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Original Research Article

Efficacy of *Habb-e-Hindi* in low back pain: a comparative clinical trial with historical control

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ABSTRACT

Background: Low Back Pain is one of the common conditions encountered in clinical practice. An estimated 65% to 80% of population will experience it during lifetime. As far as the various documented side effects of analgesics and NSAIDs have been concerned, complementary and alternative treatment options have, therefore, gained popularity. In Unani classical literature, *Habb-e-Hindi* is being indicated for joint's pain in general and can be evaluated as safe, effective and alternative treatment of LBP.
Methods: This historical control clinical trial testing the superiority of *Habb-e-Hindi* with Unani formulation used in previous study carried out at NIUM Hospital, Bengaluru. The comparison of the efficacy was made between the test group and historical control group. Primary outcome measures were improvement in LBP (VAS in NRS) and the secondary outcome measures included improvement in QOL (ODI scores and QBPDS scores). Data were analyzed by using Fisher's Exact/Chi-Square/Repeated measures and One-way ANOVA with Tukey post hoc multiple comparison test for both intergroup and intragroup comparisons.
Results: The test and the control group both equally had significant results. Test drug showed better results (in VAS). LBP associated disability (in ODI) got reduced significantly in control group as compared to the test group. The Significant Disability Change (in QBPDS) was recorded in all 20 patients of the control group as compared to that of the test group where only 4 patients showed significant reduction.
Conclusions: The results of this study suggest that the Unani formulations are effective in the treatment of Low back pain.

Keywords: Low back pain, *Habb-e-Hindi*, Unani medicine, Joint's pain, Historical control

INTRODUCTION

The vertebral column forms the central axis comparable to a pillar, which forms the main support for the bones and muscles. It is specially adapted to protect the spinal cord and to support the weight of the body and transmits the same to the ground through the pelvic girdle and inferior extremities.[1] It is generally accepted that the S-shape of the vertebral column is a consequence of the upright position.[2] Around 20,000 years ago the Neanderthal men did not suffer from low back pain, because they were not yet fully vertical. Low back pain is defined by the location of pain, typically between the lower rib margins and the buttock creases.[3]It was generally considered a problem restricted to Western countries; but, since then, growing research has shown

that it is also a major problem in low and middle-income countries. About 90% of people worldwide suffering from it at some point in their lives. Pharmacologic options include non–steroidal anti-inflammatory drugs (NSAIDs) and muscle relaxants. NSAIDs have known gastrointestinal, renal and cardiovascular side effects apart from upper gastrointestinal (GI) ulcers and associated bleeding are the most common serious adverse events.[4] Therefore**,** a clinical trial was contemplated to evaluate and validate the efficacy and safety of *Habb-e-Hindi* on scientific parameters and secondarily to compare the effectiveness was compared with the historical control. The Study outcome was assessed with subjective and objective parameters; VAS, ODI for LBP and QDI, and the data were recorded at the baseline and after every 4 weekly follow-ups. It can be concluded that the effect of test drug (*Habb-e-Hindi*) is found effective in low back pain without any adverse effect. Therefore, it is proved that the Null hypothesis is rejected

METHODS

The clinical study was carried out at Hospital of National Institute of Unani Medicine, Bangalore from Jan 2019 to Sept 2019 after obtaining ethical clearance from Institutional Ethical Committee (IEC) for Biomedical Research with IEC No. NIUM/IEC/2017-18/005/Moal/05 on 19/07/2018 and also approved by the CTRI vide No. CTRI/2019/02/017453. The study protocol was developed following the ethical standard of Good Clinical Practice and the Declaration of Helsinki.

Inclusion criteria

Patients of both the sexes; age group ≥18 to ≤45 years; LBP with a duration of less than 5 years; clinically and radiologically (X-Ray/MRI/CT) diagnosed cases of low back pain (intervertebral disc space reduction, disc bulge, disc prolapse, canal stenosis) with pathology at the level of L3-L4, L4-L5, L5-S1 without radicular symptoms were included.

Exclusion criteria

Age group <18 years and >45 years; H/o Trauma (Back); H/o Surgical Interventions for LBP; pregnant and lactating women; obesity Grade-IV; any recent epidural glucocorticoids, anaesthetics, or opioids; K/c/o Systemic or metabolic disorder; low back pain other than the spinal pathology mentioned above (intervertebral disc space reduction, disc bulge, disc prolapse, canal stenosis); congenital deformities of the spine were excluded.

