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Efficacy of Unani formulation and Roghan-e-Dhatura in Adhesive Capsulitis: An open labeled interventional study

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Abstract

Background and Objectives: Adhesive Capsulitis (AC) is commonly known as Frozen Shoulder Syndrome (FSS) is a condition characterized by intense shoulder pain, gradual fibrosis of the glenohumeral joint that causes a limited range of motion, and contracture of the glenohumeral joint capsule. The disease peaks between 40 and 70 years of age and 10 to 36% of the individuals with Diabetes mellitus are mostly affected followed by Hypothyroidism and Hyperthyroidism. In conventional medicine it is being treated with pharmacologically, non-pharmacologically and with surgery. In Unani system of medicine AC is considered as a type of articular disease and treated according to the principles of Amraz-e-Mafasil with drugs and regimens. In this study a Unani formulation and Roghan-e- Dhatura is selected to validate its indication as effective in painful joints.

Methods: This study was conducted as an open labeled interventional without control pre and post analysis on 30 patients with oral Unani formulation (Sibr, Halela Zard, Suranjan Sheerin, Saqmooniya and Aabe Mako) and local application of Roghan-e-Dhatura for 28 days with follow ups on, 7th, 14th, 21th and 28th day. The pre and post treatment effects were assessed objectively with VAS, SPADI.

Results: The study outcome measured with mean and standard deviation in VAS, before treatment 8.33 ± 0.55 and after treatment 2.23 ± 0.73 , with p value < 0.001 and SPADI 76.51 ± 2.80 and 16.61 ± 6.87 , found statistically highly significant with p value < 0.001 with Tukey-Kramer Multiple comparisons and Kruskal-Wallis tests.

Interpretation & Conclusion: This study shows clinically and statistically significant difference in ameliorating the symptoms of adhesive capsulitis without any adverse effect. Therefore, it can be concluded that the test drugs are safe and effective in management of adhesive capsulitis symptoms.

Keywords: Adhesive Capsulitis, Frozen Shoulder Syndrome, Unani Formulation, Roghan-e-Dhatura, Wajaul Mafasil, VAS, SPADI

1. Introduction

Adhesive Capsulitis (AC) results in progressive painful restriction in range of movement and can reduce function and quality of life [1]. Adhesive Capsulitis commonly known as Frozen Shoulder Syndrome (FSS) and also called pericapsulitis, peri-arthritis, adherent bursitis, obliterative bursitis, shoulder peri-arthritis, scapulo-humeral peri-arthritis, adherent subacromial bursitis, hypomobile syndrome [2, 3]. The term "frozen shoulder" commonly used to describe adhesive capsulitis and it is often self-limited, it can persist for years and may never fully resolve [4]. This disorder is one of the most common musculoskeletal problems seen in orthopedics [5]. The prevalence of adhesive capsulitis affects 2 to 3 % of the population [6]. It is more in women with a peak age of onset of 56 years and 15 % of patients develop bilateral disease [7]. The etiopathology of this disease remains unclear and understanding of pathogenesis is increasing.[8,9] Psychological factors, metabolic disorders (diabetes, obesity), older age and female gender may also be associated with frozen shoulder syndrome [10,11].

AC is commonly treated with non-steroidal anti-inflammatory drugs (NSAIDs) [5]. However, NSAIDs are associated with serious gastrointestinal adverse effects which limit their use in many patients [12]. Other drugs like opioids and non-opioid analgesics and intra-articular steroids may not be effective in all patients [13]. Hence, there is a need for searching of effective and safe drugs for the treatment of AC.

Adhesive Capsulitis can be literally termed in Arabic as *Iltehaba La'siq ul Mahsoor*, and this clinical condition is commonly known as Frozen Shoulder Syndrome (*Waja ul Katif/ Mutalazima Munjamid al Katif*). It is a restricted movement along with painful shoulder joint. In Unani literature the symptoms of Adhesive Capsulitis are met under the caption of *Wajaul Mafasil*. Wajaul Mafasil is a painful or inflammatory condition affecting joints, their surrounding muscle and ligaments [14, 15, 16, 17].

