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Original Research Article

Efficacy of Unani Formulations in *Waja-ul-Khasirah* (Low Back Pain) - A Randomised Double Dummy Clinical Trial

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ABSTRACT

Background and Objectives: Low Back Pain (LBP) is an essentially ubiquitous phenomenon. It is the major cause of disability and work absenteeism throughout the world with an enormous impact on individuals, families and communities. Aim of this study was to compare the efficacy of non-pharmacopoeial oral Unani formulation and *Roghane Suranjan* in *Waja-ul-Khasirah* (LBP) with an objective of relief in LBP and improvement in quality of life (QoL).
Methods: This randomised single blind double dummy placebo controlled clinical trial was carried out at NIUM Hospital, Bengaluru on 42 patients of either sex, between the age of 18-55 years, with specific LBP, back stiffness and difficulty in movements by randomly allocated them to group A {non-pharmacopoeial oral Unani formulation (test drug) + placebo oil, n=21} and group B {Placebo oral + *Roghane Suranjan* (test drug), n=21}. Both groups were treated with oral formulation (03 capsules of 800mg thrice a day) and oil (15ml for local application on Lumbo-sacral region daily twice a day) for 21 days with three weekly and one post treatment follow up to see the residual effect of drug. The effect of study was assessed with improvements in primary outcome such as LBP (VAS grades), Stiffness in the back and Difficulty in movements (arbitrary scale) and secondary outcome with improvement in QoL (ODI and QBPDS scores). The data was analysed by using Fisher's exact, Chi-square, Friedman, Kruskal-Wallis, Repeated measures and one way ANOVA with Tukey post hoc multiple comparison test for both intergroup and intragroup comparisons.
Results: Inter and Intragroup analysis shows statistically significant improvements in LBP, back stiffness, difficulty in movements and in QoL ($p<0.001$) whereas, residual effect of drugs was found insignificant ($p>0.05$). Both groups were found safe without any adverse effect.
Interpretation and Conclusion: The study outcome suggests that both groups were effective and safe clinically and statistically in *Waja-ul-Khasirah* (Low Back Pain) and the non-pharmacopoeial oral Unani formulation (Group A) was found superior in comparison of *Roghane Suranjan* (group B).
Keywords: LBP; double dummy; ODI; QBPDS; Unani; *Roghane Suranjan*

1. INTRODUCTION

Throughout the history Low Back Pain (LBP) has been reported to be one of the most common, frustrating and diagnostically elusive medical maladies of humankind and also a common pandemic

disorder in industrialized world and rural community. [1-4] The occurrence of LBP in India is also alarming as nearly 60% of the people have suffered from it at some time during their lifespan. [5] Annual incidence of LBP is projected to be 5% per year, with an associated prevalence of 60% to 90%. It has significant impact on functional ability by restricting occupational activities with marked socio-economic repercussion. [6] It is a common medical problem that has many outcomes including disability and work absenteeism throughout the world with an enormous impact on individual, families, communities, industries and government. [3,7] In India, most of the low-income group people are engaged in physically demanding jobs which increases the risk of LBP and disability and affects quality of life (QoL). [5]