Subjective parameters

VAS: Visual analogue scales (VAS) have been used in the social and behavioral sciences to measure a variety of subjective phenomena.[5] Patients were asked to indicate their pain intensity on a 10 cm line when using the VAS and the number that indicates the pain intensity when using the NRS.

Objective parameters

ODI for LBP: The ODI consists of 10 items and responses for each item range from 0 (least disable) to 5 (most disable), with the final score created by adding the scores for the answers to each item (0 to 5) and multiplying by 2, for a final score from 0 to 100.[6]

QDI: The scale exists of one central question: "Do you have trouble today with...?" followed by 20 activities of daily life.[7]

Duration of protocol

The treatment was given for 28 days with four follow-ups i.e. (0), 7th day, 14th day, 21st day and on 28th day.

Sample size

The sample size has been derived using the formulae.[8]

$$N= (Z_{1-\alpha/2} +Z_{1-\beta})^2\times (S_1+S_2)/ (X_1-X_2)^2$$

Based on the parameter i.e., ODI of the historical control group. The sample size of 20 subjects would be sufficient to detect a change of 5% with a power of 80% and alpha 0.05 with 20% dropouts. The sample size of 20 subjects was predicted.

Treatment procedure and follow up

Follow-ups were scheduled for 7th, 14th, 21st, and 28th day after including them for the assessment of disease progression or regression in symptoms.

Assessment of Mizaj

In each selected patient mizaj was assessed based on the *Ajnase Ashra* mentioned in Unani literature. Separate temperament assessment Performa has been enclosed with each case report form.

Investigation

Certain laboratory investigations were carried out before (0th day) and after (28th day) the completion of the trial to exclude the patients, if found, with any pathological condition as per the exclusion criteria. Moreover, to establish the safety of the intervention used, the following investigations were carried out: Haemogram with ESR, RBS, LFT (ALT, AST, Alk. Phos.), KFT (Blood Urea, Sr. Creatinine), Urinalysis (Routine and Microscopic) and ECG**.**

Allocation of patients

A total of 45 subjects were screened for the study. Out of this, 19 subjects did not meet the inclusion criteria and 4

declined to participate, finally, 22 subjects were enrolled in the study. All study participants were first assessed to safety profile and then after taking baseline measurements, were given the test drug *Habb-e-Hindi* orally in three divided doses. After the first follow-up i.e., 7th day, 3 participants lost to follow up. They were assumed as lost to follow up and evaluated using the last observation carried forward method according to the intention-to-treat principles. 19 subjects completed the study but 20 subjects were analysed statistically.

