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Research Article

EVALUATION OF THE EFFICACY OF DAWA-UL-KURKUM IN SU-E-MIZAJ KABID BARID (NON-ALCOHOLIC FATTY LIVER DISEASE): A RANDOMIZED SINGLE BLIND PLACEBO CONTROLLED STUDY

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ABSTRACT

Non-alcoholic fatty liver disease (NAFLD) is emerging as an important cause of chronic liver disease, characterized by significant lipid deposition in hepatocytes. The prevalence of NAFLD in India is around 35% with higher prevalence in urban areas. In view of high prevalence and absence of any approved therapies for NAFLD, this clinical trial was attempted to evaluate the efficacy and safety of Dawa-ul-Kurkum in Non-alcoholic fatty liver disease (Su-e-Mizaj Kabid Barid). A randomized single blind placebo controlled trial was conducted in 44 cases of non-alcoholic fatty liver disease, diagnosed by ultra-sonogram of abdomen. They were randomly assigned in to two equal groups, after obtaining voluntary informed consent, of them 40 had completed the protocol and the rest 4 were lost to follow-up. Test group was administered Dawa-ul-Kurkum 5 gm once daily for 60 days, while the control group received Suji Halwa in similar dose and for same duration. All the cases were followed up every 15th day. The results were statistically analyzed at the completion of trial. The test formulation showed statistically significant reduction in subjective and objective parameters ($p < 0.05$), both in intergroup and intra group comparison, while placebo controlled group showed statistically insignificant effect ($p > 0.05$). This study exhibits that the test drug; Dawa-ul-Kurkum has potential to reduce the symptoms and grading of NAFLD. There was no any adverse effect observed in this study. Hence it can be concluded that the test drug Dawa-ul-Kurkum is effective and safe in the management of NAFLD.

KEY WORDS: Su-e-Mizaj Kabid Barid; NAFLD; Dawa-ul-Kurkum; Unani Medicine; Non-alcoholic fatty liver disease

INTRODUCTION

The non-alcoholic fatty liver disease (NAFLD) has emerged as the leading type of chronic liver disease worldwide. Non-alcoholic steatohepatitis (NASH), the more serious form of NAFLD is the major cause for liver related morbidity and mortality. Over the years, changing lifestyle and dietary habits in addition to the genetic predisposition has increased the occurrence of obesity and diabetes mellitus and their consequences including NAFLD in the Asia-Pacific region including India¹. NAFLD is defined as an accumulation of fat, mainly triglycerides, cholesterol and phospholipids in the hepatocytes usually greater than 5- 10 % of the liver weight². Occurrence of NAFLD in general population in India fluctuates from 9% to 35% with lower Prevalence in rural areas¹.

Various factors are implicated in its causation, such as excessive dietary fructose consumption, sedentary lifestyle, various endocrinopathies such as hypothyroidism, hyperglycemias etc^{3,4,5}. Although, there is no such disease in Unani system of medicine with the term “Non-alcoholic fatty liver disease” but on surveying the existing literature, it appears that signs and symptoms of Su-e-Mizaj Kabid Barid are, up to some extent, similar to NAFLD. Hence, the line of treatment of Su-e-Mizaj Kabid Barid mentioned in Unani classical literature may be adopted for the management of NAFLD.

As far as its treatment is concerned in conventional medicine, there is no treatment available to cure it. Present scenario of treatments is concentrated at lifestyle changes to minimize or modify the Various Unani compounds formulation are available to treat Su-e-Mizaj Kabid Barid and to name a few such as Qurs-e-Afsanteen, Dawa-ut-Turanjabeen, Majoon Dabeed-ul-Ward, Sharbat-e-Deenar, Dawa-ul-Kurkum, Itriphal Sagher, Jawarish Bisbasa etc. Dawa-ul-Kurkum is a polyherbal formulation which has an edge over all these drugs in treating liver diseases, as it possesses Muhallil-e-Warm-e-Kabid wa Tihaal, Musakkin, Mufatteh-e-Sudad, Kasir-e-Riyah and Muqawwi-e-Jigar, Meda wa Am’a properties⁶.

