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A STUDY TO ASSESS EFFECT OF MA-UL-SHA'EER (BARLEY WATER) IN INTERMEDIATE HYPERGLYCEMIC (PRE-DIABETIC) SUBJECTS ATTENDING HOSPITALS IN DELHI

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ABSTRACT: Objective: To assess the efficacy of *Ma-ul-Sha'eer* (Barley water) as a dietary intervention in Intermediate Hyperglycemic subjects. **Methods:** A hospital-based prospective, pre and post interventional studies, conducted on 40 diagnosed cases of Intermediate Hyperglycemia (Pre-diabetes) as per WHO and ADA criteria at OPD of Majeedia Unani Hospital and A & U Tibbia College and Hospital, Delhi. **Results and Discussion:** The efficacy of *Ma-ul-Sha'eer* (Barley water) was mainly observed on blood sugar fasting and HbA1c. The mean value of blood sugar fasting before the intervention was 113.6±6.7, and after the intervention was 103.0±5.4. Paired 't' test was applied to the observations recorded before the intervention and after the intervention. It was observed that t=14.5 (p <0.0001) and were statistically highly significant. The most probable mechanism encountered in reducing blood sugar fasting may be the presence of β-glucan in *Ma-ul-Sha'eer*. The mean value of HbA1c before the intervention was 6.0±0.21 and after the intervention was 5.4±0.27. Paired 't' test was applied to the observations recorded before the intervention and after the intervention. It was observed that t=13.7, p <0.001, and were statistically highly significant, the most probable mechanism encountered in reducing HbA1c may be the presence of β-glucan in *Ma-ul-Sha'eer*. **Conclusion:** *Ma-ul-Sha'eer* (Barley water) has β-glucan acts as a hypoglycemic agent, which could lead to a significant reduction in fasting blood sugar and HbA1c. The results came out statistically extremely significant (p<0.0001). Further research is needed to determine how early interventions should be implemented and sustained. *Ma-ul-Sha'eer* (Barley water) was also effective in improving the health-related quality of life.

INTRODUCTION: Intermediate Hyperglycemia is a category of glucose tolerance representing an intermediate stage between normal glucose tolerance (NGT) and diabetes.

Within this category are two subcategories: impaired fasting glucose (IFG; defined as a fasting plasma glucose concentration of 100–125 mg/dl) and impaired glucose tolerance (IGT; defined as a 2-h oral glucose tolerance test (OGTT) plasma glucose concentration of 140–199 mg/dl) although both subcategories increase the risk for diabetes ¹.

About 343 million people worldwide, or 6.9 % of adults, were estimated to have Impaired Glucose Tolerance (IGT) by the year 2013.

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The vast majority (70%) of these people live in low and middle-income countries. By 2035, it is estimated that the number of people with IGT is projected to increase to 471 million². Recent data have shown that in developed countries, more than one-third of adults are prediabetics³. The natural history of Intermediate Hyperglycemia (prediabetics) is variable, with 25% progressing to diabetes, 50% remaining in abnormal glycaemic states, and 25% revert to normoglycemia⁴. The ICMR-INDIAB study is the largest nationally representative study of diabetes in India. The data from 15 states presented here represent a total adult population of 363.7 million people (51% of India's adult population). The overall prevalence of diabetes in India is estimated to be 7.3%, and the prevalence of prediabetes to be 10.3%⁵.

World Health Organization (WHO) in 2006 has recommended the term Intermediate Hyperglycemia to describe glycaemic levels between 'normal' glucose tolerance and diabetes. The term 'pre-diabetes' is discouraged to avoid any stigma associated with the word diabetes and the fact that many people do not progress to diabetes as the term implies⁶. World Health Organization (WHO) has defined the state of intermediate hyperglycemia using two specific parameters: Impaired fasting glucose (IFG) defined as fasting plasma glucose (FPG) of 6.1-6.9 mmol/L (110 to 125 mg/dl). Impaired glucose tolerance (IGT) is defined as 2h plasma glucose of 7.8-11.0 mmol/L (140-200 mg/dl) after ingestion of 75 g of oral glucose load or a combination of the two based on a 2 h oral glucose tolerance test (OGTT)⁷. The American Diabetes Association (ADA), on the other hand, has the same cut-off value for IGT (140-200 mg/dl) but has a lower cut-off value for IFG (100-125 mg/dl) and has additional hemoglobin A1c (HbA1c) based criteria of a level of 5.7% to 6.4% for the definition of Prediabetes⁸. Disturbances in the homeostasis (either excessive release or defective removal or combination of the two results in an increased glucose level). Abnormality in glucose and insulin concentration and dynamics occurs constantly and insidiously with the development of Type 2 diabetes⁹. The two major pathophysiologic defects responsible for losing glucose tolerance are insulin resistance and β -cell glucose insensitivity, both appearing in subjects of Pre-diabetes¹⁰. There are several risk factors that

are responsible for the development of Intermediate Hyperglycemia, such as: Environmental factors, Diet, Physical inactivity, Smoking, Hereditary¹¹⁻¹³. Other risk factors responsible for the development of Intermediate Hyperglycemia are: Family History, Obesity, Sedentary lifestyle, Race or ethnicity, having hypertension, cardiovascular diseases etc.^{5, 14-15} Likewise diabetes, Intermediate Hyperglycemia (prediabetes) may have concomitant damage to organs and produce health risks like: nephropathies and chronic kidney diseases, retinopathy, neuropathies, macrovascular disorders¹⁶⁻¹⁹. Numerous pharmacological interventions include anti-hyperglycemic drugs, anti-obesity medication, and others like renin-angiotensin blockers and statins, have been studied in the context of management for prediabetes²⁰. The drug-based approach for management of Intermediate Hyperglycemia (prediabetes) is associated with inherent drawbacks, including toxicity, tolerability, cost, and efficacy. Oral hypoglycemic drugs are also associated with various side effects as biguanides cause gastrointestinal upsets, anorexia, nausea, diarrhea and lactic acidosis.

