebab was introduced with 20 gms of *marzanjosh* on the 16<sup>th</sup> day and continued every day until the study's conclusion. To evaluate the individuals' activities of daily living (ADL), the before and post treatment values of the Barthel index were compared using a paired t test. After receiving treatment, patients' ADL significantly improved (p 0.001). Throughout and after the research, no unpleasant side effects were noticed in the treatment group, and overall treatment compliance was satisfactory. The study found that the test medication improved patients' ADLs in a statistically meaningful way.

**Keywords:** *Unani Medicine; Hemiplegia; ADL; Inkebab; Faliye Nisfi; Munzij Mushil*

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## INTRODUCTION

One of the main global causes of mortality and morbidity is stroke.<sup>1</sup> A major contributor to functional impairments is stroke, which leaves 20 percent of survivors needing institutional care after three months and 15 to 30 percent permanently incapacitated. (AHA 2009) Approximately 700,000 people are diagnosed with a stroke each year, and up to 90% of those who survive report having one or more disability, according to the American Stroke Association (ASA).<sup>2</sup>

This disease also affects India. Among non-communicable diseases in India, stroke was responsible for 72% of disability-adjusted life years and 41% of death.<sup>3</sup> A fundamental motor behavior skill for achieving autonomy in daily activities after a stroke is the capacity to control balance in the sitting and standing positions. It has been discovered that postural performance of patients soon after a stroke is closely correlated with long-term functional improvement.<sup>3</sup>

Hemiplegia, according to unani doctors, is the longitudinal paralysis of one half of the body with loss of sensory and motor skills on the affected side.

Falij ma'a Laqwa refers to facial, limb, and trunk paralysis (complete stroke).<sup>4,5,6</sup> The obstruction in Rooh Haiwani's pathway, which blocks Rooh Hissi's pathway, causes the hemiplegia (nervous impulse).<sup>4,5,6</sup> It is thought that the accumulation of Ghaleez Balgham or Dam in Batoone Dimagh causes this ailment to manifest.<sup>7</sup>

According to unani physicians, Sue Mizaj Balghami is the primary cause of Falij. As far as treatment of Falije Nisfi is concerned, Tanqia Mawade Raddiya followed by Ta'deel Mizaj.<sup>4,6,7,8</sup>

Munzijate Balgham Advia is used first, followed by Mushile Balgham Advia, to achieve Tanqia Mawade Raddiya. Due to their well-known Tahleel, Taqtee, and Talteef qualities, Munzijate Balgham Advia can make Balghami Mawad, asy-to-evacuate called as Nuzj. Following the application of Nuzj Mushil Advia, which has the ability to remove the morbid Akhlat from the entire body, especially from vessels and nearby structures through the intestine.<sup>4,6,7,8</sup>

After Tanqia Mawade Raddiya, Ta'deel Mizaj is attained through the use of Muqawwie drugs and/or a variety of Tadabeer (regimens), including Nutool, Takmeed, Hammam, Inkebab, and Dalk (massage).<sup>4,5,6,7,8</sup>

With this fundamental idea in mind, the well-known treatise "Al-Ikseer" by Hakeem Azam Khan, which contains Unani formulations of Joshanda Munzije Balgham, Joshanda Mushile Balgham, and Marzanjosh (for Inkebab), was chosen as the study's test medicine.<sup>7</sup>

The ingredients of Mus'hil Balgham are Beekhe Karafs (Root of *Apium graveolens*) Beekhe Izkhir (Root of *Andropogon jwarancusa*) Beekhe Badyan (Root of *Foeniculum vulgare*) Beekhe Kibr (Root of *Capparis (vulgare) spinosa*) Aslussoos (Root of *Glycyrrhiza glabra*) Khardal (Seeds of

Brassica nigra) 4 gram each. The ingredients of Mus'hil Balgham included Ustukhudoos (Flowers of *Lavendula stoechas*), Barge Sana (Leaves of *Cassia angustifolia*), Turbud (Root of *Ipomoea turpethum*), Maghze Fuloose Khayar Shambar (Fruit pulp *Cassia fistula*) Raughane Zard (Ghee). Marzanjosh (*Origanum vulgare*) 24 grams daily was used for Inkebab.<sup>7</sup>

## MATERIALS AND METHOD

The National Institute of Unani Medicine hospital served as the site of the current investigation. A thorough protocol was drafted and submitted for approval by the Institutional Ethical Committee of the National Institute of Unani Medicine, Bangalore, prior to the start of the clinical research. Following ethical approval, a clinical trial was carried out by recruiting qualified patients in accordance with the inclusion criteria. From January 2013 through October 2014, the study was conducted. The study's blueprint was imagined in terms of materials and procedures, which may each be explained under a few topics for easy comprehension.