MATERIALS & METHODS

Study entitled “Evaluation of the Efficacy of Dawa-ul-Kurkum in Su-e-Mizaj Kabid Barid (Non-Alcoholic Fatty Liver Disease) – A Randomized Single Blind Placebo Controlled Study” was designed for the duration of 60 days and was carried out on 40 patients consisting of two groups (group-A and group-B) Group-A patients received test drug formulation (Dawa-ul-Kurkum) 5gm once in the morning with Luke warm water orally and group-B patients received Placebo was prepared by mixing Suji with sugar base, 5gm once in the morning with Luke warm water orally. The trial was conducted at National Institute of Unani Medicine and Hospital, Bengaluru, from April, 2015 to March, 2016. After obtaining approval from Institutional Ethical Committee of National Institute of Unani Medicine vide NO.

NIUM /IEC / 2013-14 / 001/ Moal/ 01, Dated 24.04.2014, Majority of the patients were selected on the basis of incidental diagnosis of fatty liver from the Dept. of Radiology of NIUM Hospital Bengaluru, which were referred by Unani consultants, from NIUM, O.P.D. Inclusion criteria was Non-Alcoholic Fatty liver (Grade I (Mild) and II (Moderate) based on Ultrasonography, Patients of both gender, Age group of 20 – 60 years, BMI <39.9. Exclusion criteria included Pregnancy and lactation, Fatty liver – Grade III(severe) and above, focal fatty liver cases and cirrhosis, Known cases of Hepatitis and other liver diseases, BMI > 39.9, History of systemic and metabolic disorders like diabetes mellitus, Patients on Hypolipidemic drugs, History of alcoholism, Hypothyroidism and Cholelithiasis. Those cases that fulfill the inclusion criteria were subjected to thorough clinical history, examination and laboratory investigations and were enrolled for study after obtaining a written informed voluntary consent. During selection procedure complete history including interrogation, general, physical, systemic examination, past history, family history, personal history and socioeconomic history using Kuppaswamy Socioeconomic scale (2014) were recorded. Routine investigations were performed before and after treatment such as Hb%, TLC, DLC, ESR, SGOT (AST), SGPT (ALT), AL P, Blood Urea, S. Creatinine, LDL, HDL, S. Cholesterol, S. Triglycerides and Ultra sonogram (whole abdomen). Some investigation performed before treatment only such as Random Blood Sugar, HbsAg, and TSH. The study was conducted as per GCP guidelines. An over view of study show in figure no. 1

Dawa-ul-Kurkum: The ingredients Sunbuluttee (Nardostachys jatamansi) 1 Part, Mur Makki (Commiphora myrrha gum) 1 Part, Saleekha (Cinnamomum tamala) 1 Part, Shagufa-e-Izkhir (Cymbopogon shoenanthus) 1 Part, Qust (Saussurea lappa) 1 Part, Darcheeni (Cinnamomum zylenticum bark) 1 Part, Zafran (Crocus sativa) 1 Part, Sharab Musallas (Ethyl alcohol) Q.S, Qand Safaid (Saccharum officinarum) Q.S.

Dawa-ul-Kurkum was given in the dosage 5gm once in the morning with Luke warm water orally. The drug was prepared by NIUM pharmacy accomplishing established preparation method of Majoon as per Unani literature, and proper scrutiny of every ingredient by the concerned. Similarly Placebo was prepared by mixing Suji with sugar base.

Dietary advice and life-style modification: Patients of both groups were advised to strictly adhere with the instructions on prescribed diet (20-25 kcal/kg of body weight)^{7,8} and exercise (Brisk walk) for 40 minutes 4-5 times per week. No concomitant treatment for fatty liver was allowed during the entire study period^{8,9}.