According to Hakeem Azam Khan '*Ziabetes haar*' is the disease which is described as diabetes mellitus type 2 in the present era²¹. In Al-akseer he mentioned that the initial symptoms of diabetes are as having polydipsia without dehydration, frequent micturition without burning along with watery urine having less viscosity²²⁻²³. They described most of the symptoms of diabetes such as excessive thirst, frequency of urination, dribbling of urine, the urine appears white, losing its consistency to resemble like water, excessive micturition without burning sensation, incontinence of urine²⁴⁻²⁶. *Ma-ul-sha'eer* (Barley water) has been mentioned in *Ilaj-bil-ghiza* (Dietotherapy) segment of many classical unani books. With this pretext, the present study was conducted to evaluate the effect of *Ma-ul-sha'eer* (Barley water) in Intermediate Hyperglycemic subjects.

Need for the Study: Intermediate Hyperglycemia is not specifically defined as a disease in unani medicine; however, some classical unani physicians have described the initial symptoms and factors leading to the pathology. In Unani medicine, the risk factors are described in terms of

'*Su-e-mizaj*' as per the concept of Tibb. In this context, diabetes is described as a disease that develops due to *Su-e-mizaj haar* (abnormal hot temperament) by the majority of scholars²²⁻²³. Public health programs focused on increasing personal awareness of risk, community support and education, and government resources are necessary to slow the progression of Intermediate Hyperglycemia/prediabetes to T2DM. Importantly, health care systems need to recognize "prediabetes" as a disease and to use this term to promote programs. Diet and exercise are first-line intervention along with oral hypoglycaemic drugs to achieve the goal of improving glycaemic control and preventing both microvascular and macrovascular health risk factors.

With the above facts, both dietary and lifestyle changes can improve blood sugar level in Intermediate Hyperglycemia. Its incidence is increasing day by day and overcoming the problem of Intermediate Hyperglycemia. Several efforts have been introduced in the modern system of medicine. But most of these efforts are not effective and fail to prevent complications of Intermediate Hyperglycemia and diabetes. *Ma-ul-Sha'eer* (Barley water) is advised as part of *Ilaj-bil-Ghiza* (Dietotherapy) for diabetic subjects in most of the Unani textbooks. Recent researches have demonstrated that β -glucans from barley are very high molecular weight polysaccharides. Due to this, they increase the viscosity of meal bolus and reduce the mixing of food with digestive enzymes. Hence, the rate of starch digestion is markedly reduced. The decreased glucose levels coupled with decreased insulin levels improve insulin sensitivity over time. With this background, a study has been planned to assess the effects of *Ma-ul-sha'eer* (Barley water) on Intermediate Hyperglycemic subjects attending Hospitals in Delhi. The purpose of this study to assess the efficacy of *Ma-ul-Sha'eer* (Barley water) as a dietary intervention in Intermediate Hyperglycemic subjects.

Aims and Objectives:

- To assess the effects of *Ma-ul-sha'eer* (Barley water) in normalizing blood sugar levels in Intermediate Hyperglycemia.
- To assess the *Mizaj* (temperament) of the subjects.

- To assess the effect of *Ma-ul-sha'eer* (Barley water) on the quality of life of the subjects.

MATERIALS AND METHODS: The present study entitled as "*A Study to assess effect of Ma-ul-Sha'eer* (Barley water) in Intermediate Hyperglycemic (Pre-diabetic) Subjects attending Hospitals in Delhi" was conducted to evaluate the efficacy of *Ma-ul-Sha'eer* (Barley water) in the intervention of Intermediate Hyperglycemia on 40 subjects.

This study was a hospital-based prospective, pre and post interventional studies and conducted on 40 diagnosed cases of Intermediate Hyperglycemia (Pre-diabetes) as per WHO and ADA criteria²⁷⁻²⁸. The study setting was OPD of Majeedia Unani Hospital, and A &U Tibbia College and Hospital, Delhi, and the study duration was 1 year (including 3 months of clinical intervention). Those subjects who fulfilled the inclusion criteria (like non diabetic having blood sugar fasting (BSF) level from 100mg/dl to 125mg/dl (5.6 mmol/l to 6.9 mmol/l)⁸, 110 mg/dl to 125mg/dl (6.1 mmol/l to 6.9 mmol/l)⁷, HbA1c levels between 5.7-6.4%⁷⁻⁸, Subjects in the age-group of 18-65 years²⁹, all sexes, subjects willing to sign informed consent were given the information sheet mentioning details regarding the nature of the study. The subjects who gave written consent to participate voluntarily were included in the study. The subjects having blood sugar fasting (BSF) level < 100 mg/dl, suffering from any severe co-morbidity, diabetes mellitus, chronic kidney & liver disease, cardiovascular disorders, pregnant and lactating mothers, hormonal disorders which may lead to deranged blood glucose, e.g., PCOD, Type 1 diabetes mellitus, subjects who fail to give informed consent, subjects who fail to follow up 2 or more visits were excluded in the study. The follow-up of the subjects was done every 10 days. Total 3 months study was divided into 10 visits for providing *Ma-ul-Sha'eer* (Barley water), which were made at 0 day, 10th day, 20th day, 30th day, 40th day, 50th day, 60th day, 70th day, 80th day, 90th day. Withdrawal criteria of the patient are non-compliance or failure to follow the advised *Ilaj-bil-ghiza*, a sudden increase in blood sugar levels, any adverse reaction.

