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Article in International Journal of Research in Ayurveda and Pharmacy · November 2016

DOI: 10.7897/2277-4343.075229

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STUDY ON KNEE OSTEOARTHRITIS WITH A UNANI POLY HERBAL FORMULATION: A SERIES OF CASE STUDIES

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Received on: 14/07/16 Revised on: 01/08/16 Accepted on: 01/09/16

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DOI: 10.7897/2277-4343.075229

ABSTRACT

The most common cause for limiting mobility of the elderly people is joint disease, especially knee osteoarthritis. It is the major cause of disability and socioeconomic burden at present. Qurs-e- mafasil is a Unani poly herbal compound formulation mentioned in a Unani pharmacopeia, Qarabadeen-e-Majeedi. In which it is recommended for waja-ul-mafasil (arthralgia). This formulation contains three ingredients, Chob Zard (*Curcuma longa* Linn.), Surinjan Talkh (*Colchium luteum* Baker.) and Samaghe Arabi (*Acacia Arabica* Willd.). Aim of this study was to comprehend the effectiveness of the drug Qurs-e- mafasil in knee osteoarthritis patients. This study was done in 30 patients. Qurs-e- mafasil was administered orally as 2 pills 3 times a day with water or milk for 4 weeks. The outcome measures such as VAS (Visual Analogue Scale), KOOS (Knee injury and Osteoarthritis Outcome Score) and 15 meters walking test were used to assess the symptoms before and after treatment. These paired data were analyzed statistically according to Wilcoxon Matched paired signed rank test. KOOS mean pain score was 39.73 ± 2.399 before treatment and it was 56.93 ± 2.214 after treatment with an extremely significant improvement. Similarly there was a significant (52.14 ± 3.449) improvement at 4th week in KOOS symptoms score. There was a significant change in the mean of KOOS total score (13.6%) and, significant improvement was observed in VAS (56.80 ± 2.571) and walking time (22.85 ± 0.527) at 4th week. Therefore, it is revealed that when Qurs-e- mafasil administered orally the symptoms of osteoarthritis are relived significantly.

Keywords: Knee osteoarthritis, Walking test, Qurse mafasil, Visual Analog Scale

INTRODUCTION

'Qurse mafasil' (QM) is a Unani poly herbal formulation. One of the indications of this medicine is waja-ul- mafasil¹. Waja-ul-Mafasil is a compound Arabic word, comprised of two words, waja and mafasil which literally mean pain or ache in the joints². This formulation contains three ingredients i.e. Chob Zard-Turmeric (*Curcuma longa* Linn.), Surinjan Talkh- Golden collyrium (*Colchium luteum* Baker.) and Samagh Arabi- gum Arabic (*Acacia arabica* Willd.) as mentioned in Qarabadeen-e-Majeedi, which is recognized by Indian government as a Unani pharmacopeia. *Colchium luteum* (Surinjan) is the drug which has anti inflammatory properties and various actions on joints and extensively recommended for joint diseases by renowned Unani physicians^{3,4} and it is used in conditions like gout, arthritis, backache, sciatica, etc.⁵. *Curcuma longa* Linn. (Chob zard/ Haldi) is a good anti-inflammatory drug and also it has the analgesic and antioxidant properties^{6,8-10}. *Acacia arabica* (Samagh arabi) is also having anti inflammatory and antioxidant properties and it is used as binding agent in this compound preparation^{6,11-13}. Therefore, the combination of these three drugs can act on inflammatory conditions of the joints such as knee osteoarthritis.

Osteoarthritis (OA) is a persistent and constantly progressing degenerative disorder which is due to multifactorial aetiology characterized by loss of articular cartilage, hypertrophy of bone at the margins, subchondral sclerosis and range of biochemical and morphological alterations of the synovial membrane and joint capsule¹⁴. Clinically, the condition is characterized by joint

pain, tenderness, limitation of movement, crepitus, occasional effusion, and variable degrees of local inflammation¹⁵. OA is uncommon in adults under age of 40 years and highly prevalent in those over age 60. It is also a disease that middle-aged and elderly persons are more affected¹⁶. According to American Rheumatological association, one of the diagnostic criteria for osteoarthritis is joint pain in the patients who are more than 40 years of age. Nowadays life expectancy of the people is higher, therefore, number of elderly people also higher, hence, prevalence of OA also rises with increasing age and there are several millions of people all over the world suffering from osteoarthritis. The burden will be the greatest in developing countries due to access to arthroplasty and joint replacement is not commonly available¹⁷.

