

Original Research Article

Therapeutic Efficacy of Munzij wa Mushil-E-Balgham (Poly Herbal Formulation) and Dalk (Massage) with Roghan-E-Farfiyun in the Management of Irqunnasa (Sciatica): An Open Labelled Clinical Trial

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ABSTRACT

Sciatica is the pain that originates deep in the buttock and radiates towards the posterolateral thigh; may continue to the calf, medial malleolus (L4), lateral malleolus (L5) or heel (S1). In Unani system of medicine, *Irqunnasa* is considered a type of *Wajaul Mafasil* in which pain starts from hip joint and radiates to lateral aspect and sometimes medial aspect of thigh, generally towards calf and ankle joint. In classical Unani literature, *Munzij* and *Mushil* formulations make the cornerstone for the treatment of *Irqunnasa*. These compound crude drug formulations were trialed in a before and after without control clinical trial to evaluate their efficacy in the cases of sciatica. A total of thirty patients with the history of radiating pain to foot or toe, numbness and paraesthesia in the same distribution compounded with *Sue Mizaj Balghami*, between the age of 20 to 60 years and either gender, were included in the trial. The Duration of trial was 30 days, divided into 15 days for *Munzij wa Mushil* therapy and rest of 15 days for massage with *Roghane Farfiyun* on lower back and affected limb for 15 minutes daily. The clinical evaluation was done on the basis of three objective parameters i.e. VAS (10 points Likert's Scale), ODI (Oswestry Disability Index) and SLRT (straight leg raising test). Pre and post treatment values were statistically analyzed. The improvement was found highly significant with $p < 0.0001$ in all the three parameters.

Key Words: Irqunnasa, Sciatica, Dalk, Massage, Unani

INTRODUCTION

Irqunnasa is an Arabic term which literally stands for sciatica. In Unani system of medicine, *Irqunnasa* is considered a type of *Wajaul Mafasil*.^[1-2] In which pain starts from hip joint and radiates to lateral aspect, occasionally medial aspect of thigh, generally towards calf and ankle joint.^[1-8] “*Nasa*” is the name of *Rag* (vein) which starts from lateral aspect of thigh, traverses up to ankle joint. When *Mawad* (pathological substances) arrives in this *Rag*, produces pain along its course. Causative *Khilt*, *Balgham*, *is Lazij*, stays for a long time in the joint causes *Waja ul*

Warik. When *Waja ul Warik* persists for a longer time, it turns into *Irqunnasa*.^[1-2,5,7-8] Exact data on incidence and prevalence of sciatica are lacking. The annual prevalence of disc related sciatica in the general population is estimated at 2.2% and incidence of sciatica associated low back pain is 5% to 10%.^[9] Sciatica has the great potential to become chronic and intractable with major socioeconomic implications, if left untreated. In conventional medicine, certain topical and systemic analgesics, NSAIDs, corticosteroids, and surgical procedures are the common interventions employed in management of *Irqunnasa*

which are associated with certain side effects along with chances of higher reoccurrence rate. Therefore, search for a safe and effective regimen is the thrust area of research is required. In Unani system of medicine, *Irqunnasa* has been effectively treated since ancient times without any major side effect. All well-known Unani physicians have described etiology, pathology, and its management in greater detail. *Irqunnasa Balghami* caused by *Sue Mizaj Ma'ddi* is treated by the established principles of *Tanqiya wa Ta'deel*. Keeping these basic principles in consideration, *Joshanda Munzije Balgham*, *Joshanda Mus'hile Balgham*, and *Dalk with Roghane Farfiyun* was selected as a treatment regimen in the management of *Irqunnasa Balghami* from a well known anthology "*Al-Ikseer*" to establish its efficacy in the management of *Irqunnasa Balghami*. [8]

MATERIALS AND METHODS

This is an open, pre and post without control clinical study, conducted at National Institute of Unani Medicine (NIUM) Hospital, Bangalore over a period of 11 months from April, 2014 to February, 2015. Study was started after obtaining ethical clearance from Institutional Ethical Committee of National Institute of Unani Medicine Bangalore. Study was conducted according to the Declaration of Helsinki and the Good Clinical Practice guidelines. Inclusion criteria was patients presenting with the history of radiating pain to foot or toe, numbness and paraesthesia in the same distribution, inflicted with *Sue Mizaj Balghami*, between the age of 20 to 60 yrs, either gender. Exclusion criteria for the trial was Pregnancy, Lactation, age < 20 year, Systemic illness e.g. cancer, liver, kidney, cardiac and pulmonary diseases, Spinal injury or deformity (Congenital / Acquired), Any orthopaedic condition of hip joint restricting gait and movement, Patients unwilling to give consent for the trial and follow up. Patients fulfilling the inclusion criteria were enrolled in the trial after signing the informed consent form. Few