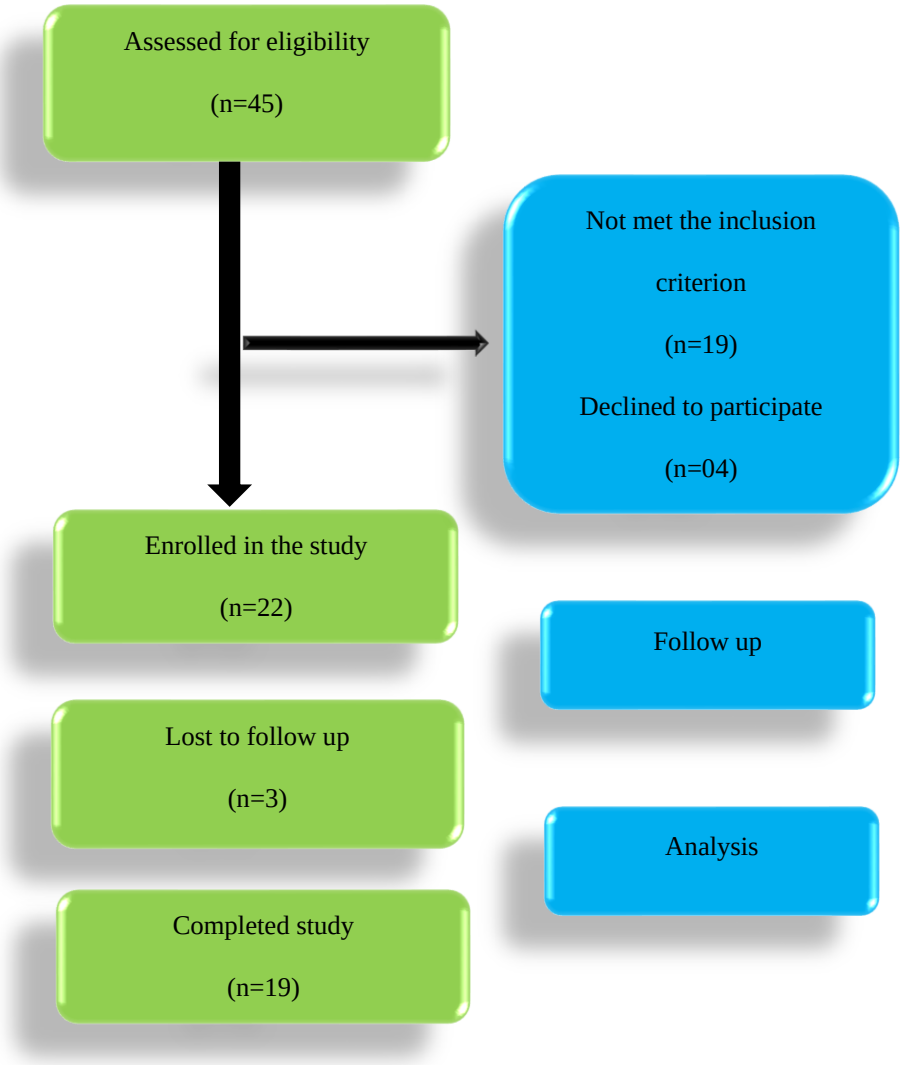

Figure 1: CONSORT flow chart.

RESULTS

Demographic data

This study enrolled 14 females (70%) and 6 males (30%); with age ranging from 18 to 55 years with an average age of 40.55±7.80 years; 19(95%) married and 1(5%) unmarried; 9(45%) with an average BMI of 27.37±4.32 kg/m^2 (Table 1).

Assessment parameters

These parameters were statistically analysed by using the Chi-Square test/Fisher Exact test and Repeated measures ANOVA with post-test for intragroup and One-way ANOVA for intergroup comparison with Tukey-Kramer multiple comparison test respectively (Table 2).

Subjective parameters

VAS: The test and the control group both equally had significant results but test drugs showed better results after the first follow-up ($p<0.001$) as compared with that of the control group ($p<0.01$).

Objective parameters

ODI scores: In both groups, the residual effect of Unani formulations was equally significant ($p<0.0001$) which means that the ODI scores were improved. There was a significantly better improvement in QOL of Control

Group patients with mean difference 13.05 as compared to the test group (6.9) which means the control group seems to be more effective in improving QOL.

Table 1: Demographic data.

Variables	No. of patients		
		Test	Control
Age		40.55±7.80	37.75±10.05
Gender	Male	6 (30%)	15 (75%)
	Female	14 (70%)	5 (25%)
Marital status	Married	19 (95%)	14 (70%)
	Unmarried	1 (5%)	6 (30%)
BMI		27.37±4.32	26.75±4.94

QBPDS scores: In both, the groups, the residual effect of Unani formulations were significant (P<0.001) which means that the QBPDS scores were improved. There was a significantly better improvement in QOL of control group patients with mean difference 22.45 as compared to the test group (11.41) which means that control drug seems to be more effective.

Test used: Repeated measures ANOVA with post-test for intra group and One-way ANOVA for intergroup comparison with Tukey-Kramer multiple comparison test.

Test used for vas in grades: Friedman Test for intra group and Kruskal-Wallis test for inter group comparison.

Safety parameters

The test drug was well tolerated with no serious adverse event reported and almost all safety parameters were within normal limits (Table 3).

Table 2: Assessment parameters.

Assessment parameters		Assessment days				
		BL	**F1**	**F2**	**F3**	**F4**
VAS in NRS	Test	6. 8±1.28	6.25±1.12	5.8±1.24	5.65±1.31	5.25±1.41
VAS in grades	Control	3 (3,3)	2.5 (2,3)	2 (1,3)	1 (0,2)	1 (0,2)
ODI scores	Test	22.35±6.38	19.75±6.63	17±6.05	15.8±7.21	15.45±7.51
	Control	28.80±3.72	26.45±4.01	20.15±4.49	15.75±3.95	14.80±4.29
QBPDS scores	Test	56.1±9.45	52.2±10.11	49.05±9.41	46.9±10.33	45.6±11.00
	Control	63.50±9.84	59.80±11.57	46.05±10.42	41.05±9.65	39.75±10.03

Table 3: Comparative evaluation of test and control group drugs on safety parameters before treatment v/s after treatment.