There are several treatment options available for the osteoarthritis at present. However, there is no cheap and effective treatment for OA which can alleviate symptoms and cure the disease. Further, none of them is completely free from side effects or cheap and effective. Hence, there is an increased demand to discover cheap, effective and less toxic drug or there is a need to validate the time tested traditional drugs scientifically for their therapeutic efficacy. In this context this series of case studies is focused to evaluate the clinical efficacy and safety of QM in knee osteoarthritis patients.

METHODOLOGY

This series of case studies was carried out in Majeedia Hospital, Jamia Hamdard University, New Delhi, in

accordance with the principles stated in the Declaration of Helsinki (2004). 30 patients were participated in this study. Patients were recruited at Unani medical OPDs.

The herbal formulation, Qurs-e-mafasil is a product of Hamdard (Wakf) Lab., Delhi (GMP certified) and this is dispensed free of cost by Unani pharmacy, Majeedia Hospital, Jamia Hamdard. Batch number: M 029. QM was administered orally as 2 pills 3 times a day with water or milk for 4 weeks. The following outcome measures were used to assess the efficacy of the treatment at 4th week.

Visual Analogue Scale (VAS) is a measurement instrument in which it is possible to measure a characteristic or attitude that is believed to range across a continuum of values and cannot easily or directly measured. It is a horizontal line, which is 100 mm in length. The two extremes of the scales are marked as 0 and 100 respectively. Zero represents no pain whereas 100 represent extreme pain (on which higher score indicates more pain). The subjects were given the scale and asked them to mark on the line, the point they feel represents their perception of their current state of pain¹⁸.

Knee injury and Osteoarthritis Outcome Score (KOOS) is developed as an instrument to assess the patients' opinion about their knee and associated problems. KOOS is meant to be used over short and long time intervals; to assess changes from week to week induced by treatment (medication, operation, physical therapy) or over years due to the primary injury or post-traumatic OA. KOOS consists of 5 subscales; pain, other symptoms, function in daily living (ADL), function in sport and recreation and knee related quality of life (QOL). KOOS has been used in patients between 14 and 78 years old. KOOS includes WOMAC Osteoarthritis Index LK 3.0 in its complete and original format. KOOS is patient-administered, the format is user friendly, and takes about 10 minutes to fill out^{19,20}. Patients were asked to walk across 15 meter distance at their natural speed; walking time was obtained with the help of stop watch. This was repeated three time and three readings were taken. The average was calculated and recorded^{21,22}.

Statistical analysis was done according to Wilcoxon Matched paired Signed rank test and applied to evaluate the paired data. The analysis of the observational data was performed and presented in the form of graphs and tables by using GraphPad instat 3 and Microsoft® Excel (2007) software.

Table 1: KOOS Subscales Values before Treatment and after Treatment

	Pain	Symptoms	ADL	Sports/Rec	QoL
BT	39.73 ± 2.39	42.74 ± 3.122	35.64 ± 2.341	18.83 ± 2.295	28.53 ± 3.109
AT	56.93** ± 2.21	52.14** ± 3.45	54.02** ± 2.30	31.33** ± 2.58	39.22* ± 3.55
Improvement	17.2 %	9.4%	18.4%	12.5%	4.9 %

BT: Before Treatment, AT: After Treatment

Table 2: KOOS Total Score, VAS & Walking Time Before and After Treatment

	KOOS total Score	VAS	Walking Time
BT	33.09 ± 2.19	66.83 ± 1.90	23.97 ± 0.62
AT	46.74** ± 2.03	56.80** ± 2.57	22.85* ± 0.53