investigations were done before and after the treatment for the purpose of exclusion of patients mentioned in exclusion criteria and as safety parameters. These investigation were HB%, TLC, DLC, ESR, Urine routine & microscopic, Blood sugar random, Blood urea, serum creatinine & serum uric acid, SGOT, SGPT, S. Bilirubin, Alkaline phosphatase, ECG, X- Ray Lumbosacral region. ECG and X- Ray Lumbosacral region were done only before treatment. Duration of the trial was 30 days. Concomitant treatment was allowed for Diabetes mellitus and hypertension during the study. The demographic representation of data are given in Table no.1

Table-1 Demographic data of the subjects (n=30)

| | | |
|---------------------|----------------------------------|---------|
| Age | 20-30 | 13.33 % |
| | 31-40 | 43.34 % |
| | 41-50 | 23.33 % |
| | 51-60 | 20 % |
| Sex | Male | 70 % |
| | Female | 30 % |
| Religion | Hindu | 30 % |
| | Muslim | 70 % |
| Marital Status | Married | 93.34 % |
| | Unmarried | 6.66 % |
| Involvement of Leg | Right | 57 % |
| | Left | 43 % |
| Duration of Illness | >3-12 months | 23 % |
| | 1-2 years | 20 % |
| | 3-5 years | 23 % |
| | 6-10 years | 27 % |
| | >10 years | 7 % |
| Dietary Habit | Vegetarian | 7 % |
| | Non vegetarian | 93 % |
| Occupation | Labourers | 40 % |
| | Traders | 23 % |
| | House Wife | 17 % |
| | Office Work | 10 % |
| | Student | 7 % |
| | Teacher | 3 % |
| KSSSS | Upper Middle | 20 % |
| | Lower Middle | 43 % |
| | Upper Lower | 37 % |
| BMI | <18.5 | 3 % |
| | 18.5- 24.9 | 34 % |
| | 25-29.9 | 53 % |
| | 30- 34.9 | 7 % |
| | >40 | 3 % |
| X-Ray Finding | Normal Study | 33.33 % |
| | Lumbar Spondylosis | 43.34 % |
| | Para Spinal Muscular Contraction | 16.66 % |
| | Reduced IVD Space | 1.34% |
| | Lysthesis | 3.33 % |

Procedure of study: The ingredients used as *Munzije Balgham* are *Asalussoo* (*Glycyrrhiza glabra*), *Anisoon* (*Pimpinella anisum*), *Tukhme Karafs* (*Apium graveolens*) 5 .0 gms each, *Badiyan*

(*Foeniculum vulgare*), Badranjboya (*Mellisa officinalis*), Mako (*Solanum nigrum*), Barg Shahatra (*Fumeria officinalis*), Suranjan (*Colchicum luteum*) 7.0 gms each, Bekh Kibr (*Capparis spinosa*), Bisfaij (*Polypodium vulgare*) 3.0 gms each and Gul Qand (*Rosa damascena petals+ sugar*) 36 gms. These ingredients were pounded and soaked in 250 ml of water for whole night. Next morning *Joshanda* (decoction) was prepared on low heat as per the standard guidelines. It was then filtered; mixed with 36 gm of *Gul Qand*, and given once in the morning before breakfast for 15 consecutive days. Ingredients of *Mus'hile Balgham* are Sana (*Cassia angustifolia*) 7.0 gms; Turbud (*Operculina turpethum*), Zanjabeel (*Zingiber officinale*), Barang kabuli (*Embelia rubusta*), Shahm-e-hanzal (*Citrulus colocynthis*), Suranjan (*Colchicum luteum*), Boozidan (*Pyrethrum indicum*) 4.0 gms each and Khayar Shamber (*Cassia fistula*) 48.0 gms. [8] The ingredients of *Mus'hile Balgham* except *Khayar Shambar* were also soaked in water at night and decoction was prepared as per standard