It can affect any joints of the body, accordingly some of these have named after the joint involved as *Wajaul warik*, *Wajauz zahr*, *Wajaur rakba*, *Wajaus saaqain*, *Wajaul waqab*, *Wajaul khasera*, *Tahajjure Mafasil* [14, 15, 16, 17]. Adhesive Capsulitis / Frozen Shoulder Syndrome is a type of articular disease and treated according to the principles of Amraze Mafasil with drugs and regimens. Therefore, to evaluate the efficacy and safety of a Unani Formulation (Sibr, Halela Zard, Suranjan Sheerin, Saqmooniya and Aabe Mako) and Roghan-e-Dhatura in alleviating pain and restoration of range of movements, this study was contemplated by selecting the drugs which are indicated for Amraz-e-Mafasil [18, 19].

2. Material and Methods

This study was conducted as an open labeled interventional without control pre and post analysis study, during March 2016 to February 2017 at the O.P.D of N.I.U.M, Bangalore after obtaining the ethical clearance from the Institutional Ethical Committee for Biomedical Research (IEC No: NIUM/IEC/2014-15/007/Moal/07).

3. Study participants

3.1 Eligibility criteria

Patients full filing the inclusion criteria i.e, shoulder pain, both gender, age >35 - ≤ 60, painful, restricted active and passive range of movement of the shoulder, and symptoms present for at least 3 months, with or without concomitant to either Diabetes Mellitus, Hypothyroidism and exclusion criteria: Patients of age <35 - >60, pregnancy and lactation, H/o shoulder injury and surgery, H/o the use of local corticosteroid injection to the affected shoulder within the last 3 months or current corticosteroid therapy, Shoulder symptoms due to other causes and history of any other systemic, metabolic and infectious diseases.

4 Study interventions

Table 1: Poly herbal Unani Formulation:- Habb.

S. No	Unani Name	Scientific Name	Weight
1	Sibr	<i>Aloe vera</i>	140 gm
2	Haleela Zard	<i>Terminlia chebula</i>	35 gm
3	Suranjan Sheerin	<i>Colchicum autumnale</i>	35 gm
4	Saqmooniya	<i>Convolvulus scamony</i>	7.5 gm
5	Aabe Makoo	<i>Solanum nigrum</i>	Q.S

Table 2: Roghane Dhatura

S. No	Unani Name	Scientific Name	Weight
1	Tukhm-e-Dhatura Siyah	<i>Dhatura stramonium</i>	100 gm
2	Roghan-e-Kunjad	<i>Sesamum indicum</i>	448 ml
3	Water	<i>Aqua</i>	1.0 ml

Dose: 2 Habbs of 800 mg each were given orally with water

Table 3: (Demographic Data)

S. No	Demographic	Intervention Group
1	Age (In Years)	35-40 8 (26.6%)
		41-50 11(36.6%)
		51-60 11 (36.6%)
2	Sex	Male 14 (46.7%)
		Female 16 (53.3%)
3	Duration of Illness (In Months)	3-6 13 (43.3%)
		6-12 14 (46.7%)
		12-24 3 (10%)
4	Mizaj	Damvi 13 (43.3%)

three times a day, whereas *Roghan-e-Dhatura* 10 ml per day for locally for four weeks [18, 19].

4.1 Study procedure

A total of 120 patients primarily complaining of shoulder pain were screened, out of which 84 patients were excluded and 36 patients fulfilling the inclusion criteria after obtaining informed consent were enrolled into the study and finally 30 subjects completed the study (Showing Fig No 1. CONSORT Diagram).