BT: Before Treatment, AT: After Treatment

RESULTS AND DISCUSSION

In present case study, 30 patients' mean values of selected parameters were taken before and after 4 weeks of treatment. Before treatment, KOOS mean pain score was 39.73 ± 2.399 and it was improved by 17.2 % after treatment at 4th week; the mean pain score was 56.93** ± 2.214 which showed an extremely significant improvement (P < 0.001). Before commencing the treatment, KOOS symptoms score was 42.74 ± 3.122, later it was improved by 9.4% at 4th week, and mean score was 52.143** ± 3.449 with an extremely significant statistical difference. KOOS function in daily living (ADL) was 35.64 ± 2.341 before treatment and it became 54.02** ± 2.304 with 18.4% of improvement at 4th week. KOOS Function in sport and recreation (Sport/Rec) was 18.83 ± 2.295 at the beginning and it was improved by 12.5% at 4th week (31.33** ± 2.581) with extremely significant statistical difference (P < 0.001). At the beginning of the treatment, KOOS knee related Quality of life (QOL) was 28.53 ± 3.109. It was improved by 4.9 % at 4th week of the treatment and mean score was 39.22* ± 3.546 with highly significant statistical difference (P < 0.01) (See Table 1 and Figure 1).

KOOS total score was 33.09 ± 2.185 before treatment and it was 46.74** ± 2.025 after treatment with having extremely significant difference (P < 0.001). Visual Analogue Scale was 66.83 ± 1.901 before treatment and it was 56.80** ± 2.571 after 4 weeks and there was statistically significant improvement noticed. Walking time was 23.97 ± 0.617 seconds at the

beginning of the treatment and it was improved to 22.85* ± 0.527 seconds with statistically significant improvement (P < 0.05) (See Table 2 and Figure 2).

Osteoarthritis is a chronic, degenerative and progressive disease that results from complex interactions of multiple physical and biochemical factors²³. It gives huge burden by the way of financial and social impact on the patients. It affects the country's economy as the victims of this disorder are usually working age group²⁴. The treatment objectives are to hold-up the degenerative process and to minimize symptoms, so that the patients of OA can move freely to perform their day to day activities by themselves; in addition to that, the therapy should be tolerable when used for a longer period without any adverse effects or with minimal side effects.

As per the Unani doctrine, derangement of the humours occur due to the presence of morbid matters in the body and the blood circulation, which are responsible for the production of many diseases. Osteoarthritis is caused by derangement of humours, which are cold in nature like Balghami (phlegm), and Saudavi (black bile) humours, known as cold derangement of temperament. In this context, Qurs-e mafasil has several advantages as the ingredients of the drug (especially *C. luteum* and *C. longa*) contains anti-inflammatory properties, anesthetic properties⁹, moreover they have the properties of eliminating bad matters which are accumulated in the joints by maturing the matters and eliminating by the way of laxative actions⁵. Further this QM has

the muqawwiyat e mafasil (strengthening the joints) actions too. The patients who were treated with this QM had decreased perception in pain and other symptoms of osteoarthritis. Moreover, they experienced improved functional ability and day to day performance.

CONCLUSION

It is observed that there were extremely statistical significant improvements in reduction of pain and other symptoms, functions in daily living, function in sport and recreation, knee related Quality of life, KOOS total score and VAS. In addition to that there was highly significant improvement in the walking time after 4 weeks of treatment. Therefore, the oral QM therapy seems to be an effective treatment for reducing symptoms of knee osteoarthritis and restoring the physical functions, moreover the therapy was found to be safe and well tolerated. Further evaluation is necessary for the scientific conclusion by means of randomized controlled clinical trial in large population with prolonged period of protocol time.

ACKNOWLEDGEMENT

Authors acknowledge the Hamdard (Wakf) Lab., Delhi for providing the herbal formulation, Qurs-e-mafasil for free of cost to conduct this study.

ABBREVIATIONS

VAS - Visual Analogue Scale
KOOS - Knee injury and Osteoarthritis Outcome Score
QM - Qurse mafasil
OA - Osteoarthritis
OPD – Out Patient Department
GMP – Good Manufacturing Practice
QOL - Quality of life
ADL - Activities in Daily Living
BT – Before Treatment
AT – After Treatment

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Cite this article as:

Mohamed Shiffa, Nazeem Fahamiya & M Akhtar Siddiqui. Study on knee osteoarthritis with a Unani poly herbal formulation: A series of case studies. Int. J. Res. Ayurveda Pharm. Sep - Oct 2016;7(Suppl 4):102-104 <http://dx.doi.org/10.7897/2277-4343.075229>

Source of support: Nil, Conflict of interest: None Declared

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