LBP is characterized by pain or discomfort in the lumbar region, below the costal margin (12th rib) and above the gluteal folds that may or may not radiate to thigh. [8] 90% of acute episodes of LBP settle within 6 weeks while 10% of patients develop chronic LBP (i.e. pain lasting more than 3 months). [9] It is a symptom of underlying condition resulting from misuse or abuse of the back as a result of habitual wrong posture and chronic strain which cannot be validated by an external standard. [6,10] In Unani system of medicine (USM), LBP is termed as "*Waja-ul-Khasirah*" [11] which occurs mainly due to *Hadba*, *Riyah al-Afrisa*, *Khaam Balgham*, *Ghaliz Riyah*, *Su'e Mizaj Barid*. Other causes are *Rutubate Mayi*, *Zarba wa Saqta*, *Kasrat-e-Jima'*, *Zoaf-e-Gurdah* and *Musharikat-e-Rahim*. [12,13] Treatment of LBP is challenging for both the patient and the health care provider. [1,14] Conventional treatment exhibits rest, physiotherapy and administration of certain topical and systemic drugs like NSAIDs, muscle relaxants including TCA, corticosteroid, traction or Lumbo-sacral belt and Surgery. [15] Attempts by conventional medicine to identify effective interventions for individuals with LBP have been largely unsuccessful. [14] USM deals with holistic approach in the treatment by following its principle of *Usool Bil Zid*, and emphasising on the elimination of cause through diet restriction or regimens (*Roghan*, *Zimad*, *Tila* and *Takmeed*, either alone or in combination with *Hijama*, *Dalk* or *Riyazat*), *Tanqiae badan* with use of *Munzij wa Mus'hil-e-Balgham*, *Mulattif* and use of *Mudirr-e-Bawl*, *Kasire Riyah*, *Musakkinat-e-Alam*, *Murakkhi*, *Muhallil* and *Muqawwiyat-i-A'sab* advia. [12,16,17] USM describes several single drugs and compound formulations for the treatment of *Waja-ul-Khasirah* which is a *Balghami* disease and occurs due to the predominance of *Balgham* or *Buroodat* in the body. So, the drugs with *Haar Yabis mizaj* contain a non-pharmacopeial oral Unani formulation (*Suranjan Shireen*, *Bozidan*, *Hanzal*, *Ghariqoon*, *Sibr*, *Turbuth*, *Muqil*) [18] and *Roghane Suranjan* [19,20] were selected. They does *Tanqiae mawaad* of *Balgham-e-khaam* by their *Munzij*, [21-23] *Mus'hil*, [22-24] *Muhallil*, [22,24-26] *Mulattif* [22-24] and *Mudirr-i-Bawl* [12,22,23,27-29] properties and also possess analgesic (*Musakkin-i-Alam*), [22,23] Muscle relaxant (*Murkhiy-i-Azlaat*), [12,30] anti-inflammatory [25,28,31] and carminative (*Kasire Riyah*) [22,23,32] properties. Pharmacological studies suggest that the ingredients of these formulations may acts as analgesic, anti-inflammatory and hepatoprotective. Hence, based on the effects and indications of the formulations it is hypothesised to validate scientifically. Though, chronic LBP may not be curable but can be surely made bearable by bringing down the symptoms like pain, stiffness and difficulty in movements (symptoms modification), with this background, this study was conducted to test the hypothesis that there is a difference between non-pharmacopoeial oral Unani formulation and *Roghane Suranjan* in relation to efficacy with the objective to provide relief in LBP, stiffness in the back, difficulty in movement and improvement in QoL in the management of *Waja-ul-Khasirah*.

2. MATERIALS AND METHODS

A Randomised single blind double-dummy placebo controlled clinical trial was carried out at National Institute of Unani Medicine Hospital, Bengaluru, over a period of 10 months from March 2016 to Jan 2017 after obtaining ethical clearance from Institutional Ethical Committee for Biomedical research vide IEC No. **NIUM/IEC/2014-2015/003/MOAL/03 Dated 16th April 2015**. The study protocol was in compliance with the Declaration of Helsinki.

2.1 Inclusion and exclusion criteria: In this study, clinically and radiologically diagnosed cases of intervertebral disc space reduction, disc bulge, disc prolapse or listhesis at L3-L4, L4-L5 and L5-S1 with or without radicular symptoms of both gender, between the age of 18-55 years, and patients who will give consent and able to do follow up were included. Whereas unstable, bed-ridden and mentally retarded patients, age below 18 and above 55 years having LBP due to trauma and other than disc bulge/ prolapse, patients of Gout and RA, patients with past history of Surgery, systemic illnesses like HTN, DM, TB and Malignancy, pregnancy and lactating women were excluded.

2.2 Sample size calculation: A power calculation was performed to determine the required number of patients. It was predicted that a sample size of 40 patients would be sufficient to detect a change of 5% with a power of 80% and α=0.05 with 20% dropouts. Thus, sample size predicted was 40 (20 patients in each group). [33]

2.3 Study Intervention: A non-pharmacopoeial oral Unani formulation and Roghane Suranjan. (Table No.1,2) [18-20]

Table No. 1: Composition of non-pharmacopoeial oral Unani formulation [18]

Names	Botanical Names	Quantity
Suranjan Shireen	Colchicum autumnale	0.75gms
Bozidan	Pyrethrum indicum	0.75gms
Hanzal	Citrullus colocynthis	0.75gms
Ghariqoon	Agaricus alba	1.75gms
Sibr	Aloe barbadensis	1.75gms
Turbuth	Operculina turpethum	3.5gms
Muqil	Commiphora mukul	3.5gms

Table No. 2: Composition of *Roghane Suranjan* [19,20]

Unani Names	Botanical Names	Quantity
Tukhme Karafs	Apium graveolens	100gms
Chiraita Shireen	Swertia chirata	50gms
Suranjan Talkh	Colchicum luteum	100gms
Tilon ka Tail	Sesamum indicum	1lit.+350ml

2.4 Method of preparation, dosage and route of administration of test drugs:

2.4.1 Collection and identification of drugs: All the ingredients of test drugs were obtained from NIUM pharmacy, after duly authentication, the compounding of drugs was made under the supervision of chief pharmacist as per the methods described in classical Unani texts. [18-20]

2.4.2 Method of preparation of oral Unani formulation: All dried crude drugs viz. *Suranjan Shireen*, *Bozidan*, *Hanzal*, *Ghariqoon*, *Sibr*, *Turbuth*, *Muqil* were cleaned by weeding out unwanted materials and then powdered by separating impurities and filled in capsules (800mg each) and packed in transparent, airtight plastic lock bags.