Assessment of efficacy: The criteria of assessment in the test and control groups were based on subjective and objective parameters. Subjective parameters include symptoms like Anorexia, Nausea, Dyspepsia and Dull ache / Heaviness in right hypochondriac region and objective parameters include SGOT, SGPT, and U.S.G of Abdomen for fatty liver changes. The effects of the study in terms of subjective parameters in both groups will be assessed in four follow up i.e., on 15th, 30th, 45th, 60th days. The objective assessment will be made at base line and on completion of the trial. An arbitrary grading scale (Table no. 1) was adopted for the assessment of subjective parameters in both the group

Statistical software: The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of data.

Data analysis: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean $\pm$ SD (Min-Max) and results on categorical measurements are presented in number (%). Significance is assessed at 5 % level of significance. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. And student t test (two tailed, dependent) has been used to find the significance of study parameters on continuous scale within each group. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

RESULT

The baseline demographic data has been given in Table no. 2. In subjective parameters it was observed that after treatment, Anorexia, Nausea, Dyspepsia and Dull ache / Heaviness in right hypochondriac region were significantly reduced in test(group-A) group. Observed result in subjective and objective parameter show in table no. 3 to table no. 10 consequently. Drug safety parameter show in table no. 11.

DISCUSSION

The study was conducted to “Evaluation of the Efficacy of Dawa-ul-Kurkum in Su-e-Mizaj Kabid Barid (Non-Alcoholic Fatty Liver Disease) - A Randomized Single Blind Placebo Controlled Study”. Out of 40 cases studied, 20.0% were in the age group of 21-30 years, 30.0% in 31-40 years, 40% in 41-50 years and 10% cases in the age group of 51-60 years. The occurrence of NAFLD increases with increasing age probably because of increasing insulin resistance and metabolic syndrome. Probable reason might be that majority of patients have one or more risk factors for metabolic syndrome such as obesity, and hypertriglyceridemia which bring the patient to medical attention¹. This study is consistent with Shivaram Prasad Singh et al, Ramesh Kumar et al, Kamran Bagheri Lankarani et al, Amarapurkar D et al, and Shahinul Alam et al.¹⁰⁻¹⁴

A majority of trial subjects (52.5%) registered were males and 47.5% were females, which supports the results stated by Singh et al and Ajay Duseja that non-alcoholic fatty liver is more common in males than females^{1,15}. The gender differences in NAFLD and NASH can be probably explained by gender disparities in body fat distribution, lifestyle, and sex hormone metabolism¹⁶. But recent studies have shown that NASH occurs with equal frequency in males and females according to Kumar V. et al.¹⁷

During the course of study, patients were divided into five categories according to their occupation, Housewife, teacher, businessman, skilled and unskilled. The number of cases falling in each category was 19 (47.5%), 7 (17.5%), 2 (5%) and 6(15%) and 6 (15%) respectively. Thus it was observed that maximum number of patients belong to Housewife followed by teacher, skilled, unskilled worker and Business class. Traditionally, in our culture housewives enjoy sedentary lifestyle and are responsible to look after cooking and kitchen so they are expected to develop fatty liver which is evident from our study. Hence maximum number of patients in our study belongs to housewife. This study is consistent with Abbas Z et al.¹⁸ Highest prevalence (80%) of NAFLD was observed among urban middle class due to their sedentary life style which was in accordance with the findings stated by Waker BR et al.³ In this trial, 80% of the subjects studied were having sedentary lifestyle, while 20%

engaged in hard work. This outcome coincide with that of Duseja A, Rector RS et al and Wilkins T et al study reiterating the fact that urbanization, physical inactivity either separately or in combination with other sedentary life style are underlying causes of non-alcoholic fatty liver^{19,20,21}. Maximum numbers of patient (95%) were found to be non-vegetarians while only 5% patients were vegetarians, which is consistent with that of Ajay Duseja and Longato L study as fat rich diet is more prone to cause metabolic syndrome or insulin resistance and its manifestations, such as NAFLD and NASH^{19,22}. Majority of the patients (45%) were overweight, 42.5% had Grade I obesity, while only 12.5% were normal weight subjects in the study. The outcome well-matched with the studies of Duseja A and Singh SP et al where in the highest prevalence is seen among patients with BMI > 25^{10,19}. This study is consistent with Amarapurkar D et al, Alam S et al, Singh SP et al, Somalwar AM et al and Hu X et al.^{13,14,23,24,25}