procedure next morning. The decoction was then filtered and *Khayar Shambar* dissolved in the filtrate and filtered again to remove the residue. The prepared decoction was given to drink before breakfast on 13th and 15th days only to induce purgation. After *Munzij wa Mushil* therapy, *Dalke Layyin Mu'tadil* (Gentle Massage) was started From 16th day onward on the low back and affected limb using 15 ml of *Roghane Farfiyun* for 15 minutes for a period of 15 consecutive days i.e. up to 30th day. Ingredients of *Roghane Farfiyun* are Suranjan (*Colchicum luteum*), Zanjabeel (*Zingiber officinale*), Jaiphal (*Myristica fragrans*), Peeplamol (*Piper longum*), Malkangni (*Celastrus peniculatus*), Rai (*Brassia nigra*), Farfiyun (*Euphorbia resinifera*) 12.0 gms each, prepared in Tilon ka Tel (*Sesamum indicum*) 720.0 ml [10]

RESULTS

Table no. 2: Effects of intervention on objective parameter (n=30) (Mean ± SEM)

| Objective scales | BT | AT | P value |
|------------------|--------------|--------------|---------|
| VAS | 8.2±0.2319 | 2.87±0.2479 | <0.0001 |
| ODI Score | 49.067±1.983 | 24.334±1.925 | <0.0001 |
| SLRT | 41±1.924 | 59.367±2.136 | <0.0001 |

Table no. 3: Effects of intervention on Safety parameters (n=30)

| Safety parameters | BT Mean± SEM | AT Mean± SEM | P value |
|-------------------|-----------------|-----------------|---------|
| HB% | 14.463 ±0.3086 | 14.23±0.3230 | 0.0843 |
| TLC | 7933.334±302.04 | 7506.667±363.98 | 0.2687 |
| Polymorphs | 56.400±1.529 | 58.417±1.205 | 0.0721 |
| Lymphocytes | 34.933±1.476 | 33.823±1.100 | 0.2983 |
| Eosinophils | 4.833±0.1523 | 4.333±0.1938 | 0.0395 |
| Monocytes | 3.800±0.2319 | 3.380±0.2134 | 0.0701 |
| Basophils | 0.00±0.00 | 0.0466± 0.0354 | - |
| ESR | 20.533±3.027 | 19.866±2.974 | 0.5362 |
| SGOT | 29.167±4.950 | 29.033±6.071 | 0.5838 |
| SGPT | 38.233±7.222 | 33.767±4.918 | 0.8740 |
| Alk. Phosphatase | 115.60±4.054 | 104.97±2.931 | 0.0027 |
| Total Bilirubin | 0.839±0.057 | 0.751±0.0555 | 0.0863 |
| S. Creatinine | 0.873±0.018 | 0.883±0.0198 | 0.5798 |
| B. Urea | 31.300±1.334 | 29.580±1.168 | 0.2584 |
| S. Uric Acid | 5.587±0.205 | 5.460±0.190 | 0.3860 |
| RBS | 136.80±14.484 | 132.37±13.145 | 0.8223 |

The clinical evaluation was done on the basis of three objective parameters i.e. VAS (10 points Likert's Scale), ODI (Oswestry Disability Index) and SLRT (straight leg raising test). The records were maintained on a proforma designed according to the objectives of the study. Follow up was done on 15th & 30th days.

Statistical analyses were carried out after 30 days of the treatment. Graph pad InStat was used for statistical analysis. Pre and post treatment values of objective parameters were analyzed using paired *t* test. Safety parameters were analyzed using paired *t* test and wilcoxon matched test to assess statistical differences. The improvement

was found highly significant with $p < 0.0001$ in all the three parameters used to assess the efficacy of the test treatment. Safety parameters were found in normal range before and after the treatment. The Unani test formulations used in the present study was found safe during the entire treatment duration. The Efficacy assessment data are given in Table no 2 and Safety assessment parameters are given in Table no. 3.

DISCUSSION

Irqunnasa Balghami results due to involvement of *Balgham Ghair Tab'ee*; leading to *Sue Mizaj Ma'ddi* which is managed by its evacuation for the restoration of *Mizaj Tabai*. Management of *Irqunnasa Balghami* is based on the principles of *Tanqiya* through *Munzij* and *Mus'hile Balgham* drugs followed by *Ta'deel* using *Murakkab Advia* along with appropriate *Tadbeer* which include *Dalk* to restore and potentiate the functions of the involved organs. [5-8, 11]