2.4.3 Method of preparation of *Roghane Suranjan*: All dried crude drugs viz. *Tukhme Karafs*, *Chiraita Shireen*, *Suranjan Talkh* were cleaned by weeding out unwanted materials and then gently crushed by separating impurities. Then the crushed drugs were left to soak in water (ten times greater than the total quantity of drugs in weight) for whole night. Next morning, the water soaked drugs were boiled to get decoction by evaporating half the volume of water and filtered it after cooling. Later, *Roghane Kunjad* (in the given quantity) heated in another vessel, and decoction were poured into it slowly and allowed it to heat till whole water gets evaporated and to get homogenous oil. Lastly, the oil was filtered and stored in dry, clean and transparent plastic containers.

2.4.4 Method of preparation of placebo: Wheat flour was filled in the capsules (800mg each) and packed in transparent, airtight plastic lock bags, whereas, *Roghane Kunjad* (placebo oil), served in dry, clean and transparent plastic containers.

2.4.5 Dose and dosage: Both groups were given 03 capsules of 800mg thrice a day orally with Luke warm water and 15 ml of

oil for local application on lumbo-sacral region with gentle massage daily twice a day for 21 days.

2.5 Study Procedure: A total of 280 patients of LBP were screened, out of which 192 patients not fulfilling the inclusion criteria and 46 patients declined to participate in the study. Finally a total of 42 patients enrolled after obtaining written informed consent and randomly assigned to group A {non-pharmacopoeial oral Unani formulation (test drug) + placebo oil; n=21} or group B {Placebo oral + *Roghane Suranjan* (test drug); n=21}. During the selection procedure, detailed general and specific history was recorded in a predesigned proforma (CRF) according to the objectives of the study and patients were graded into different SES by using Kuppuswamy's SES (Modified for 2014). After history taking, each patient was subjected to comprehensive general physical, systemic and local (Lumbo-sacral spine) examination. Investigations like Haemogram with ESR, ALT, AST, Blood Urea, Serum Creatinine were carried out in all enrolled patients before (at 0^{th} day) and after (at 21^{st} day) completion of treatment. Whereas X-ray LS-spine, RBS, Urine analysis was done only before treatment with the aim to exclude the patients if found with any pathological conditions as per the exclusion criteria. Both groups were treated for 21 days with 03 weekly (0^{th}, 7^{th}, 14^{th}, 21^{st} day) and one post treatment follow up (28^{th} day) to see any residual effect of drug (total duration of protocol = 28 days). In both treatment groups, 1-1 patient was dropped out and did not turn up for the 1^{st} follow up (7^{th}day) whereas, 02 patients in both groups were took the intervention for 21 days but did not turn up for the post test. Hence, they were assumed as lost to follow up (LFU). The details are depicted in flow chart. (Fig. No.1: CONSORT flow chart)

2.6 Randomization, Blinding and concealment of allocation: The enrolled patients were randomly allocated (1:1) in to two parallel groups; the group A (n=21) and group B (n=21), by using computer generated randomization method using Graph pad software. [34] Moreover, both capsules and oils were supplied in the visually identical forms; the patients were blinded to the study groups over the study period.

2.7 Study outcomes: Primary outcome measures was assessed by the severity of subjective parameters like LBP was documented based on the Visual Analog Scale (VAS) which is a standard tool like a 10 cm numerical Likert scale comprises 0-10 cms, where 0 represent no pain and 10 represent worst pain. The magnitude of pain increases as numerical values of scale increases. Further, this scale allows categorical consideration of pain intensity in terms of grades such as Grade 0 (None), Grade 1 (Mild 1-3), Grade 2 (Moderate >3-7), Grade 3 (Severe >7-10). The patients were asked to choose one of them according to their pain severity and the number shown on the ruler was considered as pain score. Whereas, Stiffness in the back and Difficulty in movements were assessed with 4 point Likert arbitrary grades scale where Stiffness in the back is marked as Grade 0-None, Grade 1- Mild; Barely Perceptible; can carry out daily activities, Grade 2-Moderate; can carry out daily activities with some trouble, Grade 3- Severe; cannot carry out daily activities easily) and similarly for Difficulty in movement also considered Grade 0- No difficulty in movement, Grade 1- Mild; Difficulty in movement associated with moderate work, Grade 2- Moderate; Difficulty in movement associated with mild work, Grade 3- Severe; Difficulty in movement at rest. Secondary outcome measures were assessed by ODI (Revised Oswestry Disability Index) [2,4,35] and Quebec Back Pain Disability Scale. [2,4]

