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Research Paper

Evaluation of Analgesic Effect of Unani Pharmacopoeial Formulation *Habb-E-Suranjan* and *Raughan-E-Suranjan* in Wajaul Mafasil (Joints Pain) Patients: An Open Prospective Clinical Trial

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Abstract

Wajaul Mafasil (joint pain) is the most prevalent and common cause of morbidity and disability not only in India but also throughout the world. In spite of various scientific developments in conventional medicine, there is no specific therapy or cure available for joints pain particularly when the disease has progressed to chronic stage. Therefore, it is the need of the hour to explore new formulations from herbal sources which are safe and effective. The present trial was undertaken to scientifically validate the Unani pharmacopoeial compound formulations of *Habb-e-Suranjan* and *Raughan-e-Suranjan* for its safety and efficacy in patients with joints pain.

Patients with joint pain, who gave written informed consent, were recruited in the study from general OPD of RRIUM, Chennai with the prior approval of the Institutional Ethics Committee. 97 patients completed the study treatment. The treatment protocol was followed for 14 days and the clinical evaluation was done on seventh and fourteenth day of the treatment. At the end of fourteenth day intensity of individual parameters like joints pain, swelling, tenderness and restriction of movement showed statistically significant improvement ($p<0.05$). Overall therapeutic response of the treatment observed in this study was 100%. It was observed that 47.4% cases were completely relieved; 51.4% cases were relieved while 1.2% cases showed partial relief after the treatment. The laboratory investigations showed that the drugs used in the study were safe as evident by its maintenance. It may be concluded that *Habb-e-Suranjan* in combination with *Raughan-e-Suranjan* possesses significant analgesic property and may be a better option for the patients of joint pain.

Keywords: Arthritis, Joints pain, *Wajaul Mafasil*, *Habb-e-Suranjan*, *Raughan-e-Suranjan*

INTRODUCTION

The history of *Wajaul Mafasil* (joints Pain) is as old as the history of human being. Hippocrates presented the first compendium on the disease known as *Kitab-ul-Mafasil* which deals with joint diseases (Mohammad et al., 2014)¹. *Wajaul Mafasil* is an Arabic word which literally means pain of the joints. Joint pain is the most prevalent symptoms in medical practice and one among the leading causes of disability worldwide (Neogi, 2016; Finney et al., 2017)². Arthritis is one of the commonest joint disorder affecting millions of people worldwide with an estimated 15% (40 million) of Americans had some form of arthritis in 1995 and in India it affects 15% (180 million) people (Ashraf & Mohi-ud-din, 2018)³. The causes of joints pain include trauma, inflammation, infection, degeneration and metabolic disorders. Degenerative arthritis is much more common in old age but other types of arthritis such as rheumatoid arthritis, septic arthritis, rheumatic arthritis, gonococcal arthritis and gouty arthritis may affect to all age groups of

people. The common symptoms of arthritis are pain, stiffness and swelling, but the presentation of symptoms is different according to the types of arthritis. In osteoarthritis, large joints are commonly affected and distribution of pain is usually asymmetrical in manner, while in rheumatoid arthritis, usually small joints are affected in symmetrical fashion. In acute gouty arthritis, very severe pain in first metatarsophalangeal joint is occurred particularly at night (Munjal YP, 2012)⁴.

The aetiology, pathology and principle of treatment of *Wajaul Mafasil* has been discussed in detail in Unani System of medicine (Faris, A.A. 2010)⁵ (Masuya, Y.B. 1994)⁶ (Majusi, A.A. 1889)⁷ (Qarah, S.B. 1928)⁸ (Razi, Z. 2004)⁹ (Rushd, I. 1987)¹⁰ (Siddiqui, M.K. 2009)¹¹ (Tabri, A.R. 1417)¹² (Jurjani A.H. 2010)¹³ (Sina I. 2004)¹⁴. Unani scholars have defined *Wajaul Mafasil* as the pain and inflammation which develops in the organs and surrounding structures of joints, such as synovial membrane, cartilage, ligaments, tendons and muscles. According to Razi, *Wajaul Mafasil* is one of those disorders which occur in the form of recurrent or