The study tools consist of four parts:

Part A: It has constituted the demographic profile.

Part B: It has constituted the questionnaire /CRF for analysis of the effect of *Ma-ul-Sha'eer* (Barley water) in pre-diabetic subjects.

Part C: It has constituted the temperament assessment format.

Part D: It has constituted the quality of life of subjects (SF-36v2)

TABLE 1: SCORING OF 8 DOMAINS OF SF-36V2

S. no.	Domains of SF-36	Best Score	Worst Score
1	Physical Functioning (PF)	30	10
2	Role Physical (RP)	20	4
3	Role Emotion (RE)	15	3
4	Bodily Pain (BP)	2	11
5	Social Functioning (SF)	10	2
6	Mental Health (MH)	25	5
7	Vitality (VT)	4	20
8	General Health (GH)	5	25

A 36-item short-form questionnaire was constructed to survey health status in medical outcome studies. It was used to assess the health-

related quality of life (HRQOL). It includes 36 questions organized into eight domain scales **Table 1**. Scoring was completed manually confirmed by expert.

Procedure of the Study: The present study was undertaken in the Postgraduate Department of Tahafuzzi wa Samaji Tib (Preventive and Social Medicine), School of Unani Medical Education and Research, Jamia Hamdard, New Delhi, India. This was a hospital-based prospective, pre and post interventional study conducted on diagnosed subjects of Intermediate Hyperglycemia (Pre-diabetes) as per WHO and ADA criteria²⁷⁻²⁸. Subjects fulfilling inclusion criteria and willing to participate in study were included in the study after taking written informed consent. The subjects were selected by simple random technique and advised to take 200 ml *Ma-ul-Sha'eer* (barley water) in the morning and consume it empty stomach. Subjects were advised to have breakfast half an hour after taking *Ma-ul-Sha'eer* (barley water). The subjects were visited on day 0, 10, 20, 30, 40, 50, 60, 70, 80, 90 for providing *Ma-ul-Sha'eer* (barley water). The assessment was done before and after intervention **Table 2**.

TABLE 2: SCHEMATIC REPRESENTATION OF PROCEDURE OF STUDY & VISITS

1 st Visit	2 nd Visit	3 rd Visit	4 th Visit	5 th Visit	6 th Visit	7 th Visit	8 th Visit	9 th Visit	10 th Visit
0 Day	10 th Day	20 th Day	30 th Day	40 th Day	50 th Day	60 th Day	70 th Day	80 th Day	90 th Day
Pre-intervention assessment									Post-intervention assessment:
<ul style="list-style-type: none"> Enrollment & Informed Consent Blood sugar fasting HbA1C Clinical Examination as per Case Record Form Assessment of Quality of Life Assessment of Mizaj 			<ul style="list-style-type: none"> Provide <i>Ma-ul-Sha'eer</i> Evaluation of compliance of instructions 						<ul style="list-style-type: none"> Clinical Examination as per Case Record Form Blood sugar Fasting HbA1C Assessment of Quality of Life

Preparation of Ma-ul-Sha'eer (Barley Water):

Ma-ul-Sha'eer (Barley water) was prepared in Saidla Lab under the supervision of Prof. Mohd Aftab Ahmad, HOD Ilmul Advia, as per the guidelines of Unani classical literature. We have taken 50 gm of hulled barley and wash it properly

with water. Then allowed it to boil in 1200 ml of water till the water got concentrated and its colour changed (reddish) and the barley became disintegrated in the water, after that allowed to cool it and filter it³⁰ **Fig. 1**.