2.8 Adverse events documentation: No adverse effect reported during and after study in both treatment groups.

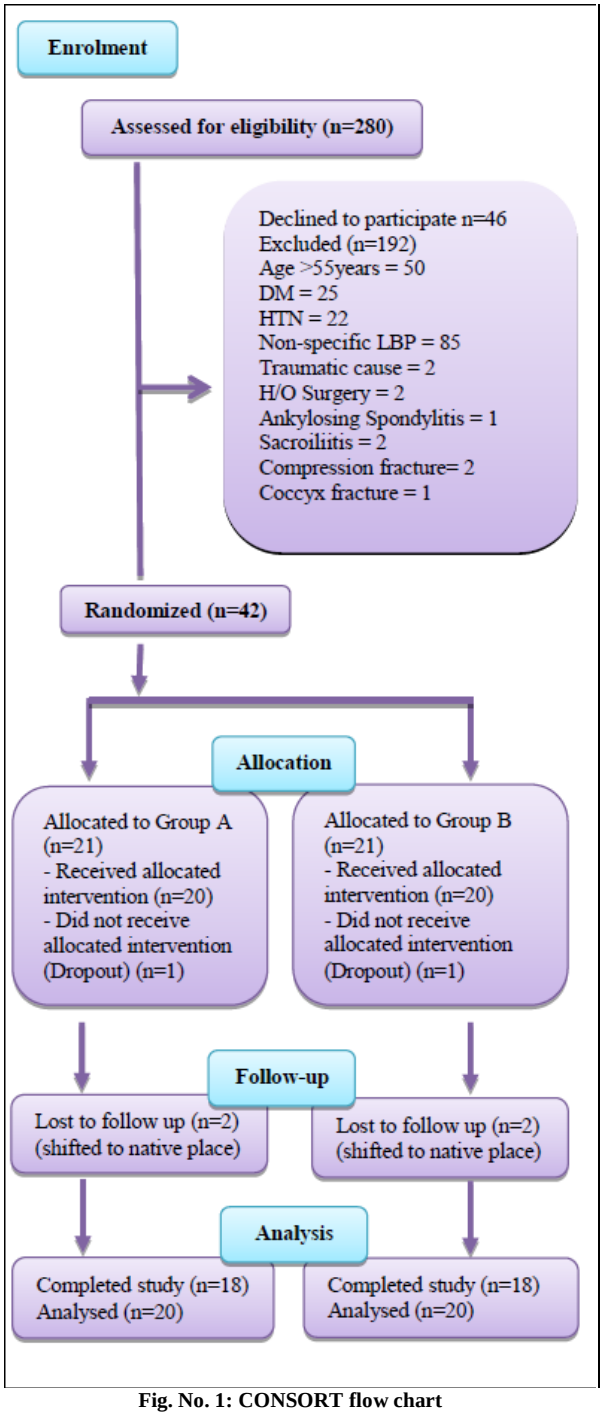

Fig. No. 1: CONSORT flow chart

3. Statistical Methods: Statistical analysis was done by using SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0, R environment ver.2.11.1 and Graph Pad software. Microsoft word and Excel have been used to generate graphs, tables etc. Efficacy analysis was performed on an intention to treat (ITT) basis using the last observation carry forward method (LOCF) on patients that received all the doses of both test drug and placebo including non-pharmacopoeial oral Unani formulation and *Roghane Suranjan*, and that underwent at least two assessment post baseline (n=40). Changes in various parameters were assessed for statistical evaluation by using Fisher's exact, Chi-square, Friedman, Kruskal-Wallis test (on categorical scale, non-parametric setting for qualitative data analysis) whereas, Repeated measures ANOVA and One way ANOVA with Tukey post hoc multiple comparison test (on continuous scale) for both intergroup and intragroup analysis at every follow-up (0^{th}, 7^{th}, 14^{th}, 21^{st} and 28^{th} day). Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). P values of less than 0.05 were considered statistically significant. [33,36]

4. RESULTS

4.1 Demographic Data: This study evidences 28 males (70%) and 12 females (30%); with mean age of 37.83±9.29 years, 30(75%) married and 10(25%) unmarried, SES wise 21(52.5%) belongs to lower middle, 19(47.5%) semi-skilled occupation group, with BMI of 27.12±4.96 kg/m^2 and 25(62.5%) patients presented with Disc bulge at L4-L5 level with chronicity of illness of 21.23±11.75 months, having radicular pain 34(85%) patients. (Table No. 3)

4.2 Primary outcome measures: Relief in LBP, stiffness of the back and difficulty in movements were significantly achieved in 65% and 95% patients of group A whereas, 40% and 70% patients of group B respectively with $p<0.001$ (intragroup). Moreover, stiffness in the back was completely relived (100%) in patients of group A as compared to group B (90%) with $p<0.001$ (intragroup). (Table No.4,5)