paroxysmal attacks and caused by accumulation of excessive *Ratubat* (fluid). Razi also quoted that *Wajaul Mafasil* is a wide term that encompasses pain of joints, *Niqras*(gout) and *Irq-un-Nisa*(sciatica) (Mohammad et al 2014)¹. Ismail Jurjani has stated that the accumulation of *mawaade fuzaoni* (morbid matters) in the structures of joint results in inflammation and pain in joint (Antaki, 1282)¹⁵. Pain occurs in joints where there is a decrease in Hararat-e-Ghariziya which causes slow absorption of the morbid humors leading to accumulation of waste matter in the joints. It is a very common problem of old age but may start at earlier stage of life specially when there is predominance of *Balgham* along with obesity, indigestion, prolonged breast-feeding, poverty, damp, exposure to cold and humid climates (Kabeeruddin, 2007)¹⁶.

Based on the dominant morbid matters affecting the joints, it is stated that the *Balgham* (phlegm) predominates over *Dam* (Blood) followed by *Safra* (bile) and *Sawda* (black bile) is rarely involved. In some cases, more than one khilt (Humours) are involved (Kabeeruddin, 2003)¹⁷. *Wajaul Mafasil Balghami* (Phlegmatic) is the Commonest form of *Wajaul Mafasil* where the onset of symptoms and sign are gradual, area of affected joint is swollen, soft, whitish and cold on touch, pain and throbbing is nominal, swelling is soft and cold with deep pain and tenderness marked, pain aggravates by exposure of cold and relieves by exposure of heat over affected part, generalized and localized symptoms of dominance of phlegm (Ghalbae Balgham) will be present (Baig MG,2014)¹⁸. Unani system of medicine is replete with many treatment regimens for joints pain. A number of single and compound drugs are in vogue since ages for joint pain and other musculoskeletal disorders. *Habb-e-Suranjan* and *Raughan-e-Suranjan* are two important and commonly prescribed formulations for the treatment of joint pain.

Study rationale

Joint pain is the most prevalent and common cause of morbidity and disability worldwide. In Unani System of Medicine, arthritis is described under a broad term *Wajaul Mafasil*, which encompasses entire joint disorders like inflammatory, non-inflammatory, infectious, metabolic and other musculoskeletal disorders. The main aim of treatment of *Wajaul Mafasil* (joint pain) is to reduce morbidity and disability. In spite of various scientific developments in conventional medicine, there is no specific therapy or cure available for joints pain particularly when the disease has progressed to chronic stage. Therefore, it is the need of the hour to explore new formulations from herbal sources which are safe and effective. Classical literature reveals that these two pharmacopoeial preparations i.e., '*Habb-e-Suranjan*' and '*Raughan-e-Suranjan*' are not only effective in treatment of joints pain, they are also safe and devoid of adverse effect. Though the drug has been in use since centuries, no clinical data is available as to its safety and efficacy. Hence, an open prospective clinical study was conducted at RRIUM, Chennai to assess the analgesic activity of the above two formulations in the relief of joints pain in patients with *Wajaul Mafasil*. This study may also be useful in commercialization of these two pharmacopoeial preparations in future.

MATERIAL AND METHODS

An open prospective clinical trial was carried out on total number of 106 patients of *Wajaul Mafasil* (Joint Pain) of which 9 participants was lost to follow-up due to varied reasons and 97 patients completed the trial. The study was approved by the Institutional Ethics Committee (IEC), RRIUM, Chennai. The study was conducted at Regional Research Institute of Unani Medicine, Chennai, during the

period of May 2013 to May 2014. Patients were registered after getting voluntary informed consent to participate in the study. Patients of *Wajaul Mafasil* (Joint pain) in the age group 18 – 65 years of either gender presenting with or without any of the symptoms/ signs such as Pain, Tenderness, Swelling and Restriction of movement involving Single / multiple joints were included in the study. The patients who fulfil the inclusion criteria were explained regarding the dosage, duration and purpose of the study. Patients having disorders requiring long term treatment like Diabetes Mellitus, Hypertension, known cases of hepatic, renal or cardiac ailments, pregnant and lactating women and patients with history of alcohol or drug abuse were excluded from the study.