Parameters		Test		P	Control		P
		BT	**AT**		**BT**	**AT**	
Hb %		13.21±1.75	13.08±1.75	0.53	13.61±1.51	13.72±1.12	0.663
TLC		8040±1594.53	7540±1952.97	0.07	7977.50±1924.25	7025.00±1591.05	0.083+
DLC	Poly	56.4±9.96	54.6±7.39	0.32	60.05±11.26	61.55±8.37	0.477
	Lymph	35.7±8.55	37.5±6.57	0.19	30.95±10.29	29.20±7.76	0.638
	Eosino	4.4±1.23	4.6±0.94	0.52	4.90±1.17	5.35±3.20	0.249
	Mono	3.5±1.28	3.25±1.02	0.44	4.10±1.45	4.20±1.40	0.246
	Baso	0.00±0.00	0.00±0.00	---	0.00±0.00	0.00±0.00	---
ESR		18.2±16.41	13.75±12.30	0.29	22.60±22.19	19.20±18.35	0.319
AST (SGOT)		24.9±10.40	26.7±15.53	0.45	31.05±11.99	32.70±12.83	0.374
ALT (SGPT)		34.25±22.87	41.05±31.21	0.08	32.30±14.08	30.30±11.71	0.405
ALK Phos.		87.5±13.37	89.55±20.49	0.58	-	-	-
Blood urea		22.05±2.63	19.4±4.56	0.02	26.23±4.06	26.70±6.01	0.685
Serum creatinine		0.82±0.12	0.75±0.11	0.02	0.90±0.13	0.90±0.13	1.000

Test used: paired t test used for intra group analysis.

DISCUSSION

The comparative clinical trial was conducted to evaluate the efficacy of *Habb-e-Hindi* in low back pain with historical control. Subjects enrolled were treated accordingly, and the responses were assessed based on pain improvement as subjective parameter through VAS in grading and NRS and objective parameters was assessed by using Oswestry Disability Index (ODI) and Quebec Back Pain Disability Scale (QBPDS) to see the improvement in Quality of Life (QOL) of patients. The discussion regarding demographic data, clinical symptoms and objective and subjective parameters findings are as follows.

In this study the maximum of 9 (45%) patients were found with the age of 41-50 years, supports the description made by Yash pal Munjal while Williams NS et al, Fauci AS et al, Goldman L et al, reported the onset of LBP most often in the age group of 30-50 years and it is the most common cause of work-related disability in people under 45 years of age.[9-12]

This study reveals that prevalence of disease is more in females because 14 (70%) out of 20 patients were found females, and 6 (30%) were males.

Out of 20 patients, 12 (60%) belongs to Muslim community and 8 (40%) Hindu community. This is may be due to the high number of patients attending NIUM hospital.

As far as the marital status of the patients concerned, 19 (95%) were married and 1 (5%) were unmarried. This finding is consistent with Biglarian et al, Henn et al, Meucci et al, as they reported a high prevalence of LBP in married men and women.[13-15] Our observation is also in conformity with the cause and relationship of Low back pain associated with active marital life mentioned by the Unani physicians such as Ibn-e-Sina, Zakariya Razi, Ismail Jurjani, Akbar Arzani in their treatise, that active sexual life is one of the causes of LBP.[13,16-19]

Out of 20 patients, the highest incidence of LBP was observed in upper-lower (IV) class i.e., 9 (45%) patients. This study indicates that LBP is more common in low socioeconomic class, which is in conformance with the study conducted by Koster et al, Meucci et al, and Thomten et al.[15,20,21]

Out of 20 patients, the highest number of patients 9 (45%) were found with BMI of 25-29.9. These data show a higher prevalence of LBP among overweight and obese which is inconsistent with findings of Biglarian et al, Webb et al, Henn et al, Chou et al, and Meucci et al.[13-15,22,23] According to them, the association of LBP with BMI is obvious, since a heavy build strains the spine and it promotes overloading of the articular structures of the lumbosacral spine which become predisposed to degeneration.