Table No. 3: Demographic Data; Test used: Student't' test, Chi-Square test, Fisher's Exact test

Sr. No	Demographic Parameters	Group A	Group B	Mean ± SD	p value
1	**Age (in Years):** 20-30 31-40 41-50 51-60	 6(30%) 5(25%) 8(40%) 1(5%)	 6(30%) 8(40%) 4(20%) 2(10%)	37.83± 9.29	p=0.960
2	**Gender:** Male Female	 15(75%) 5(25%)	 13(65%) 7(35%)		p=0.490
3	**Marital status:** Married Unmarried	 14(70%) 6(30%)	 16(80%) 4(20%)		p=0.465
4	**Socioeconomic status:** Upper (I) Upper Middle (II) Lower Middle (III) Upper Lower (IV)	 2(10%) 3(15%) 10(50%) 5(25%)	 1(5%) 4(20%) 11(55%) 4(20%)		p=1.000
5	**Occupation:** SK (skilled) SS (semiskilled) US (unskilled)	 6(30%) 9(45%) 5(25%)	 3(15%) 10(50%) 7(35%)		p=0.601
6	**BMI (Kg/m^2):** <18.5 18.5-25 25-30 >30	 1(5%) 6(30%) 8(40%) 5(25%)	 1(5%) 4(20%) 11(55%) 4(20%)	27.12± 4.96	p=0.648
7	**Duration of illness (in months):** <6 6-12 12-24 >24	 1(5%) 5(25%) 5(25%) 9(45%)	 2(10%) 8(40%) 6(30%) 4(20%)	21.23± 11.75	p=0.130
8	**Distribution of pain:** NR (non-radiating) R (radiating)	 4(20%) 16(80%)	 2(10%) 18(90%)		p=0.661
9	**Radiological findings:** IVD Space reduced(L5-S1) Listhesis (L5-S1) Disc Bulge: L3-L4 L4-L5 L5-S1 Disc Prolapse(L5-S1)	 1(5%) 1(5%) 2(10%) 13(65%) 3(15%) 0(0%)	 1(5%) 1(5%) 2(10%) 12(60%) 3(15%) 1(5%)		

Table No. 4: Effect of drugs on Subjective Parameters; Test Used: Friedman test for intra group and Kruskal-Wallis test for inter group comparison: Median (Min, Max); *p<0.001 with respect to BL (Intragroup); In both groups: F3-F4: p>0.05 (Non-Significant)

	Assessment days		**RE**
	BL	**F3**	**F3-F4**
LBP (VAS in Grades)			
Group A (n=20)	**3(3,3)**	**1(0,2)***	**1(0,2)**
Group B (n=20)	**3(3,3)**	**2(0,2)***	**1(0,2)**
Stiffness in the back			
Group A (n=20)	**2(2,3)**	**0.5(0,1)***	**0(0,1)**
Group B (n=20)	**2(2,3)**	**0.5(0,2)***	**0(0,2)**
Difficulty in movements			
Group A (n=20)	**2(2,3)**	**1(0,2)***	**1(0,1)**
Group B (n=20)	**2(2,3)**	**1(0,2)***	**1(0,2)**

4.3 Secondary outcome measures: This is achieved by improvement in QoL assessed by ODI and QBPDS. The ODI showed improvement in disability of 85% patients in group A and 70% in group B with significant mean difference of 13.05 in patients of group A as compared to group B (11.70). The QBPDS assessment showed significant reduction of LBP associated disability (with 15 points difference) in all 20 patients of group A with significant mean difference of 22.45 as compared to group B where significant reduction of LBP associated disability was noted in only 18 patients with significant mean difference of 19.75. (Table No. 6-8).

Table No. 5: Effect of drugs on Subjective parameters; Test used: Chi-square test /Fisher's Exact test

	Group A (n=20)			Group B (n=20)		
	BL	F3	% change	BL	F3	% change
LBP (in Grades)						
0 (None)	0(0%)	1(5%)	5.0%	0(0%)	1(5%)	5.0%
1 (Mild)	0(0%)	12(60%)	60.0%	0(0%)	7(35%)	35.0%
2 (Moderate)	0(0%)	7(35%)	35.0%	0(0%)	12(60%)	60.0%
3 (Severe)	20(100%)	0(0%)	-100.0%	20(100%)	0(0%)	-100.0%
Stiffness in the back						
0 (None)	0(0%)	10(50%)	50.0%	0(0%)	10(50%)	50.0%
1 (Mild)	0(0%)	10(50%)	50.0%	0(0%)	8(40%)	40.0%
2 (Moderate)	19(95%)	0(0%)	-95.0%	17(85%)	2(10%)	-75.0%
3 (Severe)	1(5%)	0(0%)	-5.0%	3(15%)	0(0%)	-15.0%
Difficulty in movements						
0 (None)	0(0%)	2(10%)	10.0%	0(0%)	3(15%)	15.0%
1 (Mild)	0(0%)	17(85%)	85.0%	0(0%)	11(55%)	55.0%
2 (Moderate)	14(70%)	1(5%)	-65.0%	13(65%)	6(30%)	-35.0%
3 (Severe)	6(30%)	0(0%)	-30.0%	7(35%)	0(0%)	-35.0%