Details of Intervention

The test formulation, *Habb-e-Suranjan* containing powder of three herbs *Elwa/Sibr* (*Aloe barbadensis*), *Halela* (*Terminalia chebula*), *Suranjan* (*Colchicum luteum*) in equal proportion (Kabeeruddin, 2005)¹⁹ and *Raughan-e-Suranjan* (*Colchicum luteum* oil) (Anonymous, 1967²⁰, Anonymous, 2006)²¹ were prepared as per standard procedure under the supervision of chief pharmacist at GMP certified pharmacy, of CRIUM, Hyderabad and supplied to the study site. Two tablets of *Habb-e-Suranjan* (500mg each) were given thrice a day after meals with water or milk for two weeks along with *Raughan-e-Suranjan* for which patients were advised to apply 5 ml lukewarm oil locally on affected joints in the morning and evening twice daily for two weeks.

Clinical parameters were assessed at base line, seventh day and fourteenth day of the treatment period. The temperament of the patients was recorded at base line and on completion of the treatment. The subjective and objective clinical observations were recorded in the CRF. For assessment of the efficacy of drugs; joints pain, tenderness, joints swelling and restriction of movement were scored on the grading basis from 1-4 at baseline and each follow ups. Percentage efficacy was calculated from reduction of scores.

The safety parameters were assessed by recording of adverse events and carrying out laboratory investigations. Laboratory investigations were carried out at baseline and on the last follow-up date.

Criteria for assessment of result:

The criteria for assessment of result of the study was based on the following:

- (a) 90-100% improvement in clinical symptoms & signs = completely relief.
- (b) 60-89 % improvement in clinical symptoms & signs = Relief.
- (c) 30-59% improvement in clinical symptoms & signs = Partial relief.
- (d) < 30% improvement in clinical symptoms & signs = Not relieved.

Statistical analysis

The discrete variable was expressed as percentage and continuous variables were expressed as mean with standard deviation. To assess the mean score changes of sign and symptoms between the baseline and after the treatment non parametric test was applied. Paired t-test was used to test the significance. All tests were two tailed and P-value <0.05 was considered as significant.

RESULTS

Table 1: Demographic profile of *Wajaul Mafasil* (Joint Pain) patients (n=97),

Characteristics	No. (%)
Age (Year)	
<=40	28 (28.9)
41-50	44 (45.4)
51-65	25 (25.8)
Mean age ± Sd	45.4 ± 10.43
Gender	
Male	33 (34.0)
Female	64 (66.0)
Duration of disease (Month)	
<=12	91 (93.8)
>12	6 (6.2)
Mizaj	
Damavi (Sanguine)	7 (7.2)
Balghami(Phlegmatic)	25 (25.8)
Safravi(Choleric)	65 (67.0)

The age distribution shows that 28.9% of the study subjects were less than 40 years and in the other two age groups the percentage was 45.4% and 25.8%. The mean age of the study subjects was 45.4 ± 10.42 years. The proportion of male and female in the study was recorded to be 34% and 66% respectively. About 94% percent of study subjects had joint pain for a duration of less than or equal to 12 months. The percentage of patients observed in Damavi (Sanguine), Balghami (Phlegmatic), and Safravi (Choleric) were 7.2%, 25.8 % and 67% respectively. (Table 1).