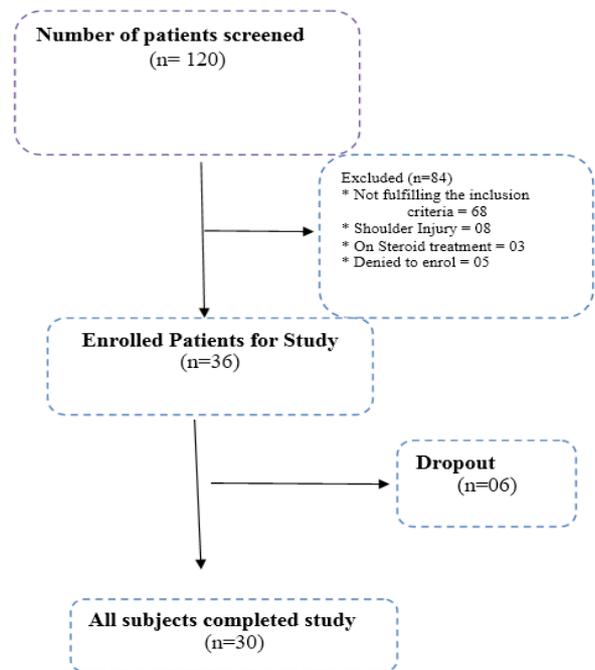


Fig 1

All the subjects are given UF orally in the form of 2 Habbs (Pill) of each 800 mg thrice a day along with 10 ml of Roghane Dhatura for local application (on affected shoulder). The effect of the study was assessed with reference to 0th day, 7th, 14th, 21st, and 28th days and observed a change in the mean difference with standard deviation in objective parameter viz VAS, and SPADI.

4.2 Statistical analysis

Data was analyzed by One Way - ANOVA with Tukey-Kramer Multiple comparisons test.

4.3 Observation

The demographic characteristics of subjects were in baseline characteristics including age, sex, duration of illness, mizaj, shoulder involvement and metabolic disorders (Table No. 3) were taken into consideration.

		Balghami	17 (56.7%)
5	Shoulder Involvement	Right	19 (63.3%)
		Left	11 (36.7%)
6	Metabolic disorders	Hypothyroidism	7(23.3%)
		Diabetes	23(76.7%)

5. Results

This study shows clinically and statistically significant difference in ameliorating the symptoms of adhesive

capsulitis without any adverse effects, and the study outcome as objective parameters VAS and SPADI were found highly significant statistically with p value <0.001 [Table No. 4].

Table 4: (Objective parameters)

		BT (Mean ± SD)	AT (Mean ±SD)	P Value
Objective Parameters	VAS	8.33±0.55	2.23±0.73	<0.001**
	SPADI	76.51±2.80	16.61±6.87	<0.001**

6. Discussion

Adhesive capsulitis is considered as fibrosis of the glenohumeral joint capsule with a chronic inflammatory response [20]. In this study the mean age of the patients was found to be 46±7.45 (35, 60) years, with maximum number of patients were in the age groups of 41 – 50 and 51-60 years with 11 in each (37%), 8 (26%) in the age group of 35-40 years. These finding suggestive of the disease is most common among the middle aged individual which supports the finding of Binder AI *et al.* (1984), [21], Manske RC *et al.* (2008), [5], Endres NK *et al.* (2009) [22] and Shamsi BSB *et al.* (2011) [23]. This trial evidence 16 (53%) were patients females and 14 (47%) were males, it is consistent with the observations support by Dias R *et al.* (2005), Gupta S *et al.* (2008) [24] and Fernandes MR (2014) [25]. as females were more prone to suffer from adhesive capsulitis. This study evidence with reference to the chronicity of illness, no. of patient 14 (47%) were found with duration of 6 months to 1 year, were 13 (43%) 3-6months, while the duration of illness was 1-2 years 3(10%). Manske RC *et al.* (2008) [5]. reported that when duration of illness is shorter than range of motion is higher, which ascertained that majority of the subjects studied were correlate the finding of Mansake RC for longer duration. This study *Mizaj* (temperamental) finding with reference to observed 17 (57%) were *Blghami* and 13 (43%) *Damvi*. AC is believed to be a type of *Wajaul Mafasil* is in Balghami *Mizaj*. The observed data is in accordance with Akbar Arzani, Azam Khan, Ibn Hubal Baghdadi, and Ibn Sina [14, 16, 17, 26]. Based on involvement of joint found to be 19(63.3%) affecting right shoulder and where as 11 (36.3%) in left shoulder. This study finding has no coincide on the disease in terms of any one shoulder (i.e. right or left involvement). 23 (76.7%) were found to be DM, and 7(23.3%) are hypothyroidism. These findings coincide with the observations made by, Tighe CB *et al.* (2008) [11], Gupta S *et al.* (2008) [24], Ahmad S *et al.* (2012), [27] Austin DC *et al.* (2014) [28]. The inflammation and capsular fibrosis seen in AC is precipitated by metabolic syndrome (DM) and chronic low grade inflammation. These pathophysiological mechanisms are highly likely to be perpetuated by upregulation of pro-inflammatory cytokine production, sympathetic dominance of autonomic balance, and neuro-immune activation which is reported by Pietrzak M (2016) [29]. The effect of the test drug on shoulder pain was assessed with Visual Analogue Scale (VAS) scores and Shoulder Pain and Disability Index (SPADI) score. The mean VAS score observed as mean difference from baseline to the subsequent follow-ups as 8.33±0.55 (BL), 8.10±0.66(F1), 6.4±0.77(F2), 4.4±0.89(F3) and 2.23±0.73(F4) where as SPADI score was assessed with the mean difference from