Table No. 6: Effect of drugs on Objective Parameters; Test used: Repeated measures ANOVA with post – test for intragroup and One – way ANOVA for intergroup comparison with Tukey – Kramer multiple comparison test; * $p<0.001$ with respect to BL (baseline); In both groups: F3-F4: $p>0.05$ (Non-Significant)

	Assessment days		RE	Mean Difference
	BL	**F3**	**F3-F4**	**BL-F3**
ODI Scores				
Group A (n=20)	**28.80±3.72**	**15.75±3.95***	**14.80±4.29**	**13.05**
Group B (n=20)	**30.40±4.08**	**18.70±4.08***	**18.10±4.05**	**11.70**
QBPDS Scores: (Total)				
Group A (n=20)	**63.50±9.84**	**41.05±9.65***	**39.75±10.03**	**22.45**
Group B (n=20)	**67.30±7.55**	**47.55±8.31***	**46.90±9.17**	**19.75**

Table No. 7: Assessment of QBPDS (Significant Disability Change)

QBPDS (Significant Disability Change)	No. of Patients with Greater Disability	No. of Patients with Significant Reduction (with 15 points difference) From BL-F3
Group A	**20**	**20**
Group B	**20**	**18**
Total	**40**	**38**

Table No. 8: Assessment for Disability: ODI Scores: In %; Test used: Chi-Square test / Fisher's Exact test

ODI Scores: (in %)	Group A (n=20)			Group B (n=20)		
	BL	F3	% change	BL	F3	% change
0-20 (minimal Disability)	0(0%)	1(5%)	5.0%	0(0%)	0(0%)	0.0%
21-40 (moderate Disability)	1(5%)	17(85%)	80.0%	0(0%)	14(70%)	70.0%
41-60 (Severe Disability)	13(65%)	2(10%)	-55.0%	7(35%)	6(30%)	-5.0%
61-80 (Crippled Disability)	6(30%)	0(0%)	-30.0%	13(65%)	0(0%)	-65.0%
81-100 (Bed-bound Disability)	0(0%)	0(0%)	0.0%	0(0%)	0(0%)	0.0%

Analyses of the primary and secondary outcome measures evidences a higher effectiveness of non-pharmacopoeial oral Unani formulation (group A) compared to *Roghane Suranjan* (group B), in terms of improvement in LBP and QoL in the patients of *Waja-ul-Khasirah.*

5. DISCUSSION

Waja-ul-Khasirah occurs due to accumulation of *Akhlate fasidah* (mainly *Ghair Tabayi Balgham*) in the joint structures of lumbosacral region which leads to *Su' Mizaj Barid* (*Su' Mizaj Mukhtalif*). Pressure exerted on these structurs (such as capsules, tendons, ligaments, blood vessels etc.) due to accumulated *Riyah*, *Akhlate fasidah*, disc bulge, disc prolapse, listhesis, osteophytes, trauma or by simple *Su' Mizaj Mukhtalif*, give rise to pressure symptoms (LBP). Back stiffness may be due to the spasm in joint structures like tendons, capsules etc. due to *Buroodat* while difficulty in movements may be directly related to pain and stiffness in the lower back. [12,13,37]

Aforementioned significant results are credited to the medicinal properties of these Unani formulations. *Mizaj* (Temperaments) of all drugs are *Haar Yabis* and possess *Munzij* and *Mus'hil-e-Balgham*, *Mulattif*, *Kasire Riyah*, *Muhallil* and

Mudirr-e-Bawl properties by which they does *Istifragh* (evacuation) and *Imala* (diversion) of vicid and sticky matter, removal of excessive *Buroodat* and *Riyah* from the joint structures of lumbosacral region and also attributed to the *Musakkine Alam, Murakkhi, Musakhkhin wa Muqawwie A'sab* properties by which it relieved *Waja-ul-Khasirah* and does restoration and normalization of *Mizaj-e-Tabayi* by eliminating the causes. [12,22-24,27-30]

Several in vitro and in vivo pharmacological studies have been reported that these Unani formulations possess proven analgesic, anti-inflammatory, diuretic and hepatoprotective properties. These effects are achieved by reducing the release of pro-inflammatory cytokines of IL-6, IL-1β, histamine, serotonin, prostaglandins (COX-2) and elevating the level of anti-inflammatory cytokine IL-4. These pharmacological properties may be attributed to the organ chemical composition: alkaloids, iridoids, steroids, flavonoids (apiin) and glycosides such as chrysanthemin, citrullin, agaricin, turpethin, amarogentin, chiratin and colchicine. [22,23,25,31,32,37-42]

A clinical trial was conducted with the same Unani formulation used in a dose of 2 tablets of 800mg thrice a day for 15 days among the cases of OA Knee with obesity. Study outcome was assessed with *Lequesne Index* for the severity of Knee joint pain and the study reported significant difference in pain and discomfort of knee joint with the p-value <0.001. [43]

Limitation: Study limitations were smaller sample size and short duration of therapy with subjective bias in relation to intensity and severity of LBP, Back stiffness and Difficulty in movement while assessing the disability and QoL.