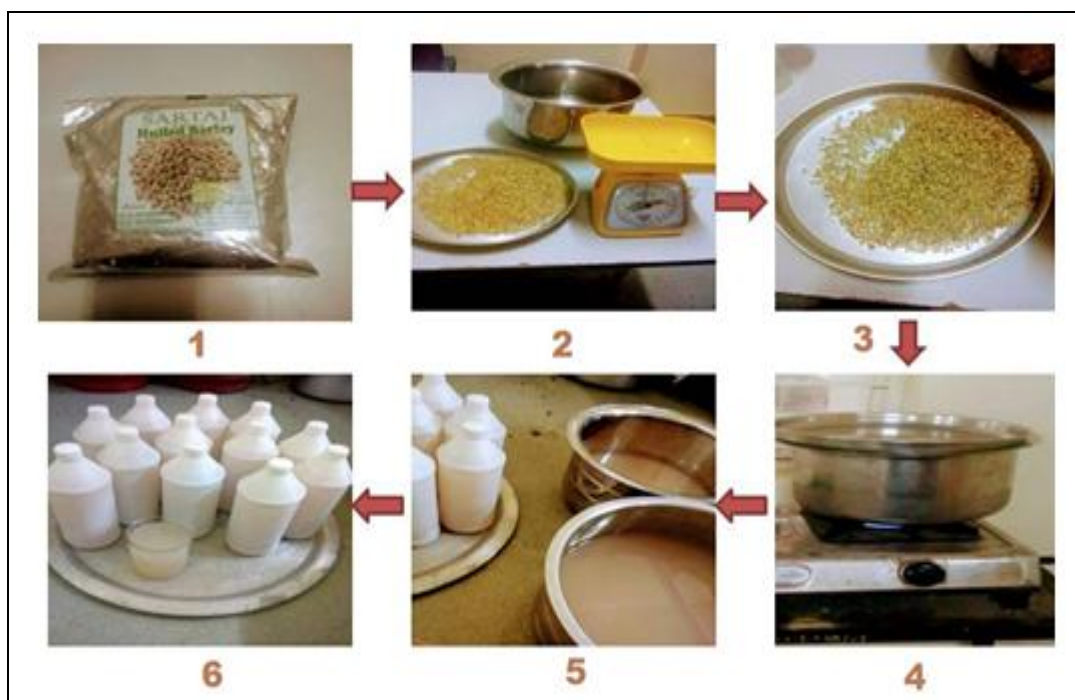


FIG. 1: METHOD OF PREPARATION OF *MA-UL-SHA'ER* (BARLEY WATER)

Outcome Assessment:

- Assessment of demographic profile
- Assessment of blood sugar fasting
- Assessment of HbA1c
- Assessment of *Mizaj* (temperament) of subjects
- Assessment of quality of life of subjects

Statistical Analysis: Statistical analysis was done pre & post-intervention using paired t-test.

Ethical Consideration: Ethical approval for the study was obtained from the Jamia Hamdard Institutional Ethics Committee (JHIEC/21/3/2018) and a written informed consent was obtained from each subject.

Observations and Results: This study was carried out on 40 subjects who have attended the OPD of Majeedia Unani Hospital and A&U Tibbiya College and Hospital, National Capital Territory of Delhi, India. Subjects were selected randomly without discrimination of age, sex, religion, marital status, occupation, dietary habits and social status. General blood picture as a routine investigation and blood sugar fasting and HbA1c were carried out in Majeedia Unani Hospital & HAHC laboratory as objective parameter. Only after confirmation of diagnosis, written consent of the subjects, and

approval of the ethical committee the trial was started with the intervention of *Ma-ul-Sha'eer* (Barley water) in a dose of 200 ml once daily in the morning for a period of 90 days. Assessment of the subjects was done on 0 day and 90th day. The duration of study was divided into 10 visits for providing *Ma-ul-Sha'eer* (Barley water) which were at 0 day, 10th day, 20th day, 30th day, 40th day, 50th day, 60th day, 70th day, 80th day, 90th day. Those who failed to come for two follow-ups were excluded from the study. Blood sugar fasting and HbA1c were done before starting the intervention and after completion to assess the effect of *Ma-ul-Sha'eer* (Barley water). LFT and KFT were done before starting the intervention and after completion to assess the adverse effect of the drug as a safety profile. The main observations of the study are below:

In the study, all subjects were allocated into four age groups *viz.*, 18-30 years, 31-40 years, 41-50 years, 51-65 years. It was observed that the maximum number of subjects *i.e.* 15 (37.5%) belonged to the age group of 51-65 years, 10 (25%) subjects fell in the age group of 41-50 years, 09 (22.5%) subjects in the age group of 31-40 years, 06 (15%) subjects in the age group of 18-30 years. **Table 3^a** and 52.5% subjects were females, and 47.5% were males **Table 3^b**.

TABLE 3: DEMOGRAPHICS OF THE SUBJECTS (N [%])

Item	Subjects (N=40)	Percentage
Age ^a (in Years)		
18-30	5	12.5
31-40	9	22.5
41-50	11	27.5
51-65	15	37.5
Gender ^b		
Male	19	47.5
Female	21	52.5
Religion ^c		
Muslim	31	77.5
Hindu	8	20
Sikh	1	2.5
Marital status ^d		
Married	34	85
Unmarried	6	15
Occupation ^e		
Business Man	2	5
Employee	10	25
Housewife	16	40
Student	3	7.5
Worker	9	22.5
Socioeconomic status ^f		
Upper (I)	2	5
Upper Middle (II)	8	20
Middle Lower Middle (III)	8	20
Lower Upper Lower (IV)	12	30
Lower (V)	10	25
Smoking ^g		
Non Smoker	30	75
Smoker	10	25
Diet ^h		
Non Veg	11	27.5
Veg	29	72.5
Exercise ⁱ		
Present	13	32.5
Absent	27	67.5
Mizaj ^j (Temperament)		
Sanguinous (<i>Damvi</i>)	6	15
Bilious (<i>Safravi</i>)	8	20
Phlegmatic (<i>Balghami</i>)	22	55
Melancholic (<i>Saudavi</i>)	4	10

Majority of the subjects were muslim (77.5%) followed by Hindu 20%, and Sikh 2% **Table 3^c**. In the study population, 85% subjects were married and 15% were unmarried. **Table 3^d** According to occupation of the study subjects, 40% subjects were housewives, 25% were employees, 22.5% were workers, 7.5% were students, 5% were businessmen **Table 3^e**. All subjects were divided into five groups according to socioeconomic status, 5% were upper (I) class, 20% upper middle (II) & middle lower middle class (III), 30% lower upper lower (IV) class and 25% were lower (V) class **Table 3^f**.