Effect on Subjective Parameters

Anorexia: In this study assessing anorexia before and after the treatment at various assessment days, it was found that, 7(35%) patients had mild anorexia, 1(5%) patient had moderate anorexia, 12 (60%) patients had no anorexia at baseline in group-A while 9 (45%) patients had mild anorexia, 1 (5%) patient had moderate anorexia, and 10 (50%) patients had no anorexia at baseline in group-B. After administration of Dawa-ul-Kurkum in group A and administration of placebo in group-B, at 60th day, it was observed that anorexia was not present in any patients in group-A, while no improvement was found in group-B. In Su-e-Mizaj Kabid Barid initially appetite increases latter on anorexia will be prevail due to dystemperament (Su-e-Mizaj) in liver cells due to accumulation of Ghair Tab'ee Balgham which hampers the Quwat-e-Jaziba of liver leads to anorexia^{26,27}. Dawa-ul-Kurkum increases appetite due to correction of dystemperament^{26,28} and due to number of its ingredients which have appetizing (Mushahhi) properties^{26,29}.

Nausea: It was found that only 5(25%) patients had mild nausea, 15 (75%) patients had no nausea at baseline in group-A while 7(35%) patients had mild nausea, and 13 (65%) patients had no nausea at baseline in group-B. after completion of trial it was observed that nausea disappeared in all patients in group-A, while no improvement was found in group-B. In Su-e-Mizaj Kabid Barid patients feel nausea due to Su-e-Tarteef-e-Ghizai (Imporper dietary habit) which leads to Su-e-Hazm (Indigestion)^{30,31}. Dawa-ul-Kurkum reduces nausea through increase production of heat (Taskhin)^{26,28} in stomach and by number of its ingredients which have digestive^{32,33} and anti-emetic properties^{26,33}.

Dyspepsia: In this study it was found that, in group A 11(55%) patients had mild dyspepsia 3(15%) patients had moderate dyspepsia, 6 (30%) patients had no dyspepsia at baseline in group-A while 11(55%)patients had mild dyspepsia, 2(10%)patients had moderate dyspepsia, and 7(35%) patients had no dyspepsia at baseline in group-B. After treatment it was observed that dyspepsia was not present in any patients in group-A, while no improvement was found in group-B. In Su-e-Mizaj Kabid Barid dyspepsia may be due to increase Burudat²⁶ and/or accumulation of Ghaleez Balgham^{26,28} in liver & stomach. Dawa ul Kurkum reduces this symptom via elimination of Balgham^{33,34} and correction of Mizaj^{26,34}.

Dull ache/Heaviness in right hypochondrium: In this study it was found that, 11 (55%) patients had mild dull ache/heaviness, 5 (25%) patients had moderate dull ache/heaviness, 4 (20%) patients had no dull ache/heaviness at baseline in group-A,

while 13(65%)patients had mild dull ache/heaviness, 5 (25%) patients had moderate dull ache/heaviness, and 2(10%) patients had no dull ache/heaviness at baseline in group-B. After protocol therapy, it was observed that even mild dull ache/heaviness was not present in any patients in group-A, while no improvement was found in group-B. Dull ache/heaviness presents in Su-e-Mizaj Kabid Barid due to Sudda-e-Kabid, Warm-e-Kabid Barid or Ghaleez Riyah^{26,28,35}. Many ingredients of Dawa-ul-Kurkum have anti-inflammatory (Muhallil)^{29,36} Deobstruent (Mufatteh)^{29,30} and carminative (Kasir-e-Riyah)^{33,36} properties, therefore Dawa-ul-Kurkum reduces dull ache or heaviness in right hypochondriac region.