Table 3: Reduction in mean score of sign and symptoms during the follow up period in patients of *Wajaul Mafasil* (Joint pain) treated with *Habb-e-Suranjan* and *Raughan-e-Suranjan*

Sign & symptoms	Base line Mean ± Sd	1 st Follow-up Mean ± Sd	2 nd Follow-up Mean ± Sd	P-value
Joint Pain	3.00± 0.0	1.7± 0.64	0.72± 0.61	<0.05
Tenderness	3.00± 0.0	1.5± 0.66	0.49± 0.60	<0.05
Joint Swelling	2.68 ± 0.49	0.64± 0.86	0.09± 0.36	<0.05
Restriction of Movements	3.00± 0.0	1.6± 0.63	0.58± 0.57	<0.05

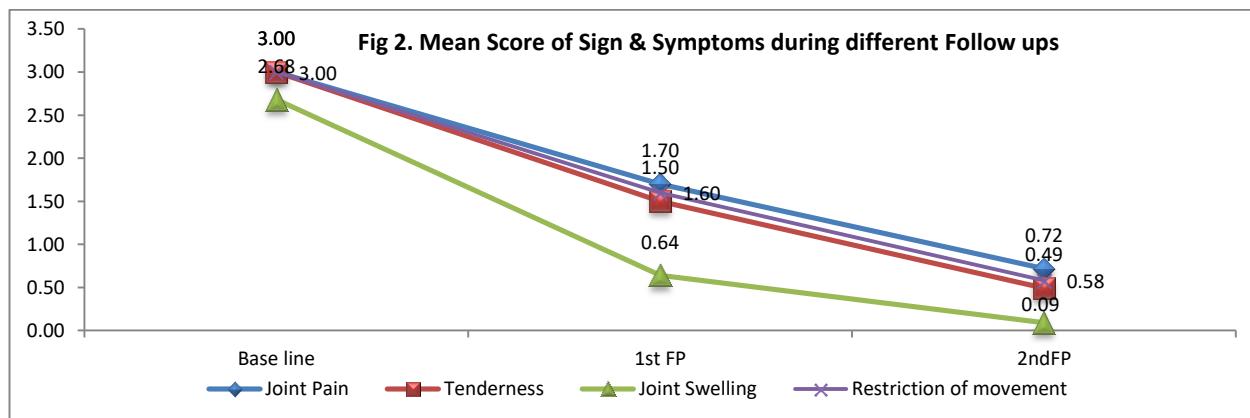


Figure 2: Mean Score of Sign & Symptoms during different Follow ups

Table 2: Response of treatment based on reduction score percentage in patients of *Wajaul Mafasil* (Joint pain) treated with *Habb-e-Suranjan* and *Raughan-e-Suranjan*

Response	No.	%
Complete relief	46	47.4
Relief	50	51.4
Partial relief	1	1.2
Total	97	100.0

With the active intervention of Unani Pharmacopoeial formulation *Habb-e-Suranjan* and *Raughan-e-Suranjan*, the analysis was done on 97 cases and found the overall therapeutic response to be 100%

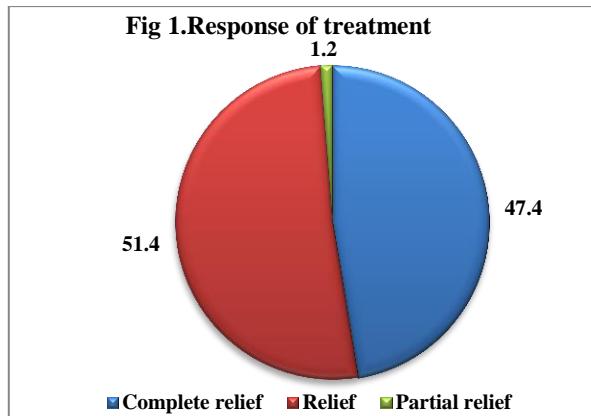


Figure 1: Response of treatment

The treatment response of complete relief, relief and partial relief were 47.4%, 51.4% and 1.2% respectively as depicted in Table 2 & Figure 1

The mean score of all the four sign and symptoms of the *Waja'ul Mafāṣil* patients were significantly ($P<0.05$) reduced at the last follow up. (Table 3; Fig 2)

Table 4: Subsidence of sign and symptoms of *Waja'ul Mafāṣil* (Joint pain) patients treated with *Habb-e-Suranjan* and *Raughan-e-Suranjan* at baseline and after trial.