In this study, 75% the subjects were non-smokers, and 25% were smokers. **Table 3^g** and 72.5%

subjects were non vegetarian and 27.5% were vegetarian. **Table 3^h** Majority of the subjects had sedentary life style, Physical Exercise was absent in 67.5% subjects and was present in 32.5% subjects **Table 3ⁱ**. According to the *Mizaj* (Temperament), all the subjects in the study were divided into four groups. In total 40 subjects, 6 (15%) subjects were observed in *Damvi mizaj* (Sanguineous temperament), 8 (20%) subjects in *Safravi mizaj* (Bilious temperament), 22 (55%) in *Balghami mizaj* (Phlegmatic temperament) and 4 (10%) in *Saudavi mizaj* (Melancholic temperament) **Table 3^j**.

The mean value of blood sugar fasting before the intervention was 113.6 ± 6.7 and after intervention was 103.0±5.4 Paired ‘t’ test was applied to the observations recorded before the intervention and after the intervention. There was significant reduction and normalization was noted on blood sugar fasting after taking *Ma-ul-Sha’eer* (Barley water) and was found statistically highly significant (p <0.0001, t=14.5 & d.f: 39) **Table 4, Fig. 2**.

TABLE 4: EFFECT OF MA-UL-SHA’EER (BARLEY WATER) ON B. SUGAR FASTING

Blood Sugar Fasting N=40	Before Interventio n (Day 0)	After Intervention (Day 90)	P value*
Mean±SD	113.6 ± 6.7	103.0 ± 5.4	P<0.0001
*Paired t-test	t= 14.5		

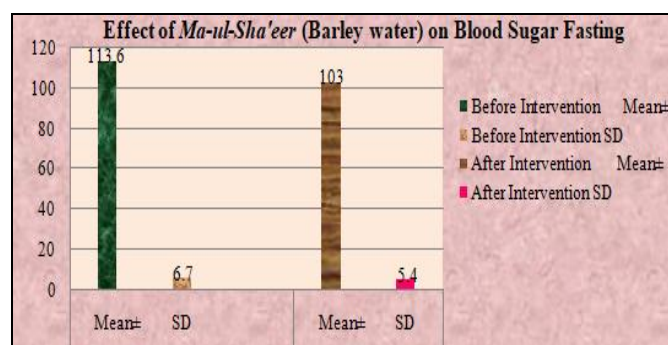


FIG. 2: EFFECT OF MA-UL-SHA’EER (BARLEY WATER) ON B. SUGAR FASTING

The mean value of HbA1c before the intervention was 6.0±0.21 and after the intervention was 5.4±0.27. Paired ‘t’ test was applied to the observations recorded before the intervention and after the intervention. There was a significant reduction, and normalization was noted on HbA1c after taking *Ma-ul-Sha’eer* (Barley water) and was found statistically highly significant (p <0.0001, t=13.7 & d.f: 39) **Table 5, Fig. 3**.

TABLE 5: EFFECT OF MA-UL-SHA'EER (BARLEY WATER) ON HBA1C

HbA1c N=40	Before Intervention (Day 0)	After Intervention (Day 90)	P value*
Mean±SD	6.0 ±0.21	5.4±0.27	P<0.0001
*Paired t-test	t=13.7		

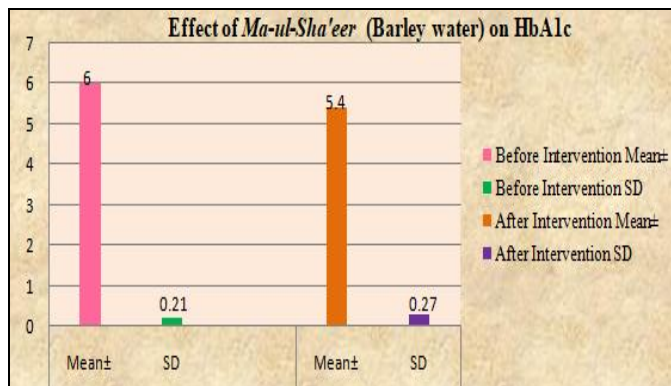


FIG. 3: EFFECT OF MA-UL-SHA'EER (BARLEY WATER) ON HBA1C

On comparison of pre-intervention and post-intervention mean score of the domains of Health-related quality of life (HRQOL) significant differences was found in the domains of Physical Functioning, Role Physical, Role Emotional, Bodily Pain, Social Functioning, Mental Health, Vitality, General Health score where p-value was P<0.0001 which indicated the efficacy of the intervention carried out to aware the subjects about Intermediate Hyperglycemia to improve the health-related quality of life in the corresponding domains Table 6, Fig. 4.