### **Inclusion criteria:**

- Post stroke disability with less than 50% score on Barthel index
- Both gender
- Patients aged between 18–70 years
- Patients having history of stroke for not less than 3 months

### **Exclusion criteria:**

- Patients with cardiac, pulmonary, hepatic and renal diseases
- Uncontrolled hypertension and diabetes mellitus
- Pregnant and lactating women
- Cognitive impairment
- Evidence of fixed contracture
- Patients who fail to give written voluntary consent
- Orthopaedic or Rheumatological diseases impairing mobility
- Minor stroke with non-disabling deficit

### **Clinical Evaluation of Disease:**

The following diagnostic procedures were used to evaluate the clinical evaluation of post-stroke activities of daily living, and the resulting data was entered onto a predetermined proforma that was created in accordance with the study's objectives:

### **Medical History:**

All patients with a history of stroke who presented with post-stroke limitations in ADL were asked about the date and time of the attack, the mode of the disease's onset, and any accompanying

symptoms such as headache, nausea, vomiting, numbness, weakness, altered consciousness, mental changes, speech and vision defects, diplopia, giddiness, vertigo, dysphagia, pain in the affected limb, incoordination, convulsions-focal or generalized,

The predetermined Proforma was used to record demographic information. When taking a patient's history, a thorough investigation of risk factors was conducted, including questions about hypertension, diabetes mellitus, smoking, tobacco addiction, alcoholism, IHD, atrial fibrillation, TIA frequency/week with its duration in hours, peripheral vascular disease, rheumatic valvular disease, dyslipidemia, anaemia, polycythemia, obesity, drug abuse with specificity, and the presence of any other pertinent risk factors.

Additionally, a record of treatment history and a history of any drug allergies were made. Patients were questioned about any relevant family histories of Hypertension, Diabetes Mellitus, transient ischaemic attack, dyslipidemia, and stroke in their parents, grandparents, and siblings. By asking patients about their education, employment, and monthly income, socioeconomic status was assessed. Patients were then classified into various socioeconomic strata using the 2012 revision of Kuppuswamy's socioeconomic scale.

### **Physical Examination:**

After taking the patient's medical history, a general physical examination was performed, with particular attention paid to the patient's height (in cm), weight (in kg), pulse rate per minute, blood pressure (in mm of Hg), peripheral pulses, temperature, and the presence of any carotid, subclavian, or vertebral bruits.

During the general physical examination, any further encouraging findings were noted in the case report form. Similar to this, a thorough systemic examination of the gastrointestinal, respiratory, renal, and cardiovascular systems was also performed to check for any indications of other serious illnesses.

A thorough neurologic examination was then conducted on each patient. The Mini Mental State Examination, which includes evaluations of orientation, registration, attention, arithmetic, recollection, and language, was used to measure higher mental functions.

The cranial nerves were studied in sequence of time. The motor system was examined by determining the size of the muscles, their tone in both the upper (shoulder, elbow, wrist, and fingers) and lower (hip, knee, ankle, and toes) limbs, motor power, the presence of involuntary movements, and the superficial (plantar and abdominal) and deep tendon reflexes (biceps, supinator, and triceps jerks) on the left and right sides.

On both the left and right sides, the Finger-Nose and Knee-Heel tests were used to assess coordination. The patients' gaits were examined for any abnormalities as well. Pin prick, light touch, temperature, vibration, location, two-point discrimination, stereognosis, and graph aesthesia were evaluated for in the sensory system.

### **Investigations:**

Investigations were conducted to rule out patients who had the pathological diseases listed in the exclusion criteria and to determine the safety of the test medication. Before beginning treatment, the following investigations were completed in each instance.