Almost all patients reported improvement in VAS, ODI and straight leg raising test. One patient complained of loose motions after taking *Joshanda Munzije Balgham*. One patient complained of abdominal discomfort probably due to not mixing the *Gulqand* in *Joshanda*. He rather used to take it as such after *Joshanda*; when he started mixing *Gulqand* in *Joshanda*, this problem subsided. Test formulations comprising single drugs have been evaluated for their efficacy in various clinical and experimental studies which lend strength to their potential results in alleviating the signs and symptoms of *Irqunnasa*. Ingredients of *Munzije Balgham*, Such as *Asalussoos (Glycyrrhiza glabra)* are reported to be *Musakkin*, *Mufatteh Sudad*, *Munzije Akhlate Murakkab* and *Muqawwi*. [12-13] *Glycyrrhizin* and *aglycone* are two important compounds of *Asalussoos* which exhibit anti-inflammatory, antiallergic, antioxidant, antiviral, antithrombotic, and neuroprotective activities. [14] *Anisoon (Pimpinella anisum)* has *Muhallil*, *Mulattif*, *Mufatteh Sudad* and

Musakkin Auja actions. [15-21] It has been reported for significant analgesic effect similar to morphine and aspirin; relaxant effect due to inhibitory effect on muscarinic receptors and anti-inflammatory action by inhibitory effect on prostaglandin synthesis. [22-23] *Tukhme Karafs (Apium graveolens)* has *Mufatteh*, *Musakkin*, *Muhallil*, *Muarriq*, *Mudire baul*, *Muqawwi Dimagh wa Aasab* actions. [12,17,21,24-26] It also contains constituents having COX inhibitory activity which may significantly reduce the inflammatory process. [27] *Badiyan (Foeniculum vulgare)* is endowed with *Mufatteh Sudad* and *Mulattif* properties. [17-19,21,28] One of its constituent 'transanethole' has been reported for its anti-inflammatory effect- blocking LPS-induced inflammation, regulating pro-inflammatory cytokines, transcription factors, and Nitrous oxide. [29] *Badranjboya (Mellisa officinalis)* possesses *Mufatteh Sudad*, *Mulattif* and *Mudir* properties. [17-19,21,26,28] In various trials, it has been explored for varied effects including anti-nociceptive, anti-inflammatory and analgesic activity. The main components of fennel Limonene and transanethole are responsible for the anti-inflammatory effects. Fennel effectively blocked LPS-induced inflammation, by regulating pro-inflammatory cytokines, transcription factors and nitric oxide. [29] *Mako (Solanum nigrum)* relieves pain by virtue of *Muhallile Warm* and *Musakkin* actions. [17,20,25,30] It possesses flavonoids, triterpenes, saponins and steroids known to have anti-inflammatory and antipyretic effects. [31] *Barg Shahatra (Fumeria officinalis)* has *Dafe Humma* and *Muffateh sudad* properties. [17,30,32] besides this, it is a potential source of valuable flavonoid compounds with high antioxidant activities. [33] *Suranjan (Colchicum luteum)*, which is the drug of choice in treatment of *Irqunnasa*, has two important *Jauhar*: at first its *Latif* and *Mus'hil Jauhar* evacuates the accumulated matter in joints one by one through the actions of *Tahlil* and *Jazb* and then *Qa'abiz Jauhar* acts as an astringent for organs as well as their passages, and

renders them cold; thus they become strong enough to not let the morbid matter deposit in the joints. [17-18,20,30,34] Colchicine, the most important anti-inflammatory compound found in *Suranjan*, has shown disease modifying activity by inhibiting the pro-inflammatory cytokines. [35] Bekh Kibr (*Capparis spinosa*) has *Muqawwie Aasab*, *Muhallil*, *Muqatte*, *Mulattif* and *Mus'hile Kham* properties. [13,17] Stachydrine, derived from it, has been reported for anti-arthritic activity, thus proving its potential in management of *Irqunnasa*. [36] Bisfajj (*Polypodium vulgare*) has *Mus'hile Balgham wa Sauda wa Kaimoos*, *Mus'hile Akhlat-e Salasa*, actions to aid in purgation of morbid matter out of the body. [12,15,17-19] An important fatty oil has been extracted which affords purgative and strongly antihelmintic actions which enhance the purgative mechanism of involved *Khilt*. [37] *GulQand* does *Tahleel*, *Talteef*, *Nujze Mawad* and *Tallayyun-e-Taba*. [13,38] A study on *Rosa damascena* extract showed active analgesic and antioxidant constituents acting both centrally and peripherally. [39]