TABLE 6: EFFECT OF MA-UL-SHA'EER (BARLEY WATER) ON HRQOL (SF36V2)

Domains of Health-Related Quality of Life (HRQOL) N=40	Before Intervention (Day 0) Mean±SD	After Intervention (Day 90) Mean±SD	t value	df	P-value*
Physical Functioning (PF) (B-30, W-10)	18.77±5.54	27.97±2.92	-9.780	39	P<0.0001
Role Physical (RP) (B-20, W-4)	9.10±2.95	18.17±1.94	-19.590	39	P<0.0001
Role Emotional (RE) (B-15, W-3)	6.97±2.16	13.37±1.68	-16.263	39	P<0.0001
Bodily Pain (BP) (B-2, W-11)	7.47±1.46	2.22±0.42	21.918	39	P<0.0001
Social Functioning (SF) (B-10, W-2)	4.50±0.98	7.20±0.82	-10.976	39	P<0.0001
Mental Health (MH) (B-25, W-5)	15.55±1.75	17.42±0.84	-6.486	39	P<0.0001
Vitality (VT) (B-4, W-20)	14.77±1.07	9.67±0.99	21.772	39	P<0.003
General Health (GH) (B-5, W-25)	16.70±1.66	12.92±1.43	11.825	39	P<0.0001

*Paired t-test

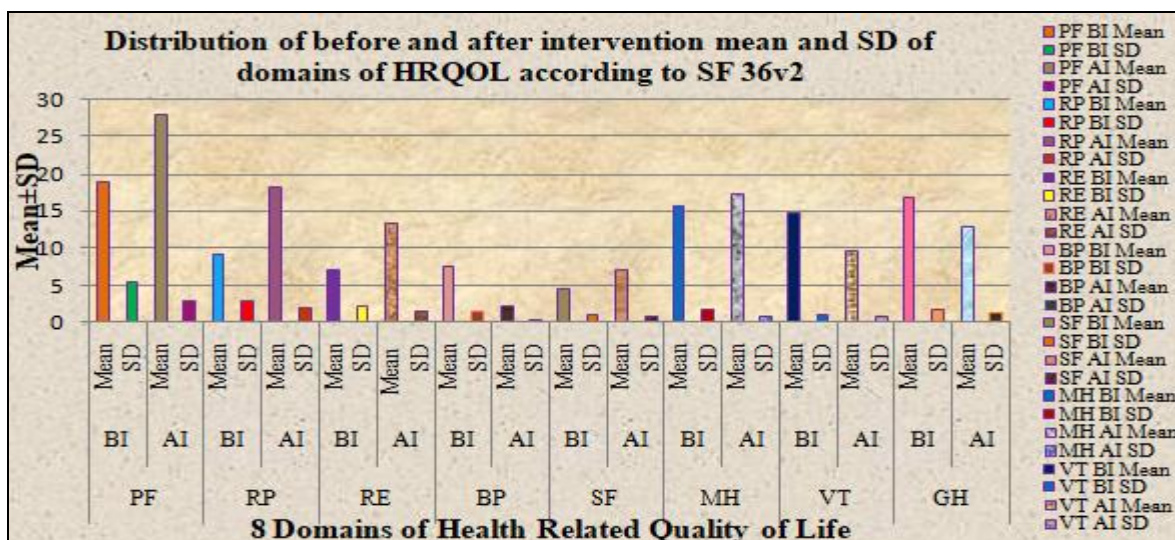


FIG. 4: EFFECT OF MA-UL-SHA'EER (BARLEY WATER) ON HRQOL (SF-36V2)

DISCUSSION: With the increase in the prevalence of Intermediate Hyperglycemic condition, there is a dire need of an alternative method of managing the Intermediate Hyperglycemia condition with either full control of Intermediate Hyperglycemia or at least to delay the process of conversion to DM2 along with the improved quality of life of the subjects. With the above aim, the present study entitled “A Study to Assess Effect of *Ma-ul-Sha’eer* (Barley water) in Intermediate Hyperglycemic (Pre-diabetic) Subjects attending Hospitals in Delhi” was planned to carry out.

This study was designed to assess the effect of *Ma-ul-Sha’eer* (Barley water) on blood sugar fasting and HbA1c levels in Intermediate Hyperglycemia. The study was conducted in Majeedia Unani Hospital & A & U Tibbiya College. Duration of protocol therapy was 3 months with visits of every 10 days (0, 10th, 20th, 30th, 40th, 50th, 60th, 70th, 80th, 90th day). Out of total 60 subjects enrolled, only 40 subjects completed the whole study period with full dataset, and 20 subjects were dropped out from the study due to failure of more than two or more visits. Assessment of efficacy and safety were done on biochemical parameters before and after completion of protocol therapy.

The main results of the study are enumerated below:

Highest incidence of Intermediate Hyperglycemia was observed in the age group of 41-65 years (65%), which was in accordance with the CDC’s³¹ which postulated that an estimated 33.9% of U.S. adults aged 18 years or older (84.1 million people) had prediabetes in 2015, based on their fasting glucose or A1C level. Nearly half (48.3%) of adults aged 65 years or older had prediabetes. A similar trend was observed by several studies conducted in different places³²⁻³⁶ where 37.98% prediabetics were in the age group of 45 to 60 years. A study conducted by K. Midthjell *et al.*, 2015 in Turkey affirmed that the pre-diabetic stage can start as early as 20 years and above³⁷. So, it gives us a strong indication to commence preventive measures and health education at an early age and utilize primordial prevention tool effectively.

A higher incidence of Intermediate Hyperglycemia 21 (52.5%) was observed in females than males 19 (47.5%). It is due to the

demographics of the catchment area of the hospital, or most probable reason is that females attending more in OPDs for their general clinical problem than males. And the findings are in cohesion with a previous prevalence study conducted in 2003 for epidemiology of impaired fasting glucose/impaired glucose tolerance^{32, 38-39}. In contrast the study conducted by Kim Ye An *et al.*, 2014, S.O. Martins *et al.*, 2017⁴⁰⁻⁴¹ indicated a higher prevalence of intermediate glyceamia in males. It is also postulated that age-adjusted data for 2011–2014 indicated that more men (36.6%) than women (29.3%) had prediabetes⁴².