- Hb%, TLC, DLC, ESR
- Urine routine & microscopic
- Blood Sugar-Fasting & Post Prandial
- KFT- Blood urea & serum creatinine
- LFT- SGOT, SGPT, S. Bilirubin
- ECG

**Study design:** The study was planned as an open, interventional, clinical trial.

**Sample size:** The sample size was fixed as 30 patients.

**Duration of protocol:** A fixed sample size of 30 patients was used.

### **Follow up:**

Until the study's conclusion, all of the patients were admitted to the IPD, maintained under close monitoring, and checked on every 15 days for disease assessment. During the trial, concomitant medication for hypertension and diabetes mellitus was permitted.

Throughout the trial time, patients were instructed to refrain from using any other drugs or treatments that have been shown to reduce post-stroke impairment.

### **Assessment**

The Barthel Index Scale was used to evaluate the study's findings. Activities of daily living (ADL) are most routinely assessed in clinical stroke trials using the Barthel Index.<sup>9,10,11</sup> It is also employed in the evaluation of stroke-related disability.<sup>12,13</sup>

The BI consists of 10 items that evaluate the feeding, chair/bed transfer, grooming, toileting, bathing, ambulation, stair climbing, dressing, bowel control, and bladder control. Although a patient with a perfect score is not necessarily able to live independently, patients with higher scores are more likely to be able to live outside of an assisted living environment.<sup>14</sup>

In his cohort of 121 patients, Ping Hsueh examined the reliability, validity, and responsiveness of a Barthel index in post-stroke patients. He came to the conclusion that BI is a valuable tool that may

be used to measure ADL capabilities in stroke patients because of its excellent internal consistency, convergent and predictive validity, high inter-rater reliability, and adequate responsiveness.<sup>15</sup>

**Withdrawal criteria:**

- Failure to follow the protocol
- Any adverse reaction or adverse event
- Drug defaulters

**Adverse drug documentation:** Any unfavourable occurrence or reaction that occurred when the test medication was administered was noted.

**Documentation:** After the study was finished, the case report form and consent forms were submitted in to the Department of Moalajat.

**Data analyses:**

The data was analyzed statistically using Graph Prism 5 version 5.03 and the website [www.vassarstat.net](http://www.vassarstat.net). At  $P < 0.05$  and  $P < 0.01$ , the difference was deemed significant and highly significant, respectively. Using a paired t test, statistical analysis of the baseline and post-treatment values of BI was performed. The paired "t" test was used to analyse safety parameters to assess statistical differences.

**RESULTS AND DISCUSSION**

**Table 1: Effect of test drug on Barthel Index (n=29)**

Mean $\pm$ SD		Difference of Mean	Df	Tc	P value
BT	AT				
34.6552 $\pm$ 4.8395	75.6897 $\pm$ 4.6311	41.0345 $\pm$ 5.58	28	20.3	< 0.001

This study assessed the activities of daily living by Barthel's index, a valid and reliable outcome measure. The difference of pre and post treatment values of the scale were analyzed using paired t test. The values have been depicted in Table 1. The p value showed highly significant result of the test formulation after the treatment.

The qualities of the test drugs given sequentially, as described in Unani literature, may be responsible for the patients' remarkable improvement in ADL. In order to accomplish Tanqia and Tadeel, the patients were treated in a systematic manner. This strategy, which has been effective and practical for centuries, translated into the usage of Nuskha Maul Usool and Mushil Balgham to achieve Tanqia and Inkebab with Marzanjosh for Tadeel. Falij nisfi is a balghami marz that is typically brought on by the impaction of a balghami sudda in the nerve pathways, which causes the rooh to stop and result in falij. The mizaj of falij is likewise thought to be similar to that of

balgham as the mizaj of balgham is barid and ratab. Ilaj-biz-zid (heterotherapy), which states that an illness should be treated with the medications having opposite mizaj to that of marz, is one of the fundamental tenets of Unani medicine.

Since the mizaj of falij is barid ratab, therefore, the drugs endowed with haar yabis mizaj as the primary temperament and properties such as tahleel, taqtee, talteef, munzije balgham, mufatteh sudad, jaali, mushile balgham, mukhrije balgham, munaqqie dimagh, muqavvie wa muharrrik aasab wa dimagh as secondary temperament are required for the treatment of falij.