Ingredients of *Mus'hile Balgham* such as *Sana* (*Cassia angustifolia*) has *Mus'hil Sauda wa Safra*, *Mus'hile Safra wa Balgham* actions. [17-18,40] *Sana* penetrates into the deepest portions of the body, and purgates out accumulated morbid substance, which is considered as part of management plan in *Irqunnasa*. *Cassia angustifolia* contains anthraquinones, flavonoids, glycosides and other constituents. *Turbud* (*Operculina turpethum*) has *Mus'hil Balgham wa Safra* *Mus'hile Raqeeq wa Kham Balgham* and *Mulayyan* properties. [15,17-18,20-21] It is endowed with important chemical constituents such as lupeol, betulin, and sitosterol which exhibit hepatoprotective, anticancer and anti-inflammatory effects. [41] *Shahm-e-hanzal* (*Citrulus colocynthis*) possesses *Mus'hile Qawi*, *Muhallil*, *Mus'hile Balgham*, *Mus'hil Sauda* and *Mus'hile Safra* properties. [17-18,21,25-26,28,40] It has also been reported for anti inflammatory, anti oxidant, anti ulcer, and

anaesthetic effects. [42] *Khayar Shamber* (*Cassia fistula*) has *Mus'hil*, *Muhallile Warm*, *Mulayyin*, *Mus'hile Balgham*, *Mus'hile Safra* and *Munaqqi-e-Aasab* activities. [16-18,21,28,32] Studies have revealed that aqueous and methanolic extracts of *Cassia fistula* possess anti-inflammatory and anti-oxidant properties. [41]

Ingredients of *Roghane Farfiyun* such as *Zanjabeel* (*Zingiber officianale*) have *Mus'hil-e-Balgham wa Sauda*, *Mullayin* *Musakhin* and *Mulattif* properties. [17,19,25,28] It evacuates *Balghami* morbid matter, and thus is very effective in treatment of *Irqunnasa*. It has been explored for anti-inflammatory, analgesic, antipyretic effects by the inhibition of prostaglandin, and leucotriene bio-synthesis. [43-44] *Jaiphal* (*Myristica fragrans*) has *Mulattif*, *Muqawwi*, *Muhallil* and *Musakkine Auja* properties. [12,15,17-18,21] One of its active constituent, myristicin has showed lasting anti-inflammatory activity approximately the same as that of Indomethacin. [43] *Filfil Daraz* (*Piper longum*) is *Mudire Baul*, *Mukhrije Balgham*, *Muhallile Warm* and *Mufatteh Sudad*. [12-13] *Piper longum* extracts and piperine exhibit inhibitory actions on prostaglandin and leukotrienes COX-1 inhibition; thus, exert anti-inflammatory actions. [45] Moreover piperine has anti-inflammatory and anti-arthritic effects. [46] *Malkangni* (*Celastrus peniculatus*) is *Musakkine Auja* and useful in *Amraz Barida*, *Sard wa Tar Amraz Dimagh wa aasab*. [13] Methanolic extract of *Celastrus peniculatus* is endowed with analgesic, anti-inflammatory and anti arthritic activities. [47] *Khardal* (*Brassica nigra*) is reported to have *Musakhkhin*, *Muhallil*, *Mulattif*, *Mufatteh Sudad* and *Qate Balgham* properties; hence, very effective in *Amraze Balghami* and *A'sabi Dard*. [13,17-18,21,28] In preclinical trials, *Brassica nigra* has been reported to improve anti arthritic changes. [48] *Farfiyun* (*Euphorbia resinifera*) is *Muhallil*, *Mulattif* and *Mus'hile Balgham wa Safra*. [17,13,30] Resiniferatoxin, isolated from *Euphorbia resinifera*, has been identified as potent analgesic agent, and

Karai et al have proved its analgesic efficacy in ablated nociceptive neurons. [49]

Tilon ka Tel (*Sesamum indicum*) is *Mulayyan*, *Muhallile Warm* and *Mufatteh*. [12-13] Major chemical constituents of the seed oil include oleic, linoleic, palmitic, and stearic fatty acids which possess antioxidant and neuroprotective properties. [50]

Therefore, the aforementioned properties of various ingredients of the test formulation documented in classical texts strongly suggest as having the potential to treat the painful and inflammatory condition of the *Irqunnasa* and validate their efficacy in this clinical trial.

CONCLUSION

This trial regimen may be a treatment of choice for patients of *Irqunnasa Balghami*. Limitation of the study is smaller sample size. Hence controlled clinical trial with large sample size is required for further evaluation of safety and efficacy of the trial regimen.

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