The maximum number of subjects observed were Muslim 31 (77.5%), Hindu 8 (20%), and Sikh 1 (2.5%). It is due to the demographics of the catchment area of the hospital, or the maximum attendees of OPD are Muslims. Similar results were found in a study conducted by S.O. Martins, 2017 in southern Nigeria⁴¹. The majority of the subjects were married, 34 (85%) followed by unmarried 6 (15 %) in this study. It can be attributed to the fact that after marriage due to increase in responsibility, People do not do physical activities which lead to obesity and greater risk of pre-diabetes. Similar results were found in the studies conducted by Khaled K. Aldossari *et al.*, 2018, S.O. Martins, 2017, T. Tzotzas *et al.*, 2010, Okwechime, *et al.*, 2015^{36, 41, 43, 44} speculated that married are more at risk for prediabetes as well as diabetes.

In the present study highest number of subjects were Housewives 16 (40%) followed by Employees 10 (25%), Worker 09 (22.5%), Students 3 (7.5%), Businessmen 02 (05%) which was in accordance with the study conducted by Medhat A Ghoraba *et al.*, 2016 in Saudi Arabia, where 38.6% were prediabetics³⁹.

A maximum number of subjects were lower upper lower class (IV) 12 (30%) followed by lower class (V) 10 (25%), middle-lower middle class (III) 08 (20%), upper-middle (II) 08 (20%) and upper (I) class 02 (5%) which as in accordance with the study conducted that about 69.2% of Prediabetic (IH) population live in low or middle-income group⁴⁵. There is also another study that reported a high occurrence of Prediabetes in those with low income⁴⁴.

Smoking association with intermediate hyperglycemia was not evident from our study as only 10

(25%) individuals in our study were smokers and majority of subjects were non-smokers 30 (75%).

The findings from the studies conducted by D. C. Aliskan *et al.*, 2006 and M. Zhao *et al.*, 2016⁴⁶⁻⁴⁷ were rational with our findings. However, study conducted by Wanamathee A *et al.*, 2001⁴⁸ found strong association of smoking with pre-diabetes.

Out of total 40 subjects, 29 (72.5%) were non-vegetarian and 11 (27.5%) subjects were vegetarian. The study conducted by Zahra Gholi *et al.*, 2016⁴⁹ also inferred that pre-diabetic subjects had higher intake of protein fat. Inadequate physical activity is a well-known risk factor for pre-diabetes. It was observed that out of the total 40 subjects, exercise was present in 13 (32.5%) subjects and absent in 27 (67.5%) which was in accordance with the study conducted by Medhat A Ghoraba *et al.*, 2016³⁹. The imbalance between physical activity and energy intake can perpetuate a sedentary lifestyle that leads to insulin resistance and prediabetes. Effects of exercise intensity on postprandial improvement in glucose disposal and insulin sensitivity in pre-diabetic adults⁵⁰.

The *Mizaj* (temperament) of the subjects determined as per the performa revealed that a maximum number of subjects were *Balghami mizaj* (Phlegmatic temperament) 22 (55%) followed by *Safravi mizaj* (Bilious temperament) 8 (20%), *Damvi mizaj* (Sanguineous temperament) 6 (15%), *Saudavi mizaj* (Melancholic temperament) 4 (10%). The predominance of *Balghami Mizaj* (Phlegmatic temperament) in pre-diabetic subjects has relevance as most of the *Balghami mizaj* (Phlegmatic temperament) people are overweight which is a known risk factor of prediabetes and diabetes.

The efficacy of *Ma-ul-Sha'eer* (Barley water) was mainly observed on blood sugar fasting and HbA1c. The mean value of blood sugar fasting before the intervention was 113.6 ± 6.7 and after the intervention was 103.0 ± 5.4 . Paired 't' test was applied to the observations recorded before the intervention and after the intervention.

It was observed that $t=14.5$, ($p < 0.0001$) and were statistically highly significant, the most probable mechanism encountered in reducing blood sugar fasting is the presence of β -glucan in *Ma-ul-Sha'eer* (Barley water).

The mean value of HbA1c before the intervention was 6.0 ± 0.21 and after the intervention was 5.4 ± 0.27 , Paired 't' test was applied to the observations recorded before the intervention and after the intervention. It was observed that $t=13.7$, $p < 0.001$ and were statistically highly significant, the most probable mechanism encountered in reducing HbA1c is the presence of β -glucan in *Ma-ul-Sha'eer* (Barley water).

On comparison of pre-intervention and post-intervention mean score of the domains of Health-related quality of life (HRQOL) significant differences was found in the domains of Physical Functioning, Bodily Pain, General Health, Vitality, Social Functioning, Mental Health, Role Emotional, Role Physical score where p-value was $P < 0.0001$ which indicated the efficacy of the intervention carried out to aware the subjects about Intermediate Hyperglycemia to improve the health-related quality of life in the corresponding domains.