The ingredients in nuskha maulusool, mushile balgham, and inkebab have the qualities listed above, which combine to produce a comprehensive therapy base for falij nisfi that complies with the principles of ilaj-biz-zid treatment in unani medicine. Due to the fact that Sue Mizaj Maddi is produced within the body as a result of Falij being brought on by Ghair Tabai Balgham, Madda must be removed in order to restore Mizaj Tabai. Tanqia is the process of removing abnormal humour (Madda), while Ta'deel is the process of restoring Mizaj Tabai.<sup>16</sup>

The first step in treating Falij is tanqia (evacuation/elimination), which is carried out using the drugs Munzij and Mushile Balgham. The second step, ta'deel, requires the institution of various compound drug preparations along with a variety of regimental procedures, such as inkebab, dalak, hijamat, and hammam, in order to restore and potentiate the functions of the involved organs.<sup>3,16,17</sup>

The properties of the Munzij medications Tahleel, Taqtee, and Talteef were administered in the form of maul usool in this study, forming the first phase of Tanqia's foundation and closely resembling the principle of stroke treatment recommended by modern medicine, which calls for the use of thrombolytic, antithrombotic, and neuroprotective drugs.<sup>6</sup> Balghami Sudda must first be dissolved and disintegrated, then the body must be purge of it. In this study, maul usool was employed for fifteen days to complete the first section. All of the maulusool medications, particularly Bekhe Karafs, Bekhe Izkhar, Badyan, Bekhe Kibr, Aslassoos, and Khardal, have the properties of Muhallil, Mulattif, Mufatteh Sudad, Munaqqie Dimagh, Muqawwie Asab, Qate Balgham, Munaqqie Akhlate Ghaleeza, Jali, etc. and are employed as a result in the treatment of diseases such Falij, Isterkha, Rasha, Zofe Asab, Sara, Laqwa, Suda, and other Balghami Amraz, etc.<sup>4,6,18,19,20,21,22,23,24</sup>

Using Nuskha Mushlie Balgham drugs, the Balghami madda (Phlegmatic substance), which has been broken down, detached, and disintegrated by the action of maul usool drugs, is then purgated away. Mushil drugs have properties to expel the Morbid Akhlat from the vessels, neighboring structures and from whole body through intestine. Nuskha Mushile Balgham's elements share affinities with Balgham and thus purge it. The Nuskha Mushile Balgham, which includes the

medications Turbud, Barg Sana, Khayar Shambar, Roghan Zard, and Ustukhuddoos, is mentioned in the materials and methods. These medications possess qualities like Mushile Akhlate Salasa, Mushile Balgham, Munaqqie Diamgh, Mukhrije Balgham, Qate Balgham, Mulattif, Jali, and Mufattehe Sudad etc., and, as a result, are commonly utilised in illnesses like Rasha, Laqwa, and Amraze Asab wa Falij.<sup>4,18,19,22,24,25</sup> Following Ghaleez Ghair Tabai Balgham's purging, which causes Sudda to create Falij, the nervous system is more open to renewal and the return of regular operations. Ta'deel is the name for this phase of recovery and rejuvenation, which is carried out utilizing a variety of routine regimenal procedures including Inkebab, massage, cupping, exercises, etc.<sup>8,16,26</sup>

In this study, the residual Baroodat that was disseminated in Asab following a course of Mushil is eliminated by using inkebab with marzanjosh for 15 days. Marzanjosh is utilised in falij, laqwa, rasha, and sara because it has Jazib, Mufatteh Sudad, Mujaffif, Musakhkhin, Mufatteh Sudade Dimagh, and Muhallil characteristics.

The treatment period ends on the 30<sup>th</sup> day after 15 days of inkebab with marzanjosh, and both phases of treatment are successfully completed using a thorough treatment plan. A statistically significant improvement in the patients' ADL was seen after therapy with the test formulations.

## CONCLUSION

The qualities of the test drugs given sequentially, as described in Unani literature, may be responsible for the patients' remarkable improvement in ADL. The patients were managed in a methodical manner to obtain Tanqia and Tadeel, which translated into the usage of Nuskha maul Usool and Mushil Balgham to accomplish Tanqia and Inkebab with Marzanjosh to achieve Tadeel.

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