Increased body weight: Highly significant weight reduction was observed in test group ($p < 0.001$), statistical significance was detected in control group also ($p < 0.05$) using paired student t test. However in between group analysis, using unpaired t test, there was no statistically significant difference present ($p > 0.05$). The outcome was in accordance with most of the studies carried where lifestyle intervention was the mainstay of treatment^{37,38,39,40}. In this study marked weight reduction may be due to instructions to strictly adhere to prescribed diet (20-25 kcal/kg/body weight)^{7,8,41} and exercise (Brisk walk) for 40 minutes 4-5 times per week^{8,9}. This study is consistent with Ahmad NZ et al.⁴²

Effect on Objective Parameters

AST (SGOT) and ALT (SGPT) assessment was done in both the groups at base line and after completion of treatment. The difference was statistically insignificant in both the groups in pre and post comparison as well as in between the group comparison using paired and unpaired student t test respectively (Table no. 10). Laboratory values may be normal in up to 80% of persons with fatty liver according to Papadakis et al and Majumdar A et al.^{5,43}

Similarly the assessment of Total Cholesterol TGS, LDL and HDL was done in both the groups at baseline and after the treatment. The differences were statistically insignificant in test and control group in pre and post comparison as well as in between the group comparison. Paired and unpaired student t test was used for comparison, respectively (Table no. 10). According to Duseja A, dyslipidemia is present in approximately 50% of Indian patients with NAFLD¹⁹, it means rest of the patient with NAFLD usually having normal lipid profile level. Moreover Mahaling DU et al stated that those patients having grade-I fatty liver have normal lipid profile level⁴⁴. In this study most of the patients were having grade-I fatty liver therefore Dawa-ul-Kurkum showed no significant difference in lipid levels. This study is consistent with studies of Shivaram Prasad Singh et al¹⁰ Kumar R et al¹¹ Gaharwar R et al⁴⁵ and Sen A et al⁴⁶.

USG Abdomen: Ultrasonography of abdomen was performed for diagnostic as well as for assessment purpose in all the cases in both the groups at baseline and after the end of trial. All the patients enrolled had positive findings of NAFLD. In test group 95% of patients had grade I and 5% had grade II FL changes, while at the end of trial, 30% of case had no fatty liver, 70% cases had grade I FL changes, and no one was in grade II category. While in group-B 19 (95%) patients had grade I and 1 (5%) patient had grade II. However after completion of trail, all patients in this group have grade I fatty liver and no patient remains in grade II fatty liver. (Table no. 09). In between group analysis it showed significant difference ($P = 0.02$).

NAFLD or Su-e-Mizaj Kabid Barid may be due to dystemperament of liver (Su-e-Mizaj Kabid)³⁰ and accumulation of Balgham in the liver⁴⁷ according to Unani system of medicine, while in modern system of medicine exact Aetiopathogenesis of NAFLD and NASH is still unknown⁴⁸. The Dawa-ul-Kurkum potentially reduced NAFLD via correction of temperament and evacuation of phlegm (Balgham), because a number of its ingredients have Musakkhin^{33,36} Munzij^{33,47} Mufatteh Sudad^{47,29} and Muhallil property^{33,36}.

Effect on Safety Parameters

The safety profiles of the test drug were evaluated after laboratory investigations which include Complete blood count, Hb%, ESR, Blood Urea, S. Creatinine, SGOT, SGPT, and Alkaline Phosphatase. There was no any adverse effect observed during and after completion of the trial in any group. The maintenance of laboratory investigations throughout the course of study confirmed that the test drug is safe for the patients and apparently has no harms.

Table. 01 Arbitrary grading scale

S.No	Nature	Grade	Score	Nature of severity
1	No	-	0	No symptoms
2	Mild	+	1	Mild symptoms but not enough to require remedial therapy to continue day to day activity.
3	Moderate	++	2	Moderate symptoms which interfere in day to day activities and require remedial therapy to continue routine work.
4	Severe	+++	3	Severe symptoms which do not allow to daily activities.