baseline to the subsequent follow-ups as 76.51±2.80 (BL), 69.76±3.95 (F1), 54.59±4.93 (F2), 33.73±6.57 (F3) and 16.61±6.87 (F4). The pre and post study findings were statistical analyzed with Tukey-Kramer Multiple comparisons test and Kruskal- Wallis test, the results were found highly significant with p value <0.001. (Table No 4.)

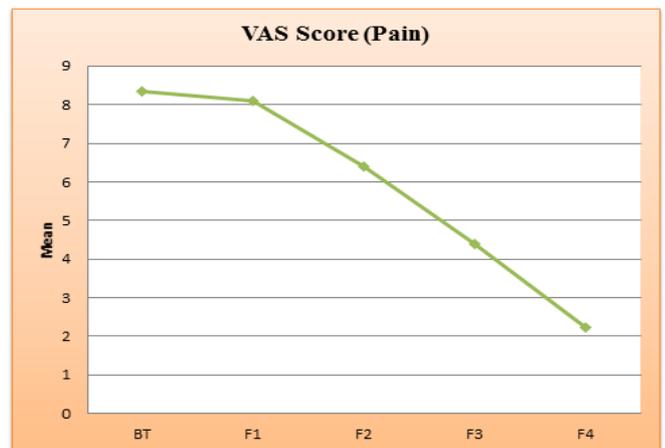


Fig 2: VAS Score (Pain): Pre and Post assessment in Objective parameter

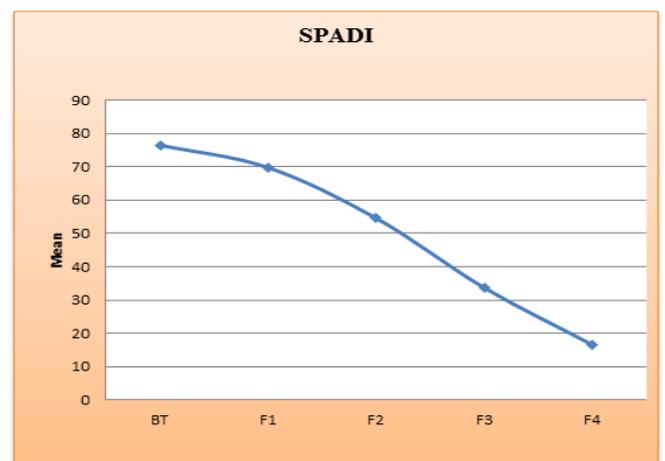


Fig 3: Shoulder Pain and Disability Index (SPADI) Scores

The Unani Formulation used in the study orally consists of Sibr, Haleela Zard, Suranjan Sheerin, Saqmoonnia, Aabe Mako and Roghan-e-Dhatura (Tukhm-e-Dhatura Siyah, Roghan-e-Kunjad). These drugs have been scientifically validate as analgesic, anti-inflammatory, cox-I inhibitors consistent with the results of the study carried out by Egesic UG *et al.* Kumar CU *et al.*, Ghosh *et al.* Nair V *et al.*, Pokuri VK *et al.* [30, 31, 32,

33, 34]. The above results therefore revealed that the use of Unani Formulation and Roghan-e Dhatura are highly effective for the pain management of adhesive capsulitis.

7. Conclusion

The study outcome with reference to finding of objective parameters VAS and SPADI were found highly significant. Hence, it may be concluded that the test drugs (Unani formulation and Roghan-e-Dhatura) were found safe and effective in adhesive capsulitis symptoms without any untoward effects. Moreover, to understand the effect of the studied drugs and their mechanism of action, this study may be re-considered for further evaluation on larger sample size with revised methodology.

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Conflict of Interest: There are no conflicts of interest.

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