Future Recommendation: Further controlled clinical trials with more comprehensive study designs on large sample size needed to be undertaken to validate further.

6. CONCLUSION

Unani formulations were well tolerated with no adverse effect was reported and the safety parameters were within normal limits. Based on this result, it can be inferred that Unani formulations are effective in the management of *Waja-ul-Khasirah* (Low Back Pain) related LBP, stiffness in the back and difficulty in movements with improvement in overall QoL of the sufferers.

Conflict of interest: The authors have no conflicts of interest that are directly relevant to the content of this study.

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REFERENCES

1. Maharty DC. "The history of lower back pain: a look "back" through the centuries". Prim. Care. 2012; 39 (3): 463–70.
2. Longo UG, Loppini M, Denaro L et al. Rating scales for low back pain. British Medical Bulletin. 2010; 94: 81–144.
3. Hoy D, Brooks P, Blyth F et al. The epidemiology of low back pain. Best Practice & Research Clinical Rheumatology. 2010; 24: 769–81.
4. Gupta S. Examining clinimetric and psychometric properties of disability assessment scales for low-back pain: exploring possibilities for adaptation to Indian context. The Indian Journal of Occupational Therapy. 2015; 47 (2): 38-45.
5. Ahdhi GS, Subramanian R, Saya1 GK et al. Prevalence of low back pain and its relation to quality of life and disability among women in rural area of Puducherry, India. Indian Journal of Pain. 2016; 30 (2): 111-15.
6. Aliyu SU, Istifanus UW, Oyeyemi AY et al. Prevalence of low back pain among peasant farmers in a rural community, North Eastern Nigeria. AARJMD. 2014; 1 (27). 64-78.
7. Biglarian A, Seifi B, Bakhshi E et al. Low back pain prevalence and associated factors