Sign & symptoms	Base line		After treatment	
	Present No. (%)	Absent No. (%)	Present No. (%)	Absent No. (%)
Joint Pain	97(100.0)	0	62(63.9)	35(36.1)
Tenderness	97(100.0)	0	43(44.3)	54(55.7)
Joint Swelling	97(100.0)	0	7(7.2)	90(92.8)
Restriction of movement	97(100.0)	0	52(53.6)	45(46.4)

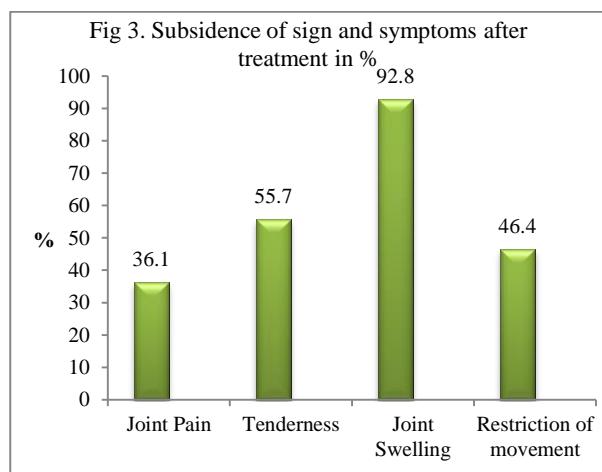


Figure 3: Subsidence of sign and symptoms after treatment in %

On observation, the joint pain completely disappeared in 36.1% cases; tenderness in 55.7% cases, joint swelling in 92.8% cases while restriction of movement was completely disappeared in 46.4% cases. This indicates that the joint

swelling has reduced to a greater extent and about half of the patients were free from tenderness and restriction of movements. (Table 4, Fig 3)

Table 5: Pathological and biochemical Parameters in *Waja'ul Mafāṣil* (Joint pain) patients treated with *Habb-e-Suranjan* and *Raughan-e-Suranjan*

Parameter	Base line Mean \pm S.D	After Treatment Mean \pm S.D	P-value
Hb (Grams %)	13.4 \pm 1.74	13.4 \pm 1.74	> 0.05
W.B.C(Cells/Cu.mm)	9229 \pm 2354.9	9446 \pm 24770.02	> 0.05
Neutrophils (%)	59 \pm 9.15	57.6 \pm 9.07	> 0.05
Lymphocytes (%)	34.9 \pm 8.05	35.6 \pm 7.8	> 0.05
Eosinophil (%)	5.5 \pm 5.06	6.1 \pm 4.98	> 0.05
Monocytes (%)	0.5 \pm 0.97	0.71 \pm 1.14	> 0.05
Basophils (%)	0.02 \pm 0.20	0.0 \pm 0.0	> 0.05
E.S.R 1 st hour(%)	30.9 \pm 25.40	30.9 \pm 27.83	> 0.05
Blood Sugar(mg %)	95.8 \pm 17.86	-	-
Blood Urea(mg %)	21.3 \pm 4.91	21.8 \pm 4.20	> 0.05
Sr.creatinine(mg %)	0.8 \pm 0.11	0.7 \pm 0.10	> 0.05
Sr. Bilirubin	0.7 \pm 0.19	0.6 \pm 0.10	> 0.05
SGOT Units/L	22.8 \pm 8.31	22.9 \pm 9.40	> 0.05
SGPT Units/L	24.8 \pm 6.54	24.5 \pm 7.21	> 0.05
Alkaline Phosphatase KA U	8.4 \pm 2.95	8.3 \pm 2.25	> 0.05

The study findings revealed that all pathological and biochemical parameters were within normal range and no significant ($P>0.05$) difference in the mean value between the baseline and after the treatment was observed.