The above effect of *Ma-ul-Sha'eer* (Barley water) can be attributed to the fact that Barley contains 10 to 17% protein, starch 65 to 68%, 4 to 9% β -glucan, 2 to 3% lipids, and 1.5 to 2.5% minerals⁵¹⁻⁵⁵. It is an excellent source of complex carbohydrates, which constitute $\approx 80\%$ of barley grain weight⁵⁶ also, barley contains high levels of β -glucans, which are important contributors to dietary fiber, a crucial component of the human diet⁵⁷⁻⁵⁸. Barley is rich in nutrients. It has abundant vitamins and minerals, e.g., selenium, calcium, iron, magnesium, and phosphorus, and some important minerals present in barley⁵⁹⁻⁶¹. Unani physicians attributed the loss of appetite to divert the attention of *Tabiyat* from feeding to fighting against the disease. Moreover, *Tabiyat* tries its best to obtain the nutrition from the body stores and from morbid matters, if any such part is present in them. *Ma-ul-Sha'eer* (Barley water) helps the *Tabiyat* in elimination, *Nuzj* and to provide *Taskeen* from morbid matter. As these matters are eliminated, *Tabiyat* started to pay more attention towards the *Tabayee afa'al*⁶². Both dietary and lifestyle changes can reduce and normalize blood sugar levels in Intermediate Hyperglycemia. Its incidence is increasing day by day, and to overcome the problem of Intermediate Hyperglycemia, several efforts have been introduced in modern system of medicine. But most of these efforts are

not effective and fail to prevent complications of Intermediate Hyperglycemia and diabetes. *Ma-ul-Sha'eer* (Barley water) is advised as part of *Ilaj-bil-Ghiza* (Dietotherapy) for diabetic subjects in most of the Unani textbooks^{24, 63-64}. Recently, the European Food Safety Authority, Panel on Dietetic Products, Nutrition and Allergies issued an opinion that "reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionately increased) may be a beneficial physiological effect". The panel recognized that a cause and effect relationship between consumption of oat and barley β -glucans and a reduction of post-prandial glycaemic responses had been established. Based on six studies, the panel concludes that "in order to obtain the claimed effect, 4g of β -glucans from oat or barley for each 30g of available carbohydrates should be consumed per meal"⁶⁵.

According to Nilsson and coworkers, eating whole grain Barley can regulate blood sugar for up to 10 h after consumption⁶⁶. The effectiveness of Barley is due to its soluble fiber content⁶⁷. Barley has a high amount of dietary fiber such as β -glucan that may decrease the risk of coronary heart disease⁶⁸. Hypoglycemic action of Glibenclamide has also been observed in normal and diabetic rats after both acute and extended treatments. These findings suggest that barley seeds hydro-alcoholic extract has a role in diabetic control in long-term consumption, and this effect might be at least due to its high fiber content.

Recent researches have demonstrated that β -glucans from barley are very high molecular weight polysaccharides. Due to this, they increase the viscosity of meal bolus and reduce the mixing of food with digestive enzymes. Hence, the rate of starch digestion is markedly reduced⁶⁹.

Limitations of Study: The present study was properly planned and executed according to the protocol. The best possible efforts were made to adopt the updated methodology with objective parameters to make it more valid scientifically. Despite all these efforts, certain limitations of this study were observed like:

- The sample size for the study was small therefore, the study observations may not be representative and generalizable.

- Storage system like a refrigerator, ice packs, is required for *Ma-ul-Sha'eer* (Barley water).
- These limitations were much because of time constraints with regards to the time-bound MD program of the study.

Recommendations: On the basis of observations of this study it is recommended that:

- On the basis of the current study that practitioners may be encouraged to use *Ma-ul-Sha'eer* (Barley water) as an important adjunct to their decision tree for intermediate hyperglycemia.
- A larger study with a statistically determined sample size and stratified design may be conducted to reach conclusions that can be extrapolated to intermediate hyperglycemia of Indian people in general.
- The subjects should also be followed up for a longer duration, to assess the long-lasting effects of *Ma-ul-Sha'eer* (Barley water) in intermediate hyperglycemia.
- Further studies can be conducted on grass root level health functionaries against intermediate hyperglycemia.
- The results emanating from such observations will make the use of *Ma-ul-Sha'eer* (Barley water) more scientific as well as cost-effective.

CONCLUSION: The Major Conclusions of the study are: Majority of the subjects (65%) were between 41-65 years of age, female (52%), Muslim (77.5%), married (85%), housewives (40%), in a lower upper lower class (30%), non-smoker (75%), non-vegetarian (72.5%), Physical Exercise was absent (67.5%) and Phlegmatic (*Balghami*) (55%).

With the observations and analysis of data and results of this study it could be concluded that *Ma-ul-Sha'eer* (Barley water) exhibited good glucose control in Intermediate Hyperglycemic condition.

It can also revert the Intermediate Hyperglycemic condition into normoglycemia and prevent the conversion of Intermediate Hyperglycemic condition into Type 2 Diabetes Mellitus. *Ma-ul-*

Sha'eer (Barley water) has β -glucan acts as hypoglycemic agent which could lead to a significant reduction in blood sugar fasting and HbA1c.

The results came out statistically extremely significant ($p < 0.0001$). Further research is needed to determine how early interventions should be implemented and sustained. *Ma-ul-Sha'eer* (Barley water) was also effective to improve the health related quality of life in 8 domains: Physical Functioning (PF), Role Physical (RP), Bodily Pain (BP), General, Health (GH), Vitality (VT), Social Functioning (SF), Role Emotion (RE), Mental Health (MH). The results being statistically highly significant ($p < 0.0001$).

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