Table No. 02 Distribution of patients according to Age, Gender, Occupation and Religion

Age in years	Group A		Group B		Total	P value
	No	%	No	%		
21-30	3	15.0	5	25.0	8(20%)	P=0.607
31-40	7	35.0	5	25.0	12(30%)	
41-50	9	45.0	7	35.0	16(40%)	
51-60	1	5.0	3	15.0	4(10%)	
Total	20	100.0	20	100.0	40(100)	
Mean $\pm$ SD	39.65 $\pm$ 8.51		39.65 $\pm$ 8.51			
Gender	Group A		Group B		Total	P value
	No	%	No	%		
Female	7	35.0	12	60.0	19(47.5%)	P=0.113
Male	13	65.0	8	40.0	21(52.5)	
Total	20	100.0	20	100.0	40(100%)	
Occupation	Group A		Group B		Total	P value
	No	%	No	%		
House-wife	7	35.0	12	60.0	19(47.5)	P=0.246 Fisher Exact test
Teacher	5	25.0	2	10.0	7(17.5)	
Business	2	10.0	0	0.0	2(5.0)	
Skilled	4	20.0	2	10.0	6(15.0)	
Unskilled	2	10.0	4	20.0	6(15.0)	
Total	20	100.0	20	100.0	40(100)	
Religion	Group A		Group B		Total	P value
	No	%	No	%		
Hindu	5	25.0	4	20.0	9(22.5)	P=1.000 Chi-Square test
Muslim	15	75.0	16	80.0	31(77.5)	
Total	20	100.0	20	100.0	40(100.0)	

Table No. 03 Distribution of patients according to KSES, Life-style, Diet and BMI

KSES	Group A		Group B		Total	P value
	No	%	No	%		
I	2	10.0	0	0.0	2(5%)	P=0.155 Fisher Exact test
II	12	60.0	7	35.0	19(47.5%)	
III	6	30.0	9	45.0	15(37.5)	
IV	0	0.0	4	20.0	6(15%)	
Total	20	100.0	20	100.0	40(100%)	
Life-Style	Group A		Group B		Total	P value
	No	%	No	%		
HW	4	20.0	4	20.0	8(20%)	P=1.000 Chi-Square test
SD	16	80.0	16	80.0	32(80%)	
Total	20	100.0	20	100.0	40(100%)	
Diet	Group A		Group B		Total	P value
	No	%	No	%		
Mixed	19	95.0	19	95.0	38(95%)	P=1.000 Fisher Exact test
Veg	1	5.0	1	5.0	2(5%)	
Total	20	100.0	20	100.0	40(100%)	
BMI (kg/m ²)	Group A		Group B		Total	P value
	No	%	No	%		
<18.5	0	0.0	0	0.0	0(0%)	P=0.273 student t test
18.5-25	4	20.0	1	5.0	5(12.5%)	

25-30	9	45.0	9	45.0	18(45%)
>30	7	35.0	10	50.0	17(42.5%)
Total	20	100.0	20	100.0	40(100)

Table No. 04 Anorexia: An assessment before treatment, 15 th day, 30 th day, 45 th day and after treatment							Chi-Square test/Fisher Exact test
Anorexia	Before Treatment	Follow up @ 15 days	Follow up @30 days	Follow up @ 45days	After Treatment	% change	
Group A (n=20)							
• No	12(60%)	14(70%)	16(80%)	17(85%)	20(100%)	40.0%	
• Mild	7(35%)	6(30%)	4(20%)	3(15%)	0(0%)	-35.0%	
• Moderate	1(5%)	0(0%)	0(0%)	0(0%)	0(0%)	-5.0%	
Group B (n=20)							
• No	10(50%)	10(50%)	10(50%)	10(50%)	10(50%)	0.0%	
• Mild	9(45%)	9(45%)	8(40%)	9(45%)	9(45%)	0.0%	
• Moderate	1(5%)	1(5%)	2(10%)	1(5%)	1(5%)	0.0%	
P value	0.868	0.333	0.121	0.041*	<0.001**	-	