DISCUSSION:

Wajaul Mafasil is one of the leading problems nowadays which causes physical impairment and disability in the community affecting millions of people throughout the world. Although Western medicine offers many anti-inflammatory and anti-arthritis drugs but they are neither optimally effective nor safe. So, Traditional Medicines, including Tibb-e-Unani are being explored for effective and safe anti-arthritis drugs.

This clinical study was conducted on 97 patients to evaluate the efficacy of Unani Pharmacopoeial formulation *Habb-e-Suranjan* for oral administration and *Raughan-e-Suranjan* for local application in the management of *Waja'ul-Mafasil*. The treatment response of complete relief, relief and partial relief were 47.4%, 51.4% and 1.2% respectively. This study revealed no adverse effects during the period of trial. A similar study carried out in Regional Research Institute of Unani Medicine, Patna, Bihar during the period of February 2013 to March 2014 with the same formulation (Mohammad IA 2018)²² revealed comparable findings which corroborates with the present study. Pain increases with age which is similar to the findings observed in a study report of national health survey (Anonymous, 2008)²³. The study findings show that Joints Pain is comparably higher among females than in males which is similar to the study 'A meta-analysis of sex differences prevalence, incidence and severity of osteoarthritis' (V K Srikanth. et.al, 2005)²⁴.

The safety and efficacy of *Habb-e-Suranjan* may also be comparable with other clinical studies. A clinical trial conducted at Ajmal Khan Tibbiya College and Hospital involving the patients of primary gout found that not only was *Habb-e-Suranjan* was clinically effective as the allopurinol but was also safe for usage (Hilal Akhtar et.al. 2019)²⁵.

The findings of the study showed beneficial effects of tested formulations revealed by the improvement of clinical symptoms. The clinical improvements are mainly because of composition of the drug. The analgesic activities of Aloe, Colchicum, and sedative (Musakkin) activity of T. chebula, are responsible for relief in pain. The anti-inflammatory action of Colchicum also play a crucial role on joint pain and painful joints movement along with reduction in swelling and tenderness and may also be responsible for the favourable response in patients. The resolving and analgesic action of Colchicum is enough to explain the mechanism through which the gradual improvements happened (Hilal Akhtar et.al. 2019)²⁵.

Both the formulations contain *Suranjan* as its main ingredient. Colchicine is the main alkaloid of *Suranjan*. Colchicine is not unfamiliar to the medical world, as it has been utilized in the treatment of gout and has been investigated in many other conditions, including familial Mediterranean fever (Shahid Suhail et.al. 2017)²⁶.

In a review study, different Nuskhaat (formulations) of *Habb-e-Suranjan* were mentioned with their different ingredients, doses and therapeutic uses which highlighted its use and effectiveness for *Waja'-al Mafasil* (Arthralgia) and 'Irq al-Nasa (Sciatica) (Shahid Suhail et.al. 2017)²⁷.

An experimental study to evaluate Sub chronic oral toxicity study of *Habb-e-Suranjan* in albino Wistar rats has revealed that the formulation is safe and did not induce any adverse effect in rats. (Khalid Ghazanfar et. al. 2017)²⁸. A disease review study on *Waja-ul- Mafasil* has also emphasised the utility of both the formulations administered in this study (Khan AA et. Al. 2019).²⁹

CONCLUSION:

Clinical improvement was observed in clinical sign and symptoms of *Wajaul Mafasil* after fourteen days of treatment with *Habb-e-Suranjan* and *Raughan-e-Suranjan*. Non-toxic nature of the drug is evident from the maintenance of laboratory parameters suggests that the drug *Habb-e-Suranjan* and *Raughan-e-Suranjan* does not have hepatic or renal toxicity. Hence it may be concluded that the studied drugs are safe and effective in the treatment of *Wajaul Mafasil* (Joint pain). Further controlled studies with large sample size with increased dosage of the drug may throw more information on the outcome of the drug in the treatment of *Wajaul Mafasil* (Joint pain).

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