The chronicity of disease was observed in a maximum of 6 (30%) patients who reported suffering from 6-10 months, which correlates with the findings of Yash Pal Munjal, Dijken et al, Fauci et al, and Humes et al.[9,11,24,25] who reported that this disease is chronic in origin. Radicular pain was observed in 14 (70%) patients followed by 6 (30%) patients with non-radicular back pain. This is in conformance with findings cited by Yash Pal Munjal and Fauci et al.[9,11] Humes et al and Goldman et al, that disc diseases with nerve root compressions are usually presented with radiculopathy who reported that 20% to 35% of LBP patients suffer from a neuropathic pain component.[25,12]

The radiological findings based upon X-ray/MRI LS-spine evidences that, in 20 patients of the test group; the pathological conditions which resulted in back pain were disc prolapse i.e. 54.71% of which 28.3% was at the level of L4-L5 followed by 15.09% at L3-L4; protrusion was 33.96% of which 15.09% was at the level of L4-L5 followed by 9.43% at L5-S1; IVD Space Reduction, Listhesis and Canal Stenosis was 3.77% each respectively which coincides with the description given by Fauci et al, Humes et al, Goldman et al, and Shenoy, that disc disease is most likely to occur at L4-L5 & L5-S1 levels comparison test.[11,12,25,26]

The test and the control group both equally had significant results but test drugs showed better results after the first follow-up ($P<0.001$) as compared with that of the control group ($P<0.01$).

In both groups, the residual effect of Unani formulations was equally significant ($P<0.0001$) which means that the ODI scores were improved. There was a significantly better improvement in QOL of control group patients with mean difference 13.05 as compared to the test group 6.9 which means the control group seems to be more effective in improving QOL.

In the test group, disability got significantly improved to minimal and moderate disability with percentage improvement of 45% whereas the improvement was 85% in the control group. The percentage difference showed the LBP associated disability got reduced significantly in the control group as compared to the test group which means control drug seems to be more effective.

In both groups, the residual effect of Unani formulations was significant ($P<0.001$) which means that the QBPDS scores were improved. There was a significantly better improvement in QOL of control group patients with mean difference 22.45 as compared to the test group (11.41) which means that control drug seems to be more effective.

The safety parameters of drugs were remained within normal limits in both groups before and after the Interventions which indicate that *Habb-e-Hindi* was found safe without any clinically or biochemical changes.

The aforementioned significant results are credited to the medicinal properties of the Unani formulations. Though temperament of all drugs is *Haar-Yabis*(Hot and dry) and possess *Munzij* (Concoctive) and *Mushile Balgham*(Purgative), *Mulattif* (Demulcent), *Kasir-e-Riyah*(Carminative), *Muhallil*(Resolvent) & *Mudirre Bol* (Diuretic) properties by which they do *Istifragh* (evacuation) and *Imala* (diversion) of vivid and sticky matter, removal of excessive *Buroodat (coldness)* and from the joint structures of lumbosacral region and also attributes to the *Musakkine alam* (Analgesic), *Murakkhi*, *Musakhkhin wa Muqawwi-e-Aasab* properties by which it relieved Low back pain and does restoration and

normalization of physiological temperament by eliminating the causes.[26,27-30,31-38]

Several in vitro and in vivo pharmacological studies have been reported that these Unani formulations possess proven analgesic, anti-inflammatory, diuretic and hepatoprotective properties. Thus, we can say that the scientific studies and reported effects of the individual ingredients of the Unani formulation conform to a greater extent with the inferences we drew out in the present study.

CONCLUSION

The test and the control group both equally had significant results but test drugs showed better results (in VAS) after the first follow-up (P<0.001) as compared to that of the control group (P<0.01). LBP associated disability (ODI) got reduced significantly in the control group (85%) as compared to the test group (45%) and there was a significantly better improvement in QOL of Control Group patients with the mean difference (13.05) as compared to the test group (6.9) which means control drug seems to be more effective. In both, the groups, the residual effect of Unani formulations were significant (P<0.001) which means that the QBPDS scores were improved. The Significant Disability Change was recorded in all the 20 patients of the control group as compared to test group where only 4 patients showed significant reduction and even there was a significantly better improvement in QOL of control group patients with the mean difference (22.45) as compared to the test group (11.41) which means that control drug seems to be more effective.

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