Table No. 05 Nausea: An assessment before treatment, 15 th day, 30 th day, 45 th day and after treatment						
Nausea	Before Treatment	Follow up @ 15 days	Follow up @30 days	Follow up @ 45days	After Treatment	% change
Group A (n=20)						
• No	15(75%)	17(85%)	17(85%)	19(95%)	20(100%)	25.0%
• Mild	5(25%)	3(15%)	3(15%)	1(5%)	0(0%)	-25.0%
Group B (n=20)						
• No	13(65%)	13(65%)	13(65%)	12(60%)	12(60%)	-5.0%
• Mild	7(35%)	7(35%)	7(35%)	8(40%)	8(40%)	5.0%
P value	0.490	0.144	0.144	0.008**	0.002**	-
Chi-Square test/Fisher Exact test						

Table No. 06 Dyspepsia: An assessment before treatment, 15 th day, 30 th day, 45 th day and after treatment						
Dyspepsia	Before treatment	Follow up @ 15 days	Follow up @30 days	Follow up @ 45days	After treatment	% change
Group A (n=20)						
• No	6(30%)	10(50%)	11(55%)	14(70%)	20(100%)	70.0%
• Mild	11(55%)	9(45%)	9(45%)	6(30%)	0(0%)	-55.0%
• Moderate	3(15%)	1(5%)	0(0%)	0(0%)	0(0%)	-15.0%
Group B (n=20)						
• No	7(35%)	7(35%)	7(35%)	7(35%)	7(35%)	0.0%
• Mild	11(55%)	11(55%)	13(65%)	10(50%)	10(50%)	-5.0%
• Moderate	2(10%)	2(10%)	0(0%)	3(15%)	3(15%)	5.0%
P value	1.000	0.627	0.341	0.039*	<0.001**	-
Chi-Square test/Fisher Exact test						

Table No. 07 Dull ache / Heaviness in right hypochondrium: An assessment before treatment, 15 th day, 30 th day, 45 th day and after treatment						
Dull ache / Heaviness in right hypochondrium	Before treatment	Follow up @ 15 days	Follow up @30 days	Follow up @ 45days	After treatment	% change
Group A (n=20)						
• No	4(20%)	9(45%)	10(50%)	14(70%)	19(95%)	75.0%
• Mild	11(55%)	10(50%)	9(45%)	6(30%)	1(5%)	-50.0%
• Moderate	5(25%)	1(5%)	1(5%)	0(0%)	0(0%)	-25.0%
Group B (n=20)						
• No	2(10%)	3(15%)	5(25%)	3(15%)	3(15%)	5.0%
• Mild	13(65%)	13(65%)	10(50%)	13(65%)	11(55%)	-10.0%
• Moderate	5(25%)	4(20%)	5(25%)	4(20%)	6(30%)	5.0%
P value	0.749	0.115	0.123	<0.001**	<0.001**	-
Chi-Square test/Fisher Exact test						

Table No. 08 Increased body weight: An assessment before treatment, 15 th day, 30 th day, 45 th day and after treatment			
Increased body weight	Group A	Group B	P value
Before treatment	74.65±9.91	76.08±10.76	0.666
Follow up @ 15 day	73.38±9.22	75.91±10.62	0.425
Follow up @ 30 day	72.34±8.68	75.56±10.59	0.299
Follow up @ 45 day	71.12±8.38	75.35±10.52	0.168
After treatment	69.90±7.80	75.09±10.66	0.087
Student t test (Unpaired)			

Table No. 09 USG Abdomen (Fatty Liver Grade): An assessment before treatment and after treatment

USG Abd. (F L Grade)	Before treatment	After treatment	% change	Chi-Square test/Fisher Exact test
Group A (n=20)				
• No	0(0%)	6(30%)	30.0%	
• Mild	19(95%)	14(70%)	-25.0%	
• Moderate	1(5%)	0(0%)	-5.0%	
Group B (n=20)				
• No	0(0%)	0(0%)	0.0%	
• Mild	19(95%)	20(100%)	5.0%	
• Moderate	1(5%)	0(0%)	-5.0%	
P value	1.000	0.020*	-	