in Iranian population: Findings from the National Health Survey. Pain Research and Treatment. 2012; 1-5.
8. Silva MROGCM, Badaró AFV, Dall'Agnol MM. Low back pain in adolescent and associated factors: A cross sectional study with schoolchildren. Braz J PhysTher. 2014; 18(5): 402-409.
9. Williams NS, Bulstrode CJK, O'Connell PR. Bailey & Love's Short Practice of Surgery. 25th edn. London: Hodder education, Hachette UK company; 2008. p.467-71.
10. Manchikanti L. Epidemiology of Low Back Pain. Pain Physician. 2000; 3 (2): 167-92.
11. Jamil SS, Ahmad Z, Siddiqui KM et al. Standard Unani Medical Terminology. New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt. of India; 2012. p.290, UMA-1082.
12. Sina I. Al Qanoon Fil Tib (Urdu translation by Kantoori GH). New Delhi: Idara Kitabul Shifa; YNM. p.45-46, 75, 125-29, 203, 343-4, 406, 435-6, 481-82, 1114-19.
13. Jurjani AH. Zakheera Khwazam Shahi (Urdu translation by Khan HH). Vol 1 & 6. New Delhi: Idara Kitabul Shifa; 2010. p.37-39, 76, 635-36.
14. Childs MJD, Fritz JM, Flynn TW et al. A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: A validation study. Annals of Internal Medicine. 2004; 141 (12). 920-28.
15. Munjal YP. API Text Book of Medicine. 9thedn. Mumbai: The Association of Physicians of India; 2012. p.1813-17.
16. Shah HM. The General Principles of Avicenna's Canon of Medicine. New Delhi: Idara Kitabul Shifa; 2007. p. 353, 508-512.
17. Nafees B. Tarjuma wa Sharah Kulliyate Nafeesi (Urdu Translation By M Kabeeruddin). New Delhi: Idara Kitabul Shifa; 1954. p.161-78, 376, 380-81, 387, 453-54, 460-62.
18. Majoosi AHABA. Kamil-ul-Sana'a (Urdu translation by Kantoori GH). Vol 1 & 2. New Delhi: Idara Kitabul Shifa; 2010. p.510, 512, 465-68, 543-45.
19. Hamdard D, All India Unani Tibbi Conference. Qarabadeen Majeedi. Delhi: Ajanta Offset& Packaging Ltd.; 1986. p.158.
20. Said HM. Hamdard Pharmacopoeia of Eastern Medicine. 2ndedn (Re-print). Delhi: Sri Satguru Publications; 1997. p.146.
21. Kirtikar KR, Basu BD. Indian Medicinal Plants. 2nd edn. Vol 1. Dehradun: International book distributors; 2006. p.526-28.
22. Ghani HN. Khazainul Advia. 2ndedn. New Delhi: Idara Kitabul Shifa; 2011. p.206-8, 281-83, 308-12, 402, 595-96, 861-63, 958-59, 1154-56, 1313-15.
23. Almaghribi ASBI. Kitabul Fateh Fil Tadawi (Urdu translation). 1st edn. New Delhi: NCPC printers; 2007. p.72-3, 110-11, 128-29, 146-47, 166-68, 188-89, 216-17, 234-35.
24. Khan HMA. Muheete Azam (Urdu translation).Vol 3.New Delhi: CCRUM; 2012.p.194-97, 634-38, 430-36.
25. Baghdadi IH. Al Mukhtaraat Fil Tib (Urdu translation). Vol 2. New Delhi: CCRUM; 2007. p.81, 139, 188-89, 209, 239-40, 293-94.
26. Kirtikar KR, Basu BD. Indian Medicinal Plants. 2nd edn. Vol 3. Dehradun: International book distributors; 2006. p.1730-32, 1664-66.
27. Chopra RN. Glossary of Indian Medicinal Plants. New Delhi: NISCIR; 2002. p.9, 13, 21-22, 62-63, 67, 73, 75, 181, 201, 208, 237.
28. Khare C.P. Indian medicinal plants- An illustrated dictionary. New Delhi: Springer; 2007.p.24, 36-37, 56-57, 79, 144-45, 152-53, 165-66, 168, 449-50, 632.
29. Nadkarni KM. Indian Materia Medica. Vol 1. Mumbai: Popular Prakashan Pvt. Ltd.; 2009. p.50-51, 73-74, 167-70, 335-37, 691-94, 1037, 119-20, 369-70, 1184-85.
30. Kirtikar KR, Basu BD. Indian Medicinal Plants. 2nd edn. Vol 4. Dehradun: International book distributors; 2006. p.2504-06, 2524-25, 2757.
31. Ghosh AK, Banerjee M, Mandal TK et al. A study on analgesic efficacy and adverse effects of Aloe Vera in Wistar Rats. Pharmacology online. 2011; 1: 1098-1108.
32. Kirtikar KR, Basu BD. Indian Medicinal Plants. 2nd edn. Vol 2. Dehradun: International book distributors; 2006. p.1147-49, 1199-1201, 1380-81.
33. Suresh KP, Chandrasekhar S. Sample Size estimation and Power analysis for Clinical research studies. Journal of Human Reproductive Sciences. 2012; 5(1):7-13.

34. http://graphpad.com/quickcalcs/randomize2/ randomization accessed on 08.6.2016.
35. Fairbank JCT, Pynsent PB. The Oswestry Disability Index. Spine. 2000; 25 (22): 2940-53.
36. Rao PSSS, Richard J. An Introduction to Biostatistics A manual for students in health sciences. 4th edn. New Delhi: Prentice hall of India; 2006.p.86-160.
37. Razi ABMBZ. Kitab al-Hawi. Vol-11th. New Delhi: CCRUM, Ministry of Health and Family Welfare, Govt of India; 2004.p.114.
38. Marzouk B, Marzouk Z, Fenina N et al. Anti-inflammatory and analgesic activities of Tunisian Citrullus colocynthis Schrad. Immature fruit and seed organic extracts. European Review for Medical and Pharmacological Sciences. 2011; 15: 665-72.
39. Al-Snafi AE. Chemical constituents and pharmacological effects of Citrullus colocynthis - A review. IOSR Journal of Pharmacy. 2016; 6 (3): 57-67.
40. Arzi A, Hemmati AS, Karampour NS et al. Anti-inflammatory effects of Celery Seed Hydroalcoholic extract on Carrageenan-induced pawedema in rats. RJPBCS. 2014; 5(6): 24-29.
41. Prabhavathi NB, Kowsalya B, Kumar SR et al. Analgesic activity of different solvent extract of Operculina turpethum by using Swiss albino mice. Asian J Pharm Clin Res. 2012; 5 (3): 215-18.
42. Kumar V, Staden JV. A review of Swertia chirayita (Gentianaceae) as a Traditional medicinal plant. Front. Pharmacol. 2016; 6 (308): 1-14.
43. Razana MCN, Quamri MA. A Clinical Trial Based Study Outcome of Osteoarthritis Knee with Lequesne Index. IJRSR. 2016; 7(1): 8518-22.

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