Table No. 10 An assessment before treatment, and after treatment

SGOT	Group A	Group B	P value	Between group: Student t test (Unpaired), Within group: Student t test (Paired)
Before treatment	24.03±10.61	23.60±7.70	0.884	
After treatment	23.85±10.27	23.20±9.21	0.834	
Difference	0.182	0.400	-	
P value	0.942	0.741	-	
SGPT	Group A	Group B	P value	
Before treatment	26.60±12.51	28.05±11.05	0.700	
After treatment	27.35±14.18	33.30±17.78	0.249	
Difference	0.750	-5.250	-	
P value	0.832	0.078+	-	
Total Cholesterol(mg/dl)	Group A	Group B	P value	
Before treatment	188.20±38.41	177.05±34.35	0.339	
After treatment	185.20±34.33	173.50±30.19	0.260	
Difference	3.000	3.550	-	
P value	0.732	0.637	-	
TG (mg/dl)	Group A	Group B	P value	
Before treatment	168.75±63.23	147.10±54.88	0.255	
After treatment	150.50±62.32	140.30±54.83	0.586	
Difference	18.250	6.800	-	
P value	0.170	0.574	-	
LDL (mg/dl)	Group A	Group B	P value	
Before treatment	111.35±35.43	100.60±26.75	0.286	
After treatment	109.90±26.02	103.80±27.66	0.477	
Difference	1.450	-3.200	-	
P value	0.877	0.664	-	
HDL (mg/dl)	Group A	Group B	P value	
Before treatment	43.40±7.13	44.20±5.23	0.688	
After treatment	45.90±11.32	41.80±6.93	0.175	
Difference	-2.500	2.400	-	
P value	0.439	0.243	-	

Table No. 11 Haemogram & ESR, LFT & KFT: An assessment before treatment and after treatment

Hb (%)	Group A	P value	Group B	P value
BT	13.55±2.01	0.923	12.17±1.78	0.191
AT	13.52±1.40		12.52±2.15	
TLC	Group A	P value	Group B	P value
BT	8255.00±1947.06	0.864	8010.00±2218.56	0.047*
AT	8315.00±1722.38		8420.00±1973.14	
Neutrophils	Group A	P value	Group B	P value
BT	61.95±6.34	0.400	57.85±6.75	0.408
AT	60.95±6.53		58.95±6.10	
Lymphocyte	Group A	P value	Group B	P value
BT	29.75±5.50	0.316	33.75±7.04	0.214
AT	30.70±5.94		32.15±6.06	
Eosinophil	Group A	P value	Group B	P value
BT	4.60±0.82	0.606	4.75±1.16	1.000
AT	4.50±0.89		4.75±1.12	
Monocytes	Group A	P value	Group B	P value
BT	3.70±1.03	0.716	3.65±1.42	1.000
AT	3.80±1.20		3.65±1.35	
ESR	Group A	P value	Group B	P value
BT	27.10±17.59	0.713	31.80±16.89	0.571
AT	28.05±19.64		34.55±22.22	
SGOT	Group A	P value	Group B	P value
BT	24.00±10.64	0.962	23.60±7.70	0.741
AT	23.88±10.24		23.20±9.21	
SGPT	Group A	P value	Group B	P value

BT	26.60±12.51	0.832	28.05±11.05	0.078+
AT	27.35±14.18		33.30±17.78	
S. Alkaline Phosphate	Group A	P value	Group B	P value
BT	159.95±59.37	0.964	180.40±67.38	0.802
AT	159.45±49.78		182.95±56.07	
Blood Urea (mg/dl)	Group A	P value	Group B	P value
BT	27.95±5.78	0.251	26.05±5.84	0.583
AT	26.06±7.80		27.30±7.03	
Serum Creatinine (mg/dl)	Group A	P value	Group B	P value
BT	0.82±0.15	0.979	0.79±0.13	0.425
AT	0.81±0.15		0.81±0.14

Figure 1: Flow Chart (An overview of study)

CONCLUSION

The study concludes that Dawa-ul-Kurkum is a novel remedy for the management of NAFLD. While modern system of medicine till date has no treatment for NAFLD, Dawa ul Kurkum can serve as a remedy for patients having NAFLD, based upon significant changes observed in Ultrasonography, though its results on liver enzymes and lipid profile were insignificant statistically.

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